UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
BRUNSWICK DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	No. 2:20-CV-10
CHIP'S DISCOUNT DRUGS, INC.,	)	
CHIP'S DISCOUNT DRUGS, LLC,	)	
and ROGERS WOOD,	)	
	)	
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 Chip's Discount Drugs, Inc., Chip's Discount Drugs, LLC (collectively, "Chip's"), and Rogers Wood (Wood), 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 fully account for the controlled substances provided to Chip's 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 Chip's because its principal place of business is in Jeff Davis County, Georgia and it transacts business within this district.

9. The Court has personal jurisdiction over Wood because he resides at 54 East Jarman Street, Hazlehurst, Georgia, which is within this district.

10. Venue lies in this district pursuant to 28 U.S.C. § 1391(b) because all 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 Chip's Discount Drugs, Inc., is registered and organized as a domestic profit corporation with the State of Georgia. Its principal place of business is 240 South Tallahassee Street, Hazlehurst, Georgia, 31539, located in this judicial district. It may be served through its registered agent, Ken W. Smith, at 53 South

Tallahassee Street, Hazlehurst, Georgia, 31539.

13. Defendant Chip's Discount Drugs, LLC, is registered and organized as a domestic limited liability company with the State of Georgia. Its principal place of business is 240 South Tallahassee Street, Hazlehurst, Georgia, 31539, located in this judicial district. It may be served through its registered agent, Ken W. Smith, at 53 South Tallahassee Street, Hazlehurst, Georgia, 31539. Its sole member is defendant Rogers Wood.

14. Defendant Chip's Discount Drugs, Inc. and Defendant Chip's Discount Drugs, LLC, have the same principal place of business, and, in some form or fashion and without regard to corporate formalities, operate the Hazlehurst pharmacy known as Chip's Discount Drugs.

15. In December 2012, Chip's Discount Drugs, LLC, filed Articles of Conversion with the Georgia Secretary of State, electing to become Chip's Discount Drugs, Inc. However, Chip's Discount Drugs, LLC, continued for years thereafter to file annual registrations, in addition to annual registrations for Chip's Discount Drugs, Inc. In addition, the Chip's DEA Registration continued under the corporate entity Chip's Discount Drugs, LLC.

16. The Chip's entities do not operate as separate companies. They operate a single pharmacy with a single set of pharmacy staff at a single location. To the government's knowledge, the Chip's entities do not maintain separate bank accounts or separate corporate records, or have independent employees.

17. The Chip's entities have such a unity of interest that each of the Chip's entities has no legal or independent significance of their own.

18. Defendant Rogers Wood is an individual who resides at 54 East Jarman Street, Hazlehurst, Georgia, which is located in this judicial district.

GENERAL ALLEGATIONS

19. At all times material to the allegations in this complaint, Chip's was registered by the United States Drug Enforcement Administration (DEA) with Schedule II-V controlled substances under registration number FC2419869.

20. At all times material to the allegations in this complaint, Chip's was licensed by the State of Georgia as a retail pharmacy under license number PHRE009723.

21. At all times material to the allegations in this complaint, Chip's employed Wood as its Pharmacist-in-Charge and Wood was its Chief Executive Officer, Chief Financial Officer, and Secretary.

22. At all times material to the allegations in this complaint, Wood was licensed as a pharmacist by the State of Georgia under license number RPH013011.

23. At all times material to the allegations in this complaint, Wood actively participated in the management of Chip's, including its operations, its inventory, and its personnel.

24. Defendant Wood had exclusive authority to order controlled substances on behalf of Chip's, and had the power, authority, and control to ensure Chip's

compliance with its obligations under the CSA.

25. 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*.

26. 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

27. 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*.

28. 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

29. 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.

30. 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*.

31. To be valid, a prescription must be issued for a legitimate medical purpose by a provider acting in the usual course of professional practice. 21 C.F.R. § 1306.04(a).

32. 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).

33. 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.

34. "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.

35. 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.*

36. 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

37. 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.

38. 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).

39. 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).

40. 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

41. For years, defendants have filled prescriptions for controlled substances that they 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.

42. In doing so, Chip's 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 controlled substances from patients who are undergoing treatment for opioid dependency;
- 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;
- early refills of controlled substances by patients who should have had

remaining doses available; and

- patients who engage in "doctor shopping" behavior.

I. Defendants' Relationship with Dr. Bynes

43. From November 23, 2015, through October 2, 2017, defendants routinely filled controlled substances prescriptions written by Dr. Frank H. Bynes, Jr., an internal medicine physician.

