UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 8:21 CV 188 T 35 AEP

WECARE PHARMACY, LLC; QINGPING ZHANG, PHARMD, MS; LI YANG, L&Y HOLDINGS, LLC.

COMPLAINT

FILED *EX PARTE* AND UNDER SEAL

Defendants.

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INTRODUCTION

1. The United States of America, by and through its undersigned attorneys, brings this action against WeCare Pharmacy, LLC, its owner, Qingping Zhang, PharmD, MS, Li Yang, and L&Y Holdings, LLC seeking injunctive relief and civil monetary penalties for Defendants' violations of the Controlled Substances Act, 21 U.S.C. § 801, et seq. (the "CSA") and its implementing regulations, 21 C.F.R. § 1301, et seq.

2. Opioid abuse is a national public health emergency. The dispensing and distributing of controlled substances, including prescription

opioid painkillers, without a legitimate medical purpose and outside the usual course of professional practice exacerbates this crisis.

3. Defendants have both fueled and profited from the opioid epidemic by repeatedly dispensing powerful opioids prone to abuse in violation of the CSA. Defendants' violations include knowingly dispensing or distributing controlled substances without a valid prescription in violation of 21 U.S.C. § 842(a)(1); knowingly dispensing or distributing controlled substances outside the usual course of the professional practice of pharmacy, in violation of 21 U.S.C. § 842(a)(1); dispensing controlled substances based on purported prescriptions that were not issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice, in violation of 21 U.S.C. § 829; and maintaining drug involved premises for the unlawful distribution of controlled substances in violation of 21 U.S.C. § 856. *See* 21 C.F.R. §§ 1306.01, 1306.04(a).

4. To protect the public health, the United States seeks to enjoin Defendants' unlawful conduct and impose civil monetary penalties for their past violations.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. §§ 842(c)(1)(A) and 882(a), 28 U.S.C. §§ 1331, 1345, 1355, and 1367(a).

6. This Court has personal jurisdiction over Defendants, and venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1391(c) because Defendants either reside in this District or transact business in this District.

PARTIES

7. Plaintiff is the United States of America.

8. Defendant WeCare Pharmacy, LLC ("WeCare") does business as a retail pharmacy and is a corporation formed and registered under the laws of Florida with its principal place of business in Tampa, Florida. WeCare is located at 7830 Gunn Highway, Tampa, Florida 33626.

9. Defendant Qingping Zhang, PharmD, MS ("Zhang") is licensed by the State of Florida as a consultant pharmacist who resides in this District. At all times relevant to this Complaint, Zhang operated, was a principal of, was identified as the prescription department manager for, and exercised control over WeCare. Zhang is also listed as the pharmacist in charge for WeCare. Zhang also is known by the pseudonym Anna Zhang.

10. Defendant Li Yang ("Yang") is a licensed pharmacy technician employed by Defendant WeCare. Yang is also the spouse of Defendant Qingping Zhang.

11. Defendant L&Y Holdings, LLC, is a Florida limited liability company that owns the building in which WeCare operates its business. The address of record for L&Y Holdings, LLC is 7830 Gunn Highway, Tampa, Florida 33626. Yang is listed as among the managers of L&Y Holdings, LLC according to Florida records.

12. Non-Party "Prescriber 1" operates a purported medical practice from 7830 Gunn Highway, Tampa, Florida 33626, in the same building as WeCare. Prescriber 1 is also listed among the managers of L&Y Holdings, LLC according to Florida records.

LEGAL BACKGROUND

A. The Controlled Substances Act

13. The CSA and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances in the United States. From the outset, Congress recognized the importance of preventing the diversion of drugs from legitimate to illegitimate uses. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance

except in a manner authorized by the CSA. *See, e.g.* 21 U.S.C 801 *et seq.*

14. The CSA categorizes controlled substances in five schedules.

15. Schedule I consists of substances that have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use under medical supervision." 21 U.S.C. § 812(b)(1); 21 C.F.R. § 1308.11.

