

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA

CIVIL ACTION

VERSUS

NO. 22-414

STEVENS PHARMACY, INC. &
STEVEN W. GOUGH

COMPLAINT

The United States of America brings this Complaint against Stevens Pharmacy, Inc. and its owner and pharmacist-in-charge, Mr. Steven W. Gough, based on violations of the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.* In support of this Complaint, the United States represents:

INTRODUCTION

1. Congress enacted the Controlled Substances Act (the “CSA”), 21 U.S.C. § 801 *et seq.*, in 1970 “to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.” *Gonzales v. Raich*, 545 U.S. 1, 12 (2005). “Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.” *Id.* at 12-13.

2. “To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Id.* at 13. “The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.” *Id.* at 14.

3. Since the CSA’s enactment, the United States has faced an opioid crisis, “[t]he magnitude and significance of [which] . . . cannot be overstated.” *In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 4686815, at *1 (N.D. Ohio Sept. 26, 2019).

4. The U.S. Department of Health and Human Services has declared “a nationwide public health emergency regarding the opioid crisis” and has noted that “[e]ach day, according to the Centers for Disease Control and Prevention, more than 140 Americans die from drug overdoses, 91 specifically due to opioids.”¹

5. According to the Centers for Disease Control and Prevention (the “CDC”), Louisiana had an opioid dispensing rate of 68.3 opioid prescriptions per 100 persons in 2020, which was the fourth highest dispensing rate in the United States for that year.²

6. The 2020 opioid dispensing rate was even higher for East Baton Rouge Parish. The CDC reports that East Baton Rouge Parish had an opioid dispensing rate of 98.194 opioid prescriptions per 100 persons in 2020—meaning that, on average, there was almost one opioid prescription for every person in East Baton Rouge Parish for that year.³

7. The United States brings this civil enforcement action against Stevens Pharmacy, Inc. (“Stevens Pharmacy”), and its owner and pharmacist-in-charge, Mr. Steven W. Gough, based on numerous, systemic violations of the CSA. In particular, between 2018 and 2020, Stevens Pharmacy and Mr. Gough filled hundreds of facially invalid prescriptions for controlled substances, including opioids. Such violations include (but are not limited to) filling prescriptions

¹ U.S. Dep’t of Health & Human Servs., *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis* (Oct. 26, 2017), <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html> [<https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>].

² Ctrs. for Disease Control & Prevention, *U.S. State Opioid Dispensing Rates, 2020*, <https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html> (last visited June 16, 2022).

³ Ctrs. for Disease Control & Prevention, *U.S. County Opioid Dispensing Rates, 2020*, <https://www.cdc.gov/drugoverdose/rxrate-maps/county2020.html> (last visited June 16, 2022).

for controlled substances lacking required data elements; dispensing more controlled substances, including opioids, than prescribed; and the early filling of prescriptions for controlled substances.

8. Further, during a 2020 audit, the Drug Enforcement Administration (DEA) uncovered evidence that Stevens Pharmacy failed to maintain accurate inventories of its controlled substances, including opioids, resulting in unexplained overages and shortages in its drug stocks.

9. These violations occurred despite a nearly decade-long history of Consent Agreements with the Louisiana Board of Pharmacy arising from prior inventory variances of controlled substances, the failure to report the theft of drugs to the DEA and the Board of Pharmacy, and the dispensing of controlled substances with an expired state license.

10. Stevens Pharmacy and Mr. Gough have therefore increased the likelihood of abuse and diversion of controlled substances, justifying substantial civil penalties under the CSA.

PARTIES

11. The United States of America brings this lawsuit on its own behalf to enforce the CSA.

12. On information and belief, Defendant Stevens Pharmacy, Inc. is a registered Louisiana corporation with a principal place of business at 520 S. Alexander Ave., Ste. 200, Port Allen, Louisiana 70767. The pharmacy currently has an active, but restricted, Controlled Dangerous Substance (CDS) License, No. CDS.038660-PHY, with the Louisiana Board of Pharmacy. Until March 4, 2020, Stevens Pharmacy held DEA Registration Number BS7083607, under which it was authorized to dispense controlled substances in Schedules II-V. Stevens Pharmacy voluntarily surrendered its DEA Registration on March 4, 2020, and does not currently dispense or distribute controlled substances.

13. On information and belief, Defendant Steven W. Gough is a Louisiana resident and the sole owner and pharmacist-in-charge of Stevens Pharmacy. Mr. Gough is registered with the

Louisiana Board of Pharmacy with license numbers PIC.013199 and PST.013199. He has been a registered pharmacist in Louisiana since 1982. On information and belief, Mr. Gough serves as the President, Treasurer, Secretary, and Director for Stevens Pharmacy.

JURISDICTION AND VENUE

14. The Court has subject-matter jurisdiction over all claims in this matter under 28 U.S.C. §§ 1331, 1345, 1355(a) and 21 U.S.C. § 842(c)(1)(A).

15. The Court may exercise personal jurisdiction over the defendants because they are residents of Louisiana and are therefore subject to the jurisdiction of a court of general jurisdiction in the state of Louisiana. *See* Fed. R. Civ. P. 4(k)(1)(A); *cf.* La. Code Civ. Proc. art. 6(A).

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d), 1395(a) because the defendants reside in and may be found in this district and because the Government's claims have accrued in this district based on the acts or omissions of the defendants within the Middle District of Louisiana.

OVERVIEW OF THE CONTROLLED SUBSTANCES ACT

17. The CSA and its implementing regulations govern the manufacturing, distributing, and dispensing of controlled substances that pose a risk of abuse and dependence in the United States. *Cf.* 21 U.S.C. §§ 811-812.

18. The CSA categorizes controlled substances into five schedules. *See* 21 U.S.C. § 812.

19. 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 of the drug or other substance under medical supervision.” 21 U.S.C. § 812(b)(1); *see also* 21 C.F.R. § 1308.11.

20. 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 in the United States or a currently accepted medical use with severe restrictions.” 21 U.S.C. § 812(b)(2); *see also* 21 C.F.R. § 1308.12.

21. With limited exceptions applicable only in emergency situations, “[a] pharmacist may dispense directly a controlled substance listed in Schedule II . . . only pursuant to a written prescription signed by the practitioner” 21 C.F.R. § 1306.11(a).

22. Schedule III contains drugs that, although the potential for abuse is less than a Schedule II drug, may lead to a moderate or low “physical dependence or high psychological dependence.” Schedule III drugs also have “a currently accepted medical use in treatment in the United States.” 21 U.S.C. § 812(b)(3); *see also* 21 C.F.R. § 1308.13.

23. Schedule IV contains drugs that, although having a lower potential for abuse than Schedule III drugs, may still lead to a limited physical or psychological dependence when abused. 21 U.S.C. § 812(b)(4); *see also* 21 C.F.R. § 1308.14.

24. Schedule V contains drugs that, although having a lower potential for abuse than Schedule IV drugs, may still lead to a limited physical or psychological dependence when abused. 21 U.S.C. § 812(b)(5); *see also* 21 C.F.R. § 1308.15.

25. The CSA requires persons or entities who dispense or propose to dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. § 822(a)(2). Such registrations are issued for between one and three years before renewal is required. *Id.*

26. “The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.” 21 U.S.C. § 821. Further, “[t]he

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