# Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

IN THE UNITED STATES DISTRICT COUR'	Γ
FOR THE NORTHERN DISTRICT OF CALIFOR	NIA

CITY AND COUNTY OF SAN FRANCISCO, et al.,

Plaintiffs,

v.

PURDUE PHARMA L.P., et al.,

Defendants.

Case No. 18-cv-07591-CRB

FINDINGS OF FACT AND CONCLUSIONS OF LAW REGARDING WALGREENS

The opioid epidemic has plagued San Francisco for over twenty years. The number of individuals who die annually from opioid overdoses continues to climb. Thousands of city residents, from all walks of life, struggle with addiction. Widespread opioid use has strained the city's hospitals. It has forced streets, parks, and public spaces to close. It has exacerbated crime and homelessness. Every year, San Francisco devotes significant resources to a multiprong fight against the opioid epidemic. That fight includes this case.

This case is part of a nationwide multidistrict litigation stemming from the ongoing opioid epidemic. Cities, counties, and states across the country have filed claims against manufacturers, distributors, and dispensers of prescription opioids. While the facts of each case vary, the claims center on the contention that each defendant has contributed to the opioid epidemic that has engulfed the country.

In this case, the People of the State of California, acting through the San Francisco City Attorney ("Plaintiff"), filed claims against dozens of defendants related to the opioid epidemic in San Francisco. By the time of trial, only four defendants remained. The Court Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

held a bench trial from April 25, 2022 to June 27, 2022. Closing argument was held from July 12 to July 13, 2022. By the close of trial, Walgreens Co. ("Walgreens") was the sole remaining defendant. The other three defendants settled their claims.

At trial, Plaintiff brought a single public nuisance claim against Walgreens. The question for the Court is whether Plaintiff proffered sufficient evidence at trial to prove this claim. To carry its burden of proof, Plaintiff had to establish that it is more likely than not that Walgreens knowingly engaged in unreasonable conduct that was a substantial factor in contributing to the opioid epidemic in San Francisco. After careful consideration of the evidence, the Court finds that Plaintiff carried its burden.

Walgreens is the largest retail pharmacy chain in San Francisco. Between 2006 and 2020, Walgreens distributed and dispensed over one hundred million prescription opioid pills in the city. The Controlled Substances Act ("CSA") and its implementing regulations impose duties on distributors and dispensers of prescription opioids. In exchange for the privilege of distributing and dispensing prescription opioids, Walgreens has regulatory obligations to take reasonable steps to prevent the drugs from being diverted and harming the public. The evidence at trial established that Walgreens breached these obligations.

Until 2014, Walgreens distributed prescription opioids to its pharmacies in San Francisco. CSA regulations require distributors to implement and maintain a system for identifying suspicious orders of opioids. Suspicious orders of opioids must be halted and reported to the DEA. They cannot be shipped to the ordering pharmacy. The evidence at trial established that Walgreens violated this regulatory duty for several years. It did not maintain an effective system for identifying suspicious orders. It shipped thousands of suspicious orders to its pharmacies without investigation. In 2012, the DEA shut down one of Walgreens' three controlled substance distribution centers because the distribution center's failure to monitor for suspicious opioid orders posed an imminent threat of harm to public health and safety. Shortly thereafter, Walgreens stopped distributing opioids all together.

Walgreens pharmacies are the largest dispenser of opioids in San Francisco. To

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

prevent diversion, CSA regulations require Walgreens to verify the medical legitimacy of opioid prescriptions before dispensing them. Fulfilling this duty requires Walgreens pharmacies to resolve "red flags" associated with a prescription before dispensing it. Red flags are well-established warning signs that raise questions about the legitimacy of a prescription. Medically legitimate prescriptions are prescribed for a patient's benefit, but medically illegitimate prescriptions are not. They are prescriptions that are misused and abused. Medically illegitimate prescriptions extend far beyond forged prescriptions and prescriptions that are written on a stolen prescription pad. Many illegitimate prescriptions come from unscrupulous doctors who write prescriptions in exchange for payment. It is not enough for a pharmacy to simply ascertain that a licensed prescriber wrote the prescription. Pharmacies have a corresponding duty to exercise independent judgment in determining whether the prescription was written for a legitimate medical purpose.

The evidence at trial established that from 2006 to 2020, Walgreens pharmacies in San Francisco dispensed hundreds of thousands of red flag opioid prescriptions without performing adequate due diligence. Tens of thousands of these prescriptions were written by doctors with suspect prescribing patterns. The evidence showed that Walgreens did not provide its pharmacists with sufficient time, staffing, or resources to perform due diligence on these prescriptions. Pharmacists experienced constant pressure to fill prescriptions as quickly as possible, and a shortage of resources to review them before dispensing. As a result of Walgreens' fifteen-year failure to perform adequate due diligence, Plaintiff proved that it is more likely than not that Walgreens pharmacies dispensed large volumes of medically illegitimate opioid prescriptions that were diverted for illicit use and that substantially contributed to the opioid epidemic in San Francisco.

The Court's findings of fact and conclusions of law are set forth below. This ruling holds only that Walgreens is liable for substantially contributing to the public nuisance in San Francisco. A subsequent trial will determine the extent to which Walgreens must abate the public nuisance that it helped to create.

# I. FINDINGS OF FACT

In a bench trial, the court's findings of fact are presumed to be based on admissible evidence. Williams v. Illinois, 567 U.S. 50, 69 (2012); Harris v. Rivera, 454 U.S. 339, 465 (1981). To the extent that objections have been raised to the evidence cited in support of the Court's findings, the objections are overruled. See City of Huntington v. Amerisource Bergen Drug Corp., No. CV 3:17-01362, 2022 WL 2399876, at \*1 (S.D.W. Va. July 4, 2022).

# A. Background

# 1. The Science of Opioid Addiction

Opioid addiction is explained by a change in an opioid user's brain chemistry. See Lembke (dkt. 1281) Decl. ¶ 3. Opioids bind to mu-pain receptors temporarily relieving pain. Lembke, May 9, 2022, Trial Tr. at 383:23–384:4. In addition, opioids cause the release of dopamine. Id. Dopamine is a naturally occurring neurotransmitter that causes feelings of pleasure and reward. See id.; Lembke, May 9, 2022, Trial Tr. at 383:23–384:9. In response to repeated additional releases of dopamine from opioid use, the brain begins to downregulate the amount of dopamine it naturally produces, a process known as neuroadaptation. Lembke Decl. ¶ 3. The result is a dopamine deficient state, in which the brain is producing less dopamine and the user is experiencing less pleasure and more pain than they were before opioid use began. Id.

In a dopamine deficient state, a user needs opioids to return to their previous dopamine baseline and to avoid the pain of prolonged dopamine deficiency. Lembke Decl. ¶ 3. Users "need opioids not to feel good but just to restore a level balance and feel normal." See Lembke, May 9, 2022, Trial Tr. at 384:10–386:3. Opioid users in this state are physically dependent on the drugs. See id. at 384:10–386:15. Someone taking opioids

<sup>&</sup>lt;sup>1</sup> Opioid addiction is synonymous with opioid use disorder. <u>See</u> Colwell, April 28, 2022, Trial Tr. at 360. Opioid use disorder has a more precise medical definition set out in The Diagnostic and Statistical Manual of Mental Disorders ("DSM"), which defines the severity as mild, moderate, or severe, depending on the symptoms present. <u>See</u> Lembke Decl. ¶ 2. But both terms describe the same form of harmful behavior: the continued use of opioids despite deleterious effects to self or others. <u>See id.</u> ¶¶ 2−5.

United States District Court Northern District of California 

for "relatively short periods of time" can develop physical dependence and experience
withdrawal if they stop taking opioids. Zevin, May 10, 2022, Trial Tr. at 640:21-641:1;
Coffin (dkt. 1376) Decl. ¶ 55. Symptoms of withdrawal include anxiety, debility,
insomnia, dysphoria, "and in the case of opioids, a very distinct and painful physical
withdrawal syndrome, including full-body pain that can be experienced and is typically
experienced in people who do not have a pain disorder." Lembke, May 9, 2022, Trial Tr
at 384:10–386:15.

Over time, opioid users generally require higher doses to experience the same effect that they initially experienced. Lembke, May 9, 2022, Trial Tr. at 386:12–387:15. This is the process of developing tolerance to the drug. <u>Id.</u> Dr. Lembke explained that "the brain adapts to the presence of the opioid molecule such that the individual needs more and more to get the same effect and ultimately is physically dependent and experiences painful withdrawal when they stop whether or not they have a pain condition." <u>Id.</u> at 387:11–15. Once the brain adapts to the presence of opioids, it can "take a very long time after the individual has stopped using their drug for the brain to reset itself to normal dopamine levels." <u>Id.</u> at 387:17–388:7; 391:25–392:18. Reducing opioid use requires tapering, which involves gradually progressing to lower doses of opioids. Lembke Decl. ¶¶ 39–41. The process of tapering off opioids "is time-intensive and requires substantial support from clinicians and other providers in the healthcare system." Coffin Decl. ¶ 55.

Opioid addiction affects people from all walks of life, regardless of age, ethnicity, or socioeconomic status. Colwell (dkt. 1284) Decl. ¶¶ 11–12. The neural pathways affected by opioid use are common across all people, which makes everyone vulnerable to opioid addiction. Lembke Decl. ¶ 4. Opioids carry risks of addiction even when prescribed by a medical professional. Keyes (dkt. 1386) Decl. ¶ 14, 40. Stronger dosages and longer durations of use increase the risk of addiction. Lembke, May 9, 2022, Trial Tr. at 398:5–16.

Opioid addiction can have devastating consequences. People suffering from the most severe forms of addiction "commit all available resources to obtaining more of the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

substance, even forgoing natural rewards like food, finding a mate, or raising children." Lembke Decl. ¶ 5. For people suffering from severe addiction, consuming more opioids often appears to be the only way to avoid the intense pain of withdrawal. See id.

## 2. The Opioid Epidemic in San Francisco

For over two decades, San Francisco has been battling an opioid epidemic, defined by high rates of opioid abuse and addiction throughout the city.<sup>2</sup> Coffin Decl. ¶ 11. The number of people in the city abusing opioids has substantially accelerated in recent years. Zevin Decl. (dkt. 1296) ¶ 5. The number of opioid-related emergency room visits has increased significantly, more than tripling from 886 in 2015 to 2,998 in 2020. Coffin Decl. ¶ 40. Since 2016, opioid overdoses have been the leading cause of death among the homeless in San Francisco. See Zevin Decl. ¶ 6. In 2019, the last year of available data, an estimated 40,958 city residents out of a total population of approximately 865,000 suffered opioid addiction. See Keyes Decl. ¶ 25. That same year, approximately 1,939 people in San Francisco overdosed on opioids, an average of 5.3 opioid overdoses per day. <u>Id.</u> ¶ 135.

Prescription opioids have been at the heart of San Francisco's ongoing opioid epidemic, which has unfolded in three different waves. The first wave started in the late 1990s and early 2000s when opioid manufacturers began to aggressively promote opioids as safe and effective for treating a broad range of medical conditions. Lembke, May 9, 2022, Trial Tr. at 382:15–383:11. The aggressive marketing resulted in increased prescribing and the increased prescribing resulted in an increase in opioid abuse, addiction, and overdoses. See id.; Coffin Decl. ¶¶ 17–19; 37. The second wave began in the early 2010s, when medical professionals began to reduce opioid prescribing based on the recognition that opioids are not a safe and effective form of treatment for many medical conditions. See id. ¶¶ 20–22. However, the massive expansion of the prescription opioid

<sup>&</sup>lt;sup>2</sup> "Epidemic" describes the outbreak of a disease that spreads quickly, affecting many people at the same time. See Lembke Decl. Part III.Q. The term appropriately describes the rapid increase in opioid-related morbidity and mortality that began in the 1990s and continues still. See id.

supply that happened in the preceding decade laid the foundation for increased use of illicit opioids. Keyes Decl. ¶ 12. In the second wave, many people who were addicted to prescription opioids but no longer readily able to obtain them from doctors shifted to heroin use. See id.; Coffin Decl. ¶ 37. The third wave started around 2015, when inexpensive and highly potent fentanyl became widely available across a city already struggling with opioid addiction. Keyes Decl. ¶ 12; Coffin Decl. ¶ 37. The city's fight against the effects of each wave of the opioid epidemic continues today.

# a. Wave One: Prescription Opioids

Heroin use has long been a public health issue in San Francisco. See Coffin Decl. ¶

12. In the late 1990s, San Francisco pioneered public health programs to address heroin use in the city, including expanding the availability of treatment programs and resources.

Id. ¶¶ 12–14; Coffin, May 26, 2022, Trial Tr. at 1896:18–1897:16. The public health programs worked. By the early 2000s, the city was winning the battle against heroin use.

See Coffin, May 26, 2022, Trial Tr. at 1896:18–1897:16. Heroin overdoses decreased dramatically from 150 per year in the late 1990s to 10 in 2010. Id.

As San Francisco was succeeding in the fight against heroin use, the volume of prescription opioids began to increase significantly. See Coffin Decl. ¶¶ 11, 16–17.

The significant increase in opioid prescribing that took place in the late 1990s throughout the 2000s resulted from changing views on the safety and efficacy of opioids as a form of pain treatment. Lembke, May 9, 2022, Trial Tr. at 382:15–19; Zevin Decl. ¶ 9. For much of the twentieth century, medical professionals used opioids sparingly because of "the legitimate concern that patients would get addicted." Lembke Decl. ¶ 7; see also Herzberg Decl. ¶ 4–5. Opioid use was generally limited to treating cancer pain, hospice patients, and for short-term use in treating pain stemming from severe injuries. See Zevin, May 10, 2022, Trial Tr. at 620:17–621:25. Medical professionals understood that opioids carried high risks of abuse, and they limited their prescribing. See Lembke, May 9, 2022, Trial Tr. at 394:7–13. This "conservative consensus" about opioid prescribing held for decades, until it began to change in the 1990s. Herzberg, May 31, 2022, Trial Tr. at 1975:18–

2 3

4

5

6 7

8

9

10

11

12

13

14

15

16

17

18 19

20

21

22

23

24

25

26

27

28

1976:12

In the 1990s and throughout the 2000s, opioid manufacturers launched aggressive marketing campaigns intended to persuade medical professionals that prescription opioids were a safe and effective form of treatment for many pain conditions. Lembke Decl. ¶¶ 11–12; Herzberg Decl. ¶ 11; Coffin Decl. ¶ 17. The marketing campaigns aimed to expand the market for prescription opioids from a limited range of acute conditions to commonplace forms of pain, such as lower back pain and headaches. Lembke Decl. ¶¶ 11–12; Herzberg Decl. ¶ 11. The marketing campaigns claimed that new formulations of prescription opioids provided highly effective pain relief and could be safely prescribed for long-term use with low risks of addiction. See Lembke, May 9, 2022, Trial Tr. at 393:14– 395:13; Herzberg, May 31, 2022, Trial Tr. at 1982:9–1987:12; Keyes Decl. ¶¶ 91–99. The marketing campaigns were extensive. Opioid manufacturers employed large salesforces, targeted high-prescribing doctors, held medical conferences promoting opioids for pain treatment, paid doctors to speak about the benefits of opioids, and funded articles in medical journals that highlighted the safety and efficacy of opioids. Lembke Decl. ¶¶ 50– 97; Herzberg Decl. ¶ 13. The marketing campaigns worked. The aggressive promotion of the use of prescription opioids to treat widespread forms of pain led to a paradigm shift in the treatment of pain. Opioids became "first-line treatment for minor and chronic pain conditions." Lembke Decl. ¶ 13; Lembke, May 9, 2022, Trial Tr. at 382:5–5.

In addition to marketing opioids as a safe and effective form of treatment, opioid manufacturers broadly promoted the idea that pain was commonplace and undertreated. See Lembke Decl. ¶ 10. Opioid manufacturers represented that millions of people across the country were living with chronic pain that affected their qualify of life. See Lembke, May 9, 2022, Trial Tr. at 393:14–395:13. Pain became the "fifth vital sign." Lembke Decl. ¶ 103. Patients began using a visual pain scale that consisted of "a series of happy or sad faces supposedly corresponding to pain levels from 0 (no pain) to 10 (the most extreme pain)" to communicate their pain to doctors. Id. State Medical Boards that received significant support and funding from opioid manufacturers warned doctors that failing to

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

adequately treat pain could be grounds for a malpractice claim. See id. ¶¶ 90–96. Doctors "lived in fear of disciplinary action from the State Medical Boards and the lawsuit that usually followed, if they denied a patient opioid painkillers." Id. ¶ 93.

Opioid manufacturers billed prescription opioids as the solution to undertreated pain. See Lembke Decl. ¶ 13; Lembke, May 9, 2022, Trial Tr. at 384:21–395:7. Doctors across all specialties began prescribing more opioids to treat a broad range of conditions. Lembke Decl. ¶ 10; Keyes Decl. ¶¶ 88–89. Drug manufacturers claimed that there was no "ceiling dose" for opioids, and doctors began writing prescriptions for higher dosages and longer durations. Lembke Decl. Part C. The number of prescriptions increased markedly. Coffin Decl. ¶¶ 17–18; Coffin, May 26, 2022, Trial Tr. at 1912:19–1913:6. From the late 1990s to 2012, opioid prescribing quadrupled. Lembke Decl. ¶ 8.

The massive increase in opioid prescriptions caused corresponding increases in opioid abuse, addiction, and overdoses. Keyes Decl. ¶¶ 11–13; Lembke ¶¶ 8–9 ("Higher doses and longer durations cause increased rates of addiction and death."). The most important risk factor for opioid addiction is access to opioids.<sup>3</sup> Lembke Decl. ¶ 4. As the opioid supply in San Francisco increased, the rates of opioid addiction and overdoses increased as a "direct consequence." Keyes Decl. ¶¶ 11–13. Each "one-pill increase in per capita pill volume" is "associated with 0.2 additional overdose deaths." Id. ¶ 79. In addition to the harms resulting directly from the increasing supply, many of the claims that manufacturers made about opioids proved to be inaccurate. See Lembke Decl. Part III. As rates of abuse and addiction increased, it became clear that opioids were not a safe and effective form of treatment for many forms of pain. See id.

By the early 2000s, prescription opioids had surpassed heroin as the leading cause of opioid overdoses in San Francisco. See Coffin, May 26, 2022, Trial Tr. at 1898:4–16. From 2000 to 2010, prescription opioids caused the overwhelming majority of opioid

<sup>&</sup>lt;sup>3</sup> A risk factor is a variable that increases the frequency with which an outcome occurs. Keyes Decl. ¶ 31. An example is cigarette smoking and lung cancer. Cigarette smoking increases the risk of lung cancer (especially the longer and more frequently that someone smokes). Id.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

overdose deaths in San Francisco. See Coffin Decl. ¶ 19; Coffin, May 26, 2022, Trial Tr. at 1906:6–20. Overdose deaths from prescription opioids continued to increase despite the city's significant investment in public health programs designed to combat opioid abuse. Coffin Decl. ¶ 28. From 2010 to 2012, the rate of opioid overdoses in San Francisco was 2.23 times the national average. Id.  $\P$  21.

In the early 2010s, the medical community's view on prescription opioids began to change again. See Coffin Decl. ¶¶ 20–22. Rates of opioid abuse, addiction, and overdoses had increased across the country for a decade. See P-19656 at 00009 (2012 DEA presentation to pharmaceutical companies stating "more Americans abuse prescription drugs than the number of: cocaine, hallucinogens, heroin, and inhalant abusers combined!!!") (cleaned up). There was a growing spotlight on recreational use of prescription opioids, including abuse by teenagers and adolescents. See id. at 00011, 00014, 00020. In addition, there was growing awareness that the medical profession and government regulators had underappreciated opioids' risks of addiction. See Zevin Decl. ¶¶ 8–10; Coffin, May 26, 2022, Trial Tr. at 1899:7–14. Medical professionals began to recognize that the "overreliance on opioids" to treat pain had caused "a crisis nationally and in San Francisco." Coffin, May 26, 2022, Trial Tr. at 1899:7–14. Doctors began to take a more careful approach to opioid prescribing and opioid prescribing rates began to decline. See Coffin, May 26, 2022, Trial Tr. at 1899:7–20; Coffin Decl. ¶¶ 20–22.

# **Wave Two: Prescription Opioids and Heroin** b.

The volume of opioids prescribed in San Francisco peaked in the early 2010s. See Coffin Decl. ¶ 11, 22. Opioid prescribing rates declined from 2011 to 2020, although they remained significantly higher than pre-2000s levels. Keyes Decl. ¶ 22. As prescription opioids became less readily available, many people addicted to prescription opioids began to turn to heroin. While the city had a heroin problem in the late 1990s, the problem became "significantly worse" following the increase in opioid prescribing in the 2000s. See Tong Decl. (dkt. 1336) ¶ 3; Tong, May 19, 2022, Trial Tr. at 1351:22–1352:6.

In the early 2010s, heroin use and heroin overdose deaths increased as the volume

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

of prescription opioids decreased. See Coffin, May 26, 2022, Trial Tr. at 1899:15–1900:2; Coffin Decl. ¶ 24 ("[A]s prescription opioid use and prescribing decreased in SF, heroin use began to increase again."). The massive increase in prescription opioids in the 2000s helped to increase the demand for heroin in the 2010s. See Coffin Decl. ¶ 24; Keyes Decl. ¶ 12. The link between prescription opioid use and heroin use is well established. See Coffin Decl. ¶¶ 24–27; see also P-19656 at 00051. The "most significant risk factor for heroin use is exposure to prescription opioids." Keyes Decl. ¶¶ 53, 66–70. Multiple studies have found that approximately 70–80% of heroin users in the last two decades used prescription opioids before using heroin. <u>Id.</u> ¶ 18. Approximately 75% of people who suffer an opioid overdose began their opioid use with prescription opioids. Id. ¶ 10. People who stop using prescription opioids have an increased risk of transitioning to heroin. Id. ¶ 107. From 2002 to 2013, heroin use increased 138% among those who use prescription opioids. Id. ¶ 57. Like opioid abuse, heroin use affects people from all walks of life. In recent years, heroin use has increased across race, gender, and social class. See <u>id.</u> ¶ 56.

Replacement theory and the gateway effect explain the transition from prescription opioids to heroin use. See Lembke Decl. ¶¶ 153–156; Coffin, May 26, 2022, Trial Tr. at 1899:11–1900:7. Replacement occurs when people are unable to obtain opioids from a medical professional and resort to heroin use to avoid the pains of withdrawal. See id. As Dr. Coffin explained, "people need opioids from somewhere. So when they can't get them from a prescription, they end up going to the street." Coffin, May 26, 2022, Trial Tr. at 1900:3–7; see also Lembke Decl. ¶ 156. In addition, people suffering from more severe opioid addiction will seek out "more potent, plentiful, and cheaper forms over time." Lembke Decl. ¶ 156. The foreseeable result is increased rates of heroin use and heroin overdose deaths. 4 See Keyes Decl. ¶¶ 108, 123–26; Coffin ¶¶ 24–25.

26

27

28

<sup>&</sup>lt;sup>4</sup> Defendants' expert Douglas Tucker testified that he was not aware of any evidence that prescription opioid use serves as a "gateway" to heroin or fentanyl use. See Tucker (dkt. 1423) ¶ 40. In light of the significant and credible evidence offered at trial demonstrating that prescription opioid use is correlated with heroin and fentanyl use, the Court assigns Dr. Tucker's testimony on

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

In the context of opioid addiction, the gateway effect similarly describes the tendency of people suffering from opioid addiction to use stronger forms of opioids over time. See Lembke Decl. ¶ 156. After developing a tolerance to prescription opioids, the "natural progression" for opioid users is to transition to more powerful opioids, like heroin. See id. Dr. Colwell, Chief of Emergency Medicine at Zuckerberg San Francisco General Hospital ("ZSFG"), testified that "approximately two-thirds of the patients who present to the [emergency department] with an opioid-related medical condition report that their addiction started with pills." Colwell Decl. ¶ 10. Many of Dr. Colwell's opioid-addicted patients "can trace very specifically their opioid use disorder and their addiction to a specific event." Colwell, April 28, 2022, Trial Tr. at 358:7–22. Dr. Colwell explained:

"Usually it's an injury, a traumatic injury, or a surgery where they were prescribed opioid pills, and this starts a process or a pattern that either results in their feeling like those pills are no longer helping their pain and they need to seek more powerful, more potent ways of managing those or they have [gotten] to the point where physicians have tried to wean them off and they don't—they're no longer feeling like they can do that. And so they then seek other areas, other ways to—to manage their pain, to manage their—what they're suffering from."