16. Schedule II contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence" but nonetheless have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2).

17. Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." Schedule III drugs also have "a currently accepted medical use." 21 U.S.C. § 812(b)(3).

18. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological dependence when abused. 21 U.S.C. § 812(b)(4).

19. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused. 21 U.S.C. § 812(b)(5).

20. As relevant here, hydromorphone and oxycodone are controlled

substances in schedule II regulated under the CSA.

21. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. § 822(a). A registrant is permitted to dispense or distribute controlled substances only "to the extent authorized by their registration and in conformity with the [CSA]." 21 U.S.C. § 822(b). A pharmacist need not be registered with DEA if the pharmacy which employs the pharmacist is registered with DEA. 21 U.S.C. § 822(c)(1); see also 21 C.F.R. § 1306.06.

22. At all times relevant to this Complaint, WeCare was registered as a retail pharmacy with DEA in Schedule II–V controlled substances under registration number FW1880079. This DEA registration authorizes WeCare to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user … by, or pursuant to the lawful order of, a practitioner." 21 U.S.C. §§ 823(f), 802(10).

23. Agents and employees of a registered manufacturer, distributor, or dispenser of controlled substances, such as a pharmacist employed by a registered pharmacy, are not required to register with DEA, "if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. § 822(c)(1).

24. Under the CSA, the lawful dispensing of controlled substances is

governed by 28 U.S.C. § 829 and more specifically in Part 1306 of the CSA's implementing regulations. *See* generally 21 C.F.R. § 1306.

25. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency. 21 U.S.C. § 829(a). Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner. 21 U.S.C. § 829(b).

26. Such a prescription for a controlled substance may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1306.03.

27. A prescription, whether written or oral, is legally valid under the CSA only if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). "An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent" of [21 U.S.C. § 829] "and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled

substances." *Id.* "Person" is defined to include an individual, a corporation, a partnership, an association, and any other legal entity. 21 C.F.R. §§ 1300.01, 1306.02.

28. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R 1306.04(a). Thus, a pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose.

29. Moreover, "[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 (emphasis added).

30. Additionally, the CSA prohibits maintaining a drug-involved premises. This means (1) knowingly opening, leasing, renting, using, or maintaining any place for the purpose of distributing a controlled substance or (2) managing or controlling any place and knowingly making that place available for use for the purpose of unlawfully distributing a controlled substance. 21 U.S.C. § 856.

B. Florida Law Governing the Practice of Pharmacy

31. Florida law defines the "Practice of the profession of pharmacy"

to include "compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services." Section 465.003(1), Florida Statutes.

32. Federal law authorizes only a pharmacist acting in the usual course of professional pharmacy practice to fill a controlled substance prescription. *See* 21 C.F.R § 1306.06. Under Florida Law, only a "pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances . . . ." 893.04(1)(a). A pharmacy must keep records of the individual pharmacist responsible for dispensing of each prescription. *See* Fla. Admin. Code 64B16-28.140(3)(b)(7). The responsibility for the functions related to the practice of the profession of pharmacy may not be delegated to any non-pharmacist, nor to any pharmacy technician. *See* Section 465.014, Florida Statutes. Indeed, the pharmacy department of any pharmacy must close whenever a licensed pharmacist is not present and on duty. Section 465.003(11)(b), Florida Statutes.

33. Florida law requires, as a condition of obtaining a pharmacy permit, that the pharmacy designate a licensed pharmacist as a "prescription

department manager." *See* Section 465.018(2), Florida Statutes. A Prescription Department Manager, which is also commonly referred to as a pharmacist in charge, must be identified to the Florida Board of Pharmacy, and no pharmacist may serve as a prescription department manager at more than one pharmacy. Section 465.022(11)(c), Florida Statutes. The prescription department manager is "responsible for ensuring [. . .] compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities as a prescription department manager." Fla. Admin. Code. 64B16-27-450(2).

