

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

_____)	
UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	Jury Trial Demanded
)	
v.)	Case No. _____
)	
WALMART INC. AND WAL-MART STORES)	
EAST, LP,)	
)	
Defendants.)	
_____)	

COMPLAINT

TABLE OF CONTENTS

INTRODUCTION 5

 A. As a pharmacy, Walmart violated the rules for dispensing controlled substances. 8

 B. As a distributor, Walmart violated its duty to detect and report suspicious orders of controlled substances..... 12

 C. Walmart systematically violated the CSA even as it recognized the prescription drug abuse epidemic gripping the nation..... 14

PARTIES 16

JURISDICTION AND VENUE 17

I. WALMART’S CSA OBLIGATIONS AS A PHARMACY AND A DISTRIBUTOR..... 17

 A. Controlled substances generally. 17

 B. The CSA creates a closed system for regulating controlled substances. 19

 C. A pharmacy must comply with certain rules before it fills a controlled-substance prescription. 20

 1. The pharmacist must determine whether the prescription was issued in the usual course of professional practice and for a legitimate medical purpose. 22

 2. The pharmacist also must adhere to professional pharmacist practice standards, which require identifying and resolving any “red flags.” 23

 3. Violations of these dispensing rules subject the pharmacy to civil penalties and other appropriate relief. 25

 D. Distributors must abide by certain legal obligations when they receive controlled-substance orders from pharmacies..... 27

 1. Distributors must detect and report suspicious orders. 27

 2. Failure to report suspicious orders subjects the distributor to civil penalties. 28

II. WALMART, AS A PHARMACY, VIOLATED THE CSA. 29

 A. Walmart impeded its pharmacists’ ability to comply with the legal requirements for dispensing controlled substances..... 31

 1. Walmart managers pressured pharmacists to fill prescriptions as quickly as possible..... 31

 2. Walmart’s compliance unit chose not to give its pharmacists the information and authority it knew they needed to comply with the rules. 36

 a. Consistent with the CSA, Walmart’s own policy required pharmacists to identify and resolve red flags, and to document any resolution of red flags. 36

 b. After Walmart was accused of dispensing violations, it committed to adopting a nationwide compliance program to identify red flags and prevent diversion. 40

 c. While Walmart’s compliance unit did compile red-flag information, it chose not to disseminate that information to pharmacists. 41

 d. Walmart prohibited its pharmacists from refusing to fill, as a blanket matter, all prescriptions issued by pill-mill prescribers. 48

B. Even after Walmart pharmacists identified pill-mill prescribers who were issuing invalid prescriptions, Walmart kept filling their prescriptions..... 50

1. D.C.: “95% of the prescriptions from this prescriber are for controlled substances” 52
2. F.B.: “Always writes excessive quantities for all of his patients” 53
3. F.T.: Prescribed “too many [drugs] for one person to take” 56
4. G.G.: “gives patients what they want and [does] not practice real medicine.” 57
5. G.H. and R.M.: “well known as a pill mill” 60
6. H.D.: “filling for him is a risk that keeps me up at night”; “our concerns are falling upon deaf ears” 63
7. J.F.: Prescriber of very heavy doses..... 67
8. J.I.: A “known pill-mill doctor” 69
9. M.L.: “continually writes for high quantities of narcotics” 71
10. M.M.: A “known pill mill” who sent his patients to Walmart..... 72
11. M.N-A.: “many DEA red flags present” 76
12. P.T.: “too many questions regarding the ethics and integrity of this physician” 77
13. R.K.: Filling prescriptions from this “pill mill” was “putting pharmacists and Walmart in a bad situation legally”..... 79
14. R.M.: Prescriptions “are likely not prescribed for ethical purposes” 81
15. R.P.: “horrendous prescribing practices”; “customers that were under the influence tell me that this doctor will write whatever they want” 83
16. R.W.: Prescribed “cocktails” and recommended patients fill at Walmart 85
17. S.K.: “there is no way that many 25 year olds need 120 to 240 oxycodone per month” 86
18. V.S.: A “shady doctor” who “writes only controlled medications for every patient” 89
19. W.W.: A “pill mill prescriber” for “drug-seekers” 90
20. Z.B.: A “questionable” prescriber sending patients to fill at Walmart 92