Id.

The association between prescription opioid use and heroin use is even stronger for people who use prescription opioids non-medically. Taking prescription opioids nonmedically makes the likelihood of using heroin significantly higher. See Keyes Decl. ¶¶ 60–63. One study found that individuals using prescription opioids non-medically have a 5 times higher likelihood of using heroin than individuals who do not use prescription opioids non-medically. Id. ¶ 61. A 2020 longitudinal study found that individuals who used opioids medically were 2.7 times more likely to transition to heroin compared to individuals who did not use opioids. Id. ¶ 63. Individuals who used opioids nonmedically were 6.8 times more likely to transition to heroin. Id. A different 2020 study found that only 9.5% of individuals who began using heroin had "never used

this subject no weight.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

pharmaceutical opioids in a non-prescribed manner" before beginning heroin use. <u>Id.</u> ¶ 64. Consistent with these studies, an internal Walgreens presentation reported that "[n]early 80% of Americans using heroin reported misusing opioids first" and that "[i]ndividuals who misuse prescription opioid pain pills are forty times more likely to abuse heroin." P-25545 at 00008. The increased rates of heroin use in San Francisco in the 2010s reflect the link between prescription opioids and heroin use.

#### Wave Three: Prescription Opioids, Heroin, and Fentanyl c.

Fentanyl is cheap to produce, and it is extremely potent. Coffin Decl. ¶ 35. In the mid-2010s, drug traffickers responded to increasing demand for opioids by increasing the production and distribution of black-market fentanyl. Id. ¶ 36. Fentanyl emerged on the East Coast around 2013, and it arrived in San Francisco around 2015. Coffin, May 26, 2022, Trial Tr. at 1900:8–11. The lower cost and higher potency of fentanyl resulted in increased demand for the drug throughout the city, especially as the supply of prescription opioids decreased. See Coffin Decl. ¶¶ 36–37. Demand for fentanyl is a function of the opioid abuse that resulted from the significantly increased supplies of prescription opioids throughout the 2000s. See id. ¶¶ 34–36, 49; Coffin, May 26, 2022, Trial Tr. at 1900:12– 22; Keyes Decl. ¶ 12. Prescription opioids laid the groundwork for the current wave of fentanyl abuse. Keyes Decl. ¶¶ 53, 71; Coffin Decl. ¶¶ 41–42. People began to "seek out fentanyl to maintain their opioid dependence or use disorder." Keyes Decl. ¶ 12, 74.

Fentanyl is deadly. While heroin generally contains only 5%–15% active drug, "fentanyl is often 100% pure." Coffin Decl. ¶ 35. It is "100 times more potent than morphine" and as much as 50 times more potent than heroin. Id. ¶ 38; Coffin, May 26, 2022, Trial Tr. at 1902:18–1903:01. Compared to heroin, fentanyl is four times more likely to cause an overdose, and the victims of fentanyl overdoses are on average 11 years younger than the victims of heroin overdoses. Coffin Decl. ¶ 41. A dash of fentanyl—not much larger than a few grains of sand—can be fatal. See Coffin, May 26, 2022, Trial Tr. at 1903:02-11.

The flood of prescription opioids, heroin, and fentanyl continue to cause severe

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

harm in San Francisco. From 2015 to 2020, the number of opioid-related emergency room visits in San Francisco tripled. Coffin Decl. ¶ 40. During this time period, the number of opioid overdoses surged 478%, increasing from 101 in 2015 to 584 in 2020. See id. ¶ 39. Despite the spread of heroin and fentanyl, prescription opioids remain the leading cause of opioid overdose deaths. Id. ¶¶ 39–44. From 2010 to 2019, "prescription opioids caused as many overdose deaths as heroin and fentanyl combined." <u>Id.</u> ¶ 44.

# **3.** The Opioid Epidemic's Interference with Public Rights in San

San Franciscans grapple with the effects of the opioid epidemic every day. City workers, including park rangers, street cleaners, fire fighters, paramedics, doctors, and librarians, respond to overdoses, clean up opioid debris, and work to help those suffering from opioid addiction. Neighborhoods across the city have been devastated. Residents' use of public areas—like parks, sidewalks, and libraries—has been significantly impaired and, in some cases, ruined. Even right outside this courthouse, people suffering from severe opioid addiction buy, sell, and use opioids in plain sight. The impact on the city has been "worse than catastrophic." Zevin, April 25, 2022, Trial Tr. at 632:4–8.

From 2009 to 2019, prescription opioid-related deaths in San Francisco exceeded rates across the country. See Keyes Decl. ¶ 117. ZSFG—one of the largest hospitals in the Bay Area—receives approximately 10 to 20 opioid-related overdoses each day. Colwell Decl. ¶ 1, 5. Opioid-related harms extend far beyond overdoses. Every day, ZSFG receives numerous patients suffering from serious health conditions stemming from opioid use. Id. ¶ 9. On a typical day, as many as 25% of the visits to ZSFG's emergency room are opioid related. <u>Id.</u> Opioid addiction can be all consuming, and some people suffering from it neglect their basic needs, arriving at ZSFG badly dehydrated or malnourished. Lembke Decl. ¶ 4; Coffin Decl. ¶ 8; Colwell, April 28, 2022, Trial Tr. at 355:13–356:14. Many people suffering from opioid addiction need treatment for "sepsis, localized infections or abscesses from unsterile injection practices[.]" Colwell Decl. ¶ 8. The number of those suffering from opioid addiction who need care for severe health

conditions has only continued to go up in recent years. See id. ¶¶ 4–9.

# a. The Fire Department's Response to the Opioid Epidemic

Sandy Tong served as a Rescue Captain in the San Francisco Fire Department's ("SFFD") Emergency Medical Services ("EMS") team for decades before being promoted to Assistant Deputy Chief of Emergency Services in 2017. Tong Decl. ¶¶ 1–2. During her many years of service in San Francisco, the opioid epidemic became "significantly worse." Id. ¶ 3. From July 2018 to March 2022, SFFD administered over 7,600 doses of naloxone in response to opioid overdoses. Id. ¶ 6. This figure understates the number of overdose calls because SFFD does not respond to every overdose call and not every opioid overdose requires naloxone. See id. Opioid overdoses have become so commonplace in San Francisco that when an SFFD paramedic encounters someone who has no pulse and is not breathing, the presumption is that they have overdosed on opioids. Id. ¶ 7.

The number of opioid overdose calls that EMS receives is so high that EMS created a team of "dedicated community paramedic response teams specifically to address the crisis." Tong Decl. ¶ 4. The paramedic teams provide immediate care and treatment to residents experiencing health emergencies, and they work to connect residents "to appropriate systems of care, care coordination, and follow-up care." Id. While EMS's goal has been "to break the cycle of frequent callers who rotate from the street to the emergency room and back to the street," the majority of "individuals who die of an opioid overdose in SF have had prior contact with SFFD EMS." Id. ¶ 10. Finding "people unconscious on the streets and encountering the same patients overdosing on opioids multiple times" has "become 'the new normal'" for EMS. Id. Tong testified that "for those of us who have done this job for a long time, you know, when you see sort of the repeated and the increasing numbers of people who die from drugs, it can be really difficult. It can be depressing." Tong, May 19, 2022, Trial Tr. at 1356:24–1357:14.

# b. The Department of Public Works' Response to the Opioid

<sup>&</sup>lt;sup>5</sup> Naloxone—commonly known by the brand name Narcan—is a highly effective medicine administered to individuals who have experienced an opioid overdose. <u>See</u> Tong Decl. ¶¶ 4–6.

# **Epidemic**

The duration and severity of the opioid epidemic has impaired the use of streets and sidewalks across the city. Carla Short, Interim Director of the San Francisco Department of Public Works, oversees approximately 1,600 employees who work to keep the city's streets and sidewalks clean and free from hazards. Short Decl. (dkt. 1368) ¶¶ 2–3. The opioid epidemic has made that effort significantly more challenging because of the large number of opioid users who "often vomit, have diarrhea, and leave used needles in public right of ways." Id. ¶ 3. To improve conditions in the city, San Francisco Public Works has been opening "Pit Stops" across the city since 2014. Id. ¶ 3. The Pit Stops are monitored restrooms that also have syringe disposal kiosks. Id. ¶¶ 3–4. Staff members who monitor the Pit Stops have been trained on how to administer naloxone and safely dispose of used syringes. Id. ¶¶ 4–7.

Public Works also deploys "Hot Spot Crews" that work across the city to clean up streets and sidewalks. Short Decl. ¶ 8. The Hot Spot Crews clean up needles and dispose of waste. Id. In recent years, Hot Spot Crews and other Public Works employees have collected approximately 95,000 used syringes each year. Id. ¶ 9; Short, May 31, 2022, Trial Tr. at 1962:11–24. Members of the Hot Spot Crews are not trained first responders, and they have "experienced a lot of stress and anxiety dealing with some of the impacts of the epidemic." Short, May 31, 2022, Trial Tr. at 1968:7–22; Short Decl. ¶ 9. Public Works employees have been stuck with used syringes, they routinely encounter people experiencing opioid overdoses on city sidewalks, and they have found the dead bodies of overdose victims. Id. ¶ 9, 12; Short, May 31, 2022, Trial Tr. at 1967:22–1968:22. Public Works has invested in mental health programs to provide support for employees who experience these traumas in the course of their daily work. Short Decl. ¶ 9; Short, May 31, 2022, Trial Tr. at 1968:23–1969:10.

# c. The Recreation and Parks Department's Response to the Opioid Epidemic

San Francisco has over 220 parks, playgrounds, recreation centers, and sports fields, all of which have been impacted by the opioid epidemic in the city. See Follin Decl. (dkt.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

1367) ¶¶ 2–4, 7. Park rangers regularly see signs of opioid use in the city's parks, including used syringes, human feces, and drug-related refuse. Id. ¶ 4; Follin, May 31, 2022, Trial Tr. at 2066:16–2067:11. Because of increasing opioid abuse in the city's parks, park rangers are now trained on how to administer naloxone and safely collect and dispose of used syringes. Follin, May 31, 2022, Trial Tr. at 2071:4–2072:15.

The San Francisco Recreation and Parks Department ("RPD") has special teams to help address the harms caused by opioid use across the city's park system. The Outreach Team consists of rangers who are specially trained to engage with homeless people who live in San Francisco's parks, the vast majority of whom struggle with substance abuse. Follin Decl. ¶ 4. The Environmental Services team is specially trained to clean up biohazards and drug paraphernalia, including used syringes and human feces, across the city's park systems. <u>Id.</u> ¶ 6. In 2019, the Environmental Services team collected 10,360 syringes from Golden Gate Park, the city's largest park. Id. ¶ 9; Follin, May 31, 2022, Trial Tr. at 2073:12–18. Follin testified that "[f]inding needles in the park is so common that it is not notable, it is just a routine occurrence, like changing out the toilet paper in the restrooms." Follin Decl. ¶ 11.

The used syringes and opioid-related refuse interfere with the public's ability to use the city's parks. Follin, May 31, 2022, Trial Tr. at 2075:6–22. Parts of the park system are regularly closed because of the prevalence of human feces and used syringes. Follin Decl. ¶¶ 11–13. Biohazards like these present serious health risks and must be removed before the public can safely use the space. Id. For example, after a spending \$28 million on renovations, RPD has struggled to keep the restrooms at the Margaret Hayward Playground open "because needles from opioid use are being found in them every few hours." Id. ¶ 13. Parts of Civic Center Plaza—a public park in the heart of the city—must be regularly "taken offline with caution tape and the doors are shut because there's both feces, the needles, and actually people using drugs in those areas [in] pretty significant quantities almost on a daily basis." Follin, May 31, 2022, Trial Tr. at 2075:23–2076:13. Large numbers of needles have been "thrown in" the children's play area at Dolores Park,

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

requiring RPD to close the area to "sift through the sand" to remove the needles and ensure that the area is safe for children to play. See id. at 2075:23–2076:4. The recently renovated McCoppin Plaza—an area designed for the public to enjoy food trucks and eat lunch outside—"had to be gated off after large numbers of needles were routinely found there." Short Decl. ¶ 10. At Jose Coronado Park, there are "so many people who were kind of obstructing the sidewalk using drugs and spending the day just basically lying across the sidewalk and making it impossible for people to really access the park or even just walk down the sidewalk" that the city had to install "barricades to try to create a space where people could walk safely." Short, May 31, 2022, Trial Tr. at 1971:6–17.

# d. The Public Library's Response to the Opioid Epidemic

Michael Lambert, the City Librarian responsible for overseeing all library services in San Francisco, testified that the opioid epidemic is one of the largest challenges facing the city's library system. See Lambert Decl. (dkt. 1316) ¶ 4. The San Francisco Public Library system ("SFPL") consists of 28 libraries throughout the city that have recently drawn over six million visitors each year. Id. ¶ 2. It is "one of the premier urban libraries in the country," and a recent winner of the National Library of The Year award. Lambert, May 16, 2022, Trial Tr. at 944:2–12. The SFPL, however, has been "severely" impacted by the opioid epidemic, which has created serious health and safety risks for library visitors and staff alike. See Lambert, May 16, 2022, Trial Tr. at 944:13–945:1; Lambert Decl. ¶ 5.

In 2014, the SFPL updated its code of conduct to respond "to the proliferation of drug use at SFPL and inappropriate behaviors associated with it." Lambert Decl. ¶¶ 5–6. The opioid-related issues have only "increased in frequency and degree" since then. Id. ¶ 8. Library staff routinely observe patrons under the influence of opioids and "have discovered patrons using and overdosing on opioids outside of the building, in the stacks, and in the bathrooms." Id. ¶ 4. Library staff find "used needles in our restrooms, in our stacks, inside of books, on shelves, outside on the perimeter of the library." Lambert, May 16, 2022, Trial Tr. at 945:13–18. Library staff have been stuck by used syringes, and they

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

have found them in the children's reading areas. Lambert Decl. ¶ 4. Drug users regularly flush used syringes down the library toilets. Id. ¶ 10. The large volume of syringes that are flushed down library toilets has caused them to overflow and has repeatedly destroyed plumbing. Id. Plumbing damage has caused multiple library closures and cost SFPL tens of thousands of dollars. Id. ¶ 11.

The city has also had to address the "substantial mental and emotional toll" that the opioid epidemic has had on library staff." Lambert Decl. ¶ 8. It is the first library system in the country to hire a full-time social worker, Leah Esguerra, who helps connect library visitors suffering from opioid addiction with support services. Lambert, May 16, 2022, Trial Tr. at 947:14–948:10. In addition, Ms. Esguerra provides counseling to library staff to help them process the emotional strain of the daily opioid use they witness and the difficult encounters they have with patrons using opioids. Id. Library staff regularly see "paramedics carting people out of the restrooms." See Lambert Decl. ¶¶ 12–13. Recently, a library visitor—"young and in the prime of their life"—died of an opioid overdose in a bathroom and staff watched the "blue body being removed from the library." Id. ¶¶ 12–13. In January 2022, two security guards responded to reports of a man who exhibited signs of opioid use and lay slumped unresponsive at a computer kiosk. Id. ¶ 24. As the guards approached the man to check on him, the man's dog attacked one of the guards, causing severe injuries that "will have long-lasting negative effects on [the] guard's health and quality of life." Id.

The increased drug use has also required the library to increase security. Lambert Decl. ¶ 17. SFPL has contracted with the San Francisco Police Department to provide officers to patrol libraries and respond to reports of opioid use and overdoses. <u>Id.</u> ¶¶ 17– 20. At the Main Library—an "anchor library" located in the heart of San Francisco— SFPL employs a non-profit organization to monitor the gender-neutral bathrooms because the rates of drug use in them are so high. <u>Id.</u>  $\P$  21. A restroom monitor "knocks on the door if a patron is inside for more than eight minutes, to ensure they are safe." Id. Describing the situation, Lambert testified that "I have to decide if we can keep these

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

restrooms open . . . or risk someone dying from an opioid overdose in them." <u>Id.</u>

## 4. Walgreens

Walgreens is one of the largest retail pharmacy chains in the United States. From 2001 to 2020, Walgreens had between 7,000 to 10,000 stores across the country, almost all of which have a pharmacy. Polster, June 2, 2022, Trial Tr. at 2261:25–2262:18; 2359: 6– 13. Walgreens employs over 200,000 employees, approximately 26,000 of whom are pharmacists and approximately 80,000–90,000 of whom are technicians who support pharmacists. See id. at 2360:24–2361:7. During its period of peak growth in the 2000s, Walgreens aimed to open one new store per day, with the goal of having a store within five minutes of approximately 75% of the United States population. Coman, May 11, 2022, Trial Tr. at 704:11-24.

Walgreens enjoys especially large market share in San Francisco, where it is the dominant chain retail pharmacy. Between 2006 and 2020, the number of pharmacies in San Francisco varied, with a high of 75 stores and an average of approximately 60 stores operating across the city each year. See Gerspacher Tr. (dkt. 1362–1) at 9:4–11; McCann Decl. (dkt. 1328) ¶ 20, 57. Walgreens pharmacies received 58.7% of the prescription opioid pills sold to chain and retail pharmacies in San Francisco. McCann Decl. ¶ 39. From 2006 to 2020, Walgreens pharmacies dispensed 155,763,131 opioid pills in San Francisco. Id. ¶ 57, Table 55.

In addition to its pharmacies, Walgreens operates distribution centers throughout the country that provide medications and inventory to Walgreens stores. Coman, May 11, 2022, Trial Tr. at 696:25–697:4. Until 2014, Walgreens distribution centers provided controlled substances, including prescription opioids, to Walgreens pharmacies. Polster Decl. (dkt. 1399) ¶ 8. In 2014, Walgreens stopped distributing controlled substances and began outsourcing all controlled substance distribution to third-party distributors. <u>Id.</u>

As a dispenser and distributor of controlled substances, Walgreens was at all relevant times subject to the requirements of the Controlled Substances Act and its implementing regulations. See generally 21 U.S.C. § 829.

# 5. The Controlled Substances Act

The Controlled Substances Act ("CSA") and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances. 21 U.S.C. § 801 et seq. The CSA categorizes controlled substances into five schedules based on a drug's risk profile and accepted medical uses. See Rannazzisi I Tr. at 405:10–408:10. Schedule I drugs may not be prescribed because they have high potential for abuse and no currently accepted medical use. Catizone Decl. (dkt. 1299) ¶ 6. Schedule II drugs are the most dangerous drugs that may be dispensed: they have a high potential for abuse—including risks of psychological or physical dependence—but they also have accepted medical use. Id. ¶ 6–7. Schedule III and IV drugs have moderate to low potential for abuse. Id. Most prescription opioids are Schedule II drugs, but a minority are Schedule III or IV drugs. Id. ¶ 7; Rannazzisi I Tr. at 407:14–408:10; Catizone Decl. ¶ 6–7.

The CSA and its implementing regulations determine what persons and entities are authorized to make, distribute, prescribe, and dispense controlled substances. Rannazzisi I Tr. at 410:08–413:1. Every person or entity that manufactures, distributes, prescribes, or dispenses controlled substances must apply for registration with the DEA. See 21 U.S.C. § 822(a)(1)–(2). The DEA "shall register an applicant" unless it determines "that the issuance of such registration is inconsistent with the public interest." Id. § 823(b). Manufacturers and distributors must renew their DEA registrations every year, and pharmacies and prescribers must renew their registration every three years. See id. § 822(1)–(2).

Requiring entities to register with the DEA creates a "closed system of distribution" for controlled substances. Catizone Decl. ¶ 6. Under the closed system, each person or entity in the controlled substance supply chain is a DEA registrant, enabling the DEA to monitor the flow of controlled substances from manufacture to dispensation. See Rannazzisi I Tr. at 412:16–413:1; 436:10–437:17. DEA-registered manufacturers sell to DEA-registered distributors that sell to DEA-registered dispensers. Id. at 410:8–413:01. DEA-registered dispensers may only dispense controlled substance prescriptions pursuant

to prescriptions written by DEA-registered prescribers. <u>Id.</u>

The closed system of distribution aims to secure the controlled substance supply chain against diversion. See Rannazzisi I Tr. at 436:10–437:25. Diversion happens when controlled substances are taken from "the legitimate stream of commerce and moved into the illicit marketplace." Id. at 381:23–382:5. Registrants are subject to regulations that require them to take steps to prevent diversion of controlled substances. See 21 C.F.R. § 1301.74 (a); P-03669 at 00002. For example, they have regulatory obligations to securely house controlled substances. See 21 C.F.R. § 1301.72. Each registrant is also subject to regulatory requirements that are specific to their role in the controlled substance supply chain. See Rannazzisi I Tr. at 410:8–411:15.

# **B.** Walgreens Distribution Operations

# 1. DEA Oversight of Distributor Operations

Under the CSA and its implementing regulations, distributors of controlled substances must maintain a suspicious order monitoring system that identifies suspicious orders. See Rannazzisi I Tr. at 419:10–21. Suspicious orders identified through these systems must be reported to the DEA. Id. The relevant provision of the CSA regulations states:

"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."

21 C.F.R. § 1301.74(b).

The CSA's implementing regulations define a "suspicious order" as "a controlled substance order that is of unusual size, unusual frequency or substantially deviating from the normal ordering pattern." See id.; see also Rannazzisi I Tr. at 421:5–12; P-03670 at 00001. Determining whether an order is suspicious is a context-based inquiry that requires consideration of the totality of the circumstances. See Mapes Tr. at 87:21–88:10. A distributor must "inform the Field Division Office of the Administration in his area of

suspicious orders when discovered by the registrant." 21 C.F.R. § 1301.74(b).

To identify suspicious orders, the regulations require distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). No regulation defines the specific aspects of the system that distributors must use to monitor and report suspicious orders. Rannazzisi I Tr. at 419:10–421:03; Mapes Tr. at 82:12–21. Rather, it is the responsibility of the registrant to determine what type of suspicious order monitoring system is "correct for their business model or how they are doing business[.]" See Rannazzisi I Tr. at 419:10–421:03; see also P-03670. The main determinant of an effective suspicious order monitoring system is that it effectively identifies and reports suspicious orders. See Rannazzisi I Tr. at 420:23–421:3.

The DEA's guidance on reporting suspicious orders changed in the mid-2000s. See Mapes I Tr. at 92:1–126:14. In the fall of 2005, in the wake of diversion of controlled substances through "internet pharmacies," DEA officers began meeting with distributors to provide updated guidance on the process for reporting suspicious orders. Rannazzisi II Tr. at 40:12–18; 107:1–16; Mapes I Tr. at 130:12–131:15. Internet pharmacies enabled patients to obtain prescriptions for controlled substances through an online process, as opposed to in person visits with a doctor. See Mapes I Tr. at 130:12–131:15. The DEA was concerned that the internet pharmacies presented risks for diversion because there was no doctor-patient relationship and "the pharmacies were filling prescriptions for patients that they knew nothing about, for doctors that weren't within the geographic area, all for the same drug." See id.; see also id. at 214:5–215:10.