34. Florida pharmacy law requires that a pharmacist maintain a patient record system for all patients which "shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing." Fla. Admin. Code 64B16-27.800. Moreover, the pharmacist must "ensure that a reasonable effort is made to obtain, record and maintain" patient information relevant to pharmacy practice including, "Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug." *Id.*

35. Under Florida law, the practice of pharmacy requires that a licensed pharmacist conduct a prospective drug utilization review prior to dispensing each new and refill prescription. Fla Admin. Code 64B16-27.810. A pharmacist must review the patient pharmacy record to promote therapeutic appropriateness and identify, (a) Over-utilization or under-utilization; (b) Therapeutic duplication; (c) Drug-disease contraindications; (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; (f) Drug-allergy interactions; (g) Clinical abuse/misuse. A licensed pharmacist must, upon recognizing any of these indications, take appropriate steps to avoid or resolve the potential problems, including consulting with the prescriber, if necessary. *Id.*

36. The knowing dispensing of controlled substances when deliberately ignoring warning signals that a prescription was not issued for a legitimate purpose by a practitioner acting in the usual course of professional practice violates the prescription requirement contained in 21 U.S.C. § 829 because doing so violated the pharmacist's corresponding responsibility to ensure that a prescription was issued by a practitioner acting in the usual course of medical practice and for a legitimate medical purpose (21 C.F.R. § 1306.04) and because the a controlled substance prescription may only be filled in the usual course of professional pharmacy practice (21 C.F.R. §

1306.06).

37. Florida law also states that a pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient without first determining, in the exercise of her or his professional judgment, that the prescription is valid. *See* Section 893.04(2)(a), Florida Statutes. The pharmacist may dispense the controlled substance when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent. *Id.* Florida law requires that pharmacists interpret and act on clinical data, perform therapeutic interventions when necessary. 465.016(t).

38. Pharmacists are therefore permitted to dispense a controlled substance only in accordance with a generally accepted, objective standard of practice, i.e., "the usual course of his professional practice" of pharmacy and only when a prescription is issued for a legitimate medical purpose. *Id.*

39. Consequently, 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, 1306.06.

40. A pharmacist must exercise sound professional judgment in determining the legitimacy of a controlled substance prescription. Fla. Admin. Code § 64B16-27.831. "[W]hen a pharmacist is presented with a

prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment." Fla Admin. Code § 64B16-27.831(2). As of June, 2018, Florida law requires all pharmacists to complete continuing education on detecting illegitimate prescriptions. Fla. Admin. Code § 64B16-27.831(6).

41. Under 21 U.S.C. § 842(a)(1) it is "unlawful for any person who is subject to the requirements of Part C" of the CSA "to distribute or dispense a controlled substance in violation of [21 U.S.C. § 829]." Thus, a pharmacist who fills a prescription in violation of 21 U.S.C. § 829 and 21 C.F.R. § 1306 subjects the pharmacy who employs him or her to civil penalties under 21 U.S.C. § 842(a)(1).

42. Violations of 21 U.S.C. § 842(a)(1) are subject to a civil penalty. For violations occurring after November 2, 2015, the maximum penalty is $62,820. 21 U.S.C. § 842(c)(1)(B), as adjusted by Section 701 of the Bipartisan Budget Act of 2015, Public Law 114-74 (Nov. 2, 2015); 28 C.F.R. § 85.5.

43. The penalty for any person who violates 21 U.S.C. § 856 is no more than the greater of (1) $333,328 or (2) two times the gross receipts, either

known or estimated, that were derived from each violation that is attributable to the person. 28 C.F.R. § 85.5.

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

DEFENDANTS VIOLATED THE CSA

A. WeCare Dispenses Hydromorphone and Oxycodone at Extraordinary Rates

45. All DEA registrants that manufacture and distribute specific controlled substances pursuant to 21 C.F.R. § 1304.33 are required to report transactions to the DEA for inclusion in a database known as ARCOS (Automation of Reports and Consolidated Orders System). The wholesalers who sold controlled substances to WeCare reported applicable transactions to ARCOS.