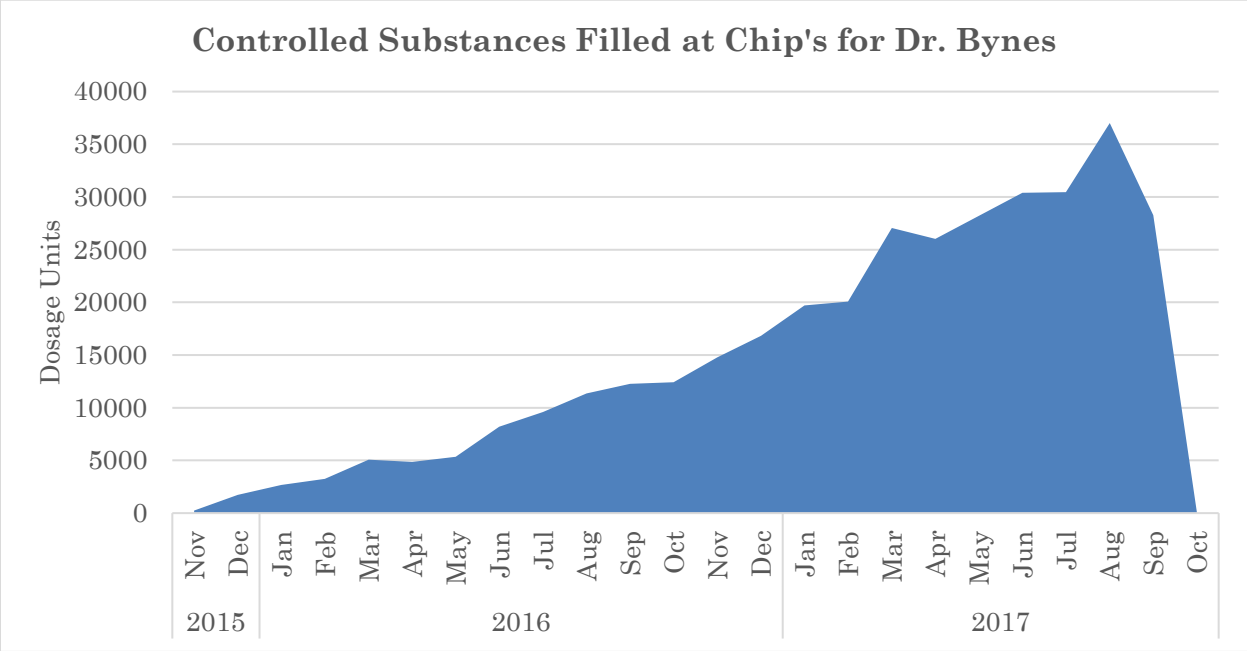
44. Dr. Bynes voluntarily surrendered his DEA registration for cause on September 21, 2017 and, following a jury trial, was convicted of 13 counts of unlawfully dispensing controlled substances and three counts of health care fraud. *See United States v. Bynes*, No. 4:18-CR-153, Doc. 152 (S.D. Ga.). The evidence presented at trial showed Dr. Bynes prescribed controlled substances without a legitimate medical purpose and outside the course of usual professional practice, including, *inter alia*, 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.

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

46. Indeed, Dr. Bynes testified at trial that many pharmacies would not fill

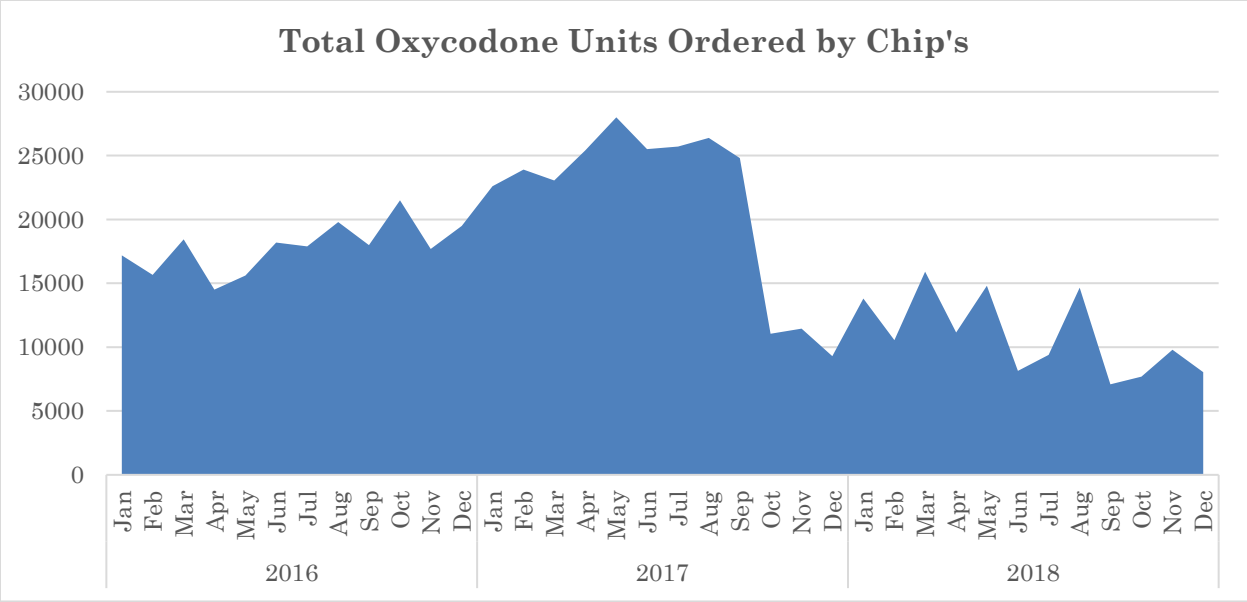
prescriptions when they discovered he was the physician who wrote them.