Prior to fall of 2005, distributors sent DEA field offices "excessive purchase" reports, which were reports of controlled substance purchases that the distributors found to be potentially excessive. Mapes I Tr. at 91:18–94:3; Wright I Tr. at 69:23–71:13. The excessive purchase reports sent to the DEA were for orders that had already been shipped to customers. Mapes I Tr. at 96:9–22; Wright I Tr. at 113:23–116:12. Having distributors send excessive purchase reports to the DEA was the standard practice for registrants to

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

report suspicious orders in that time period, and the DEA considered the practice sufficient to comply with registrant's statutory obligation to report suspicious orders. Mapes I Tr. at 93:21–96:22; Wright I Tr. at 75:2–9.

The DEA launched the "Distributor Initiative" in late 2005 to change the process by which distributors reported suspicious orders. See Mapes I Tr. at 125:3–130:23. The initiative involved a series of presentations to distributors regarding the DEA's changed position on the expectations for suspicious order reporting. See id. at 132:8–133:20; 188:14–189:9; 197:23–198:12. Instead of sending excessive purchase reports at the end of the month, the DEA informed distributors, including Walgreens, that it expected them to begin identifying and reporting suspicious orders before shipping them. See id. at 189:15– 23; 197:23–203:24. The DEA communicated to distributors that they were expected to perform an assessment to determine whether an order was in fact suspicious, as opposed to sending the DEA reports of all orders that exceeded certain thresholds. Id. at 203:9– 208:10; Wright I Tr. at 103:1–110:19. The DEA did not require distributors to change their suspicious order reporting practices by a specific date. Mapes II Tr. (dkt. 1437–2) at 518:10–520:21. But its expectation was that distributors would begin making the changes following the meetings with DEA agents. See Mapes II Tr. at 518:10–520:21; Wright I Tr. at 123:2-125:16.

In 2006 and 2007, Joe Rannazzisi, the Deputy Assistant Administrator of the DEA's Office of Diversion Control, sent letters to every entity registered with the DEA to distribute controlled substances, including Walgreens. Rannazzisi I Tr. at 428:6–430:22; see also P-00015 at 00002. The letters reiterated that every entity registered to distribute controlled substances has a duty under the CSA to identify and report suspicious orders, and the letters provided further guidance on identification and reporting requirements. Rannazzisi I Tr. at 428:6–430:10. Rannazzisi testified that he sent the letters in part because he was concerned that distributors were not maintaining systems to identify suspicious orders and were not reporting suspicious orders. See id. at 416:9–417:9. He was also concerned about the growing problem of prescription opioid abuse in the United

States. Id. at 433:13–434:9.

Rannazzisi sent the first letter in September 2006. It emphasizes that the abuse of controlled prescription drugs is "a serious and growing health problem in this country." P-03669 at 00001. The letter reiterates distributors' statutory responsibility "to exercise due diligence to avoid filing suspicious orders that might be diverted" for illegitimate use, provides a non-exclusive overview of circumstances that may indicate suspicious orders from a pharmacy customer, and states that distributors have a statutory duty to timely report suspicious orders to the DEA. <u>Id.</u> at 00002.

Rannazzisi sent another letter in December 2007. It focuses on the importance of reporting suspicious orders to the DEA and resolving any indicia of suspicion before shipping the order. See P-27368. The letter makes clear that sending a monthly report of completed orders to the DEA is not sufficient. Id. It specifically states that "[f]iling a monthly report of completed transactions (e.g., 'excessive purchase report' or 'high unity purchases') does not meet the statutory requirement to report suspicious orders." Id. In addition, the letter states that registrants "must conduct an independent analysis of suspicious orders" before filling them. Id. at 00002–03. The letter further states that suspicious order monitoring systems that rely on "rigid formulas" to identify suspicious orders are insufficient. Id. at 00003. Determining whether an order is suspicious "depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry." Id. The letter concludes that filling "orders without first determining that order is not being diverted . . . may be failing to maintain effective controls against diversion." Id.

# 2. Walgreens Distribution Centers

Until 2014, Walgreens operated three distribution centers in the United States that distributed prescription opioids to Walgreens pharmacies.<sup>6</sup> Coman, May 11, 2022, Trial

<sup>&</sup>lt;sup>6</sup> The distribution centers no longer distribute controlled substances to Walgreens pharmacies, but they continue to distribute other medications and inventory items to Walgreens stores. <u>See</u> Polster

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Tr. at 695:25-697:4; Polster I Tr. at 326:4-16. The distribution centers were in Perrysburg, Ohio, Jupiter, Florida, and Woodland, California. Coman, May 11, 2022, Trial Tr. at 695:25–696:14. The Woodland facility, which is the primary distribution center for Walgreens pharmacies in San Francisco, distributed controlled substances to approximately 2,500 stores across 25 different states. Id. 695:25–696:24.

From 2006 to 2014, Walgreens distributed 102.4 million dosage units of opioids to its pharmacies in San Francisco. McCann Decl. ¶ 10, 37. But Walgreens was not the exclusive distributor to its pharmacies. Polster Decl. ¶ 5. The company also used third party distributors, including Cardinal Health, AmerisourceBergen, and McKesson, to fill orders from its pharmacies. See McCann Decl. ¶ 12. Walgreens did not distribute controlled substances to third parties, including other chain pharmacies, independent pharmacies, or hospitals. Polster Decl. ¶ 5.

Before 2012, the evidence showed that Walgreens Woodland distribution center periodically generated a suspicious order report to identify suspicious controlled substance orders. Coman, May 11, 2022, Trial Tr. at 708:12–22. The report used a "DEA" factor that was multiplied by a store's average monthly order volume to identify suspicious orders. See P-27553; Coman, May 11, 2022, Trial Tr. at 711:1–17. For example, if the average monthly order for a store is six and the DEA factor is three, then a monthly order that exceeds 18 is flagged as suspicious. See id.; see also Coman, May 11, 2022, Trial Tr. at 708:12–22. There was no evidence presented at trial about how Walgreens developed the DEA factor that it used to identify suspicious orders.

The evidence established that the system for monitoring suspicious orders used at Walgreens Woodland distribution center was deficient. Using a DEA factor that identified suspicious orders based on fixed thresholds contravened the DEA's direction to apply a holistic review to identify suspicious orders. See P-27368 at 00002–03. In addition, the evidence established that Walgreens shipped the suspicious orders that appeared on its

Decl. ¶8.

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

suspicious order report without any investigation. Joe Ferry, who managed distribution of controlled substances at the Woodland distribution center, testified that Walgreens corporate managed suspicious order monitoring, not his team at the distribution center.<sup>7</sup> Ferry Tr. (dkt. 1485–1) at 38:7–39:2 ("[F]rom my understanding [] there were controls in place at corporate level, that they handled that."); see also id. at 344:13–345:6. Ferry testified that to the extent that personnel at the distribution center reviewed controlled substance orders, it was to make sure that the order had been entered correctly and that a pharmacy had not accidentally ordered far more or less than intended. Id. at 48:10–51:20.

John Coman, the "buck stops here" General Manager of the Woodland distribution center, testified that he was not aware of any employees at the distribution center who used the suspicious order report to reduce orders for controlled substances that were shipped to pharmacies. Coman, May 11, 2022, Trial Tr. at 721:8–21. Coman also testified that he was not aware of any training for distribution center employees on how to review and resolve suspicious orders. Id. at 739:16–740:6; see also Lucas Tr. at 612:4–5; 615:19–23. In response to the question, "did Walgreens allocate to you, as manager of the Woodland's distribution center, resources necessary to identify, monitor, and perform due diligence on suspicious orders," Coman testified, "No." Coman, May 11, 2022, Trial Tr. at 741:19-742:1.

In contrast to the testimony of Coman and Ferry, Tasha Polster, Head of Walgreens Pharmaceutical Integrity Team, testified that Walgreens distribution centers—not Walgreens corporate—were responsible for suspicious order monitoring before 2012. See Polster Decl. ¶ 6 ("Walgreens' suspicious order monitoring system was conducted by distribution center personnel."). Polster's testimony on this point is not credible. Ferry, who managed controlled substance orders at Walgreens' Woodland distribution center, testified that the distribution center did not oversee suspicious order monitoring. See Ferry

<sup>&</sup>lt;sup>7</sup> "Walgreens corporate" refers to the company's corporate offices located in Deerfield, Illinois. The corporate offices oversees pharmacy operations and develops policies and processes that are implemented at Walgreens stores and pharmacies throughout the United States. Polster, June 2, 2022, Trial Tr. at 2258:3–18.

18

19

20

21

22

23

24

25

26

27

28

1

2

3

4

5

6

7

8

9

Tr. at 38:7-39:2; 344:13-345:6. And Coman, the general manager of the Walgreens' Woodland distribution center, testified that the distribution center shipped orders that had been identified as suspicious without any investigation in violation of 21 C.F.R. § 1301.74. Coman, May 11, 2022, Trial Tr. at 725:15–727:20. In light of this testimony, Polster was pressed during cross-examination on the basis of her understanding that distribution centers—not corporate—oversaw suspicious order monitoring. Polster, June 2, 2022, Trial Tr. at 2349:25–2353:23. Polster provided no specifics as to the basis of her understanding that distribution centers were responsible for maintaining systems that identified and halted suspicious orders, and her answers were vague and evasive. See id. Coman and Ferry, on the other hand, were the Woodland distribution center managers who oversaw fulfillment of controlled substance orders, and their answers were unambiguous. Given their direct involvement in the process and their straightforward answers, the Court credits their testimony over Polster's. Consistent with this finding, the following evidence showed that neither Walgreens corporate nor its distribution centers maintained effective suspicious order monitoring systems for years.

# 3. Walgreens' Failure to Monitor and Report Suspicious Orders

In 2006, a DEA audit of Walgreens' Perrysburg, Ohio distribution center found that Walgreens' suspicious order monitoring system was "insufficient." P-09128 at 00004. In particular, the DEA found that the "DEA factor" that Walgreens used to identify suspicious orders was "inadequate." <u>Id.</u> at 00002. The DEA found that simply using a DEA factor to identify suspicious orders was insufficient and that Walgreens needed to develop a suspicious order monitoring system that captured orders based on size, pattern, and frequency. <u>Id.</u> at 00002, 00004; <u>see also P-27368</u> ("Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders.").

Two years later, in 2008, Walgreens' Internal Audit team audited the Perrysburg distribution center. See P-19904. The Internal Audit team concluded that the deficiencies that the DEA had identified in the suspicious order monitoring system had not been

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

resolved. <u>Id.</u> at 00001. Specifically, the audit team found that "Walgreens is filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order, which could lead to non-compliance with DEA regulation Section 1301.74." Id. at 00004. The audit team noted that the deficiencies in "suspicious controlled drug order processing and reporting" existed across all of the company's distribution centers and "should be addressed to avoid potential DEA sanctions." Id. at 00001.

In January 2008, Walgreens' Internal Audit team performed an audit of the Woodland distribution center. See P-20656 & P-20657. Coman testified that the audit team was composed of subject matter experts who had access to all internal documents and all employees who worked at the Woodland distribution center. Coman, May 11, 2022, Trial Tr. at 722:3–724:19. One of the main purposes of the audits was to assess whether the distribution center was complying with federal regulations. Id. at 724:23–725:1.

As was the case with the Perrysburg audit, the audit team "found non-compliance with certain DEA regulations." P-20656 at 00002. Among the forms of non-compliance, the audit team found "numerous instances" where the Woodland distribution center was shipping "suspicious controlled substance orders" without performing any investigation. Id. The audit team also found that "there is no monitoring process in place to stop a suspicious order to assess if the order is suspicious or not." Id. The audit team concluded that "filling orders that have been deemed suspicious without performing any research to ascertain the legitimacy of the order [] could lead to non-compliance with DEA Regulation Section 1301.74." P-20657 at 00002. Walgreens' management responded to the audit report by setting a deadline of June 2008 for the Woodland distribution center to address the deficiencies. Id.

The deficiencies identified in the internal audit were not resolved by June 2008. Coman, May 11, 2022, Trial Tr. at 730:23–731:10; P-27384. In the fourth quarter of Walgreens' 2011 fiscal year, the Internal Audit team performed a follow-up audit of the Woodland distribution center. See Coman, May 11, 2022, Trial Tr. at 735:20–739:8. The Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

audit found that the Woodland distribution center still did not have a system in place to prevent fulfillment of orders identified as suspicious on the suspicious order report. Id. The deficiencies in Walgreens' suspicious order monitoring system identified in the 2008 internal audit remained three years later. <u>Id.</u> at 739:1–8. (Q. "And here we are three years later, and they are still concerned about Walgreens not having a monitoring process in place; correct, sir?" A. "Correct.").

Walgreens presented evidence that DEA agents performed in person audits of the Woodland distribution center approximately every two years. Coman, May 11, 2022, Trial Tr. at 760:24–761:4; see also Ferry Tr. at 323:14–25. During the audits, DEA agents set up a workspace in the distribution center and requested various reports. Coman, May 11, 2022, Trial Tr. at 763:20–764:4. Michael Mapes, a former DEA Diversion Investigator, testified that reviewing a distributor's suspicious order monitoring system was a standard part of the DEA audits. Mapes I Tr. at 49:22–51:12. And Coman testified that he did not recall the DEA ever identifying any issues with Woodland's suspicious order monitoring system. Coman, May 11, 2022, Trial Tr. at 764:7–766:17; 771:6–9.

Walgreens' internal audits, on the other hand, repeatedly found that the company's suspicious order monitoring systems were deficient. See P-20657 & P-27384. Coman also testified that the DEA audits focused mainly on whether there was adequate physical security for controlled substances and whether any controlled substances had been lost. Coman, May 11, 2022, Trial Tr. at 764:7–766:17; 771:6–9. Furthermore, Coman testified that he met with DEA agents as part of the DEA's audit and—despite being aware of deficiencies in Walgreens' suspicious order monitoring systems—he did not tell the agents that the company had identified deficiencies or that the deficiencies persisted for several years. Id. at 771:16–773:11. The Court finds that the specific evidence showing deficiencies in suspicious order monitoring systems carries more weight than the testimony about what the DEA's audits generally included. That the DEA audits apparently did not identify deficiencies in Walgreens' suspicious ordering monitoring system does not establish that deficiencies did not exist, especially because Walgreens' own documents

show that they did.

Between 2009 and 2012, Walgreens began a phased roll out of a new Controlled Substances Reporting ("CSR") system to identify suspicious orders. See Polster Decl. ¶ 6. The CSR system "provided a centralized means of reviewing orders for controlled substances placed by Walgreens pharmacies and identifying orders that might be of concern." Id. Polster testified that the CSR system used historical ordering patterns from groups of stores to assign ceiling limit thresholds for each store within the group. Id. ¶ 7. But she could not describe in any detail how the ceiling limits were set. She testified that she could only speak in "generalities" about the ceiling limits and that she did not know any specifics about how Walgreens determined the numerical ceiling assigned to each store. See Polster, June 2, 2022, Trial Tr. at 2271:14–2275:11.

The evidence also showed that the CSR system could be circumvented. Although the CSR system set "ceiling limits" that capped the amount of controlled substances a pharmacy could order, field leadership and Walgreens corporate executives could approve orders that exceeded the ceiling limits. Polster, June 2, 2022, Trial Tr. at 2269:2–2270:4. In fiscal years 2014 and 2015, Walgreens approved over 95% of the requests for orders that exceeded ceiling limits. Id. at 2331:8–2332:2. There were other ways around the ceiling limits. Walgreens pharmacies could place "PDQ" orders—company shorthand for orders that are needed "pretty darn quick"—and PDQ orders did not count against a pharmacy's ceiling limit. See id. at 2332:19–2333:20. Pharmacies could also place "interstore" orders, where one pharmacy sends controlled substances to another pharmacy. Id. at 2334:8–21. Until 2013, a Walgreens pharmacy could receive controlled substances from another pharmacy without those orders counting against its ceiling limit. Id.

Dan Coughlin, a Walgreens Vice President of Supply Chain, contemporaneously expressed concern that suspicious orders were not being reviewed prior to the launch of the CSR system. P-00058 at 00001. In a 2010 email to members of Walgreens' corporate compliance team, Coughlin, referring to suspicious controlled drug orders, wrote, "Who from your group has been reviewing the data collected for the past twenty-five years?"

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

<u>See id.</u> The record does not contain a response. Consistent with Coughlin's concern that suspicious orders were not being reviewed, Walgreens employees worried that once the CSR system was implemented across all stores, it was "expected to generate thousands of 'orders of interest' per week" that "will all require review prior to allowing the drugs to be shipped to our pharmacies." P-00027 at 00001. Internally, people raised concerns about the company's ability to perform due diligence on these orders because they had only 10 employees on the compliance team. See Polster Trial Tr. at 2395:05–2396:06. An email from Pharmaceutical Integrity Manager Edward Bratton confirms the deficiencies in Walgreens' prior suspicious order monitoring system. In 2013, Bratton wrote:

"The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens."

P-00139 (emphasis added).

As Walgreens was rolling out the CSR system, the DEA served an Immediate Suspension Order on the Jupiter, Florida distribution center. The order required the Jupiter distribution center to immediately suspend all distribution of controlled substances based on findings that the distribution center's violations of the CSA created an imminent threat of harm to public health and safety. P-00015 at 00001; see also 21 U.S.C. §§ 823, 824. Kristine Lucas, who was the Controlled Substances Manager at the Jupiter distribution center when the suspension order was served, testified that the DEA shut down the distribution center because of the extraordinarily massive volumes of opioids that it was receiving and shipping to Walgreens pharmacies. See Lucas Tr. (dkt. 1339–1) at 612:16– 613:12; 630:8–633:2; 635:15–636:15; 658:17–659:10.

Lucas testified that Walgreens pharmacies began ordering increasingly large volumes of opioids from the Jupiter distribution center starting in 2010. See Lucas Tr. at 623:14–625:20. She testified, "I'd send this store 30 bottles a week. And then, it went to 90 bottles a week, and then 300 bottles a week, and then 600 bottles a week, and it just kept progressing more and more and more." <u>Id.</u> The Jupiter distribution center had a

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

secure cage where controlled substances were stored, but the increasingly large orders for opioids exceeded the cage's capacity. Id. at 629:1–13. To manage the influx of orders, distribution center personnel first took all the shelves out of the secure cage so that boxes of opioids could be stacked from floor to ceiling. <u>Id.</u> This solution did not last. Even with boxes stacked from floor to ceiling, the secure cage could not fit all of the opioids that the distribution center was receiving. <u>Id.</u> at 629:9–24. Distribution center personnel began stacking pallets of opioids outside of the secure cage. Id. at 629:1–630:3.

Delivering the growing volumes of opioids to pharmacies also required the distribution center to use bigger trucks. The standard trucks used to fill pharmacy orders did not provide enough space, so the distribution center began using a "box truck with no shelves . . . that you could stack floor to ceiling." Lucas Tr. at 626:13-21. Lucas raised concerns with pharmacists about the rapidly increasingly orders. She testified that pharmacists "would call wanting a large number of bottles. And I'm like, I – I just sent you 300 bottles. You need 300 more? It's been three days, you know." Id. at 631:3–17. Lucas asked pharmacists if they were concerned that they were filling suspicious prescriptions and they told her, "I'm not a pharmacist, and that they were pharmacists, and they said if somebody brings me a script, I'm going to fill it." <u>Id.</u> at 631:18–632:1. She asked pharmacists if they were doing due diligence on prescriptions, and she testified that "I was told that was not their job. They have a script, they will fill it." Id. at 632:2–10.

Lucas repeatedly expressed concern to her managers that the opioid orders were not being securely stored and that Walgreens pharmacies were ordering concerningly high volumes of opioids. Lucas Tr. at 630:8–633:2; 635:15–636:15; see also P-00004 ("I ran a query to see how many bottles we have sent to store #3836 and we have shipped them 3271 bottles between 12/1/10 and 1/10/11. I don't know how they can even house this many bottle[s] to be honest."). Her concerns went unaddressed, and Lucas described the situation as "a ticking time bomb." Lucas Tr. at 635:15–636:9.

On September 13, 2012, the DEA issued its order directing that Walgreens immediately suspend all distribution of controlled substances. P-00015 at 00001. The

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

suspension order was based on the distribution center's failure to monitor for suspicious orders and to securely house controlled substances. See P-00015 at 00028-40. Lucas testified that approximately 20 agents arrived at the distribution center, "came in and shut down the operation." Lucas Tr. at 658:17–659:10. Distribution center personnel were directed to return all unshipped controlled substance orders to the secure cage, and after the orders were returned, DEA agents changed the combinations for the cage and set up workspaces at the facility. Id. at 659:3–23. Controlled substances shipments from the Jupiter distribution center never resumed. Id. at 666:13–16.

In 2014, Walgreens stopped distributing controlled substances to its pharmacies entirely. It now uses third-party distributors that receive and fill controlled substance orders from Walgreens pharmacies. Polster Decl. ¶ 8; Coman, May 11, 2022, Trial Tr. at 745:22-746:4.

#### C. **Walgreens Pharmacy Operations**

# 1. **Pharmacy Regulations and Industry Standards**

In California, a medical professional must be registered with the DEA and licensed by the state in order to write prescriptions for controlled substances. 21 C.F.R. § 1306.03; Cal. Health & Safety Code § 11150. Under both California and federal law, a medical professional can only write a controlled substance prescription if they believe, based on their medical judgment, that the drug is an appropriate form of treatment for a patient's medical condition. Cal. Health & Safety Code § 11153; 21.C.F.R. § 1306.04(a); see also Rannazzisi I Tr. at 1574:18–1576:17. California law requires a pharmacy to fill a valid prescription that has been issued for a legitimate medical purpose by a prescriber acting within their scope of practice. Cal. Bus. & Prof. Code § 733(a).

A prescription that is not for the purpose of treating a patient's medical condition is an illegitimate prescription. See 21 C.F.R. § 1306.04(a). Two sources of illegitimate prescriptions are unscrupulous prescribers and drug-seeking patients. Unscrupulous prescribers—often referred to as "pill mills"—write medically unnecessary prescriptions for patients, often in exchange for cash payment. See Keyes Decl. ¶ 88; Mathews Porter

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

(dkt. 1362–7) at 101:12–23. Drug-seeking patients also deceive prescribers into writing unnecessary prescriptions in a variety of ways, including by faking symptoms and visiting multiple prescribers to obtain multiple prescriptions for the same condition. See Keyes ¶ 87; see also Besinque Decl. ¶ 26. Illegitimate prescriptions are not used to treat a medical condition—they are generally abused by the recipient or sold illegally. See Rannazzisi II Tr. at 195:9–24; Rannazzisi I Tr. at 426:6–427:2. When an illegitimate prescription is filled, the drugs are diverted because they are not being obtained for a legitimate medical use. See Catizone Decl. ¶¶ 10–11.

Under the CSA's implementing regulations, pharmacists have a "corresponding responsibility" to determine whether a prescription for a controlled substance is written for a legitimate medical purpose before dispensing it. 21.C.F.R. § 1306.04(a) ("The responsibility for the proper prescribing and dispensing is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.") (emphasis added). While the corresponding responsibility requires pharmacists to perform due diligence on controlled substance prescriptions, pharmacies also have a duty to ensure that the corresponding responsibility is being fulfilled. Catizone, May 12, 2022 Trial Tr. at 796:5–25. Pharmacies are DEA registrants and are subject to CSA regulations. Rannazzisi I Tr. at 1579:3–1580:20. Pharmacists are the agents of a pharmacy, and the pharmacy is responsible for their conduct.<sup>8</sup> Id. ("[I]t's ultimately the responsibility of the pharmacy for whatever the pharmacist is doing."); see also id. at 1710:03-20. In this regulatory framework, pharmacies act as the "last line of defense" for guarding against diversion by providing their pharmacists with the training and resources needed to ensure that pharmacists only dispense legitimate prescriptions for controlled substances. See Catizone Decl. ¶ 10.

Pharmacists are highly trained medical professionals who generally have "six to

<sup>&</sup>lt;sup>8</sup> Depending on the conduct at issue, pharmacists themselves may also be subject to individual disciplinary proceedings with the state board of pharmacy in their practicing jurisdiction and they may also be subject to criminal charges. See Rannazzisi I Tr. at 1579:21–1580:20.