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

47. From between 2016 and 2020, WeCare purchased hundreds of thousands of dosage units of schedule II controlled substances, including hydromorphone and oxycodone.

48. WeCare's purchasing volume of hydromorphone exceeded Florida State averages. Based on data available for 2020, WeCare's hydromorphone purchases were more than four times the Florida state average, and nearly three times the average for Hillsborough County. In 2019, WeCare purchased nearly ten times more hydromorphone than the Florida average and more than four times the average for Hillsborough County. In 2018, WeCare purchased nearly thirty times more hydromorphone than the average Florida pharmacy and more than five times more than the average for Hillsborough County. In 2017, WeCare purchased nearly nine times more hydromorphone than the average Florida pharmacy and nearly four times more than the average for Hillsborough County. In 2016, WeCare purchased more than thirteen times more hydromorphone than the average Florida pharmacy and more than four times more than the average for Hillsborough County.

49. WeCare's purchasing of oxycodone is generally more in line with total quantities purchased by other Tampa area pharmacies, but noteworthy given the relatively small customer base at WeCare compared to larger, national chain-style pharmacy, which have larger customer bases and whose controlled substances purchases are typically proportional in size to customer base.

50. In a single month, WeCare attempted to purchase oxycodone 30mg tablets and hydromorphone 8mg tablets in transactions on 14 different days from 11 different distributors. Oxycodone 30mg immediate release tablets and hydromorphone 8mg tablets are both the highest strength formulation generally available of these powerful opioids. Purchasing only the highest-strength formulation of opioids from multiple distributors is unusual for a pharmacy, because most pharmacies purchase controlled substances from a single distributor absent extenuating circumstances.

51. In contrast to the relatively high amounts of hydromorphone and oxycodone WeCare purchases, WeCare purchases almost negligible amounts of methadone, morphine, or hydrocodone compared to its peer pharmacies in Florida and the Tampa area. Methadone, morphine, and hydrocodone are commonly prescribed opioids in Florida. In fact, based on available data for 2020, WeCare purchased zero hydrocodone, the most commonly prescribed opioid nationally.

52. Section § 893.055, Florida Statutes, requires that pharmacies report to the Florida Prescription Drug Monitoring Program ("PDMP") each time a controlled substance is dispensed to an individual. The data collected by the PDMP is made available to health care practitioners, among others, to guide their decision in prescribing and dispensing highly abused prescription

drugs. WeCare reported to the PDMP reports of its dispensing of controlled substances described in this complaint.

53. Hydromorphone and oxycodone are powerful opioids and "high-alert" drugs in pharmacy practice that draw particular attention because of their extraordinary potency and risk of abuse and diversion. Both hydromorphone and oxycodone are available in a variety of strength formulations. It is uncommon for a single prescriber to issue controlled substance prescriptions only in the maximum strength formulation.

54. PDMP data from 2016 through January 6, 2021, shows that WeCare predominantly dispensed to individuals the highest-strength formulation of oxycodone (30 milligrams) and hydromorphone (8 milligrams). A large percentage of WeCare's customers received the same high-strength formulations and tablet amounts, which indicates a lack of individualized treatment.

55. PDMP data from January 1, 2016 through January 7, 2021, shows that WeCare dispensed 11,793 controlled substance prescriptions, written by 473 unique prescribers to 615 patients. Of those prescriptions, 4,333 (36.5 percent) were issued by Prescriber 1. By contrast, WeCare dispensed only an average of roughly 16 controlled substance prescriptions written by each of the other 472 unique prescribers. No individual prescriber

other than Prescriber 1 represented more than 5 percent of WeCare's total dispensing of controlled substance prescriptions. This analysis indicates that a large majority of WeCare's controlled substance customer base comes to the pharmacy seeking to fill prescriptions issued by Prescriber 1.