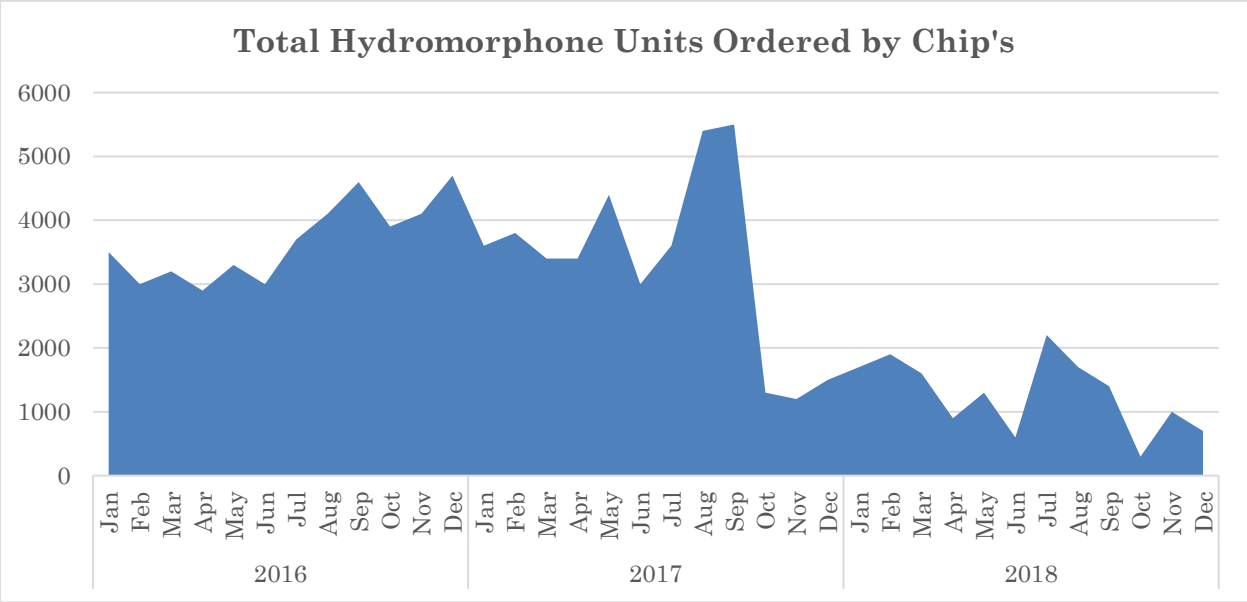
47. As other pharmacies progressively refused to fill Dr. Bynes' prescriptions, Chip's took up the slack, filling more and more of Dr. Bynes' illegitimate prescriptions over time.



48. Indeed, for each month between April and August 2017—the month before Dr. Bynes surrendered his DEA registration—Chip's dispensed more oxycodone pills prescribed by Dr. Bynes than those prescribed by every other provider combined.

49. Illustrating the pharmacy's reliance on Dr. Bynes' illegitimate prescriptions, Chip's ordering history shows a precipitous drop-off in orders for the opioids oxycodone and hydromorphone following Dr. Bynes' voluntary surrender of his DEA registration on September 21, 2017:





50. 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.

51. From November 23, 2015 through October 2, 2017, Chip's dispensed over 350,000 dosage units of controlled substances to Dr. Bynes' patients.