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

eight years of training in drugs and medication therapy" before they begin practicing. See Catizone, May 12, 2022 Trial Tr. at 797:7–14; Polster Decl. ¶ 10. A pharmacist's education includes drug interactions, what drugs are used to treat certain diseases, and the appropriate dose and duration of drugs used to treat specific conditions. Catizone, May 12, 2022 Trial Tr. at 797:7–25. Prescribers and pharmacists "work together" to ensure that patients receive the appropriate treatment for their medical conditions. See id. at 797:7– 799:1. The role of the pharmacist includes confirming the accuracy of a doctor's prescription, checking to see whether the prescription is likely to have any adverse interactions with other drugs the patient may be taking, and advising the patient on how to take the prescription. See id.; see also Polster Decl. ¶ 11.

The corresponding responsibility requires pharmacists to draw on their education, training, and experience to assess whether a prescription was issued for a legitimate medical purpose before dispensing it. Besinque Decl. ¶¶ 9–10; Catizone, May 12, 2022 Trial Tr. at 796:5–11. In practice, pharmacists fulfill their corresponding responsibility by identifying and resolving any signs "arising during the presentation of a prescription" that create "a reasonable suspicion that the prescription is not, on its face, legitimate." Catizone Decl. ¶ 16; Besinque Decl. ¶¶ 9–10. Signs that a prescription may be illegitimate are commonly referred to a "red flags." See Besinque Decl. ¶ 9. Red flags are "warning signs" indicating that "further inquiry" is required. Catizone, May 12, 2022 Trial Tr. at 841:4–22; Catizone Decl. ¶ 16. Any red flags present on the face of a prescription must be resolved before the prescription is dispensed. Polster Decl. ¶ 14; Park (dkt. 1317) Decl. ¶ 8; P-15314 at 00029. If a pharmacist cannot resolve a red flag, the prescription cannot be dispensed. See Park Decl. § 8; Stahmann Tr. at 96:4–22; Catizone Decl. § 23.

A red flag does not mean that a prescription is illegitimate. See Catizone, May 12, 2022 Trial Tr. at 838:23–839:2; Besinque Decl. ¶ 9. Red flags are signs that a prescription might be illegitimate, but a pharmacist can sometimes resolve a red flag through due diligence. Catizone, May 12, 2022 Trial Tr. at 801:2–12; Besinque Decl. ¶¶ 9–10. Generally speaking, the due diligence process involves four steps: identify any red flags,

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

obtain information relevant to resolving the red flags, evaluate the information, and document the reasons supporting filling or refusing to fill the prescription. Catizone Decl. ¶ 24, 36; Park, June 16, 2022, Trial Tr. at 962:9–23; Park Decl. ¶ 7.

Throughout their career, pharmacists balance their obligation to dispense legitimate medications to patients who need them with their obligation to identify and refrain from filling medically illegitimate prescriptions that pose risks of diversion, abuse, and harm. Polster, June 2, 2022, Trial Tr. at 2281:4-23.

#### 2. **Walgreens Pharmacy Operations**

From 2006 to 2020, Walgreens operated approximately 50 to 75 pharmacies in San Francisco. See Gerspacher Tr. at 9:4-11; McCann Decl. ¶ 20, 57. This section provides a general overview of Walgreens pharmacy operations.

## **Pharmacy Staffing**

In general, Walgreens assigns "two and a half" pharmacists to each San Francisco pharmacy. <sup>9</sup> See Polster, June 2, 2022, Trial Tr. at 2263:11–17; 2296:2–10. Walgreens pharmacies generally operate from 8 am to 9 pm; one pharmacist opens the store while the other pharmacist comes in mid-day to provide a lunch break and to close the store. 10 Id. at 2296:11–2302:12. Pharmacist technicians help the pharmacists perform their work. Id. The technicians are not licensed pharmacists—they cannot approve prescriptions—but they help pharmacists with various tasks, including receiving prescriptions, performing drug interaction reviews, and collecting insurance information. See WAG-MDL-01662.00007.

Walgreens determines staffing at its pharmacies based on the volume of

<sup>&</sup>lt;sup>9</sup> The "half" pharmacist is a pharmacist who work at multiple pharmacies. Polster, June 2, 2022, Trial Tr. at 2263:11–17. These are referred to as "floater" pharmacists. While more pharmacists may be assigned to 24-hour pharmacies, there was no evidence that any Walgreens pharmacy in San Francisco operates 24 hours per day.

10 As a point of account.

As a point of comparison, the ZSFG pharmacy has far more staff performing due diligence before filling a prescription than Walgreens pharmacies. While Walgreens pharmacies have 1-2 pharmacists and 2-4 pharmacy technicians working on a regular day, the ZSFG pharmacy has seven pharmacists and ten pharmacy technicians working on a regular day. Patel, May 19, 2022, Trial Tr. at 1321:1–11.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

prescriptions filled at a pharmacy and the time that it takes to fill different types of prescriptions. Polster Decl. ¶ 36. Walgreens' Labor and Capacity Department determines the staffing levels at the pharmacies. <u>Id.</u> The Labor and Capacity Department performs analyses of the expected time necessary to complete certain tasks and uses these analyses to set store staffing. Id. Pharmacy Managers who believe the staffing for a particular store is insufficient can request additional staffing. Id.

#### b. **Dispensing Process**

Walgreens pharmacies receive prescriptions in three main ways: electronically, telephonically, or in person drop-off. Lo, May 12, 2022, Trial Tr. at 924:12–927:16; Polster Decl. ¶ 35. Each prescription that arrives at a Walgreens pharmacy is assigned a "promised time." Id. The promised time is the time by which the pharmacist is expected to have the prescription ready for the patient to pick up. <u>Id</u>. Promised times are generally assigned by Walgreens' computer system, but pharmacists may also set promised times. Lo, May 12, 2022, Trial Tr. at 924:12–927:16; Polster Decl. ¶ 35. A pharmacist's ability to meet promised time is a factor relevant to the pharmacist's year-end review and bonus. Polster Decl. ¶ 35. However, Walgreens excluded promised times for controlled substances from the bonus calculations starting in 2013. Id. ¶ 36.

Walgreens pharmacists use a system called IntercomPlus ("IC+") to dispense prescription medications. Polster Decl. ¶ 26; Polster, June 2, 2022 Trial Tr. at 2412:11–15. Each patient has a patient profile, and the patient's history of prescriptions are associated with the profile. Id. A patient's history of prescriptions includes information such as "the name of the medication, the dose, the quantity, the doctor's name and address, the date the prescription was written, the date it was filled, and any notes on the prescription." <u>Id.</u>

The IC+ interface enables pharmacists to document notes regarding patients, prescribers, and prescriptions. Polster Decl. ¶ 26. Walgreens pharmacists across different pharmacies can access the notes regarding a particular patient or prescription. <u>Id.</u> If a pharmacist refuses to fill a prescription because they are unable to resolve a red flag associated with the prescription, Walgreens' dispensing policy directs the pharmacist to

17

18

19

20

21

22

23

24

25

26

27

28

1

2

3

4

5

6

7

8

9

document the refusal to fill in the patient comment section of the IC+ interface. Polster, June 2, 2022 Trial Tr. at 2415:11–2416:22. If a patient whose prescription is refused at one Walgreens attempts to fill the prescription at a second Walgreens, the pharmacist at the second Walgreens is able to see the refusal to fill notation in the patient comment section. Id. at 2421:1-2424:2.

#### Walgreens' Good Faith Policy c.

Tasha Polster, Walgreens' Head of Pharmaceutical Integrity Team, explained that the "guiding principle" underlying Walgreens' controlled substance dispensing policies is that pharmacists are "licensed professionals who must exercise their own professional judgment in deciding whether to fill a prescription for a controlled substance." Polster Decl. ¶ 12. To guide pharmacists in the exercise of their professional judgment, the company has a policy regarding controlled substance dispensing called the Good Faith Dispensing Policy ("Good Faith Policy"). Id. at ¶ 13. The Good Faith Policy has been in place at Walgreens for over 30 years, though it has changed over time. Polster, June 2, 2022, Trial Tr. at 2282:1–10. One of the main purposes of the Good Faith Policy is to provide pharmacists with guidance on how to identify and resolve red flags. See Polster Decl. ¶¶ 12–13.

Four different iterations of the Good Faith Policy were introduced at trial: the 1998, 2006, 2011, and 2012 policies. See WAG-MDL-00018; WAG-MDL-01756; WAG-MDL-00211; WAG-MDL-00304. While all four versions of the Good Faith Policy include guidance on how to identify and resolve red flags, the guidance became significantly more detailed over time. See Polster Decl. ¶ 14. The following sections describe how the Good Faith Policy's guidance on red flags evolved from 1998 to 2012.

#### i. 1998 Policy

The 1998 Good Faith Policy is a one-page policy that states that a "pharmacist must determine if a prescription for a controlled substance is dispensed for a legitimate medical purpose." See WAG-MDL-00018. The policy includes examples of various "questionable circumstances" that should alert a pharmacist to a suspicious prescription. Id. The

questionable circumstances include high volume prescribers, frequent filling patients, large volumes or dosages, traveling unusual distances, and regular prescribing of habit-forming drugs. <u>Id.</u> The policy states that if a pharmacist becomes aware of questionable circumstances that they cannot resolve, they should "[n]ot dispense the drug" and should "[n]otify the pharmacy supervisor." <u>Id.</u>

## ii. 2006 Policy

Walgreens updated the Good Faith Policy in 2006. WAG-MDL-01756. The 2006 policy is a two-page policy that lists the same "questionable circumstances" as the 1998 policy. <u>Id.</u> However, the 2006 policy provides updated guidance on how pharmacists should handle prescriptions that present "questionable circumstances." <u>Id.</u> The policy directs pharmacists to "[c]ontact the prescriber to confirm or clarify the prescription," and "[i]f the prescriber confirms the validity of the prescription, document this on the hard copy and process the prescription as normal." <u>Id.</u> If a prescriber informs the pharmacist that the prescription is not authorized, the pharmacist should not dispense the prescription and should keep a copy of the prescription. <u>Id.</u> The policy allows the pharmacist to return the original prescription "to the patient upon the patient's request." Id.

## iii. 2011 Policy

Walgreens updated the Good Faith Policy again in 2011. The 2011 policy is also two pages, but it includes additional examples of "questionable circumstances" that should alert a pharmacist to a potentially suspicious prescription. See WAG-MDL-00211. The additional questionable circumstances include "[c]onsistent requests for early refills" and "[u]nusual presentation – prescriber's handwriting too legible, written in different color inks, different handwriting or with erasure marks." Id. The policy also includes updates on the steps that a pharmacist should take to resolve questionable prescriptions. Id. The policy states that before calling a prescriber to confirm a prescription, the pharmacist should verify the identity of the patient and verify the validity of the prescriber's information "including the DEA number and state license number." Id. If both are confirmed, the pharmacist should contact the prescriber to verify the prescription. Id. The

policy states that if the prescriber "confirms the validity of the prescription," the pharmacist should "then process the prescription as normal." <u>Id.</u>

## iv. 2012 Policy

The 2012 policy runs seven pages and includes extensive revisions compared to the earlier iterations of the policy. See WAG-MDL-00304; Polster, June 2, 2022, Trial Tr. at 2287:2–13. The policy expands the procedures that pharmacists must use to validate a prescription, including more detailed directions on the process for checking prescription drug monitoring programs. WAG-MDL-00304. In addition to the validation process, the policy adds a non-exhaustive list of indicators of suspicious prescribing that a pharmacist should consider in evaluating a prescription. Id. The indicators include patient-related concerns (e.g. "Consistently request early refills? Exhibit 'drug seeking' type behaviors?"), prescriber-related concerns (e.g. "Operate as a 'cash only' business and not accept government or 3<sup>rd</sup> party insurance as payment? Abusive or threatening?"), and prescription-related concerns (e.g. "Appear to be altered or forged? Contain misspellings?"). See id. (cleaned up).

In addition, although earlier versions of the Good Faith Policy state that verifying a prescription with a prescriber is sufficient due diligence, the 2012 Good Faith Policy states that "[e]ven if the prescriber verifies that the prescription is valid, it is the pharmacist's responsibility to confirm that the elements of good faith dispensing are satisfied prior to dispensing." WAG-MDL-00304.00002. If a pharmacist determines that the good faith elements are not met, they should not dispense the prescription, even if the prescriber informs the pharmacist that the prescription is valid. <u>Id</u> at 00304.0004. The 2012 policy further states that "[i]t is imperative that pharmacists document all efforts used to validate good faith dispensing." <u>Id</u>. The policy lists examples of the type of information that

<sup>&</sup>lt;sup>11</sup> A prescription drug monitoring program ("PDMP") is a statewide electronic database that is maintained by a state agency and contains data on controlled substance dispensing across the state. WAG-MDL-03189.00012. California's PDMP is called CURES. Polster Decl. ¶ 28. Checking a PDMP is part of the process of determining a prescription's legitimacy. See Besinque Decl. ¶¶ 19–21. For example, checking CURES would show whether a patient has received the same prescription from different prescribers. See id.; Besinque, June 6, 2022, Trial Tr. at 2574:7–14.

Walgreens expects its pharmacists to document, including prescriber information, patient information, and "any information pertaining to the elements of good faith." Id.

## d. Monitoring Compliance with The Good Faith Policy

Walgreens' field leadership is key to overseeing compliance with the company's Good Faith Policy. See Polster Decl. ¶ 30. The field leadership team includes pharmacy supervisors and district managers who oversee the operation of pharmacies. Id. One of the main responsibilities of the field leadership team is to visit the pharmacies within an assigned territory to review pharmacy operations and compliance measures. Id. The visits are known as "Store Walks," and members of the field leadership team use a "Store Walk Summary" checklist to guide their review of a store. See, e.g. WAG-MDL-03098. With regard to dispensing practices, the summary checklists ask, "Is the pharmacy following the Good Faith Dispensing policy?" See id.

## 3. DEA Actions against Walgreens Pharmacies

In the late 2000s and early 2010s, Walgreens was subject to multiple DEA enforcement actions based on charges that its pharmacies failed to implement and maintain adequate policies to prevent dispensing of suspicious prescriptions. In September 2009, the DEA issued an order for Walgreens to show cause as to why the certificate of registration for a San Diego, California pharmacy should not be revoked. P-20642 at 00001. The show cause order was based on the charges that:

- Since at least January 2007, Walgreens dispensed controlled substances to individuals located in California based on prescriptions issued by physicians who were not licensed to practice medicine in California. <u>Id.</u> at 00001.
- Walgreens dispensed controlled substances to individuals located in California based on purported prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice in contravention of 21 C.F.R. § 1306.04(a). <u>Id.</u> at 00002.
- Controlled Substance Utilization Review and Evaluation System ("CURES")
   data revealed that Walgreens also dispensed controlled substances to individuals

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

that Walgreens knew or should have known were diverting the controlled substances. Id.

In 2011, Walgreens entered a memorandum of agreement with the DEA to resolve the September 2009 show cause order. See P-19651 at 00008. The terms of the agreement applied "to all current and future Walgreens walk-in, retail pharmacy locations registered with the DEA to dispense controlled substances" (i.e., Walgreens nationally), and required Walgreens to strengthen its due diligence policies and improve the training and resources that it provides to pharmacists regarding how to identify and resolve suspicious prescriptions. Id. at 00002.

In 2012, the DEA issued multiple show cause orders to Walgreens' pharmacies in Florida, based in part on the charge that its pharmacies "ignored readily identifiable red flags that controlled substances were being diverted and dispensed controlled substances despite unresolved red flags." See P-19716 at 00002, 000010-11, and 00016. The red flags identified by the DEA included "multiple patients coming with prescriptions for the same drugs in the same quantities coming from the same doctor; patients traveling long distances to the pharmacy; patients with the same address presenting substantially similar prescriptions; and patients presenting combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam." See id. at 00016, 00023, and 00034.

In 2013, Walgreens entered into a memorandum of agreement with the DEA to resolve the charges that its pharmacies in Florida violated the CSA by filling illegitimate prescriptions for controlled substances. See generally P-00015. In the memorandum of agreement, Walgreens acknowledged that "certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA." Id. at 0002. To resolve the charges, Walgreens agreed to:

Implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized ultimate users pursuant to federal and state law and regulations.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

- Direct and train its pharmacists that their corresponding responsibility under federal law requires them not to fill a prescription that such pharmacist knows or has reason to know was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice.
- Remove controlled substance prescriptions from the dispensing volumes used to calculate bonuses for pharmacists.

P-00015 at 00006; P-17195; Polster, June 2, 2022, Trial Tr. at 2356:12–18.

#### 4. Walgreens Pharmaceutical Integrity Team

The 2013 DEA settlement required Walgreens to create a Pharmaceutical Integrity Team to develop and implement policies and procedures around controlled substance dispensing. Polster, June 2, 2022, Trial Tr. at 2354:3–2356:3. The team's mandate was to develop training programs and processes to better enable pharmacists to fulfill their corresponding responsibilities when dispensing controlled substances. See id.; Stahmann Tr. at 14:22–31:24.

Walgreens appointed Tasha Polster as the Head of the Pharmaceutical Integrity Team. See Polster Decl. ¶ 2. Even though the 2013 DEA memorandum of agreement set forth in detail the violations of the CSA that Walgreens pharmacies committed, Polster only read 13 pages of the 349-page agreement. See Polster, June 2, 2022, Trial Tr. at 2362:4–12. When asked "do you understand in the next 336 pages that there is significant detail walking through the numerous problems at Walgreens," Polster testified, "I haven't read this entire document." Polster I Tr. at 61:17–22. In response to the question "[y]ou didn't read over 90% of this document, correct," Polster answered, "Correct." Id. at 75:22-24.

The Pharmaceutical Integrity Team developed the Target Drug Good Faith Dispensing Policy ("Target Drug list"), which Walgreens began implementing in 2013. See Polster Decl. ¶ 20; see also WAG-MDL-00365; WAG-MDL-00547. The Target Drug list required pharmacists to complete a due diligence checklist before dispensing three "target drugs": oxycodone, methadone, and hydromorphone. Stahmann Tr. at 38:3–19;

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Polster II Tr. at 30:10–16; WAG-MDL-00547. Walgreens expected its pharmacists to apply both the Good Faith Policy and the Target Drug list before dispensing the target drugs. Polster Decl. ¶ 20. In explaining how Walgreens selected the three drugs that it placed on the checklist, Polster testified that the DEA "had expressed the greatest concern for diversion and overdose risk" for oxycodone, hydromorphone, and methadone and that the checklist served "to ensure consistency among our pharmacists in documenting the process for these drugs." Id.

In fact, the Target Drug list omitted some of the most frequently dispensed and widely abused opioids in the United States. Catizone Decl. ¶43. The most conspicuous omission from the Target Drug list was hydrocodone, which "was the number one prescribed, dispensed, and abused drug in the United States" at the time the Target Drug list was created. Catizone, May 12, 2022, Trial Tr. at 810:17-811:6. From 2012 to 2013, the DEA gave a series of regional presentations around the country to alert registrants about the risks of opioid abuse and diversion. Polster, June 2, 2022, Trial Tr. at 2374:23– 2375:7. These presentations identified hydrocodone as the most "commonly abused controlled pharmaceuticals." P-19656 at 00004, 00046. The presentation described hydrocodone as a frequent starting point in a "circle of addiction," where opioid users progress from abuse of hydrocodone to more potent and dangerous opioids, including heroin. See id. The DEA presentation identified oxycodone as a commonly abused controlled substance, but it does not identify the other two drugs on Walgreens' Target Drug list—methadone and hydromorphone—as among the commonly abused opioids. Id. at 00004. As the Head of the Pharmaceutical Integrity Team, Polster attended one of the DEA presentations, and she circulated takeaways from the presentation among the "highest levels" of Walgreens. See Polster, June 2, 2022, Trial Tr. at 2375:1–18.

Despite being aware that hydrocodone was a frequently prescribed and commonly abused opioid, the Pharmaceutical Integrity Team did not include it on the Target Drug list. Polster, June 2, 2022, Trial Tr. at 2380:3–20; Stahmann Tr. at 40:19–41:1. Polster testified that the decision was based in part on the fact that adding hydrocodone to the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

target drug list "would have increased the number of paper forms that the pharmacist had to fill out." See Polster II Tr. at 313:24-314:7; Polster, June 2, 2022, Trial Tr. at 2385:4-24. Financial considerations also influenced the creation of the Target Drug list, because adding frequently prescribed drugs would have increased the time and labor costs associated with performing due diligence. See Polster, June 2, 2022, Trial Tr. at 2385:4– 2386:3; 2387:2–16; see also P-20639 at 00011–12.<sup>12</sup> From January 2006 to June 2020, hydrocodone prescriptions accounted for 49.1% of the opioid prescriptions dispensed at Walgreens pharmacies in San Francisco. P-29837 at 00002.

In addition to omitting the most commonly abused opioid in the country, the Target Drug list was cumbersome to use, because pharmacists were required to complete a paper checklist—as opposed to an electronic document—until 2019. Polster II Tr. at 46:21–52:6 ("The checklist is not in the computer system."). Because the checklist was a paper record rather than an electronic file, information that pharmacists collected during the due diligence process—which included information relating to red flags—was not stored in any centralized computer system that was accessible to pharmacists across different Walgreens pharmacies. Id. at 52:19–53:11; 71:2–13. Instead, completed Target Drug checklists were stored in literal file cabinets at each pharmacy. Id. at 53:24–54:12. Because the paper checklists were stored in file cabinets at individual pharmacies, the information on the checklist was not readily accessible to pharmacists outside of the store where the checklist was kept. See id. at 53:12-23; 58:25-59:9; 73:2-13; Polster, June 2, 2022, Trial Tr. at 2396:14–24; 2398:1–20.

In fact, information collected through the Target Drug checklists was not even readily accessible to pharmacists at the store where the checklist was kept. The checklists were difficult to access because pharmacists, pursuant to Walgreens' policy, organized the checklists by prescription number, not patient name. See Polster II Tr. at 57:18–58:24.

<sup>&</sup>lt;sup>12</sup> Polster also testified that hydrocodone was not added to the Target Drug list because it was a Schedule III drug, but shortly after the Target Drug list was created, the DEA reclassified hydrocodone as a Schedule II drug. Polster II Tr. at 299:3–9. Walgreens did not add it to the Target Drug list.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Locating a paper checklist required a pharmacist to look up the patient's name, identify the prescription number for the past prescription that had an associated checklist, and retrieve the checklist from the file cabinet. See id. From 2013 to 2019, a pharmacist who wanted to locate the Target Drug list associated with a previously dispensed prescription had to complete this manual process to retrieve the paper checklist from a file cabinet. See id.

Walgreens' executives repeatedly denied requests from the Pharmaceutical Integrity Team to develop an electronic Target Drug checklist. See P-20795; Polster II Tr. at 52:7– 18. Shortly after taking the helm of the Pharmaceutical Integrity Team in 2012, Polster requested an electronic record-keeping process "to make things efficient and easier for the filling pharmacist." Id. at 62:11–21. The request was denied. Id. Polster testified that digitizing the due diligence process "did not get priority." Polster II Tr. at 263:13–18; 267:5–19; see also P-20795 at 00001 (November 2019 email in which Polster states "I have been wanting to do this from day one and Kermit wouldn't let me so this is a huge win for my team and the field."). The main reason was cost. See Polster, June 2, 2022, Trial Tr. at 2396:24–2397:25. Polster testified that "year after year," she submitted a budget request that included funding to digitize the Target Drug list, but Walgreens' President repeatedly denied the requests. See id. at 2396:7–2397:25. Instead, Walgreens pharmacists used paper checklists—stored in file cabinets—for six years. See id. at 2396:7–13; Polster II Tr. at 52:7–53:11.

