UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. McELROY PHARMACY, INC. and JEFFREY ESHELMAN, Defendants.	Civil Action No. Jury Trial Demanded

COMPLAINT

The United States brings this suit to hold McElroy Pharmacy and owner-pharmacist Jeffrey Eshelman accountable for illegally dispensing controlled substances and healthcare fraud. McElroy, a small community pharmacy in Lititz, Pennsylvania, was owned and operated in part by Eshleman. Until the Drug Enforcement Administration arrived at the pharmacy, McElroy was an outlier in its geographic area as the top purchaser of high-risk Schedule II opioid hydrocodone. An investigation revealed that the pharmacy, through its lead pharmacist and co-owner Eshelman, engaged in a years-long practice of dispensing countless pills of high-risk hydrocodone to individuals in the Lititz area, knowing that the individuals had a substance use disorder, without requiring a prescription. Eshelman engaged in this practice despite the licensing board disciplining him for the same misconduct years prior. In addition to hydrocodone, the investigation showed that the pharmacy illegally dispensed other controlled substances, engaged in healthcare fraud by billing Medicare for drugs that were not actually dispensed to beneficiaries, and failed to account for tens of thousands of controlled substance pills due to inaccurate inventory. The egregious misconduct, particularly providing opioids to individuals with opioid use disorder, caused serious public harm in the community. The United States files this suit to impose civil penalties, damages, and prevent defendants from dispensing controlled substances and falsely billing for other prescription medications in the future.

PARTIES

1. Plaintiff is the United States of America.

2. Defendant McElroy Pharmacy Inc. is a Pennsylvania corporate entity. McElroy is owned by Jeffrey and Brenda Eshelman. McElroy was registered with the Pennsylvania pharmacy licensing board. The Drug Enforcement Administration (DEA) granted McElroy a registration on April 16, 1991, as a retail pharmacy authorized to purchase and dispense Schedule II-V controlled substances at 100 East Main Street, Lititz, Pennsylvania. McElroy Pharmacy Inc. surrendered its DEA registration in November 2019 after the Drug Enforcement Administration executed an administrative inspection warrant at the pharmacy.

3. Defendant Jeffrey Eshelman is an individual residing in Lititz, Pennsylvania. Jeffrey Eshleman owned and managed McElroy Pharmacy at all times relevant to this Complaint. He was registered with the Pennsylvania pharmacy licensing board as McElroy Pharmacy's pharmacist-in-charge at all times relevant to this Complaint.

4. Defendants McElroy Pharmacy and Jeffrey Eshelman are collectively referred to as the "defendants."

JURISDICTION AND VENUE

5. This action is brought by the United States for civil penalties and injunctive relief under the Controlled Substances Act, 21 U.S.C. §§ 801-971, as well as civil damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-33.

6. This Court has subject matter jurisdiction over the Controlled Substances Act civil penalties, 21 U.S.C. § 842, pursuant to 21 U.S.C. § 842(c)(1)(A), and 28 U.S.C. §§ 1331, 1345, 1355.

7. This Court has subject matter jurisdiction over the Controlled Substances Act injunctive relief, 21 U.S.C. §§ 843(f), 882, pursuant to 21 U.S.C. §§ 843(f), 882, and 28 U.S.C. §§ 1331, 1345.

8. This Court has subject matter jurisdiction over the False Claims Act count for civil damages and penalties pursuant to 31 U.S.C. § 3732, and 28 U.S.C. §§ 1331, 1345, and 1355.

9. This Court has personal jurisdiction over McElroy Pharmacy, Inc. because, *inter alia*, the entity is found in, was incorporated in, transacted business in, is licensed in, and engaged in the illegal conduct alleged below in this District, all of which harmed the public and the United States in this District.

10. This Court has personal jurisdiction over Jeffrey Eshelman because, *inter alia*, he resides in, is domiciled in, transacted business in, was licensed in, and engaged in the illegal conduct alleged below in this District, all of which harmed the public and the United States in this District.

11. Venue is proper in the Eastern District of Pennsylvania because the defendants reside in this District, and a substantial part of the events or omissions giving rise to the claims occurred in this District, 28 U.S.C. § 1391; the claims accrued in this District, and the defendants are found in this District, 28 U.S.C. § 1395; and because the defendants are located, reside, did business, and engaged in the illegal conduct in this District, 21 U.S.C. § 843(f); 31 U.S.C. § 3732(a).

THE CONTROLLED SUBSTANCES ACT

12. The Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, and its regulations govern the distribution and dispensing of controlled substances. The CSA establishes strict guidelines "to ensure a sufficient supply for legitimate medical . . . purposes and to deter

diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances." 75 Fed. Reg. 61613 (Oct. 6, 2010).

I. Controlled substances are strictly regulated and scheduled based on their potential for abuse and medical uses.

13. Federal legislation dictates how prescription drugs are categorized. Drugs can be placed in Schedules I through V based on, *inter alia*, their "potential for abuse" and whether they have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b). For example, Schedule II controlled substances are those that have a "high potential for abuse" that "may lead to severe psychological or physical dependence," but have "a currently accepted medical use in treatment." *Id.*

14. Pursuant to legislation and administrative action by the Drug Enforcement Administration:

a) oxycodone (including drugs that contain it such as oxycodone-acetaminophen), hydrocodone, and methadone are opioids categorized as Schedule II controlled substances, *see* 21 C.F.R. § 1308.12; and

b) buprenorphine (including drugs that contain it, and with brand names including Suboxone) is a drug categorized as a Schedule III controlled substance, *see* 21 C.F.R. § 1308.13.

II. Entities that purchase and dispense controlled substances directly to patients, such as retail pharmacies, are required to register with the DEA and subject to strict controls.

15. The CSA requires those who distribute or dispense controlled substances, including pharmacies that dispense controlled substances pursuant to a prescription, to obtain a

registration from the Drug Enforcement Administration. 21 U.S.C. § 822(a). Individuals or entities who have a registration are commonly referred to as "registrants."

16. The registration requirements for those who dispense are based on the statute's definition of a "dispenser," which is defined as "a practitioner who [] delivers a controlled substance to an *ultimate user*" "pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance." 21 U.S.C. § 802(10) (emphasis added). That definition includes retail pharmacies that dispense controlled substances directly to patients. *See id.* § 802(21) (defining "practitioner" to include a "pharmacy").

17. Even when a registrant such as a retail pharmacy falls within the definition of "dispenser" and receives authorization through a DEA registration to dispense controlled substances, it may only dispense a controlled substance as "authorized by their registration and in conformity with the other provisions of" the CSA. *Id.* § 822(b).

III. Retail pharmacies registered with the DEA are generally permitted to deliver controlled substances only to patients with a valid prescription for a legitimate medical purpose.

18. For those entities such as retail pharmacies registered to dispense, the CSA establishes strict limitations on when a controlled substance can be dispensed to the patient and ultimate user. It generally provides that, unless a non-pharmacy practitioner dispenses directly or there is an emergency, Schedule II, III, and IV controlled substances can only be dispensed upon a "prescription." 21 U.S.C. § 829(a), (b).

19. Even with an emergency, the "prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist" "[w]ithin 7 days after authorizing [the] emergency oral prescription." 21 C.F.R.

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