52. During that period, defendants dispensed more controlled substances dosage units prescribed by Dr. Bynes than those for all but one other prescriber, whose practice was located approximately one mile from Chip's.

53. Following Dr. Bynes' surrender of his DEA registration, defendants sought to downplay their extensive reliance on his prescriptions.

54. On or about October 11, 2018, Chip's primary supplier of controlled substances performed a site visit at Chip's.

55. At that time, defendant Wood falsely told the supplier that Chip's only filled "an occasional opioid prescription" from Dr. Bynes before his prescribing privileges were taken away, and that "less than one percent" of Chip's customers saw an out-of-town doctor. Defendant Wood stated that Chip's had refused to fill large quantities of Dr. Bynes' prescriptions.

A. Defendants Ignored Red Flags Presented by Dr. Bynes' Prescriptions

i. Distance

56. 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.

57. Each of Dr. Bynes' clinics were located approximately 102 miles—about a two-hour drive—from Chip's.

58. The majority of defendants' customers are located in Jeff Davis County, where Chip's is located.

59. In filling Dr. Bynes' prescriptions, defendants therefore knew that most of Dr. Bynes' patients were driving approximately two hours to office visits and another two hours to return to Chip's, despite the presence of numerous other internal medicine doctors located closer to Chip's, and numerous other pharmacies located closer to Dr. Bynes.

60. Defendants knew or should have known that local patients were travelling such distances because they could not find another, closer internal medicine doctor willing to write similar prescriptions.

61. In other cases, patients would travel lengthy distances from their homes to fill Dr. Bynes' prescriptions at Chip's. Defendants knew or should have known that these patients were travelling such distances because they could not find a closer pharmacy willing to fill Dr. Bynes' illegitimate prescriptions.

62. Indeed, on or about December 15, 2014, defendant Wood represented to Chip's primary supplier of controlled substances that Chip's limits its patients to those who live within a 15- or 16-mile radius of the pharmacy. Defendant Wood made

this representation as part of the supplier's evaluation of whether to increase the amount of controlled substances it would provide to Chip's.

63. Again on or about March 11, 2016, defendant Wood represented to Chip's primary supplier that Chip's patient base lived within 25 miles of the pharmacy.

64. On October 11, 2017, defendant Wood again represented to Chip's primary supplier that the pharmacy had implemented a policy that its patients must be from Hazlehurst or a neighboring county or the prescription would be refused. Defendant Wood advised at that time that the maximum patient radius was 40 miles.

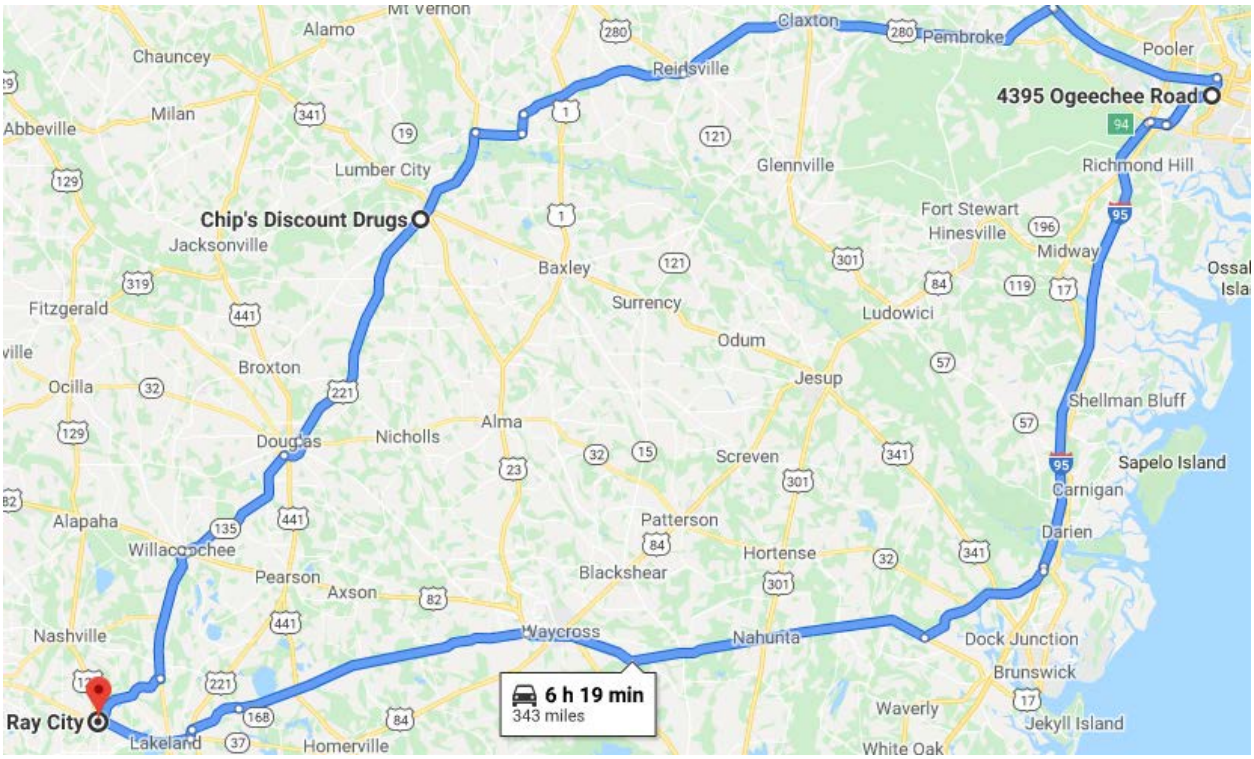
65. During a DEA on-site inspection on August 21, 2018, defendant Wood expanded this radius even further, stating that defendants only fill for patients located within a 45-mile radius.