In response to questions about why it took Walgreens six years to implement an electronic record-keeping system "to make things better, simpler, faster for our pharmacy team members," Polster testified that Walgreens was in the process of waiting for a "new computer system" and that it did not want to perform "throw-away work" by creating an electronic record-keeping system before the "new computer system" was ready. See Polster II Tr. at 256:24–267:19. But Polster provided no details as to why it took six years for Walgreens to develop a "new computer system," nor did she provide any detail about what other functionality the "new computer system" provided. Although developing a "new computer system" may partly explain the delay, the evidence established that at least

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

part of the reason it took Walgreens six years to implement an electronic Target Drug checklist was that spending additional money on compliance was not a priority for the company, even though it would have made "things better, simpler, faster" for Walgreens pharmacists. See P-20795.

Pharmacists faced additional challenges in attempting to follow the Target Drug list. Walgreens' policy directed pharmacists who refused to fill a prescription for a target drug to note the refusal in the Patient Comment section of Walgreens' IC+ computer system. See P-20789 at 00038. Adding notations to the Patient Comment section enabled one pharmacy to see that another pharmacy had refused to fill a prescription. Polster II Tr. at 321:20–322:8. But the Patient Comment section only held 320 characters, which limited pharmacists' ability to note their due diligence. See Catizone Decl. ¶ 48. In April 2013, pharmacists expressed concern that they were "running out of room" to add notations to the Patient Comment section. P-20801 at 00001. In response, the Pharmaceutical Integrity Team directed pharmacists to "delete older comments or refusals." Id.; Polster II Tr. at 321:10–18; 328:11–329:21.

Polster testified that even though historical comments were being actively deleted, pharmacists could still look up hardcopy paper files stored in the file cabinets at their store to locate previously completed refusal to fill forms. See Polster II Tr. at 328:11–329:6. She also testified that they could call other pharmacies to ask the pharmacists to look through the hardcopy paper files stored in the file cabinets at their store to determine whether a prescription from a particular prescriber had previously been refused. See id. None of the evidence at trial established that either was a reasonable substitute for lengthening the comment field. As Catizone explained, "As a pharmacist, I'm filling prescriptions. Even in the same store, I may not know that the pharmacist who worked three days before me refused to dispense a prescription because I don't have an electronic record of that prescription. It's paper." See Catizone, May 12, 2022, Trial Tr. at 803:16– 24.

Deleting the existing patient comments also made it more challenging to investigate

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

the legitimacy of new prescriptions. See, e.g., Lo Decl. ¶ 19 ("I remember very clearly that one day all of my prescriber comments disappeared. This was very frustrating and made my job much harder."); Kamali Tr. at 69:17-70:5 ("[O]ne day I noticed they were all wiped out."). Members of the Pharmaceutical Integrity Team recognized that the character and storage limitations created barriers for pharmacists performing due diligence. See Stahmann Tr. at 83:8–84:1. But Walgreens did not expand the comment field beyond 320 characters or develop other ways for pharmacists to better preserve the records of their due diligence.

Walgreens also instructed pharmacists not to write any comments that were critical of prescribers in the IC+ system, even though these comments were intended to flag concerns about a doctor's prescribing practices. See Lo Decl. ¶¶ 16–19 ("Walgreens instructed pharmacists to keep notes brief and to omit anything potentially negative."); P-27332 at 00001 ("[P]lease note the comment of 'Candy Doc' has been removed from all prescriber profiles."); P-17229 at 00001 ("Any comments such as 'prescriber under investigation' in the prescriber's profile should be removed.").

#### a. **Impediments to Identifying Suspicious Prescribers**

There was no standard process for alerting other Walgreens pharmacies about suspicious prescribers. Lo Decl. ¶¶ 16–19 ("Even when suspicious prescribers were identified, Walgreens offered no effective way to spread that information."). The inability to share information about suspicious prescribers across Walgreens pharmacies made it challenging to perform consistent due diligence. See Mathews Porter Tr. at 103:16–104:5. Several Walgreens pharmacists testified that one pharmacy would stop filling prescriptions for a particular prescriber only to learn that nearby Walgreens pharmacies were filling prescriptions from the same prescriber. Mathews Porter Tr. at 103:16–104:5; Yagar Tr. at 69:17–75:20. Walgreens pharmacies operated in information silos.

This need not have been so. Walgreens had access to large volumes of prescribing data that could have been used to identify suspicious prescribing trends. See Polster, June 2, 2022, Trial Tr. at 2303:7–21. In 2014, the Pharmaceutical Integrity Team developed

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

"an internal portal" that provided insights on prescriber's prescribing patterns. Stahmann Tr. at 67:3–20. The portal included data indicative of red flags, like high quantity prescriptions or early refills. <u>Id.</u> at 79:17–80:14. But Walgreens chose to make the portal available only to "field leadership," not to store pharmacists. <u>Id.</u> at 67:21–68:8. Eric Stahmann, a Manager on the Pharmaceutical Integrity Team, testified that Walgreens did not provide the data directly to pharmacists out of a concern that it would "cloud" their decisions about "whether or not to fill or not to fill a prescription." Id. at 68:9–1. In addition, Polster claimed that there was no need to provide pharmacists with a tool that flagged high frequency prescribers because if a pharmacist was filling prescriptions "multiple times in a day for the same prescriptions for the same prescriber," that would naturally be a red flag for a pharmacist. Polster II Tr. at 144:12–145:11. But Polster conceded that a pharmacist "wouldn't have easy visibility" into prescriptions from a high prescriber that were filled by other pharmacists, including pharmacists who worked in the same store. See id. at 145:13–146:17.

The Pharmaceutical Integrity Team also had access to information about prescribers across the entire chain of Walgreens stores. Stahmann Tr. at 102:15–103:2. The data included the total number of prescriptions filled by a prescriber as well as the percentage of prescriptions for controlled substances versus non-controlled substances. Id. at 104:22-105:6. The Pharmaceutical Integrity Team could rank prescribers based on their rates of prescribing relative to their peers. See id. at 106:2–15. Access to information regarding prescribing rates and related data would have helped pharmacists perform dispensing due diligence. As one example, before dispensing a prescription for a controlled substance, the Good Faith Policy required pharmacists to consider information such as "whether or not the prescriber prescribes the same diagnosis for the majority" of prescriptions and "whether the prescriber commonly writes narcotic prescriptions for individuals between 18 and 35." See Polster II Tr. at 148:12–24. These criteria require consideration of aggregate information, but there were no automated tools at the pharmacy-level for pharmacists to use in making these assessments. Polster II Tr. at 148:25–15. Pharmacists lacked

resources that would enable them to follow Walgreens' policy.

Unlike Walgreens, other retail pharmacy chains—like Walmart and Rite Aid—prohibited their pharmacies from filling prescriptions from certain prescribers determined to be suspicious. See Stahmann Tr. at 132:22–134:15; Mathews Porter Tr. at 106:16–107:02. In contrast, Walgreens' policy is to not "block a prescriber that had an active DEA and state license," regardless "of [the] prescriber's prescribing history." Stahmann Tr. at 14:01–06; 134:03–06; P-25638 at 00001. Its exceptions to the policy are extremely limited. Polster testified that Walgreens may block pharmacies from filling prescriptions from an individual prescriber if the prescriber's "office was indeed raided, it was completely shut down, we may potentially block their prescriptions from being filled." Polster, June 2, 2022, Trial Tr. at 2305:01–2306:01. With the limited exception of DEA raids that resulted in a prescriber's office being completely shut down, Walgreens did not block prescriptions from specific prescribers, no matter the volume of controlled substance prescriptions that they wrote. See id.

Because it did not implement a program for categorically blocking prescriptions from suspicious prescribers, Walgreens pharmacies continued to fill prescriptions from prescribers whom other retail pharmacy chains blocked. For example, Eric Stahmann, a Manager on the Pharmaceutical Integrity Team, received a question from a Walgreens Regional Healthcare Director about how to handle a doctor whose prescriptions were categorically blocked at three other chain pharmacies. P-29904 at 00002. Despite determining that 4,134 opioid prescriptions written by the doctor had been filled at Walgreens pharmacies in the past 90-day period and that the doctor ranked in the "100th percentile for oxycodone, 99th percentile for hydrocodone, and 98th percentile for buprenorphine" prescribing, Stahmann instructed that the doctor's prescriptions should

<sup>&</sup>lt;sup>13</sup> Walgreens ran a pilot program to test blocking certain prescribers, but it did not adopt the program. Polster, June 2, 2022, Trial Tr. at 2305:01–2306:01; Polster Decl. ¶ 24. Polster testified that the company did not implement the program nationwide largely out of concern that it would intrude on pharmacists' ability to exercise their own judgment in evaluating prescriptions. Polster Decl. ¶ 24; Stahmann Tr. at 127:20–131:13.

continue to be evaluated on a case-by-case basis. <u>Id.</u> at 00001–02. Stahmann further directed the Regional Healthcare Director to "advise the pharmacy staff to refrain from entering any slanderous comments in the prescriber's IC+ profile and stick with generic comments such as 'verify GFD.'" <u>Id.</u> at 00001.

5. Walgreens' Systemic Failure to Perform Due Diligence on Opio

# 5. Walgreens' Systemic Failure to Perform Due Diligence on Opioid Prescriptions

The DEA actions brought in the late 2000s and early 2010s against Walgreens identified systemic deficiencies in Walgreens' due diligence policies and processes. The creation of the Pharmaceutical Integrity Team did not resolve these systemic deficiencies, and these deficiencies continued to hamstring pharmacists' ability to perform adequate due diligence before dispensing prescription opioids. The evidence at trial established that Walgreens failed to provide its San Francisco pharmacists with the time, training, and resources needed to consistently perform adequate due diligence on opioid prescriptions before dispensing them. The evidence at trial established that pharmacists experienced constant time pressure, inadequate staffing, lack of training, insufficient resources, and misaligned incentives, all of which severely limited their ability to perform due diligence.

### a. Time Pressure

Intense time pressure impeded pharmacists' ability to perform due diligence. The time pressure largely resulted from the promised times assigned to each prescription.

Because the pharmacies received such high volumes of prescriptions, pharmacists had to work through breaks and limit their due diligence in an attempt to keep up with demand.

From 2010 to 2021, Victor Lo worked as a pharmacist at a Walgreens store in San Francisco's Bayview neighborhood. Lo Decl. ¶ 1. The Bayview pharmacy was "very busy" and to stay on top of the prescriptions they were receiving, pharmacists had to work "morning to evening non-stop." Lo, May 12, 2022, Trial Tr. at 915:7–23. Completing prescriptions by the assigned "promised time" was a "monumental" task. Id. at 918:14–919:4. Lo testified that he "operated under tremendous pressure to fill prescriptions and fill them quickly" and that the working environment prevented him "from devoting the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

time needed for thorough due diligence, which put our patients in danger." Lo Decl. ¶ 1; Lo, May 12, 2022, Trial Tr. at 918:17–919:4 ("Everything was about numbers, always.").

Rebecca Gayle worked as a Walgreens staff pharmacist at six different stores in San Francisco's Mission neighborhood from October 2012 to January 2016. Gayle Tr. (dkt. 1340–1) at 9:15–11:18. Like Lo, Gayle testified that she "constantly felt like there was a pressure to fill, fill, fill and that was what the company cared about most, was the message that I got." Id. at 17:1–4. In an effort to fill the high volumes of prescriptions that the pharmacy received, Gayle "skipped virtually all of [her] breaks for years" and "also I would routinely work off the clock." <u>Id.</u> at 16:5–19:15; 38:4–12. She testified that "[t]oward the end of my time at Walgreens, I worked most days off the clock probably for an hour extra unpaid." See id. She explained that:

"[I]f you spent too long doing things that didn't result in dispensing of a prescription I felt that your manager – your relationship with your manager would be negative. And you worked alongside with them every day. So the potential for retaliation and just the horrible daily work life if your manager didn't like you or thought you were prioritizing the wrong thing, that potential for retaliation and just making an already hard day that much harder was very real."

Id. at 35:4–15.

Christy Mathews Porter worked as a pharmacist at Walgreens stores in Redding, California.<sup>14</sup> Mathews Porter Tr. at 134:24–137:4. Like Lo and Gayle, she experienced time pressures at Walgreens pharmacies "all the time." Id. at 54:6–8. The time pressure stemmed in part from the "promised time" that was assigned to the prescriptions sent to the pharmacies. Id. at 19:19–20:8. The promised time created an intensely demanding work environment, as pharmacists rushed to manage the constant inflow of new prescriptions.

<sup>&</sup>lt;sup>14</sup> In addition to pharmacists who worked at Walgreens stores in San Francisco, the Court heard testimony from three pharmacists who worked at Walgreens pharmacies elsewhere California— Golnaz Kamali, Robert Yagar, and Christy Mathews Porter. Taken alongside the other evidence presented at trial, the testimony from these pharmacists supports the finding that many of the issues that prevented Walgreens pharmacies from performing adequate due diligence were systemic and impacted pharmacies across the country. See, e.g., Mathews Porter Tr. at 13:13-14:10 (testifying that the policies in place across Walgreens stores are the same).

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

See id. at 24:22-25:17. In addition, pharmacists' ability to meet the promised time was a factor that Walgreens used in their reviews, that impacted their bonuses, and that affected their relationships with their supervisors. See id. As a result, Mathews Porter testified that pharmacists are "strapped for time all the time. You work in flight or fight mode. It's constant stress." Id. at 68:24-69:2.

Robert Yagar has worked as a pharmacist at Walgreens pharmacies in Southern California for over two decades. Yagar Tr. (dkt. 1363–1) at 8:24–10:10. Yagar testified that there is a constant pressure to fill prescriptions that affects pharmacists' ability to perform due diligence. <u>Id.</u> at 54:1–55:11. Like Lo, Gayle, and Mathews Porter, Yagar attributed the pressure to the desire to provide good customer service and to the "promised times" assigned to prescriptions. <u>Id.</u> at 54:1–55:11. Yagar described the pace of work as "trying to squeeze 7 gallons of water into a 5-gallon bucket." <u>Id.</u> at 20:12–22:8.

Walgreens executives knew that the pressure cooker work environment created significant stress for pharmacists. In a February 2013 email, Mike Umbleby, Walgreens Director of Health & Wellness Initiatives, emailed a Divisional Vice President and Group Vice President of Pharmacy Operations after visiting Walgreens pharmacies. See P-27333. Umbleby wrote that "[f]atigue and sustainability of our pharmacists is a real concern. We're asking them to do a lot but how long can they continue?" Id. at 00002. A Weekly Performance dashboard from May 2013 included comments from pharmacy managers that the "[f]ocus is on profit and not on patient care. Example of lack of middle shifts saves labor but reduces patient care." P-17218 at 00005. The dashboard reported that pharmacy managers are "[s]truggling to keep our heads above water let alone manage." Id. Discussing the dashboard, Mark Wagner, Walgreens' President of Operations and Community Management, wrote that "I am concerned with the pharmacy manager comments regarding lack of hours. I heard this loud and clear in San Francisco this past week." Id. at 00001.

Walgreens corporate received internal complaints from pharmacy employees about

orthern District of California

these same issues.<sup>15</sup> See P-27296 at 00002 ("Pharmacy Manager . . . has been bypassing safety checks with the customer's prescriptions . . . to meet the promise time."); P-27300 at 00002 ("Dispensing medications ASAP was the companies [sic] priority and I was to dispense the medications immediately and contact the prescriber for verification and complete [Good Faith Dispensing] form later at a more convenient time. [Pharmacy manager] said that our GFD files would never be audited by the company, so it was OK to do so in apparent violation of policy."); P-27328 at 00003 ("Vice President . . . informed District Manager . . . that all Pharmacists would be required to work twelve hour days without lunches or breaks . . . Walgreens could have more prescription errors . . . because the Pharmacists will be overworked."); P-27295 at 00002 ("Promise Time has a target percentage goal that is not realistic giving [sic] the staffing level at most Walgreens . . . The company seems to be more concerned with speed and making more profits than the safety of the patients that we serve.").

The work environment stressors did not improve over time. A December 2019 internal report titled "Rx Fulfillment" included a section titled "Errors resulting from stress." P- 20793 at 00034. The section described how pharmacists "expressed a high level of stress in trying to meet promise time and the belief that, given current levels of staffing, promise time was unreasonable while following proper procedure." Id. The "Errors resulting from stress" section noted "multiple reports of improper behavior which was largely attributed to the desire to keep below promise time," including "that pill bottles had been found to contain more than one medication." Id. Consistent with the testimony of Walgreens pharmacists, the section described pharmacists' concerns about "taking their lunch break[,] as they feel they are judged for not making promise time following the lunch break and cut their break short." Id.

<sup>&</sup>lt;sup>15</sup> While the internal complaints include complaints from pharmacies outside of California, they are persuasive evidence of how Walgreens pharmacies operate in practice because the staffing, policies, and procedures across Walgreens pharmacies are the same or highly similar. <u>See generally</u> Polster Decl. ¶¶ 12–17, 25–36 (describing policies and practices across Walgreens pharmacies); Mathews Porter Tr. at 13:13–14:10.

## b. Inadequate Staffing

Inadequate staffing compounded the time pressure and further limited the ability of pharmacists to perform adequate due diligence before dispensing opioids.

Lo testified that inadequate staffing at Walgreens pharmacies "impacted patient care and pharmacists' ability to perform prescription due diligence[.]" Lo Decl. ¶ 4; Lo, May 12, 2022, Trial Tr. at 917:13–22 ("And so many times there were prescriptions that were let out that I just hoped they were not wrong."). Lo was often the only pharmacist on duty and was responsible for filling large volumes of prescriptions by himself. See id. ¶ 5. He worked through breaks to keep up with the prescription volume and spent much of his time on tasks other than due diligence. Id. ¶ 6. Lo "called Walgreens' employee hotline several times to complain about dangerously low staffing levels." Id. ¶ 10. He warned that "we were at risk of 'killing' a patient." Id. ¶ 10. But rather than improve, Lo testified that the staffing issues "got worse, not better." Id. ¶ 4. Lo testified that he asked his district manager for additional staffing, and she told him that if he filled additional prescriptions, his store would be eligible to receive additional staffing. See Lo, May 12, 2022, Trial Tr. at 919:25–920:12 ("[S]he came back with a response saying, 'All you have to do is, you know, average another 25 or 50 prescriptions a day. You'll reach a new tier and you'll get more hours."").

Like Lo, Gayle testified that the lack of adequate staffing created a "very stressful" work environment that caused her to experience "situations where I was afraid I made a lot of mistakes that could result in, you know, severe patient harm, potentially, or even death, depending on the medication and the type of error." Gayle Tr. at 17:9–16; see also id. at 19:6–7. The risks created by the working environment made her so concerned that she began telling "friends and family" who filled prescriptions at Walgreens "please, please double-check your medicines," because she was so worried that given "how severely understaffed the pharmacies are," pharmacists would make mistakes in filling their prescriptions. Id. at 22:07–22:19; see also id. at 22:17–19 ("And even strangers on the street I would recommend it to them.").

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Golnaz Kamali worked as a pharmacist in Walgreens stores throughout Southern California from 2011 to 2015. She testified that inadequate staffing was a "chronic problem" at the stores where she worked. Kamali Tr. at 61:23–63:3. The volumes of prescriptions at the pharmacies where Kamali worked were so high that it reached "the point that [she] could not even take a bathroom break." Id. at 62:1–15. Though she and her fellow pharmacists repeatedly told supervisors and district managers that the pharmacies needed more staff, Walgreens did not increase staffing levels. Id. at 63:7– 64:3. Walgreens' managers told Kamali that Walgreens corporate set the staffing levels at the pharmacies and that "[w]e could not go beyond those hours." <u>Id.</u> at 63:20–63:25. The chronic lack of staffing impacted Kamali's ability to fulfill her responsibilities as a pharmacist. Id. at 62:16–20. She testified that "we had to cut corners because there was no time." Id.

Mathews Porter testified that inadequate staffing exacerbated the time pressures, and hindered her ability to perform prescription due diligence. Mathews Porter Tr. at 66:16–69:5. Time pressures and understaffing caused her to cut corners when filling prescriptions, including not calling prescribers to verify prescriptions and not reviewing the CURES database. <u>Id.</u> at 59:16–21; 71:6–11. Among other things, reviewing the CURES database enables pharmacists to see whether a patient is receiving multiple prescriptions for the same drug from different prescribers. See Besinque Decl. ¶¶ 19–21. Mathews Porter testified that there were "definitely" times when prescriptions had been dispensed even though the red flags associated with the prescription had not been resolved. Id. at 63:18–25. She testified that, "I'm sure that I filled prescriptions with red flags at some point, but you do the best you can do." <u>Id.</u> at 65:16–66:4.

Yagar testified that the working environment has become increasingly stressful over the past ten years because stores were increasingly understaffed. Yagar Tr. at 22:9–14; 50:5–51:1. In an attempt to address the understaffing, some Walgreens stores assigned employees from other parts of the store (e.g. "somebody from photo") to help take in prescriptions in the pharmacies. <u>Id.</u> at 51:2–11. These employees "are given some

training," but "they're not officially licensed as technicians," let alone as pharmacists. <u>Id.</u> see also P-27304 at 00002 ("[T]he pharmacy has been short staffed . . . They can't service customer[s] properly and are at a higher risk to make mistakes because they are constantly rushing to try to get caught up."); P-27327 at 00003 ("The lack of adequate staffing pos[es] risks to patient safety and standards of customer service.").

### c. Lack of Training

The 2012 memorandum of agreement that Walgreens entered with the DEA to resolve charges that its pharmacies violated the CSA by dispensing illegitimate controlled substance prescriptions required Walgreens to implement increased due diligence training across its pharmacies. See P-00015 at 00006. The evidence established that before 2012, Walgreens did not have controlled substance training for its pharmacists. After 2012, the training that Walgreens provided to its pharmacists was limited, at best. The lack of training affected pharmacists' ability to perform due diligence.

Lo testified that he did not receive adequate training on due diligence policies or practices. He could not recall receiving any training on identifying red flags before "2012 or 2013." Id. ¶ 11; see also Lo, May 12, 2022 Trial Tr. at 914:14–19. Consistent with Lo's testimony, Cheryl Creek, Walgreens' Manager of Pharmacy Training, testified that the company did not do regular training before 2012. See Creek Tr. at 14:9–14; 28:19–29:1; 67:11–20 (Q. "In this time period, 2011, is there any training for pharmacists or other pharmacy employees regarding the dispensing of controlled substances?" A. "I do not believe that we had any training that was assigned to pharmacist regarding this specifically.").

The 2012 DEA settlement required Walgreens to implement periodic controlled substance training for its pharmacists. See Creek Tr. at 75:11–21. Jeremy Gerspacher started working at Walgreens in 2014. He testified that Walgreens' due diligence training "was basically a one-page brochure that you kind of read through and then you check a box in the training module[.]" Gerspacher Tr. 30:16–32:10. Gerspacher worked as a floater pharmacist at pharmacies throughout San Francisco. See id. at 8:25–9:2. Though

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

he began working at Walgreens "right out of pharmacy school," Gerspacher was the only pharmacist working on his shifts at least 75% of the time. Id. at 27:3–9. He recalled a specific time when the lack of training failed him: a customer came in late at night to fill an opioid prescription that presented red flags, and after Gerspacher filled the prescription, he realized, "I shouldn't have done that." Id. at 33:16–34:8.

Contrary to the testimony of Walgreens pharmacists, Polster testified that the company made training readily available. Polster Decl. ¶ 25. The Court assigns this testimony little weight. In 2010—following Walgreens' 2009 settlement with the DEA over its San Diego, California pharmacy's alleged failure to prevent diversion of opioids— Polster wrote that Walgreens needed to develop "periodic training of all Walgreens retail employees for dispensing controlled substances." P-19566. She stated: "No such training exists today." <u>Id.</u>; see also Creek Tr. at 65:21–66:15. Creek also testified that Walgreens did not have regular or "formal" training on controlled substance dispensing before 2012. Creek Tr. at 65:21–67:20.

