UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 8:22-cv-01725-TPB-JSS
FILED UNDER SEAL

NATHANIEL ESALOMI,

Defendant.
_____/

COMPLAINT UNDER THE CONTROLLED SUBSTANCES ACT FOR INJUNCTIVE RELIEF AND CIVIL PENALTIES

INTRODUCTION

1. The United States of America sues for injunctive relief and civil monetary penalties based on the defendant's 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 and harms the public health.

3. The defendant, Nathaniel Esalomi, has both fueled and profited from the opioid epidemic by repeatedly dispensing powerful opioids prone to abuse in violation of the CSA through the guise of Apexx Pharmacy, which he owns and runs

as the sole pharmacist. In transactions with undercover law enforcement, Esalomi repeatedly filled prescriptions for controlled substances that he knew were not legitimate in exchange for cash. Esalomi also repeatedly filled prescriptions in the names of dead patients and falsely recorded that these patients were present in the pharmacy when the drugs were dispensed. In so doing, Esalomi violated the CSA.

4. Accordingly, the United States seeks to enjoin defendant's unlawful conduct to protect the public health and impose civil monetary penalties for past violations of the CSA.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over the defendant, and venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1391(c) because the defendant either resides in this district or transacts business in this district.

PARTIES

7. The plaintiff is the United States of America.

8. The defendant, Nathaniel Esalomi, is licensed by the State of Florida as a pharmacist. At all times relevant to this Complaint, Esalomi owned and operated Apexx Pharmacy, LLC ("Apexx"), which does business as a retail pharmacy, located at 10343 State Road 52, Hudson, Florida 34669. Esalomi is the sole pharmacist and the pharmacist-in-charge of Apexx.

LEGAL BACKGROUND

A. Applicable statutes, regulations, and guidelines

9. The CSA and its implementing regulations govern the manufacturing, distributing, and dispensing of controlled substances in the United States. Congress recognized the importance of preventing the diversion of drugs from legitimate medical or scientific uses to any other illegitimate uses. The CSA establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§ 841(a), 842(a).

10. The CSA categorizes controlled substances in five schedules.

11. 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.

12. 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).

13. 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).

14. 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).

15. 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).

16. As relevant here, the following substances are controlled substances regulated under the CSA:

a. Promethazine-Codeine (Schedule V);
b. Oxycodone (Schedule II);
c. Hydromorphone (Schedule II);
d. Suboxone (Schedule III).

17. The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical. 21 U.S.C. § 802(11).

18. The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject. 21 U.S.C. § 802(10).

19. The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there

exists an agency relationship. 21 U.S.C. § 802(8).

20. 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.

21. At all times relevant to this Complaint, Apexx was registered as a retail pharmacy with DEA in Schedule II–V controlled substances under registration number FA54933363. This DEA registration authorizes Apexx to "dispense" controlled substances.

22. 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).

23. 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.

24. Unless dispensed directly by a practitioner (other than a pharmacist) to an ultimate user, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician. 21 U.S.C. § 829(a). Unless

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