66. Contradicting defendant Wood's representations, however, defendants filled prescriptions for Dr. Bynes' patients who lived well beyond 15, 16, 25, 40 or even 45 miles away.

67. For example, defendants dispensed controlled substances to P.D., a Dr. Bynes patient, on 10 separate dates between April 6, 2017 and September 13, 2017, despite the fact that P.D. lived in Ray City, Georgia, approximately 75 miles south of Chip's. On these occasions, defendants dispensed controlled substances including oxycodone, hydrocodone, alprazolam, carisoprodol and phentermine to P.D.

68. For a patient living in Ray City to obtain a prescription from Dr. Bynes,

fill it at Chip's, and return home would require the patient to travel approximately 343 miles, more than 6 hours by car:



69. As another example, on three occasions between February 15, 2016, and March 8, 2016, defendants dispensed 120 dosage units of oxycodone 15mg or 30mg, or a combination of both, to patient B.H., living in Eden, Georgia, approximately 85 miles northeast of Chip's.

70. Patient B.H. advised the DEA that after obtaining a prescription from Dr. Bynes, B.H. would spend three to four days driving to different pharmacies, trying to find one willing to fill Dr. Bynes' prescriptions. B.H. eventually stopped seeing Dr. Bynes due to the difficulty in finding a pharmacy to fill his prescriptions.

71. In addition to P.D. and B.H., defendants also filled for Dr. Bynes'

patients who lived in Bloomingdale, Georgia (93 miles away); Blackshear, Georgia (50 miles away);[5] Crescent, Georgia (98 miles away); and Townsend, Georgia (76 miles away).

72. Despite the distance between Dr. Bynes' clinics and Chip's, Chip's filled more of Dr. Bynes' prescriptions for controlled substances than all but two other pharmacies.

ii. Dangerously High Daily Doses of Opioids

73. On March 18, 2016, the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain*.[6] 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.

74. The *CDC Guideline* warned that clinicians "should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents[7] (MME)/day, and should avoid increasing dosage to

[5] Notably, on December 15, 2014, defendant Wood specifically advised his supplier that patients from Blackshear were "not welcome" at Chip's.

[6] 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).

[7] 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.

≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day."

75. 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 six 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 practice.

76. Almost all the patients who filled Dr. Bynes' prescriptions at Chip's—more than 90%—were able to obtain prescriptions for 120 units of oxycodone 30mg, the highest strength of immediate-release oxycodone available at Chip's. 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.

77. Defendants dispensed far greater daily doses of opioids to many of Dr. Bynes' patients.

78. One example is patient K.G., to whom defendants dispensed 120 units of oxycodone 30mg, 120 units of hydromorphone 8mg, and 10 fentanyl 100 mcg/hr patches on August 28, 2017, pursuant to a prescription written by Dr. Bynes. If taken as directed, K.G. would have received 548 MME/day.

79. Defendants' decision to fill K.G.'s prescription on August 28, 2017, was a particularly egregious violation of their corresponding responsibility. On 17 dates

over the previous nine weeks, defendants dispensed buprenorphine—commonly used to treat opioid addiction—to K.G. pursuant to prescriptions written by a different, local doctor. Indeed, this doctor had a special DEA registration number to alert the pharmacist that the doctor was treating K.G. for opioid dependence.