In 2012, Walgreens began developing controlled substance training materials, but even then, the training resources consisted largely of materials or guidance that pharmacists had to affirmatively seek out. See Polster, June 2, 2022 Trial Tr. at 2431:23– 2434:16. With respect to the training materials available to pharmacists, Polster testified, "We have documents on our intranet. Sometimes there's various continuing educations that, you know, we'll post on the intranet. My team is a source of help and coaching and answering questions. That's a form of training." Id. at 2298:15–24.

In September 2012, Walgreens launched a training module on controlled substance dispensing that pharmacists were required to complete within 60 days of beginning work at Walgreens. See Creek Tr. at 425:5–14; P-20633. The materials cover a broad range of subjects, including administering flu shots, responding to robberies, and safely storing vaccines. See id. at 00006. The time assigned for the training on controlled substance dispensing is 10 minutes. Id. In comparison, the time assigned for training on Walgreens' "Prescription Savings Club" is 20 minutes, while the time assigned for "Gift Card Training

and Policy" is 40 minutes. See id.; Creek Tr. at 425:22–426:7.

### d. Lack of Resources

Walgreens pharmacists also testified that they lacked the tools and resources to fully investigate suspicious prescriptions and to alert their colleagues to suspicious prescribing patterns.

There was no effective way to share concerns among pharmacies about suspicious patients. As a result, patients could move from one pharmacy to another and seek to fill the same prescriptions. Lo recalled an instance where he saw a patient "hopping back and forth" between Walgreens stores, making payments for prescription narcotics with cash and filling "overlapping narcotic prescriptions of the same strength and quality." Lo Decl. ¶ 15. He raised concerns about the patient with his Pharmacy Supervisor, but no action was taken. Id. Walgreens continued to fill the patient's prescriptions. Id.

Consistent with the evidence showing that the Pharmaceutical Integrity Team provided pharmacists with inadequate resources to identify suspicious prescribing, pharmacists testified that the tools for identifying suspicious prescribers were also "very limited." Lo Decl. ¶ 16. For example, the pharmacies' computer system "did not list the prescriber's most recent prescriptions, what percentage were for narcotics, or how many had been filled." Id. For most of Lo's time at Walgreens, the company blocked pharmacists' access to external websites, preventing them from doing basic internet research on prescribers whose prescriptions gave them pause. Id. Lo raised concerns about certain doctors he believed were overprescribing to his Pharmacy Supervisor, but Walgreens did not meaningfully address his concerns. Lo Decl. ¶ 17–18; Lo, May 12, 2022, Trial Tr. at 917:23–918:10. Lo also testified that there was no process for pharmacists at one store to share their concerns with other pharmacists in the city. Lo Decl. ¶ 20.

Gayle similarly testified that the lack of tools made due diligence more difficult. She testified that Walgreens could have used its own data to identify doctors who might have been overprescribing opioids. Gayle Tr. at 67:17–68:6. She described times when

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

she saw "patterns of unusual prescribing" from particular doctors but she would still fill an opioid prescription, even though she "felt like [she] didn't have all the information" about the prescriber. Id. at 68:08–69:12. She would "go home and look up the provider and then find a lot of complaints online or things with the [American Medical Association] about current disciplinary actions with their license that was in progress." Id. Gayle believed that Walgreens could have made this information available to her and other pharmacists. See id.

Gayle testified that the pharmacy where she worked after leaving Walgreens regularly performed analyses of prescribing trends to screen for suspicious prescribers.<sup>16</sup> Gayle Tr. at 87:4–10. Like Gayle, Mathews Porter testified that the pharmacy where she worked after leaving Walgreens provides its pharmacists with analyses that identify suspicious prescribing trends. Mathews Porter Tr. at 111:7–111:25. Walgreens did not provide its pharmacists with similar tools. Instead, Gayle testified that, on her own initiative, she kept a sticky note in the pharmacy with a list of prescribers whose prescribing patterns raised suspicion. Gayle Tr. at 69:15–70:6. Gayle testified about why it was important to alert colleagues to suspicious prescriptions:

"[G]enerally what would happen is, if I refused it at my store, patients would likely attempt to walk down the street along Mission Street and try it at each subsequent store along Mission Street and then I assume that if everyone denied it along Mission Street they would probably continue until they found a pharmacy that might fill it for them."

Gayle Tr. at 70:6–13.

Yagar testified that the lack of tools makes due diligence harder. Like Gayle, Yagar keeps a list of suspicious prescribers "on a piece of paper," which he references when reviewing prescriptions. Yagar Tr. at 102:18–103:1. Yagar testified that it would be helpful if Walgreens had a standardized way of providing information on suspicious

<sup>&</sup>lt;sup>16</sup> In response to a question from Walgreens' counsel about why Walgreens did not provide prescriber data to pharmacists, Polster testified, "That's just not how pharmacy is practiced." Polster II Tr. at 428:3–7. But the evidence at trial showed that other chain pharmacies provided more data to pharmacists and blocked prescriptions from suspicious prescribers.

prescribers, but "I have to take it upon myself, really." Id.

Like Lo, Yagar testified that he has refused to fill opioid prescriptions because of concerns about their legitimacy—only to see that pharmacists at nearby Walgreens filled the prescriptions. Yagar Tr. at 69:17–21. For example, Yagar testified that he refused to fill an opioid prescription in December 2021 based on the doctor's "extremely bad pattern of writing" prescriptions. <u>Id.</u> at 70:1–17. Shortly after he refused to fill the prescription because he believed that it was "not a legitimate prescription," Yagar discovered that the prescription "got filled at another Walgreens." <u>Id.</u> at 70:1–73:23. He testified, "I think this happens quite frequently." <u>Id.</u> at 75:17–20.

As another example, Yagar recalled that Walgreens management sent an email telling pharmacies that they should not categorically block Lisa Tseng's prescriptions, despite her established patterns of suspicious prescribing. See Yagar Tr. at 94:20–95:7. Yagar's pharmacy had begun to refuse to fill Tseng's prescription because of concerns about their legitimacy, but other Walgreens pharmacies had continued to fill them. Id. at 101:10–20. Yagar testified that after Walgreens management sent the email directing pharmacies to continue to receive Tseng's prescriptions, Tseng was arrested, charged, and sentenced to prison for writing grossly excessive opioid prescriptions that caused multiple fatal overdoses. See id. at 95:1–101:20.

## e. Misaligned Incentives

Filling prescriptions generates revenue for Walgreens, and multiple pharmacists testified that the company prioritized increasing the volume of prescriptions filled over performing due diligence that might result in prescriptions being denied.

Gayle testified that she felt pressured to fill prescriptions because "filling prescriptions is what drove the profits." Gayle Tr. at 32:10–20. She received feedback during her evaluations that she should reduce the time spent on other tasks "to focus more on filling prescriptions." <u>Id.</u> The pressure to fill prescriptions impacted her ability to perform due diligence before dispensing. <u>See id.</u> at 34:17–21. Spending too much time performing due diligence negatively impacted her relationship with her managers and

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

created the prospect of "the horrible daily work life if your manager didn't like you." <u>Id.</u> at 34:23–35:15. As a result of the pressure to fill, Gayle would sometimes "cut corners" on due diligence, including the "due diligence into red flag opioid prescriptions." Id. at 37:12–20. She testified that it was "well known" among "our pharmacy managers that corners were being cut because everyone was cutting them to survive." Id. at 37:24–38:23.

Gayle testified that in 2013 or 2014, Walgreens' policy changed with respect to the mandatory qualifications for district managers. Gayle Tr. at 130:8–130:24. When she started at Walgreens, the company required district managers to be licensed pharmacists. <u>Id.</u> Walgreens subsequently dropped that requirement. <u>Id.</u> Dropping the requirement created a "potential conflict" because the managers overseeing the pharmacists did not always fully appreciate or understand their role and duties. Id.

Kamali also had concerns about the incentive structure at Walgreens pharmacies. She testified that the managers at Walgreens stores are primarily driven by quotas, including for prescription fill volume. Kamali Tr. at 71:1–21. In her view, the quotas presented a conflict because they "would force the pharmacist to not be concerned with the patient's health; rather, to be concerned with sales amounts." Id. at 72:5–72:8; see also id. at 39:17–23. Pharmacists exercising their professional judgment and declining to fill a prescription that they believed was illegitimate under the Good Faith Policy were at risk of being reprimanded for poor customer service by refusing to fill prescriptions. Id. at 23:10– 19. The tension between due diligence and customer service created pressure to fill prescriptions despite the presence of unresolved red flags. Id. at 24:3–27:7.

For Kamali, this tension became outright conflict. After refusing to fill opioid prescriptions that had red flags that she could not resolve, Kamali received critical feedback from her supervisors for poor customer service. Kamali Tr. at 35:9–37:11; 44:4– 9. She raised concerns with pharmacy supervisors and district managers that she was being unfairly disciplined for her good faith due diligence, but Walgreens management did not address her concerns. Id. at 30:16–31:20. She felt that Walgreens' policies forced her

to make a choice between "a patient's health and being written up and being fired." Id. at 60:22–61:3.

Similar conflicts caused Mathews Porter to leave Walgreens. She testified that conducting due diligence often resulted in negative customer service reviews because customers would complain about having to wait or about not having their prescription filled. Mathews Porter Tr. at 28:18–29:2 ("But, yeah, every time we refused a prescription, it – it resulted in a complaint"). In her final year at the store, Mathews Porter was deemed ineligible for a pay raise because of her low customer review scores. <u>Id.</u> at 120:7–122:21. She sent an email to her manager explaining that there was significant "doctor shopping and overprescribing in our town" and that she felt she was being unfairly penalized for performing due diligence on controlled substance prescriptions. <u>Id.</u> In her mind, Walgreens appeared to be prioritizing profit over due diligence. <u>Id.</u> at 123:15–22. She testified that it was not surprising that there were complaints when she refused to fill suspicious prescriptions because "[t]hat's what happens when you tell drugs addicts no." <u>Id.</u> at 126:12–19. Matthews Porter ultimately resigned from Walgreens because she felt that her concerns about the conflict between due diligence and customer service were not being meaningfully addressed. <u>See id.</u> at 126:12–127:3.

Yagar also filed an internal complaint expressing his concern with how the due diligence polices were being applied. See Yagar Tr. at 127:18–131:4. The complaint stemmed from an incident in which Yagar refused to fill a customer's prescription because it appeared illegitimate. Id. at 131:5–132:13. After the customer complained, two non-pharmacist store managers began to instruct Yagar on how to assess the legitimacy of a prescription. Id. at 138:13–20. Yagar considered it to be a conflict of interest that non-

<sup>&</sup>lt;sup>17</sup> After she made several complaints about the conflict between customer service and due diligence, Walgreens fired Kamali on September 24, 2015—two weeks after she filed an internal complaint raising concern that Walgreens pharmacies were committing legal and ethical violations by filling illegitimate prescriptions. Kamali Tr. at 56:6–60:8; 168:15–23. In response, Kamali sued Walgreens for wrongful termination. <u>Id.</u> at 16:10–24:16. She alleged that Walgreens unlawfully terminated her for flagging concerns about violations of state and federal law. <u>Id.</u> Walgreens settled Kamali's claims, paying her \$437,500. <u>Id.</u> at 50:21–51:3.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

pharmacist managers—whose performance is assessed in part based on the volume of drugs dispensed at the stores they oversee—were instructing pharmacists on how to comply with their obligations under the CSA. <u>Id.</u> at 138:17–22; 155:17–160:7. In response to Yagar's complaint, Walgreens' compliance personnel informed him that they had investigated the matter and found "no evidence of a systemic issue regarding GFD policy compliance." <u>Id.</u> at 176:6–177:2. Yagar did not believe that Walgreens performed a meaningful investigation. Id. at 184:11–18.

Other pharmacists across Walgreens stores have made similar complaints about the conflict between generating revenue by filling volumes of prescriptions and performing due diligence on those prescriptions. P-27297 at 00002 ("The caller said [the doctor] was running a 'pill mill' . . . Management was trying to fill every prescription possible after an account was lost. The caller did not want to be pressured to fill prescription from [the doctor] knowing the circumstances."); P-27298 at 00003 ("Caller . . . reported that . . . Store Manager . . . violated Walgreen's National Target Drug Good Faith Dispending Policy, when she overrode and removed his decision not to dispense a prescription to customer . . . [The manager] told him that she could not afford to lose a customer who spends \$6,000 a month in her store."); P-27305 at 00002 ("[The caller] feels pressured by [the managers] because they want her to fill narcotic prescriptions without verification first.").

In 2012, the DEA expressed concerns to Walgreens executives "that pressure from owners/operators to fill scripts is driving the problem" of prescription drug abuse. See P-19827 at 00001. A year later, Tasha Polster wrote to Walgreens' Vice President of Pharmacy Services that the message being delivered to pharmacies was that Good Faith dispensing "concerns [don't] relieve you from trying to attain the numbers that have been set for you." See P-00060 at 00002. Pharmacists understood this message all too clearly.

## Walgreens' Systemic Failure to Perform Due Diligence Caused Harm in San Francisco 6.

Pharmacies are the "last line of defense" against the diversion of controlled

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

65:16-66:4.

substances. Catizone Decl. ¶ 10. Pharmacists experiencing relentless pressure and lacking adequate support are at risk of missing red flags and failing to completely investigate the red flags that they do identify. See id. ¶¶ 63–66. And pharmacies that maintain such working environments are at a heightened risk of filling illegitimate prescriptions because the pharmacists lack the ability to fully investigate them before dispensing. See id.

Walgreens pharmacists testified that as a result of the obstacles that prevented them from performing due diligence, they dispensed opioid prescriptions that should not have been filled. In response to the question, "[c]an you tell us whether or not you believe that you filled some prescriptions that you probably should not have," Lo testified, "I know that I did." Lo, May 12, 2022, Trial Tr. at 919:22–24. Gerspacher testified that he filled a prescription and only afterwards realized, "I shouldn't have done that . . . the red flags were there, it just wasn't engrained in me at the time." Gerspacher Tr. at 33:16–34:8; see also id. at 82:1–82:8 (testifying that "soon after filling [the prescription at a San Francisco pharmacy], it was being sold in the parking lot"). In response to the question, "[d]oes that mean, Dr. Kamali, that some prescriptions were being filled at Walgreens that should not have been," Kamali answered, "Yes." Kamali Tr. at 24:13-16. When asked "did you identify instances in which a prescription for a controlled substance, an opioid, had been filled, but it did not appear that red flags had been resolved," Mathews Porter testified, "Definitely." 18 Mathews Porter Tr. at 63:18–25.

Dispensing opioid prescriptions without resolving red flags was not limited to the pharmacists who testified. The evidence at trial demonstrated that from 2006 to 2020, Walgreens pharmacies in San Francisco received over one million opioid prescriptions that presented red flags and dispensed many of these prescriptions without first resolving the red flags. The evidence further supports the conclusion that a significant number of the

<sup>&</sup>lt;sup>18</sup> Throughout trial, Walgreens pointed to evidence that Walgreens pharmacists testified that they followed the Good Faith Policy. But the testimony was qualified. Consistent with the extensive evidence showing the hurdles that pharmacists faced in performing due diligence, pharmacists testified that they followed Walgreens' Good Faith Policy "to the best of [their] ability." See Gayle Tr. at 164:18–165:3; Yagar Tr. at 217:13–21; Kamali Tr. at 82:3–17; Mathews Porter Tr. at

## 2 3

4

6

7

5

8

9

10

11 12

13 14

15 16

17

18 19

20

21 22

23

24

25

26

27

28

opioid prescriptions dispensed with unresolved red flags were illegitimate.

#### **Red Flag Analysis** a.

Red flags are objective warning signs that indicate that a prescription may not be legitimate. Catizone Decl. ¶ 16. Plaintiff's expert Carmen Catizone identified fourteen red flags that are commonly used to identify controlled substance prescriptions that may be at risk for diversion. 19 See Id. ¶ 18. Catizone testified that he based his red flags on several sources, including Walgreens' own policies, DEA and state board of pharmacy guidance, and DEA administrative actions. Catizone, May 12, 2022, Trial Tr. at 799:10–24; Catizone Decl.  $\P$  4–22. The red flags fall into the following categories.

Category	Flag No. <sup>20</sup>		
	(1) An opioid was dispensed to a patient who traveled more than 25 miles to visit the pharmacy		
Long Distance Travel	(2) An opioid was dispensed to a patient who traveled more than 25 miles to visit their prescriber		
Doctor-Shopping	(3) Patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers		
Pharmacy-Shopping	(4) Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies		
Drug Cocktail	Patient was dispensed:  (5) An opioid, a benzodiazepine, and a muscle relaxer for overlapping days of supply		

<sup>&</sup>lt;sup>19</sup> Catizone is well-qualified to offer opinions on pharmacists' corresponding responsibilities as well as on their identification and resolution of red flags. He is a licensed pharmacist with experience working in chain and retail pharmacy settings, he worked for the National Association of Board of Pharmacies for 35 years developing pharmacy regulation, and he has lectured, presented, and testified regarding pharmacy regulations, including those related to pharmacists' corresponding responsibilities. See generally Catizone, May 12, 2022, Trial Tr. at 790:22–796:4. Catizone originally identified 16 red flags, but subsequently removed two. See Catizone Decl. ¶ 18, fn. 4. For purposes of consistency, however, the original numbering schemes were preserved. Id.

2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19

	<ul> <li>(6) An opioid, a benzodiazepine, and a muscle relaxer on the same day, and all the prescriptions were written by the same prescriber</li> <li>(7) An opioid and a benzodiazepine within 30 days of one another</li> </ul>
	(8) An opioid and a benzodiazepine on the same day, and both prescriptions were written by the same prescriber
	(9) Patient was dispensed two short-acting opioid drugs on the same day
Excessive Dispensing	(11) Patient was dispensed an opioid prescription of over 200 MME per day on or before December 31, 2018 or over 90 MME per day after December 31, 2018
	(15) A patient was dispensed more than 210 "days of supply" of all opioids combined in a 6-month period
Pattern Prescribing	(12) An opioid was dispensed to at least 4 different patients on the same day and the opioid prescriptions were for the same base drug, strength, and dosage form and were written by the same prescriber
Early Refills	(14) An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out
Cash Payment	(16) A patient was dispensed an opioid and paid cash

The red flags that Catizone identified are indeed consistent with the red flags set forth in Walgreens' Good Faith Policy. See, e.g., P-19745 at 00002; Catizone, May 12, 2022, Trial Tr. at 799:10–24; Catizone Decl. ¶¶ 18–22. For example, the 2012 Good Faith Policy identifies the following as red flags: "unusual geographical distances between the patient, pharmacist and/or prescriber," which is consistent with red flags (1) and (2); "controlled substance prescriptions from several different prescribers," which is consistent with red flag (3); "unusual dosages, directions, or quantities beyond those normally

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

prescribed," which is consistent with red flags (4), (9), (11), and (15); "frequent combination prescriptions for known drug 'cocktails," which is consistent with red flags (5)–(8); "prescriber consistently write[s] prescriptions for controlled substances," which is consistent with red flag (12); "consistently request early refills," which is consistent with red flag (14); and "request to pay by cash or by using a cash discount card," which is consistent with (16). See WAG-MDL-00304 (cleaned up).

The "most challenging" red flag for a pharmacist is a prescription for a drug "cocktail." Polster Decl. ¶ 17. Drug cocktails consist of prescriptions for an opioid and a benzodiazepine, and may also include a muscle relaxant. Id. These drug combinations "can be abused and present special risks for patients." Id.

Pharmacists disagree about whether it is ever appropriate to dispense prescriptions for an opioid, benzodiazepine, and muscle relaxant, a combination known as the "holy trinity." Compare Catizone, May 12, 2022, Trial Tr. at 839:3–9 (testifying that a "trinity cocktail" should never be dispensed) with Polster II Tr. at 176:19-180:15 (testifying that a "trinity cocktail" may be appropriate in some circumstances). Eric Stahmann, a Manager on the Pharmaceutical Integrity Team, testified that based on DEA guidance, pharmacists should not fill prescriptions for the three-drug cocktail. Stahmann Tr. at 145:13–17. In an email providing guidance to Walgreens pharmacists, Stahmann explained, "It isn't specifically stated in the GFD policy . . . . however it is publically [sic] documented that the 'trinity' or 'cocktail' of an opioid, benzodiazepine and a muscle relaxer is a major red flag in the eyes of the DEA and NABP." P-19677 (original emphasis). Relatedly, Polster testified that the "DEA has gone on the record saying that they do not feel that there is a clinically significant reason as to why a cocktail combination would need to be prescribed." Polster II Tr. at 176:2–10.

Nonetheless, the DEA has not taken the formal step of prohibiting pharmacies from dispensing trinity cocktails. See Besinque, June 6, 2022, Trial Tr. at 2590:19–2591:1. And Walgreens has not imposed a blanket ban filling prescriptions for opioid cocktails, including for the "holy trinity." See Polster Decl. ¶ 17. The company's policy is to have

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

pharmacists exercise their professional judgment and independently assess the legitimacy of each prescription for an opioid cocktail. Id. Based on her experience as a dispensing pharmacist, Polster testified without elaboration that "there are occasions where it may appropriate" to dispense an opioid cocktail, including a "trinity" cocktail. Polster II Tr. at 176:19–180:15; see also Besingue, June 6, 2022, Trial Tr. at 2587:14–2591:5.

#### i. Red Flags Trigger a Duty to Investigate

The presence of one or more red flags does not establish that a prescription is illegitimate. Catizone, May 12, 2022, Trial Tr. at 829:3–836:1. Rather, the presence of a red flag triggers a pharmacist's duty to perform a reasonable inquiry to determine whether the prescription is legitimate before dispensing it. Catizone Decl. ¶¶ 19–27; Park Decl. ¶ 7. Pharmacists should not dispense a prescription if they cannot resolve the red flags. Catizone Decl. ¶ 15.

#### ii. **Red Flags Are Both Over and Underinclusive**

Red flags are not perfect proxies for identifying suspicious prescriptions. As Polster testified, "[o]f necessity, any list of red flags in our Good Faith Dispensing Policies (or elsewhere) will be both underinclusive and overinclusive." Polster Decl. ¶ 15.

Some prescriptions may trigger red flags that are easily resolvable. In those situations, the red flag is overinclusive, flagging prescriptions that are not in fact being diverted. For example, the distance that a patient travels to a pharmacy triggers a red flag. Catizone Decl. ¶¶ 18–22. However, a patient may commute over 25 miles to work and may fill their prescription at a pharmacy near their office where they regularly interact with the same pharmacist. See Polster ¶ 15. The initial prescription may trigger a red flag, but if the patient explains the reason for the red flag and continues to fill prescriptions with the same pharmacist, the red flag presented by later prescriptions would be easily resolved. See id. The pharmacist knows why the patient is filling a prescription from an out-of-the area prescriber.

On the other hand, red flags are also underinclusive because there "will always be unique circumstances, which will not be captured on any list, that make a pharmacist

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

uncomfortable filling a prescription without additional information." Polster ¶ 15. For example, Walgreens' Good Faith Policy directs pharmacists to consider whether a patient exhibits "'drug seeking' type behaviors," a circumstantial assessment that a pharmacist can only make in the context of their interaction with a particular patient. See WAG-MDL-00304. These types of subjective red flags are not included in Catizone's list of fourteen red flags.

Walgreens' expert Kathleen Besinque opined that Catizone's red flags cannot reliably identify suspicious prescriptions. The Court assigns this testimony little weight. One of Besinque's main criticisms is that no list of red flags can completely reflect the judgment that a prescriber must make in the circumstances when evaluating a prescription. See Besinque Decl. ¶¶ 9–11. This criticism is unpersuasive. Although Catizone's red flags are not a foolproof means of identifying suspicious prescriptions, the red flags are an overall reliable way to screen for suspicious prescriptions and they are consistent with Walgreens' policies. See Catizone Decl. ¶¶ 16–27; Catizone, May 12, 2022, Trial Tr. at 799:10-800:21.