56. Of the 11,793 controlled substance prescriptions dispensed by WeCare from January 1, 2016 to January 7, 2021, roughly 50 percent involved a schedule II opioid. The following list shows the most-dispensed controlled substances by WeCare during this period:

a. Hydromorphone, with 97 percent, or 198,855 of the 204,644 hydromorphone tablets dispensed by WeCare for hydromorphone 8mg, the highest-strength formulation.

b. Oxycodone, with 78 percent, 224,436 of the 286,989 oxycodone tablets dispensed by WeCare being the for oxycodone 30mg, the highest-strength formulation.

57. In total, WeCare dispensed high-dosage oxycodone 30mg and hydromorphone 8mg tablets more than any other controlled substances. It is rare for a pharmacy to mostly dispense the highest strength formulation of two of the most powerful and mostly commonly abused prescription opioids.

58. WeCare dispensed an extraordinary volume of controlled substances to Prescriber 1's customers. Even though Prescriber 1 has no

specialty training in pain management, she is responsible for roughly 36.5 percent of all controlled substance prescriptions, and 97 percent of all hydromorphone 8mg prescriptions and 78 percent of all oxycodone 30mg prescriptions dispensed by WeCare.

B. **Defendants Ignored "Red Flags" of Abuse or Diversion**

59. From on or about January 1, 2016 to at least on or about January 6, 2021, Defendants violated the CSA by dispensing controlled substances in violation of their corresponding responsibility and outside the usual course of pharmacy practice. 21 C.F.R. §§ 1306.04; 1306.06.

60. For example, WeCare Pharmacy and Zhang ignored indicators of diversion. Common indicators of diversion, called "red flags," suggest that a prescription may not be legitimate.

61. In some situations, multiple red flags presented together cannot plausibly be resolved, and no reasonable pharmacist, discharging their professional duties, would dispense controlled substances under such circumstances. Such combinations of red flags are sometimes referred to as unresolvable red flags.

62. Defendants were presented with multiple red flags and/or repeated signs that prescriptions presented to the pharmacy could not

plausibly have been issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

63. Because 21 U.S.C. § 829 authorizes the dispensing of controlled substances only pursuant to a valid prescription, a pharmacist who fills a prescription in the face of red flags which cannot plausibly be resolved exceeds their authorization to dispense controlled substances under the CSA, and subjects the pharmacist and the pharmacy to civil penalties.

64. Consequently, dispensing controlled substances when faced with red flags with no plausible explanation indicating that a prescription was not issued for a legitimate purpose by a practitioner acting in the usual course of professional practice violates 21 U.S.C. § 842(a). Defendants repeatedly ignored egregious red flags of abuse and diversion, and knowingly filled prescriptions for controlled substances without regard for the lack of any plausible legitimacy of those purported prescriptions.

65. Rather than reject prescriptions presenting unresolvable red flags obvious to any reasonable pharmacist, Defendants systematically dispensed prescriptions issued by the same prescriber for the same maximum dosages of oxycodone and hydromorphone, often to individuals who travelled long distances to obtain these prescriptions, and often to multiple individuals reporting the same address. Taken together, these circumstances reflect

egregious and dangerous practices by WeCare pharmacy in dispensing powerful narcotics.

C. Red Flag: Pattern Prescribing

66. WeCare ignored Prescriber 1's pattern prescribing, that is, Prescriber 1's repetitive issuing of the same high-strength medications for the same patients over long periods of time without regard for individual patient factors. This pattern of prescribing would be an obvious red flag to any legitimate pharmacist.

67. WeCare regularly dispensed either 90 oxycodone 30 mg tablet or 120 hydromorphone 8 mg tablets pursuant to purported prescriptions issued by Prescriber 1. Oxycodone 30 mg is the highest strength of oxycodone immediate-release formulation and is among the most commonly abused prescription opioids. Similarly, hydromorphone 8 mg is the highest generally available form of that drug, which is an exceptionally powerful and commonly abused opioid.

68. During 2019 and 2020, Prescriber 1 issued approximately 988 prescriptions for oxycodone 30 mg tablets to be filled at WeCare. Based on these purported prescriptions, nearly every oxycodone 30 mg prescription was dispensed by WeCare for 90 tablets, except for a handful of prescriptions dispensed for 89 or 88 tablets.

