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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

JANELLE HARRIS

Defendant.

**COMPLAINT OF THE
UNITED STATES OF AMERICA**

25 Civ. 6456

Plaintiff, the United States of America, by its attorney, Jay Clayton, United States Attorney for the Southern District of New York, alleges upon information and belief as follows:

INTRODUCTION

1. The United States of America brings this civil enforcement action seeking penalties and injunctive relief against defendant Janelle Harris (“Harris”), the former owner and pharmacist-in-charge of The Pharmacy @ LLC (“The Pharmacy”), for violating the Controlled Substance Act (“CSA”) by knowingly failing to ensure that the prescriptions for controlled substances that she filled were legitimate.

2. Specifically, from 2014 through 2018 (the “Covered Period”), Harris

violated the CSA and its implementing regulations by accepting and filling prescriptions for controlled substances at The Pharmacy, and by supervising employees at The Pharmacy who accepted and filled prescriptions for controlled substances, without adequately fulfilling her responsibility to ensure that the prescriptions were for a legitimate medical purpose. In particular, The Pharmacy, under Harris's supervision and direction, repeatedly filled prescriptions for controlled substances that contained "red flags"—warning signs that should have created a reasonable suspicion that the prescriptions were not legitimate. These red flags included a single physician writing numerous prescriptions for 120 tablets of Oxycodone 30mg, which is a quantity and strength that suggests that the prescription is at risk for abuse and diversion. Red flags such as this should lead to further diligence by the pharmacist. Harris, however, repeatedly failed to conduct such adequate diligence before dispensing controlled substances to customers.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1), 843(f)(2) and 882(a), and 28 U.S.C. §§ 1345 and 1355.

4. Venue is proper in the Southern District of New York pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b) and 1395(a).

PARTIES

5. Plaintiff is the United States of America ("United States").

6. Defendant Janelle Harris is a pharmacist licensed in the State of New York and was the owner and supervising pharmacist of The Pharmacy @ LLC, which was a retail pharmacy located at 2541 Adam Clayton Powell Jr. Blvd., New York, New York 10039.

REGULATORY BACKGROUND

7. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. It is unlawful to manufacture, distribute, or dispense any controlled substance except in a manner authorized by the CSA or its implementing regulations.

8. Drugs and other substances that are considered controlled substances under the CSA are divided into five “schedules,” which are designated by Roman numerals I through V. As relevant here, Schedule II controlled substances, as defined under the CSA, are drugs that have a currently accepted medical use in the United States, but also a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2). Examples of Schedule II controlled substances include opioid-based painkillers such as Oxycodone and Hydrocodone.

9. To prevent the diversion of controlled substances, the CSA imposes requirements for the distribution and dispensing of these drugs. Among other requirements, pharmacies must register with the United States Drug Enforcement Administration (the “DEA”) before distributing or dispensing controlled substances. *See* 21 U.S.C. § 822(a). Once registered, a pharmacy, as well as its agents and employees, are only permitted to distribute or dispense controlled substances to the extent authorized by their registration and in conformity with the CSA. *See* 21 U.S.C. § 822(b).

10. The CSA defines dispensing to mean delivering a controlled substance to an ultimate user (*e.g.*, a patient) by, or pursuant to a lawful order (*i.e.*, a prescription) of, a practitioner. *See* 21 U.S.C. § 802(10). Distributing means delivering a controlled substance other than by dispensing or administering (which is direct application of a drug to a patient).

See id. §§ 802(11); 802(2)(A).

11. Among its other provisions, the CSA and its implementing regulations limit when a controlled substance may be dispensed pursuant to an oral or written prescription. *See* 21 U.S.C. § 829. Under 21 C.F.R. § 1306.04(a), a prescription for a controlled substance is valid only if it is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” Along with the prescribing practitioner, a pharmacist considering whether to fill a prescription bears a “corresponding responsibility” to ensure “the proper prescribing and dispensing of controlled substances.” *Id.* Any “person knowingly filling” a prescription that is not issued in the usual course of professional treatment “shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” *Id.*; *see also id.* §§ 1300.01, 1306.02 (defining “person” to include individuals or any legal entity).

12. In assessing whether a prescription is issued for a “legitimate medical purpose,” a pharmacist must look to see whether the prescription or patient presents “red flags,” or warning signs that create a reasonable suspicion that the prescription is not legitimate. “Red flags” may include, for example: the amount or combination of controlled substances prescribed; the abuse potential of those controlled substances; the temporal proximity to other prescriptions filled for the patient; the prescriber’s office location relative to the patient’s home; the prescriber’s prescribing history with the patient, or general prescribing practices; or the behavior of the individual presenting the prescription (such as a request for early refills).