During cross-examination, Besinque was pressed on the overlap between Catizone's red flags and Walgreens' Good Faith Policy, and her responses were lacking. For example, Catizone's red flags one and two identify prescriptions as suspicious when a customer travels more than 25 miles to a prescriber or a pharmacy. See Catizone Decl. ¶ 18. Besingue criticized the 25-mile threshold as "arbitrary," even in a dense city environment like San Francisco. Besinque, June 7, 2022, Trial Tr. at 2637:7–2638:22. She testified that she was not aware of authority that considered 25 miles to be indicative of a potentially suspicious prescription. <u>Id.</u> at 2642:10–24. But then Besinque was presented with evidence that both the DEA and Walgreens have considered distances of 25 miles and 30 miles, respectively, to be a red flag. See id. at 2644:2-2648:4; 2653:10-2657:19. Despite the evidence, she continued to maintain that the 25 mile threshold was "arbitrary." See id. at 2658:6–11. Besinque's unwillingness to confront evidence that directly undermined her opinions casts serious doubts on her credibility.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Further, Besingue opined that many of the prescriptions that hit on one of Catizone's red flags "did not present an actual red flag." Besinque, June 7, 2022, Trial Tr. at 2658:21–2659:2; 2672:4–15. But she did not perform any analysis to show how many of the prescriptions did not, in her view, "present an actual red flag." See id. In fact, over 1,200,000 opioid prescriptions dispensed at San Francisco Walgreens between 2006 and 2020 hit on one of Catizone's red flags, and Besinque identified only two that she claimed did not present an actual red flag. See id. at 2672:16–22; see McCann Rebuttal Decl. (dkt. 1521) ¶ 4. Besinque's opinions generally suffered this shortcoming. See id. at 2672:23– 2674:13. She broadly criticized Catizone's analysis, but she did not support her criticisms with evidence. Her testimony thus carries little weight.

#### b. Red Flags Applied to Walgreens' Dispensing Data

From 2006 to 2020, Walgreens pharmacies in San Francisco filled 2,478,103 opioid prescriptions, with the average prescription containing approximately 60 pills. <sup>21</sup> See McCann Decl. ¶ 57, 85. Plaintiff's expert Dr. Craig McCann applied Catizone's red flags to Walgreens' dispensing data to calculate the number of opioid prescriptions that hit on at least one red flag. Id. ¶ 85. McCann calculated that the total number of red flagged prescriptions dispensed at Walgreens pharmacies from 2006 to 2020 was 1,428,393. Id. The below table sets forth the total number of prescriptions and the number of red flag prescriptions dispensed each year.

Year	Total Number of Opioid Pills	Total Number of Opioid Prescriptions	Number of Red Flag Opioid Prescriptions	Percentage of Red Flag Opioid Prescriptions
2006	4,374,538	77,260	41,809	54%
2007	10,146,416	180,670	103,353	57%
2008	11.344.092	194.543	110.957	57%

<sup>&</sup>lt;sup>21</sup> The dispensing data that Walgreens produced was for eight opioids—fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and tapentadol. McCann Decl. ¶ 20. Walgreens also produced dispensing data for benzodiazepines and muscle relaxers. Id.

2009	12,827,071	212,331	122,892	58%
2010	14,705,471	230,318	137,973	60%
2011	15,467,823	239,767	143,437	60%
2012	14,450,471	217,328	131,679	61%
2013	13,793,950	210,989	124,596	59%
2014	12,115,575	187,900	105,422	56%
2015	11,313,749	168,725	94,169	56%
2016	10,367,883	157,527	88,640	56%
2017	9,192,814	142,345	79,958	56%
2018	7,371,633	118,425	65,189	55%
2019	5,834,356	99,132	56,225	57%
2020	2,457,289	40,843	22,094	54%
Totals:	155,763,131	2,478,103	1,428,393	

At trial, Walgreens demonstrated that McCann's analysis overstated the number of opioid prescriptions that hit on red flags by 177,086 prescriptions. Brunner, June 6, 2022, Trial Tr. at 2483:15–2486:15. Walgreens' expert Robert Brunner showed that red flags 3, 4, 5, 7, 12, and 14 all involve multiple prescriptions, and that McCann incorrectly counted the first prescription in his totals, although that prescription by itself would not have triggered a red flag. See McCann Rebuttal Decl. ¶¶ 2–3. For example, red flag 4 identifies prescriptions where the patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies. See Catizone ¶ 18. Brunner demonstrated that McCann's red flag analysis counted both prescriptions under red flag 4. See Brunner Decl. ¶¶ 11–12; see also Brunner, June 6, 2022, Trial Tr. at 2486:7–15. But for red flag 4 (and related red flags), the first prescription should not be counted as suspicious. The second prescription is suspicious because of the first prescription, but, assuming the first prescription does not trigger another a red flag, there is nothing about that prescription that

is suspicious. The result is overcounting.

According to Brunner, this error led McCann to overcount 437,786 red flag prescriptions. See Brunner, June 6, 2022, Trial Tr. at 2485:23–2486:2. But Brunner overcounted the overcounting. He did not go on to analyze whether the first prescription for red flags 3, 4, 5, 7, 12, and 14 hit on a separate red flag. See McCann Rebuttal Decl. ¶¶ 1–5. As McCann demonstrated in his rebuttal testimony, 260,700 of the first prescriptions that Brunner claimed were overcounted did in fact hit on separate red flags. Id. As a result, the total number of red flag prescriptions that were overcounted was 177,086. Id.

In light of this adjustment, the total number of Walgreens opioid prescriptions that hit on red flags between 2006 and 2020 was 1,251,307. See McCann Rebuttal Decl. ¶ 4. The downward adjustment of 177,086 prescriptions affects the number of prescriptions listed in the above table, but Plaintiff did not submit an updated table that corrects for the overcounting. Some number of the red flag prescriptions in the fourth column should be reduced, but it is unclear which ones. Nonetheless, the reduction would not remove more than 177,086 red flag prescriptions from the table. Because the corrected analysis shows that Walgreens still distributed over 1.2 million red flag prescriptions in a fifteen-year period, the Court finds that McCann's initial methodological error was immaterial. McCann's initial methodology flagged 61.5% of prescriptions for opioids and opioid cocktails; the adjusted methodology flagged 55.4% of the prescriptions for opioids and opioid cocktails. See McCann Rebuttal Decl. ¶¶ 4–5. Even with the adjustment, the data shows that Walgreens pharmacies in San Francisco dispensed on average 83,420 red flag prescriptions per year from 2006 to 2020. See id. ¶¶ 3–4.

In an attempt to show that Plaintiff's red flag analysis was overinclusive, Walgreens offered evidence that many of the prescriptions written by three doctors who work for the city of San Francisco would trigger large volumes of red flags. Brunner Decl. ¶ 6. But this evidence does not undermine Plaintiff's red flags because of the high-risk patient population with whom these doctors work. Dr. Claire Horton, for example, testified that she works "in a really high-risk setting with really high-risk patients," that she would

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

expect many of her prescriptions to trigger red flags, and that she would expect a pharmacist to perform due diligence before filling her prescriptions. See Horton Tr. at 48:21–49:16; 149:19–150:21; 159:22–160:16; 170:19–171:11 ("I am just going to say that . . . it would not surprise me to know that the majority of my prescriptions over my prescribing life would trigger a safety review on behalf of a dispensing pharmacist.").

In addition, over 1.2 million opioid prescriptions dispensed by Walgreens triggered at least one red flag, and the city-employed prescribers that Walgreens cites to accounted for a small fraction of these prescriptions. See WAG-MDL-03591 (1,582 of Dr. Zevin's prescriptions triggered red flags); WAG-MDL-03596 (2,042 of Dr. Horton's prescriptions triggered red flags); WAG-MDL-03606 (2,910 of Dr. Pace's prescriptions triggered red flags). Walgreens' argument comes up short for this reason as well. Even if Walgreens could establish that Catizone's red flags were somewhat overinclusive—despite being consistent with Walgreens' policy and DEA guidance—that would not change the factual findings discussed in detail below. See infra I.C.6.c. & I.C.7. As will be discussed, the evidence established that hundreds of thousands of red flag prescriptions were written by prescribers other than doctors working for the city of San Francisco, including several whose medical licenses were later suspended or who would go to prison. These, in particular, are the prescribers that the red flags are meant to identify, and the evidence established that the vast majority of their prescriptions triggered red flags. See id. Walgreens dispensed them anyway.

Finally, the fact that prescriptions written by well-regarded prescribers triggered red flags does not demonstrate that Catizone's red flags are unreliably broad. Red flags apply to controlled substances that pose high risks of harm if used inappropriately. That many opioid prescriptions trigger red flags reflects the importance of pharmacies' regulatory obligation to perform due diligence before dispensing them. As Dr. Horton testified, "I have reconsidered my prescriptions based on discussions with pharmacists in the past." See Horton Tr. at 151:2–14. Pharmacies are the last line of defense against diversion, and the fact that a well-respected doctor wrote a prescription does not relieve pharmacies of the

independent obligation to perform due diligence before dispensing it. <u>See</u> 21 C.F.R. § 1306.04(a).

# c. Red Flags Were Not Resolved before Opioid Prescriptions Were Dispensed

On average, Walgreens pharmacies in San Francisco dispensed a total of 83,420 red flag prescriptions each year from 2006 to 2020. See McCann Rebuttal Decl. ¶¶ 3–4. Red flag prescriptions are not necessarily illegitimate. Park Decl. ¶ 7. But a pharmacist must resolve the suspicions presented by a red flag prescription before dispensing it, and pursuant to Walgreens' policy and California standard of practice, pharmacists must document the steps that they took to resolve the red flags before the prescriptions is dispensed. Catizone Decl. ¶¶ 23–27; Park Decl. ¶ 10.

### i. Documenting The Resolution of Red Flags

Walgreens' Good Faith Policy states that it is "[i]t is <u>imperative</u> that pharmacists document all efforts used to validate good faith dispensing." WAG-MDL-00304.00004 (emphasis added). Pharmacies are expected to comply with their own dispensing policies under the standard of practice in California. Park Decl. ¶ 6. Pharmacies and pharmacists fall below the standard of practice if they do not identify "the existence of red flags," perform "a reasonable inquiry," and document "the resolution of every red flag." <u>Id.</u> at ¶ 10. As a general matter, documenting the resolution of a prior red flag does not relieve a pharmacist of the obligation to resolve red flags present in subsequent prescriptions. <u>Id.</u> ¶ 12; <u>see also</u> Besinque Decl. ¶ 16.

Documentation provides pharmacists with information that can be helpful to assessing the legitimacy of a prescription. See Catizone, May 12, 2022, Trial Tr. at 801:2–802:17. And it provides proof that a pharmacist performed proper due diligence before dispensing a prescription. See id. A guiding principle of pharmacy is that "if you didn't document it, it didn't happen." Gayle Tr. at 51:21–22; Mathews Porter Tr. at 72:14–16 ("if you didn't document it, it didn't happen"); Park Decl. ¶ 10. If there is no record of documentation, it

is likely that due diligence did not occur. See Mathews Porter Tr. at 74:9–15.

Eric Stahmann, a Manager on the Pharmaceutical Integrity Team, testified that documenting resolution of red flags is part of Walgreens' "standard operating procedures." Stahmann Tr. at 97:8–15. Stahmann testified that Walgreens pharmacists "are supposed to document any activity they did to either clear red flags or not able to clear a red flag [sic]." Id. Consistent with his testimony, Stahmann told Walgreens Regional Healthcare Director that "[r]egardless if the decision is to fill or refuse, make sure [the pharmacists] properly document the steps taken to reach that decision either on the prescription hardcopy or IC+ image/profile." P-29904 at 00001. While Walgreens' pharmacy expert Kathleen Besinque testified that no state or federal laws or regulations "list any specific actions that must be taken by the pharmacist or specify documentation that needs to be completed prior to dispensing," she also testified that "documentation of red flag resolution is a good practice" and that Walgreens Good Faith Policy included a documentation requirement starting in 2006. Besinque Decl. ¶ 11, 16; see also Besinque, June 6, 2022, Trial Tr. at 2618:2–2619:24.

In support of its contention that pharmacy best practices do not necessarily require documenting due diligence, Walgreens offered evidence that the ZSFG pharmacy does not have a written policy requiring pharmacists to document resolution of red flags. See Patel, May 19, 2022, Trial Tr. at 1310:5–8. The evidence is not persuasive. Swati Patel, ZSFG's Director of Pharmacy, testified that ZSFG pharmacists must resolve any red flag presented by a prescription before dispensing it. Id. at 1325:5–1326:2. She testified that pharmacists meet daily to discuss pharmacy operations, including any questions that have come up regarding the legitimacy of prescriptions. See id. at 1335:11–1336:4. And she testified that while there is no written provision, ZSFG pharmacists are expected to document resolution of red flags as a matter of policy. Id. at 1346:1–1348:3.

In addition, the ZSFG pharmacy operates in a different environment and serves a different patient population than Walgreens pharmacies. See, e.g., Patel, May 19, 2022, Trial Tr. at 1292:20–1293:3; 1326:3–23; 1332:23–24. For example, the ZSFG pharmacy

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

only dispenses medications to patients at the ZSFG hospital or patients at health clinics affiliated with the ZSFG hospital. Id. at 1329:4–1331:23; 1340:16–1341:12. Most opioid prescriptions that the ZSFG pharmacy dispenses are short duration prescriptions to patients being released from the hospital. Patel Decl. ¶ 5. Between 2017 and 2020, for example, "approximately 80% of opioid prescriptions the pharmacy dispensed were at discharge from a hospital stay with an average days' supply of between 4 and 5 days." Id.

The evidence at trial overwhelmingly established that Walgreens pharmacists understood that the company's policies along with pharmacy best practices required documentation of the resolution of red flags prior to dispensing a prescription for controlled substances.

#### ii. Walgreens San Francisco Pharmacies Dispensed Red Flag Prescriptions without Performing Due Diligence

Plaintiff's pharmacy expert Elizabeth Park reviewed due diligence materials from Walgreens pharmacies to evaluate the extent to which the pharmacies documented the resolution of red flags. Specifically, Park reviewed the due diligence documentation for 2,265 prescriptions for opioids and opioid cocktails that 12 Walgreens pharmacies in San Francisco dispensed from 2010 to 2019.<sup>22</sup> See Park Decl. ¶ 16; Park, June 16, 2022, Trial Tr. at 963:11–21; McCann Decl. ¶ 63. Each of the prescriptions included in the sample review hit on one or more of Catizone's red flags. Park Decl. ¶ 17. The data that Park reviewed included all of the electronic data fields and scanned images associated with each prescription that Walgreens pharmacists performed before dispensing the prescription. <u>Id.</u> ¶ 18. Her opinion was limited to whether there was adequate documentation of due diligence for the prescriptions—she did not opine on the medical legitimacy of any of the prescriptions. Park, June 16, 2022, Trial Tr. at 1015:6–25.

Based on her review of the due diligence materials produced by Walgreens, Park

<sup>&</sup>lt;sup>22</sup> During discovery, a magistrate judge ordered Walgreens to produce 5,000 prescriptions along with the due diligence materials that accompanied the prescriptions. Ultimately, it only produced the due diligence materials for 2,265 prescriptions because it could not reasonably locate the due diligence materials for all 5,000 prescriptions. See Park, June 16, 2022, Trial Tr. at 964:2–18.

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

found "evidence of an appropriate effort to resolve red flags in fewer than 5% of cases." Park Decl. ¶ 24. Put another way, for over 95% of the 2,265 prescriptions she reviewed that hit on at least one red flag, the documentation was either non-existent or insufficient to establish that the red flag had been identified or resolved before the pharmacist dispensed the prescription. See id. ¶¶ 24–26 ("[T]he notes I reviewed from Walgreens' computer system provide little to no information that any reasonable pharmacist or pharmacy would interpret as documentation that red flags were identified or resolved."). Based on Park's findings, McCann determined that the results of Park's analysis for the 12 San Francisco pharmacies—namely, that adequate due diligence existed for less than 5% of red flag opioid prescriptions—could be extrapolated to all Walgreens pharmacies in San Francisco. See McCann ¶ 67.

In addition to finding that adequate documentation did not exist for many of the opioid prescriptions dispensed at the twelve Walgreens pharmacies, Park found that the vast majority of the comment fields in the IC+ system where pharmacists are expected to document their due diligence were blank. Park Decl. ¶ 26. Polster testified that Walgreens expects its pharmacists to document red flags in the "Annotation Text" field in the IC+ system. See Polster, June 2, 2022, Trial Tr. at 2414:23–2415:4. However, the Annotation Text field was blank for 89% of prescriptions and the Patient Comments field was blank for 86% of the prescriptions that Park reviewed. See Park Decl. ¶ 26. For the small number of prescriptions that Park reviewed where these fields included comments, the comments were largely unrelated to due diligence. See id. Of the 319 prescriptions where the Patient Comments field included a notation, "266 (83%) included nothing more than an email address." Id. Consistent with Park's findings, Walgreens' pharmacy expert Kathleen Besingue reviewed the Annotation Text field for fifty of the prescriptions that Park reviewed, and for forty-four of the fifty prescriptions, the Annotation Text field was blank.<sup>23</sup> Besinque, June 7, 2022, Trial Tr. at 2676:1–18.

27

28

<sup>&</sup>lt;sup>23</sup> In the six instances where the Annotation Text field did have a note, only 3 of the notes, at most, appeared related to due diligence. See Besinque, June 7, 2022, Trial Tr. at 2677:16–2680:19.

### iii. Failure to Perform Due Diligence

The evidence presented at trial demonstrated why Walgreens pharmacies failed to perform due diligence before dispensing prescriptions. See supra I.C.5.a–e. Walgreens pharmacists operated under intense time pressure that forced them to skip breaks, work off the clock, and dispense prescriptions with limited or no review. Walgreens pharmacists repeatedly requested additional staffing to help mitigate these challenges, but Walgreens did not provide it. The evidence showed that Walgreens pharmacies were chronically understaffed. The inadequate resources made a hard job even harder. Walgreens required its pharmacists to complete paper due diligence checklists and store them in file cabinets. Its pharmacists had no effective way to share concerns about suspicious prescribers. Their comments regarding suspicious prescribing practices were deleted, and they had to resort to keeping "sticky notes" posted in the pharmacy to track prescribers they considered to be suspicious. In this environment, pharmacists "had to cut corners because there was no time." Kamali Tr. at 62:16–20. As Gayle testified, "it was well known anyway among [] our pharmacy managers that corners were being cut because everyone was cutting them to survive." Gayle Tr. at 38:22–23.

In addition, the evidence established that Walgreens' due diligence practices from 2003 to 2012 meant only one thing: contact the prescriber. See P-19613 at 00012; P-15119 at 00011. Walgreens' Good Faith Policy through this period stated that "[i]f the prescriber confirms the validity of the prescription, document this on the hard copy and process the prescription as normal." P-15119 at 00011; P-19613 at 00012. Directing pharmacists to defer to prescribers abdicated the pharmacies' corresponding responsibility to independently ensure that controlled substance prescriptions were legitimate. See Catizone Decl. ¶ 37.

Polster testified that it was never Walgreens' policy that pharmacists should defer to the judgment of a prescriber. Polster, June 2, 2022, Trial Tr. at 2285:4–2286:13. This testimony receives no weight. The words of Walgreens' policies squarely contradict Polster's testimony, and Polster herself conceded that the policies do not direct

pharmacists to conduct additional due diligence after verifying a prescription with a prescriber. Id. at 2425:14–2426:21. Polster's own words further undermine her testimony. In 2012—after the DEA issued multiple show cause orders charging that Walgreens pharmacies violated the CSA by filling illegitimate prescriptions—Polster wrote, "The game has changed; we can no longer rely on the 'I spoke to the prescriber and he said it was okay' . . . We are going down a different path now and we have to make sure that we are prepared."<sup>24</sup> P-20639 at 00009. Consistent with Polster's statement that the "game has changed" and that the company was "going down a different path," Walgreens amended its Good Faith Policy to state: "there are also circumstances in which calling the prescriber will not resolve the red flags because the red flags indicate that the prescriber is collaborating with the patient to divert drugs." P-15085 at 00007. The amendment demonstrates that under prior policies, Walgreens considered simply verifying a prescription with a prescriber to be adequate due diligence. Instructing pharmacists in 2012 that they should not rely solely on the words of a prescriber was a "different path" for Walgreens.

# iv. Walgreens Corporate was Aware of The Lack of Due Diligence

One of the main functions of the Pharmaceutical Integrity Team was "to ensure that our pharmacists were being consistent when they were documenting their corresponding responsibility when filling prescriptions." Polster II Tr. at 25:19–26:16. After the Pharmaceutical Integrity Team instituted the Target Drug checklists, Polster testified that "field leadership would follow up to ensure that the checklists were being used." <u>Id.</u> at 348:13–349:20.

Walgreens' internal audits, however, found deficiencies in pharmacies' compliance with the Target Drug checklist. <u>See</u> P-15095 at 00006. A December 2014 audit—

<sup>&</sup>lt;sup>24</sup> In her testimony at trial, Polster attempted to walk back these statements, explaining that they were "not all I said" and that they "were my personal speaker notes." Polster, June 2, 2022, Trial Tr. at 2427:6–2429:18. The Court finds this testimony to be nothing more than a bald denial and assigns it no weight.

performed almost two years after Walgreens implemented the Target Drug checklist—
found that there was "no corporate reporting" process in place to monitor compliance with
the Target Drug checklist. P-25492; see also Polster II Tr. at 350:4–353:24. The audit
found that the only compliance process in place was a "Store Walk" program. P-25492 at
00015. As part of the "Store Walk" process, "questions are asked" about compliance with
the Target Drug checklist, but Walgreens management did not formally document any
responses to the compliance questions, nor did they otherwise follow a process for
documenting pharmacies' compliance with Walgreens' policies. P-25492 at 00015
("[T]here is no monitoring performed outside of the Store Walk program to determine
whether Pharmacists across the chain are adhering to the requirements set forth by the
Target Drug Good Faith Dispensing policy."). The "Store Walk" audits consisted of a
manual spot check of the hardcopy due diligence checklists that were stored in the file
cabinets at Walgreens pharmacies. See Polster II Tr. at 355:3–357:2.

In 2015, Walgreens audited 2,407 pharmacies to check compliance with the due diligence policies. P-15085. Regarding the audit results, Polster wrote to Managers on the Pharmaceutical Integrity Team, "put your seat belts on . . . I hope that the results are not as bad as I am thinking they will be." P-20803. The audit results were "unfavorable." P-15085 at 00006. The audit found that 1,432 stores out of 2,407 "correctly had a completed TD GFD Checklist attached to the filled TD prescription hard copies" for a "59.5% compliance rate." Id. at 00007; see also id. at 00008 ("Number of stores that correctly had completed TD GFD Checklist attached to the refused TD prescription hard copies or copies [sic]" were "1,820 stores (75.7% compliance rate)."). Even though Walgreens pharmacies directed its pharmacies to retain the prescriptions for the Target Drugs that they refused to fill, the audit found that 1,160 out of 2,407 stores had failed to retain any refused prescriptions. Id. at 00009.

Walgreens' internal audit results were consistent with the results of analyses based on due diligence materials produced during discovery. Walgreens produced the Target Drug checklists for twelve of its San Francisco pharmacies. See P-29849. From 2013 to

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

2020, the twelve pharmacies dispensed 82,507 prescriptions for target drugs. <u>Id.</u> at 00001. There were Target Drug checklists for only 32,566 of those prescriptions. Id. In other words, for 60.53% of prescriptions over an eight-year period, there was no record that due diligence had been performed through the Target Drug checklist. See id.