69. Similarly, in 2019 and 2020, Prescriber 1 issued approximately 630 prescriptions for hydromorphone 8mg to be filled at WeCare Pharmacy. Based on these purported prescriptions, with only five exceptions, every hydrocodone 8 mg prescription was dispensed by WeCare for 120 tablets.

70. This pattern of Prescriber 1 issuing prescriptions again and again for maximum strength oxycodone and hydromorphone in generally the same quantities to nearly every individual is an unavoidably glaring red flag. Any reasonable pharmacist would have identified this red flag pattern. After recognizing this pattern from Prescriber 1 for maximum strength oxycodone in the exact same quantity to each individual, and the same pattern of maximum strength hydromorphone in the exact same quantity would prompt any reasonable pharmacist to immediately stop filling these hydromorphone and oxycodone prescriptions.

71. To take a recent date as an example, PDMP records show that on January 5, 2021, WeCare pharmacy filled a total of 13 controlled substance prescriptions. Prescriber 1 issued 11 of those prescriptions, 10 of which called for either 120 hydromorphone 8 mg tablets or 90 oxycodone 30 mg tablets. The very next day, on January 6, 2021, an additional six individuals presented prescriptions from Prescrber 1; half for 90 oxycodone 30 mg and the other half for 120 hydromorphone 8 mg. WeCare filled them all.

72. WeCare's pattern of rubber stamping prescriptions is further reflected in the fact that several of the very same individuals presented the same oxycodone 30 mg prescriptions or hydromorphone 8 mg prescriptions from Prescriber 1 on the same days in sequential months. For example, in October, November, and December of 2020, customers D.L., M.O., B.S, and T.S. all presented prescriptions at WeCare issued by Prescriber 1 for either oxycodone 30 mg or hydromorphone 8 mg on the same day of each month.

73. When the same individuals present the same prescriptions for commonly abused opioid drugs in their highest available formulation on the same day each month for several months, pharmacists should recognize such behavior as a red flag.

74. WeCare repeatedly filled on the same day multiple pattern prescriptions issued by Prescriber 1. For example, on each of the dates identified below, WeCare filled large numbers of prescriptions from Prescriber 1 for 90 oxycodone 30 mg or 120 hydromorphone 8mg tablets on the same day:

a. 10/22/2018: 13 customers

b. 12/17/2018: 12 customers

c. 07/29/2019: 18 customers

d. 09/23/2019: 12 customers

e. 02/05/2020: 11 customers

f. 06/30/2020: 11 customers

g. 01/05/2021: 10 customers

D. Red Flag: Long-Distance Travel to Obtain Opioids

75. Individuals traveling long distances to obtain or fill opioid prescriptions is a well-recognized red flag of abuse or diversion. Most people typically see physicians near their home or place of employment. Individuals willing to travel long distances to obtain or fill prescriptions often do so because other doctors would not issue such prescriptions and nearby pharmacies would decline to fill them.

76. Like other red flags, traveling long distances may be a resolvable circumstance where, for example, a person works far from their home and sees a doctor or fills a prescription near their workplace; a person may travel a long distance to see a practitioner with a recognized specialty; or other reasons. However, when multiple red flags are present, the standard of care for the practice of pharmacy requires that a pharmacist, acting as a gatekeeper of controlled substances, exercise sound professional judgment in evaluating and potentially resolving those red flags.

77. WeCare filled prescriptions for oxycodone 30 mg or hydromorphone 8 mg issued by Prescriber 1 to multiple individuals who traveled long distances according to PDMP data. For example:

a. P.M. traveled 90 miles from her home in Ocala to Tampa to obtain high-strength opioid prescriptions from Prescriber 1 and fill them at WeCare, an approximately three-hour round trip.

b. T.J. traveled 100 miles from his Ocala home to Tampa to obtain high-strength opioid prescriptions from Prescriber 1 and fill them at WeCare, a round trip requiring more than three hours.