80. In filling K.G.'s prescription on August 28, 2017, defendants therefore knew or should have recognized K.G. was addicted to opioids, was undergoing treatment for that addiction with a local doctor, yet had driven nearly four hours to obtain a prescription from a different doctor, Dr. Bynes, who had no specialization, at more than six times the MME levels the CDC recommends clinicians to avoid. Defendants filled the August 28, 2017 prescription anyway.

81. K.G.'s August 28, 2017 prescription was not an outlier. Defendants dispensed the combination of 120 units of oxycodone 30mg, 120 units of hydromorphone 8mg, and 10 fentanyl 100 mcg/hr patches, amounting to 548 MME/day, to 10 other patients pursuant to prescriptions written by Dr. Bynes.

iii. *Therapeutic Duplication*

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

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

84. 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.

85. 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).

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

87. Indeed, the majority of Dr. Bynes' patients who filled prescriptions at Chip's were able to obtain concurrent prescriptions for multiple immediate-release opioids. As merely a few examples, defendants dispensed both 120 units of oxycodone 30mg and 120 units hydromorphone 8mg—the highest commonly available strength of each—to B.C. each month between August 2016 and May 2017. Defendants dispensed three immediate-release opioids (hydromorphone 4mg, hydromorphone 8mg, and either oxycodone 10/325mg or hydrocodone 10/325mg) on multiple occasions to patient S.A. And during May, June, July, and August of 2017, defendants dispensed 120 dosage units of oxycodone 30mg and 120 units of hydrocodone 10/325mg to patient L.U.

88. In addition to opioids, defendants ignored red flags presented by other types of therapeutic duplication in Dr. Bynes' prescriptions as well. For example, in June, July, and August of 2017, defendants dispensed two benzodiazepines—90 dosage units of both alprazolam 2mg and clonazepam 2mg—to patient A.S.

Defendants also gave patient D.C. two forms of sleeping pills (30 dosage units of temazepam 30mg and zolpidem tartrate 10mg) in March, April, and May 2016 pursuant to Dr. Bynes' prescriptions.

iv. *Multiple Strengths of Oxycodone for Concurrent Use*

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

90. 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.

91. This combination was so routine that the six out of the first seven patients ever to fill Dr. Bynes' prescriptions at Chip's presented 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, and even though one of these patients lived approximately 93 miles away in Bloomindale, Georgia.

v. *Drug Cocktails*

92. 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. Combining these drugs results in a near quadrupling of risk of overdose death compared to opioid use alone.

93. 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]

94. 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.

95. 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

[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).

further, resulting in increased risk of death.

96. 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."

97. 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.

98. More than half of Dr. Bynes' patients who filled prescriptions at Chip's obtained the "holy trinity" cocktail from defendants.

99. Frequently, defendants filled additional controlled substances prescribed by Dr. Bynes to patients beyond the "holy trinity" cocktail. For example, on July 28, 2017, defendants provided Dr. Bynes' patient J.T. with five controlled substances consisting of:

- 120 dosage units of oxycodone 10/325mg;
- 240 dosage units of hydrocodone 10/325mg;
- 120 dosage units of alprazolam 2mg;
- 90 dosage units of carisoprodol 350mg; and
- 60 dosage units of zolpidem 10mg.

100. Defendants dispensed the same combination, in different quantities, to J.T. between August 28 and 31, 2017.

101. At Dr. Bynes' criminal trial, J.T. testified that Dr. Bynes had sex with

her on three occasions and exchanged sexually explicit text messages with her. J.T. testified that Dr. Bynes did not perform a physical exam before prescribing her controlled substances, to which she was addicted, and once his practice closed, J.T. turned to street drugs such as heroin.

102. Defendants filled J.T.'s prescriptions despite easily identifiable red flags. The prescriptions contained a well-known, commonly abused drug cocktail as well as therapeutic duplication from two different immediate-release opioids. Plus, J.T. lived in Townsend, Georgia, located approximately 75 miles from Chip's.

103. As another example, defendants dispensed eight controlled substances—four of which were opioids—to A.S. pursuant to Dr. Bynes' prescriptions between July 10 and 27, 2017, consisting of:

- 120 dosage units of oxycodone 30mg;
- 120 dosage units of oxycodone 15mg;
- 120 dosage units of oxycodone 10/325mg;
- 240 mL of hydromorphone 1mg/mL solution;
- 90 dosage units of alprazolam 2mg;
- 90 dosage units of clonazepam 2mg;
- 90 dosage units of carisoprodol 350mg; and
- 30 dosage units of zolpidem 10mg.