13. When a “red flag” is present, a pharmacist must conduct further and sufficient inquiry to determine whether the prescription is legitimate. A pharmacist must refuse to fill a controlled substance prescription if the pharmacist knows or was willfully blind to the

fact that the prescription was not written for a legitimate medical purpose or in the usual course of the physician's professional practice. 21 C.F.R. § 1306.04. Additionally, pharmacists must act in the usual course of their professional practice as pharmacists when filling a prescription. 21 C.F.R. § 1306.06. This means that a pharmacist may dispense a controlled substance only in accord with a generally accepted, objective standard of pharmacy practice.

FACTUAL ALLEGATIONS

14. For the entirety of the Covered Period, Harris was a pharmacist licensed in the State of New York. Harris owned and operated The Pharmacy and served as its head pharmacist. In those capacities, Harris was actively involved in, supervised, and was responsible for dispensing Schedule II controlled substances and other prescription medications to customers.

15. Further, as The Pharmacy's owner and head pharmacist, Harris had a duty to ensure that prescriptions filled at The Pharmacy for controlled substances, including Schedule II controlled substances, were for a legitimate medical purpose before dispensing those drugs. As part of this duty, Harris was required to look for "red flags" indicating that the prescribed controlled substances were at risk for abuse or diversion, or not for a legitimate medical purpose. As described above, such red flags can include: prescriptions for high dosage strengths or for large quantities of controlled substances; cash payments for controlled substances; sequential prescription numbers; and multiple prescriptions for controlled substances to a single individual within a short period of time.

16. Throughout the Covered Period, Harris and her supervisees knowingly and repeatedly filled prescriptions for Schedule II controlled substances, such as Oxycodone, that presented significant red flags with respect to the prescriptions' medical legitimacy and/or with

respect to whether they were written by a practitioner in the usual course of professional treatment. Such red flags included cash payments by customers for Schedule II controlled substances, numerous prescriptions for a Schedule II controlled substance written by a single doctor, and prescriptions with semi-consecutive prescription numbers. Harris and her supervisees ignored these red flags and failed to take sufficient steps to resolve them before filling the prescriptions. Some of The Pharmacy's prescriptions for Schedule II controlled substances, such as Oxycodone, were ultimately determined to be issued without a legitimate medical purpose.

17. For example, over a four-month period, The Pharmacy, under Harris's supervision and direction, filled 115 prescriptions written by a single doctor, 114 of which were for 120 tablets of Oxycodone 30 mg. This combination of quantity (120 tablets) and dosage strength (30 mg) for Oxycodone is considered a red flag because of its high potential for abuse and diversion. Here, this concern is further elevated because virtually every prescription written by this one doctor over a four-month period is for this suspect combination. However, during this period, no one from The Pharmacy called this doctor to confirm the validity of these prescriptions before filling them for customers.

18. Similarly, during the Covered Period, The Pharmacy, under Harris's supervision and direction, received over 200 prescriptions for Oxycodone that were either written in the name of a single customer or picked up by this customer using a fake identification card. Moreover, the customer paid for all of these prescriptions in cash. Despite these glaring red flags, The Pharmacy, under Harris's supervision and direction, filled these prescriptions without conducting adequate further diligence.

19. Further, over an 11-month period, every prescription presented to The

Pharmacy by one single doctor was for 120 tablets of Oxycodone 30 mg, including 18 such prescriptions written on a single day that contained semi-consecutive prescription numbers (another “red flag”). Again, despite these glaring red flags, The Pharmacy, under Harris’s supervision and direction filled these prescriptions without conducting adequate further diligence.

CAUSE OF ACTION

(Accepting False or Fraudulent Prescriptions – Numerous Violations)

20. The United States realleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

21. 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 the owner-manager of a DEA registrant dispensing controlled substances, Harris is subject to Part C of the CSA.

22. Harris violated 21 U.S.C. § 829 by filling prescriptions for Schedule II controlled substances outside the usual course of pharmacy practice and not in compliance with her “corresponding responsibility.” 21 C.F.R. §§ 1306.04 & 1306.06.

23. Namely, Harris filled prescriptions that were not written for a legitimate medical purpose or were written outside the usual course of professional treatment, as evidenced by the numerous red flags that Harris, and/or individuals under her supervision, failed to diligence adequately prior to filling such prescriptions.

24. Under 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5, each violation of 21 U.S.C. § 842(a)(1) subjects Harris to a civil penalty of not more than \$25,000.00 for violations occurring on or before November 2, 2015, and not more than \$67,627.00 for violations

occurring after November 2, 2015.

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

- (a) A sum equal to civil penalties to the maximum amount allowed by law;
- (b) Appropriate injunctive relief pursuant to 21 U.S.C. § 843(f); and
- (c) Granting the United States such further relief as the Court may deem proper.

Dated: New York, New York
August 6, 2025

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