c. R.S. traveled 120 miles from his home in Fanning Springs to Tampa to obtain high-strength opioid prescriptions from Prescriber 1 and fill them at WeCare, a more than four-hour round trip.

d. L.L. traveled 60 miles from her Sarasota home to Tampa to obtain high-strength opioid prescriptions from Prescriber 1 and fill them at WeCare, a round trip of 120 miles.

e. V.H. traveled 145 miles from her home in Lehigh Acres, outside of Fort Myers, to Tampa to obtain high-strength opioid prescriptions from Prescriber 1 and fill them at WeCare, a round trip of more than four hours.

f. J.N. traveled 150 miles from his home in Port Orange to Tampa to obtain high-strength opioid prescriptions from Prescriber 1 and fill them at WeCare, a round trip of approximately five hours.

78. These examples of individuals traveling long distances to obtain opioids raises a red flag that in combination with the pattern prescribing and rubber stamping red flags discussed above, create circumstances in which no reasonable pharmacist would fill controlled substance prescriptions.

D. Red Flag: Multiple Individuals Sharing a Common Address

79. DEA regulations at 21 C.F.R. § 1306.05 require that a prescription contain the patient's address. A pharmacy is required to document a patient's address in their records and report this information to the PDMP. Multiple individuals sharing a common address, particularly when they all receive controlled substances from a single prescriber, is a circumstance that pharmacists know or should know is a red flag of abuse or diversion.

80. A common address shared by multiple individuals may reflect an attempt to conceal an unusual distance traveled by a customer, fictitious identities used to obtain drugs, or other attempts made by a prescriber or individual to conceal indications of abuse or diversion.

81. PDMP data reflects that WeCare dispensed opioids to individuals sharing common addresses on multiple occasions. For example:

a. From 2016 through the present, WeCare filled opioid prescriptions from Prescriber 1 for six different individuals listed as having the same address on North Church Avenue in Tampa.

b. From 2017 through the present, WeCare filled opioid prescriptions from Prescriber 1 for three individuals listed as having the same address on North Armenia Avenue in Tampa.

c. From 2016 through the present, WeCare filled opioid prescriptions from Prescriber 1 for three different individuals listed as having the same address on Round Lake Court in Tampa.

82. These examples of multiple individuals listed at common addresses raise a red flag that in combination with the other red flags discussed above, create circumstances in which no reasonable pharmacist would fill controlled substance prescriptions.

E. WeCare Was Warned About Its Dispensing Practices By a Distributor Which Suspended Subsequent Controlled Substances Sales

83. By letter dated October 7, 2019, a national wholesale distributor of controlled substances (the "Distributor") notified WeCare and Zhang that it was suspending all sales of controlled substances to WeCare.

84. In the October 7, 2019 letter, the Distributor notified WeCare that after a review of WeCare's controlled substance purchasing and dispensing activity, the Distributor noted multiple red flags that placed the Distributor and WeCare "at risk for regulatory action by state and/or federal agencies." The Distributor specifically cited multiple red flags including:

a. "Monotonous prescribing activity by [Prescriber 1], primarily for hydromorphone and oxycodone in the highest dosage strengths for majority of patients."

b. "Chronic pain dispensing for [Practitioner 1] who lacks board certification in pain related discipline."

c. "Hydromorphone purchasing at rates approximately [eight] times national average for similar pharmacies."

d. "Majority of opioid controlled substance dispensing is for patients of one physician."

e. "Multiple suppliers for hydromorphone, the top controlled substance purchased from the Distributor by the pharmacy."

85. Defendant Zhang received the Distributor's October 7, 2019 letter.

86. Defendants already knew or should have known about the red flags described in the Distributor's October 2019 letter, which only made those

red flags all the more obvious. Nevertheless, Defendants continued their pattern of violative conduct to the present.

COUNT I

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

87. The United States re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

88. Title 21, U.S.C. § 842(a)(1) makes it unlawful for any person subject to Part C of the CSA to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829. As a DEA registrant, owner-pharmacist, and pharmacist technician of a registrant dispensing controlled substances, respectively, WeCare Pharmacy, LLC, Zhang, and Yang are subject to Part C of the CSA.