104. 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, known to produce a sought-after upper and downer effect. This combination also presents life-threatening cardiovascular risks such as a stroke or heart attack. For example, each month between March and June, 2017, defendants dispensed to patient H.D. a cocktail consisting of:

- 120 dosage units of oxycodone 30mg;
- 120 dosage units of oxycodone 15mg;
- 90 dosage units of alprazolam 2mg;
- 90 dosage units of carisoprodol 350mg;
- 60 dosage units of amphetamine salts 30mg; and
- 30 dosage units of zolpidem 10mg.

105. 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*

106. 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.

107. 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.

108. During the times material to this complaint, Chip's stocked immediate-release oxycodone tablets in 5/325mg, 7.5/325mg, 10/325mg, 10mg, 15mg, 20mg, and 30mg strengths.

109. The vast majority of Dr. Bynes' prescriptions filled by defendants for oxycodone were for the 30mg strength. And where a lower strength of oxycodone was dispensed for Dr. Bynes, it often was accompanied by a concurrent prescription for

oxycodone 30mg. None of the oxycodone dispensed for Dr. Bynes at Chip's was in the lowest strengths of 5/325mg or 7.5/325mg

110. During the times material to this complaint, Chip's stocked hydrocodone tablets in 10/325mg, 7.5/325mg, and 5/325mg strengths.

111. Every tablet of hydrocodone defendants dispensed for Dr. Bynes' was the 10/325mg strength. Not a single tablet was in a lower strength.

112. During the times material to this complaint, Chip's stocked hydromorphone tablets in 8mg, 4mg, and 2mg strengths.

113. The vast majority of Dr. Bynes' prescriptions filled by defendants for hydromorphone tablets were for the 8mg strength. And where a lower strength of hydromorphone was dispensed for Dr. Bynes, it often was accompanied by a concurrent prescription for hydromorphone 8mg. None of the hydromorphone tablets dispensed for Dr. Bynes at Chip's was in the lowest strength of 2mg.

114. During the times material to this complaint, Chip's stocked fentanyl patches in 100mcg/hr, 75mcg/hr, 50mcg/hr, 37.5mcg/hr, 25mcg/hr, and 12mcg/hr strengths.

115. Nearly all of Dr. Bynes' prescriptions filled by defendants for fentanyl patches were either the 100mcg/hr or the 75mcg/hr strengths. None of the fentanyl patches dispensed for Dr. Bynes at Chip's was in the lowest strengths of 37.5mcg/hr, 25mcg/hr, or 12mcg/hr.

116. During the times material to this complaint, Chip's stocked alprazolam

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

117. Nearly all of Dr. Bynes' prescriptions filled by defendants for alprazolam were in the 2mg strength. None of the alprazolam filled by defendants for Dr. Bynes was in the lowest strengths of 0.5mg or 0.25mg.

vii. Disproportionate Cash Sales

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

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

120. 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.

121. According to information submitted to the Georgia Prescription Drug Monitoring Program by Chip's from August 2016 to August 2018, only 44% of Dr. Bynes' controlled substance prescriptions filled at Chip's were paid through insurance, Medicare, Medicaid, or workers' compensation. For the remaining 55%, Chip's reported that the method of payment was "unknown" or "paid," indicating cash

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

transactions at more than six times the national rate.

122. In contrast, according to the same data, Chip's reported that only 33% of controlled substances prescribed by other doctors were paid through cash transactions.

123. Where defendants did not accept cash payments for Dr. Bynes' illegitimate prescriptions, defendants submitted claims for reimbursement of them to government programs, including Medicare and Medicaid.

viii. *Early Refills*

124. 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.

125. 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.

126. Defendants filled numerous early refill prescriptions for Dr. Bynes' patients, including more than 20 times for patient G.B., most notably:

- a prescription for fentanyl 100 mcg/hr patches 15 days early on July 14, 2017;
- a prescription for carisoprodol 350mg 15 days early on October 25, 2016; and
- two prescriptions for clonazepam 2mg 15 days early on November 21, 2016 and again on June 22, 2017.

127. Defendants knew or should have known that Dr. Bynes' patients were

not taking his prescriptions as prescribed when refilling these patients' controlled substances prescriptions early.

ix. Multiple Patients at the Same Address

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

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

130. For example, between June and September 2017, defendants filled prescriptions written by Dr. Bynes for seven patients (J.C., R.C., J.G., R.M.-1, R.M.-2, K.T. and J.W.), all of whom reported the same address to defendants. Defendants provided each of these patients multiple, concurrent opioids combined with a benzodiazepine. All but two of these patients received the "holy trinity" cocktail from defendants.