C. Walmart filled many prescriptions showing, on their face, such glaring red flags that its pharmacists would have known that the prescriptions had a very high probability of being invalid. 94

1. Red Flag No. 1: Dangerous combinations of opioids 95
2. Red Flag No. 2: Dangerous “cocktails” of opioids and non-opioids. 101
3. Red Flag No. 3: Repeated fills of very high dosages of opioids..... 108
4. Red Flag No. 4: Schedule IIs filled unusually early 109

D. Walmart filled many invalid prescriptions that were the same or similar to other prescriptions Walmart pharmacists had previously identified as invalid for the same customer 112

III. IN ITS ROLE AS A DISTRIBUTOR, WALMART VIOLATED THE CSA..... 116

- A. Walmart had access to a wealth of information and data such that it could readily have designed a system to adequately detect suspicious orders 116

1.	Walmart’s self-distribution to its own pharmacies gave it extensive knowledge and data about dispensing patterns and orders.....	116
2.	Walmart had information on the millions of orders for controlled substances its pharmacies placed with—and received from—independent distributors.....	120
B.	For years, Walmart knew of significant defects with its policies and procedures for detecting and reporting suspicious orders, but failed to fix them.....	121
1.	Prior to August 2015, Walmart had a rudimentary suspicious-order monitoring system that failed to adequately detect and report suspicious orders.....	121
a.	Walmart failed to detect and report orders of unusual frequency or pattern.....	124
b.	Walmart failed to adequately detect and report unusually large orders.....	125
c.	Walmart ignored specific signs of diversion from its own pharmacies.....	136
d.	Walmart failed to adequately staff and train its compliance personnel, and shipped flagged orders before compliance personnel could examine them.....	138
e.	Walmart routinely failed to investigate flagged “orders of interest” and report any orders to DEA that Walmart was unable to clear.....	141
f.	Walmart often failed to document its evaluation of flagged orders, which deprived Walmart of crucial information needed to assess subsequent orders.....	144
2.	From August 2015 through November 2017, Walmart adopted a modified system for detecting and reporting suspicious orders, but this system remained defective...	145
a.	Despite the modifications to Reddwerks, many of the same flaws remained.....	146
b.	Walmart continued to fail to report unusually large orders.....	147
c.	Walmart set hard limits for pharmacies that had already placed suspicious orders—then disregarded those hard limits.....	151
C.	Walmart’s flawed approach to monitoring pharmacy orders resulted in a failure to detect and report at least hundreds of thousands of suspicious orders.....	153
D.	Walmart’s failure to detect and report suspicious orders deprived Walmart of the opportunity, during the prescription drug abuse epidemic, to timely address potentially unlawful conduct.....	154
	CLAIMS FOR RELIEF.....	157
	PRAYER FOR RELIEF.....	159

The United States of America files this Complaint against Walmart Inc. and Wal-Mart Stores East, LP (collectively “Walmart”), and alleges as follows:

INTRODUCTION

1. The United States of America brings this civil enforcement action against Walmart for violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (“Controlled Substances Act” or “CSA”), 21 U.S.C. §§ 801 *et seq.*

2. The CSA comprehensively regulates every participant in the supply chain for controlled substances, from manufacturers to wholesale distributors to retail pharmacies. Because controlled substances by definition are drugs with the potential for abuse, this comprehensive scheme is designed to prevent the “diversion”—*i.e.*, the illegal misuse—of controlled substances, including prescription opioids. Under the CSA, every participant in the supply chain bears responsibility for preventing the misuse of controlled substances.

3. Walmart operates more than 5,000 pharmacies nationwide that dispense prescription opioids and other controlled substances. In addition, until 2018, Walmart acted as a wholesale distributor of controlled substances for its own pharmacies.

4. As both a pharmacy and a distributor, Walmart assumed critical gatekeeping responsibilities under the CSA. At two stages—when deciding whether to fill its pharmacies’ wholesale orders for controlled substances from its distribution warehouse, and when deciding whether to fill individuals’ prescriptions for controlled substances—Walmart was required by the CSA to take steps to prevent the diversion of the prescription drugs it sold.

5. As a nationwide dispenser *and* distributor of opioids, and given the sheer number of pharmacies it operates, Walmart was uniquely well positioned to prevent the illegal diversion of opioids. Yet, for years, as the prescription drug abuse epidemic ravaged the country, Walmart

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.