89. Defendants violated 21 U.S.C. § 829 by filling prescriptions for Schedule II, III, or IV controlled substances that also were prescription drugs under the Federal Food, Drug, and Cosmetic Act, outside the usual course of pharmacy practice in violation of 21 C.F.R. § 1306.06; and in violation of their "corresponding responsibility" by knowingly dispensing controlled substances pursuant to prescriptions that were issued outside the usual course

of professional practice or not for a legitimate medical purpose in violation of 21 C.F.R. § 1306.04.

90. Namely, in an amount to be determined at trial, and upon information and belief, Defendants filled prescriptions despite red flags with no plausible resolution indicating that such prescriptions were not written for a legitimate medical purpose or in the usual course of professional treatment.

91. Defendants are liable to the United States for a civil penalty in the amount of not more than $25,000 for each violation occurring on or before November 2, 2015, and not more than $67,627 for each violation after November 2, 2015, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT II

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

92. The United States re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

93. Under 21 U.S.C. § 843(f), the Attorney General of the United States is authorized to seek appropriate declaratory or injunctive relief relating to violations of 21 U.S.C. § 842. More broadly, 21 U.S.C. § 882(a) provides for any violation of the CSA to be enjoined.

94. Based on the violations set forth herein and Defendants' years-long pattern of conduct, the United States requests that the Court enter a preliminary and permanent injunction (i) prohibiting Defendants from administering, dispensing, or distributing any controlled substance; (ii) prohibiting Zhang and Yang from serving as a manager, owner, operator, or pharmacist-in-charge of any entity, including a pharmacy, that administers, dispenses, or distributes controlled substances; (iii) prohibiting Zhang and Yang from applying for or seeking renewal of any DEA Certificate of Registration on their behalf or on behalf of any corporate entity; and (iv) any other injunctive relief the Court deems appropriate and just.

COUNT III

Controlled Substances Act
21 U.S.C. § 856
Civil Penalty Liability and Permanent Injunctive Relief

95. The United States re-alleges and incorporates by reference the allegations contained in the foregoing paragraphs as though fully set forth herein.

96. Defendants WeCare Pharmacy, LLC, Zhang, Yang, and L&Y Holdings, LLC knowingly used, managed, or controlled 7830 Gunn Highway, Tampa, Florida 33626 for the purpose of operating WeCare Pharmacy to unlawfully distribute controlled substances.

97. As a result, Defendants are liable to the United States under 21 U.S.C. § 856 for not more than the greater of (1) $374,763 or (2) two times the gross receipts, either known or estimated, that were derived from each violation that is attributable to each of them for violations occurring on or after June 19, 2020.[1]

98. Additionally, Defendants are subject to an injunction to restrain further violations of Section 856 under 21 U.S.C. § 843(f).

PRAYER FOR RELIEF

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

1. Impose civil penalties up to the maximum amount allowed by law for each violation of 21 U.S.C. § 842(a)(1) committed by Defendants;

2. Enter a preliminary and permanent injunction (i) prohibiting Defendants from administering, dispensing, or distributing any controlled substance; (ii) prohibiting Zhang and Yang from serving as a manager, owner, operator, or pharmacist-in-charge of any entity, including a pharmacy, that administers, dispenses, or distributes controlled substances; (iii) prohibiting Zhang and Yang from applying for or seeking renewal of any DEA Certificate of Registration on their behalf or on behalf of any corporate entity; and (iv)

[1] This penalty amount has been adjusted pursuant to 28 C.F.R. § 85.5.

prohibiting WeCare LLC, Zhang, Yang, and L&Y Holdings, LLC from using, managing, or controlling any property where controlled substances are manufactured, distributed or dispensed.

3. Award the costs associated with the investigation, prosecution, and collection of the penalties and other relief in this matter; and

4. Award any other relief deemed just by the Court.

Dated: January 26, 2021

Respectfully submitted,

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