131. Defendants knew or should have known how unlikely it was for seven different people at a single-family dwelling to each have medical needs that could possibly have justified the regimen of controlled substances they dispensed.

132. As another example, defendants dispensed multiple "holy trinity" cocktails to G.B., J.B.-1, and J.B.-2, all of whom reported the same address to defendants, pursuant to Dr. Bynes' prescriptions. From April 2016 to September 2017, defendants dispensed between five and eight different controlled substances

prescribed by Dr. Bynes to G.B. each month, often including a "holy trinity" cocktail and multiple kinds of opioids. Nearly every month from April 2016 to February 2017, J.B.-1 also received similar cocktails consisting of two immediate-release opioids and the "holy trinity" cocktail. J.B.-2 also received monthly supplies of a combination of drugs that included a "holy trinity" cocktail from April 2016 to March 2017. In total, defendants dispensed over 17,500 dosage units of controlled substances to G.B., J.B.-1, and J.B.-2 pursuant to Dr. Bynes' prescriptions.

133. Even worse, defendants filled G.B.'s prescriptions despite the presence of other obvious red flags. On top of the dangerous amounts and combinations of controlled substances defendants dispensed to G.B. pursuant to Dr. Bynes' prescriptions, during this same period, G.B. presented prescriptions written by four other doctors as well, including for oxycodone, hydrocodone, clonazepam, and carisoprodol. Defendants knew or should have known that this type of doctor shopping is a classic sign of drug abuse. Making this conclusion even more obvious, as noted in paragraph 126, defendants frequently refilled G.B.'s prescriptions early, alerting defendants that G.B. was not taking them as directed.

134. Approximately ten other examples exist of defendants providing multiple individuals at the same address with controlled substances pursuant to prescriptions written by Dr. Bynes.

* * *

135. 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, patches, and solutions to drug seekers that ordinary pharmacists acting in the course of their duties would not have dispensed.

II. DEA's On-Site Inspection

136. From August 21, 2018, to August 22, 2018, DEA conducted an on-site inspection at Chip's to determine its compliance with the CSA and its implementing regulations.

137. During the inspection, DEA conducted an audit of certain controlled substances by comparing Chip'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.

138. The results of the controlled substances audit revealed that between May 1, 2017, and August 21, 2018, defendants were unable to account for more than 9,000 dosage units of oxycodone 30mg and hydrocodone 10/325mg, two of the most commonly abused opioids.

139. Defendants therefore violated 21 U.S.C. § 842(a)(5) by negligently failing to make, keep, or furnish records accounting for these controlled substances.

140. DEA Diversion Investigators advised defendant Wood of the auditing shortages and other recordkeeping violations on August 22, 2018.

141. On or about January 30, 2019, defendant Wood falsely advised Chip's

primary supplier of controlled substances that DEA had identified no deficiencies during its inspection.

COUNT ONE

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

142. Plaintiff repeats and realleges each allegation of paragraphs 1 through 141 as if fully set forth herein.

143. The CSA prohibited defendants Chip's and Wood from filling prescriptions for controlled substances unless they were supported by valid prescriptions.

144. Despite this prohibition, defendants Chip's and Wood filled tens of thousands of prescriptions for controlled substances that they knew or should have known were not supported by valid prescriptions.

145. Each time defendants Chip's and Wood 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.

146. Each of the thousands of violations subjects defendants Chip's and Wood 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)

147. Plaintiff repeats and realleges each allegation of paragraphs 1 through 141 as if fully set forth herein.

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

149. Between the beginning of business on May 1, 2017 and the close of business on August 21, 2018, defendants Chip's and Wood negligently failed to make, keep, and furnish accurate records of each dosage unit of oxycodone 30mg and hydrocodone 10/325mg "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).

150. Each of the more than 9,000 dosage units for which defendants Chip's and Wood are unable to account represents a separate violation of 21 U.S.C. § 842(a)(5).

151. Each of the more than 9,000 violations subjects defendants Chip's and Wood 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 Chip's and Wood on each Count of this complaint;

2. Impose a civil penalty on defendants Chip's and Wood 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 Chip's and Wood of not more than $15,040.00 for each of the more than 9,000 violations of 21 U.S.C. § 842(a)(5);

4. Pierce the corporate veil of the Chip's entities and find their shareholders responsible for the debts of each respective entity;

5. Find that the Chip's entities are the alter egos of each other and of Wood and that each is responsible for each other's debts and liabilities;

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

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

Date: February 12, 2020

Respectfully submitted,

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