Polster testified that Walgreens pharmacists are diligent about documenting steps they take to resolve concerns posed by a prescription. See Polster Decl. ¶ 23. She testified that if a prescription triggered a red flag and there is nothing documenting its resolution, then "the pharmacist simply did not believe the circumstances gave rise to any real concern that they had to take steps to resolve[.]" <u>Id.</u> ¶ 23. The Court assigns this testimony no weight. Polster has not worked as a pharmacist since 2003, she provided no explanation for the basis of this testimony, and she has no foundation to provide such sweeping testimony about all Walgreens pharmacies. See Polster, June 6, 2022 Trial Tr. at 2446:20– 2454:16; see also Polster ¶ 19. The testimony is no more than say-so.

Further, the Court finds that Polster's long tenure at Walgreens and her position as Head of Pharmaceutical Integrity colored her testimony. In the face of significant evidence showing that Walgreens pharmacists faced systemic pressures and challenges that prevented them from consistently performing due diligence, Polster's unsupported claims that Walgreens pharmacists always fulfilled their corresponding responsibility as a matter of course are not credible. Along this line, throughout her testimony, Polster was shown documents identifying issues involving Walgreens pharmacies, and rather than confront the document, she repeatedly testified, "That's what it says." See, e.g., Polster II Tr. at 361:9–12 (Q. "In the roughly [] 2400 stores that were audited, the results were unfavorable, correct?" A. "That's what it says."); id. at 353:17-24 (Q. "[T]here is no monitoring performed outside of the store walk program to determine whether pharmacists across the chain are adhering to the requirements set forth by the Target Drug Good Faith Dispensing Policy. Did I get that right?" A. "Yeah, that's what it says there."); id. at 365:5–9 (Q. "40 percent of the stores did not correctly complete the TD GFD checklist, correct?" A. "That is what it says."). Polster's repeated refusal to engage with unfavorable

documents that undermine her testimony casts doubt on her credibility as a whole. To the extent Polster tried to explain away the documents, her explanations were unconvincing.

Ronda Lowe worked as a Walgreens pharmacy supervisor and district manager.

Lowe Decl. ¶ 3, 7–8. In these roles, she oversaw several stores in San Francisco from 1993 to 2019. Id. ¶ 1–4, 7–8. One of her responsibilities as both a pharmacy supervisor and district manager was to ensure that the stores under her supervision were complying with Walgreens' Good Faith Policy and Target Drug checklist. Lowe, June 13, 2022, Trial Tr. at 3010:2–16. To check compliance, she would visit stores, speak with staff, and work through a Store Walk Summary. Id. at 3017:6–3021:2. The Store Walk Summary contained questions to guide a supervisor during a compliance check and space for the supervisor to document answers. Id. Lowe testified generally that she believed that the stores she oversaw in San Francisco complied with Walgreens controlled substance dispensing policies. See Lowe Decl. ¶ 11–14; Lowe, June 13, 2022, Trial Tr. at 3028:23–3029:4; 3037:15–3038:4.

The Court finds Lowe's testimony unpersuasive. The evidence showed that store supervisors and district managers performed a review that included "40-plus tasks," only one of which directly involved good faith dispensing. Lowe, June 13, 2022, Trial Tr. at 3041:1–3042:8; WAG-MDL-03100. During their store walks, Walgreens expected its supervisors and district managers to cover dozens of broad questions across a range of topics with store employees. <u>See</u> WAG-MDL-03100. The questions included:

- "Is the pharmacy manager and/store manager recognizing team members for doing their best work?"
- "Are store leaders sharing the store's FY Delight target <u>AND</u> monthly Delight scores?"
- "Does the RXM and/store manager have an effective plan to sustain Extraordinary Customer Care?"
- "Talk about your high performers. What is being done to help develop, make them feel challenged and grow their careers?"

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

<u>Id.</u> (original emphasis). The one question regarding the Good Faith Policy was: "Is the pharmacy following the Good Faith Policy?" Id. The general nature of the questions and the broad subject matter do not show that supervisors and district managers performed thorough audits of pharmacy operations. See id.

Indeed, Lowe's testimony demonstrated that the store walks consisted largely of cursory spot checks that involved little more than briefly monitoring and speaking with pharmacy employees. See Lowe, June 13, 2022, Trial Tr. at 3042:16-3043:14 ("I did do audits when I was at the store. I looked over the shoulders of the pharmacists as they were filling prescriptions."); see also id. at 3043:3–14. One would expect that employees would take a more proactive approach to complying with a corporate policy when a supervisor with a checklist was present. Moreover, because Lowe only visited each store under her supervision once or twice a month, she lacks foundation to offer meaningful testimony about how the stores ran on a usual day. See id. at 3043:3–20. Lowe's periodic store walks do not establish that Walgreens pharmacies were policy compliant.

Additional evidence showed that Lowe's oversight of her stores was imperfect. In April 2019, one of the pharmacies under Lowe's supervision noted that it was refusing all prescriptions from a suspicious doctor named Guido Gores who was prescribing enormous volumes of opioids. Lowe, June 13, 2022, Trial Tr. at 3050:4–3051:8. At trial, Lowe did not recall the refusal to fill, but she testified that she would have seen it. Id. at 3051:8–17. In October 2020, another Walgreens pharmacy stopped filling prescriptions for Gores because of his suspicious prescribing patterns. See id. at 3051:25–3053:7. During this time, Walgreens also learned that Gores was under DEA investigation based on his prescribing. <u>Id.</u> at 3053:19–24. Even though Lowe knew about the concerns around Gores' prescribing and that two pharmacies had stopped filling his prescriptions, she testified that she did not alert the other pharmacies that she supervised to be on the lookout for Gores' prescriptions. See id. at 3055:10-3057:4. The available dispensing data showed that after the first San Francisco Walgreens pharmacy began refusing to fill Gores' prescriptions, other San Francisco Walgreens pharmacies went on to dispense 86,904

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

opioid pills pursuant to his prescriptions.<sup>25</sup> See id. at 3057:3–24. Lowe conceded that if she had sent out an email directing pharmacies not to fill his prescriptions, the 86,904 opioid pills would not have been dispensed. Id. at 3058:5–3062:5. Clearly no email was ever sent.

#### 7. **Illegitimate Prescribing in San Francisco**

Illegitimate prescriptions helped to fuel the opioid epidemic. See Keyes Decl. ¶ 88. An illegitimate prescription is one that is not written by a prescriber or not filled by a patient for the purpose of medical treatment. See 21 C.F.R. § 1306.04(a). People who take opioids for non-medical purposes often obtain them from doctors. See Keyes Decl. ¶¶ 65–67, 81; Keyes, June 1, 2022, Trial Tr. at 2232:9–17. Approximately 25% of people who take opioid prescriptions non-medically report receiving an opioid prescription from a physician. Keyes Decl. ¶ 82. One study found that as many as 75% of non-medical users obtained a prescription for opioids during the course of their use. <sup>26</sup> Id. ¶ 67. In another recent study of individuals undergoing treatment for opioid addiction, 25% reported that doctors were their primary ways of obtaining opioids, and over 50% reported that doctors were among the various ways in which they obtained opioids. Id. ¶ 82.

Diversion of prescriptions occurs in many ways. Two of the main ones are through unscrupulous doctors and individuals who doctor shop. See Keyes Decl. ¶81, 88. High volume, unprincipled prescribers—often known as "pill mills"—write opioid prescriptions that are not medically necessary in exchange for payment. See id. In addition, individuals engage in "doctor shopping" and manipulation. Id.; Keyes, June 1, 2022, Trial Tr. at 2232:14–17. Doctor shopping involves deceiving prescribers into writing medically unnecessary prescriptions, including by going to multiple doctors for the same treatment

<sup>&</sup>lt;sup>25</sup> Walgreens dispensing data was available through June 2020.

<sup>&</sup>lt;sup>26</sup> The terms "illegitimate" and "non-medical use" are used interchangeably to describe prescription opioids that a person has obtained without a legitimate medical prescription. In these cases, a prescriber has written a user a prescription despite a lack of medical need, a user has deceived a doctor into writing a prescription despite lack of medical need, or a user has obtained prescription opioids from a third party, such as a friend or drug dealer. In all of these cases, the user has no legitimate medical need for the opioid.

3

4

5

67

8

9

10

11

12

13

14

15

16

17

18 19

20

21

22

23

24

25

26

2728

<sup>27</sup> The "Bay Area" includes San Francisco and the surrounding counties for which Walgreens produced dispensing data, namely Alameda, Contra Costa, Marin, Napa, San Mateo, Santa Clara, Solano, and Sonoma. See P-18323a.

and feigning symptoms. See Keyes Decl. ¶ 81.

Walgreens presented evidence at trial suggesting that most prescribers write medically appropriate prescriptions. The Court assigns the evidence moderate weight. The evidence comes from former DEA deputy Joe Rannazzisi. Rannazzisi testified that "[t]he overwhelming majority of prescribing done by physicians in America is conducted responsibly" and "I think that, if you are talking about 99.5% of the prescribers, no, they are not overprescribing." Rannazzisi II Tr. at 188:14-21; 192:6-19. But there was no evidence that either statement is based on a study, survey, or analysis, as opposed to Rannazzisi's general impressions. Further, while it may be reasonable to conclude that most prescribers act in good faith and write prescriptions with the intention of providing medical benefits to their patients, there is no dispute that some unscrupulous prescribers write prescriptions for financial gain, even though the drugs being prescribed have no medical benefit for the person taking them. Indeed, Rannazzisi testified that the focus of the DEA was on "rogue pain clinics and rogue doctors who are overprescribing." Id. at 191:8–192:14. And Keyes testified that illegitimate prescribing by pill mill prescribers was a substantial cause of the opioid epidemic. Keyes, June 1, 2022, Trial Tr. at 2232:9– 13.

At trial, Plaintiff presented specific evidence that "rogue pain clinics and rogue doctors" prescribed large volumes of opioids and that tens of thousands of these opioid prescriptions were filled at Walgreens San Francisco pharmacies. For example, from 2006 to 2020, Walgreens pharmacies in the Bay Area filed 161,696 opioid prescriptions for suspicious and high-volume prescribers, all of whom faced discipline for their prescribing practices and several of whom lost their medical licenses. <sup>27</sup> See P-18323a; Catizone Decl. ¶¶ 73–86. Over these fifteen years, Walgreens dispensed more than 6 million opioid pills pursuant to prescriptions written just by these thirty-one prescribers in San Francisco, and

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

more than 20 million opioid pills across the Bay Area. See P-18323a; P-28506b. During this period, these thirty-one prescribers accounted for 7.8% of the opioid MMEs dispensed at Walgreens stores in San Francisco. See P-18323a; P-28506b. Four specific prescribers—each of whom ultimately lost their medical license—are discussed below. Most of the opioid prescriptions that these prescribers wrote triggered red flags, but Walgreens nonetheless filled them.

#### **Guido Gores** a.

In February 2021, Gores surrendered his medical license after agreeing that the Medical Board of California could establish that he engaged in gross negligence by overprescribing controlled substances, including prescription opioids. See generally P-22297. In particular, Gores prescribed opioids to patients for multi-year periods without any meaningful investigation of the pain they claimed to be suffering. See id. at 000011– 13. Gores prescribed opioids to a patient who also received opioid prescriptions from other prescribers and tested positive for heroin use. <u>Id.</u> Another patient complaining of hip pain received an opioid prescription from Gores, even though Gores did not examine his hip. Id. at 00014–15. For over two years, Gores prescribed a third patient over 500 milligrams of oxycodone per day—well over five times the 90-milligram daily threshold above which CDC guidelines recommend exercising caution in prescribing—without an examination of the patient's back pain. Id. at 00020–21. One day after visiting Gores for a refill, a third patient died of an accidental drug overdose. <u>Id.</u> at 00021. Gores continued to increase the dosage of opioid prescriptions for a fourth patient without appropriate examination. <u>Id.</u> at 00022–23. And he wrote the patient a new opioid prescription when the patient claimed—well before he was due for a refill—that his pills had been stolen. See id.

Data available to Walgreens showed that Gores was the second highest opioid prescriber in San Francisco and that he was in the ninety-ninth percentile of opioid prescribers nationwide. Keller (dkt. 1392) Decl. ¶¶ 18–20. From 2006 to 2020, nearly 10,000 opioid prescriptions written by Gores were filled at Walgreens' pharmacies, and

approximately 82% of these prescriptions triggered at least one red flag. P-28506b.

As discussed above in connection with Lowe's testimony regarding Store Walk summaries, in 2019, one Walgreens pharmacy in San Francisco stopped filling Gores' prescriptions because "[h]e has red flag prescribing habits that do not satisfy GFD." P-27265 at 00002 ("We have not filled controlled substances from this doctor since 2019."). Another Walgreens pharmacy in San Francisco similarly "[r]efused all controls from this MD beginning 4/2019." See P-27532 at 0003 (noting "High Qtys of opioids. Not a pain MD."). Nonetheless, almost all other Walgreens pharmacies in San Francisco continued to fill Gores' opioid prescriptions until he was forced to surrender his license. P-28506b.

#### b. Andrew Giovannini

In May 2012, Giovannini surrendered his medical license for gross negligence based on overprescribing of opioids. P-27514. For one patient, Giovannini prescribed over 530 milligrams of OxyContin each day. <u>Id.</u> at 00011. Records for the patient show that Giovannini's examinations were "limited and inadequate" and many of "his office notes are virtual duplicates." <u>Id.</u> at 00012. For a second patient, Giovannini prescribed over 800 milligrams of oxycodone per day, despite having information showing that the patient obtained opioid prescriptions from other physicians. <u>Id.</u> at 00013. Four days after another healthcare provider informed Giovannini that the patient was receiving opioids from multiple prescribers, Giovannini prescribed the patient "250 oxycodone 30 mg tablets, 120 OxyContin 80 mg tablets, and 180 oxycodone 40 mg tablets[.]" <u>Id.</u> For a third patient, Giovannini prescribed 1,110 milligrams of oxycodone per day, and he prescribed "well over a thousand" milligrams per day to a fourth. <u>Id.</u> at 00014–16.

The volume of Giovannini's annual opioid prescriptions increased thirteen-fold between 2006 to 2010, going from 306 in 2006 to 3,960 in 2010. Catizone Decl. ¶ 79. From 2006 to 2010, Walgreens pharmacies in San Francisco filled nearly 9,000 opioid prescriptions written by Giovannini. See P-28506b. Approximately 94% of Giovannini's opioid prescriptions filled in San Francisco triggered at least one red flag, and almost 25% of the opioid prescriptions were paired with a prescription for a benzodiazepine. P-

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

28506b.

As with Gores, Walgreens pharmacists expressed concern about the legitimacy of Giovannini's prescriptions. Gayle Tr. at 97:7–15 ("I believe that most everyone in the area knew he was a real fishy doctor to fill for"); Lo Decl. ¶ 22 (testifying that his store had "an informal policy" of not filling Giovannini's prescriptions because of his "prescribing patterns and patients' suspicious behaviors"). Gayle recalled a suspicious incident that stuck with her "even now [] six years later" when three patients carpooled to her pharmacy with prescriptions from Giovannini that were "very, very similar, if not the same." Gayle Tr. at 92:8–94:25. She testified that the prescriptions were all for the holy trinity and that the patients had traveled from Oakland and paid cash, all of which are red flags. Id. at 94:16–95:22. Despite the numerous concerns around Giovannini's prescribing, Walgreens pharmacies continued to fill his prescriptions. See P-28506b.

#### **Collin Leong** c.

Leong surrendered his medical license in 2014 after criminal charges were filed against him. See P-27610; P-27568. The criminal complaint alleged that he wrote opioid prescriptions to homeless people who would fill the prescriptions and turn them over to Leong's co-conspirator who would sell them on the street. See P-27568. In addition to being charged with engaging in a criminal enterprise, the California State Medical Board revoked Leong's license for acting with gross negligence in writing controlled substance prescriptions. See P-27610. One of Leong's patients was a 22-year-old who paid cash for each visit and to whom Leong prescribed "large quantities" of opioids and muscle relaxers without any evidence of any medical examination. P-27610 at 00011 ("[Leong's] medical record for [that patient] fails to document physical examination or findings, and contains insufficient physical findings to support his clinical diagnosis."). A second patient was a 20-year-old who also paid cash and received large quantities of prescription opioids. Id. at 00014 ("[Leong] prescribed Vicodin, Norco, oxycodone, Soma, Valium, and promethazine with codeine cough syrup. Respondent's chart fails to document any rationale for the prescriptions."). A third patient was a 27-year-old who received several opioid

prescriptions without physical examination. <u>Id.</u> at 00019. Leong also prescribed opioids for patients in their 50's and 60's without meaningful examination of the patients' medical conditions. Id. at 00016–17, 00021–22, 00023–24.

Between 2006 and 2013, Walgreens pharmacies in or near San Francisco filled almost 2,200 of Leong's opioid prescriptions, almost 79% of which hit on red flags. P-28506b. As was the case with Giovannini, some San Francisco Walgreens pharmacies adopted an informal policy of refusing Leong's prescriptions because of his suspicious prescribing practices, but the majority continued to fill them. See Lo Decl. ¶ 22; P-28506b.

#### d. John Pierce

In December 2019, Pierce agreed to surrender his medical license in response to charges of gross negligence in overprescribing controlled substances, including opioids.

See P-28430. Without performing any meaningful medical examination, Pierce and his physician assistant prescribed high volumes of opioids and muscle relaxers to one patient who had several underlying health conditions and a history of alcohol abuse. Id. at 00016–17 ("There was no documentation of the patient's complaints of pain, history of present illness, no details of physical features/symptoms, and no vital signs were taken."). Pierce continued to prescribe another patient morphine sulfate and Fentanyl patches "without documenting findings to support the prescribing." Id. at 00018–19. He later began prescribing the patient benzodiazepines as well, despite the high risks presented by taking benzodiazepines at the same time as opioids. See id. Pierce wrote the patient several prescriptions for early refills after the patient claimed that his opioids prescription had been stolen. Id. at 00020.

Walgreens pharmacies in or near San Francisco dispensed more than 10,000 prescriptions written by Pierce, 75% of which hit on at least one red flag. See P-28506b. Gayle testified that Pierce "frequently" prescribed "a triad of medications that were suspicious that I mentioned earlier, Soma, which is a muscle relaxant, a benzodiazepine like clonazepam, and then I believe like a Norco, hydrocodone /acetaminophen." Gayle

1.0

Tr. at 74:17–75:3. This is a "pretty serious" red flag. <u>Id.</u> at 75:4–75:10.

In August 2019, the Walgreens Pharmaceutical Integrity Team received the question: "Should we stop filling control substances for this provider if the CA BOP sent out this email that John WINTHROP Pierce (CA license G45225) license has been suspended (see copy of email below) – but showing current on the CA Medical board's website?" P-28997 at 00001. Lowe, a district manager of Walgreens San Francisco pharmacies at the time, testified that it would surprise her that Walgreens pharmacies in San Francisco would continue to fill Pierce's prescription despite his admission of gross negligence. Lowe, June 13, 2022, Trial Tr. at 3064:1–20. The record does not contain a response from the Pharmaceutical Integrity Team. But even though Pierce's license was suspended, Walgreens San Francisco pharmacies continued filling his prescriptions for several more months. See P-28506b.

# D. Walgreens Substantially Contributed to The Opioid Epidemic in San Francisco

As detailed above, the evidence presented at trial supports a reasonable inference that from 2006 to 2020, Walgreens pharmacies in San Francisco filled a significant volume of illegitimate opioid prescriptions that caused more than negligible or theoretical harm in the city.

The CSA and its implementing regulations create a "closed system of distribution" in order to guard against diversion of controlled substances. See Catizone Decl. ¶ 6. In exchange for the authority to deal in controlled substances, every entity that operates within this system must take reasonable steps to prevent diversion. See Rannazzisi I Tr. at 410:13–411:15. Within this system, pharmacies are "the last line of defense." Catizone Decl. ¶ 10. Pharmacies that fill illegitimate opioid prescriptions directly contribute to opioid diversion. See Rannazzisi II Tr. at 190:10–195:9; Keyes Decl. ¶ 88. To prevent the harms that result from illegitimate prescribing, pharmacies and pharmacists have a "corresponding responsibility" to develop and maintain effective systems to identify and prevent dispensation of illegitimate prescriptions. See 21 C.F.R. § 1306.04(a). Walgreens

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

1

2

3

4

did not honor this responsibility.

A decade ago, the DEA issued multiple show cause orders to Walgreens based on
findings that several Walgreens pharmacies filled illegitimate opioid prescriptions. See P-
20642; P-19716. The memorandums of agreement that Walgreens entered into to resolve
those actions identified systemic deficiencies in Walgreens' due diligence policies and
procedures. See P-19651; P-00015. The memorandums of agreement required Walgreens
to develop more effective controls for preventing fulfillment of illegitimate prescriptions.
See id. The evidence at trial showed that Walgreens did not hold up its end of the
agreement.

Following the DEA settlements, Walgreens created the Pharmaceutical Integrity Team in a purported effort "to ensure that our pharmacists were being consistent" when they were fulfilling their corresponding responsibility. See Polster II Tr. at 25:19–26:16. The Pharmaceutical Integrity Team's efforts were inadequate window dressing. The due diligence policies that the Pharmaceutical Integrity Team implemented excluded some of the most widely abused opioids in the country, and the due diligence processes that the team developed were both impractical and inadequate. See supra I.C.4. Pharmacists completed due diligence on paper checklists, had inadequate tools to identify suspicious prescribers even when Walgreens corporate had such information on hand, and lacked the ability to share concerns about suspect prescribers that they identified. Id. In addition, pharmacists continued to face systemic obstacles that prevented them from consistently performing due diligence. See supra I.C.5.a-e. These obstacles included understaffing, intense time pressure, insufficient resources, lack of training, and misaligned incentives. <u>See id.</u> The evidence presented at trial showed that Walgreens corporate was more concerned about increasing the volumes of prescriptions that its pharmacies filled than it was with ensuring that its pharmacies performed adequate due diligence before dispensing drugs that carry high risks of abuse.

Walgreens' failure to support its pharmacists resulted in those pharmacists dispensing hundreds of thousands of red flag opioid prescriptions without adequate due

diligence. Walgreens' "fill, fill, fill" culture prevented pharmacists from consistently
resolving red flags before dispensing prescriptions. See Gayle Tr. at 17:1 –4; Lo, May 12,
2022, Trial Tr. at 915:7–919:4. Walgreens' Good Faith Policy states that it is "imperative"
that pharmacists document resolution of red flags before dispensing a prescription. WAG-
MDL-00304.00004 (emphasis added); see also P-29904 at 00001 ("Regardless if the
decision is to fill or refuse, make sure they properly document the steps taken to reach that
decision either on the prescription hardcopy or the IC+ image/profile."). Yet the evidence
of documentation was exceedingly thin. The evidence demonstrated that Walgreens
pharmacists in San Francisco performed adequate due diligence for less than $5\%$ of opioid
prescriptions that hit on red flags. See Park Decl. $\P\P$ 24–26 ("[T]he notes I reviewed from
Walgreens' computer system provide little to no information that any reasonable
pharmacist or pharmacy would interpret as documentation that red flags were identified or
resolved."); see also McCann Decl. ¶ 67.

Walgreens' multi-decade-long failure to take reasonable steps to ensure that its pharmacies could perform adequate due diligence on controlled substance prescriptions is especially striking given the enormous volume of opioid prescriptions that Walgreens pharmacies dispensed in San Francisco. From 2006 to 2020, Walgreens pharmacies in San Francisco filled 2,478,103 opioid prescriptions. See McCann Rebuttal Decl. ¶ 4. Of these prescriptions, 1,251,307 (or 50%) hit on at least one red flag. See id. Each year, Walgreens pharmacies in San Francisco dispensed an average of 83,420 red flag opioid prescriptions each year. Id. In total, the red flag opioid prescriptions dispensed each year contained an average of 5,005,200 opioid pills. <u>Id.</u>

That a prescription hit on one or more red flags does not prove that the prescription was illegitimate. But the sheer volume of red flag prescriptions that Walgreens San Francisco pharmacies dispensed without adequate due diligence supports a reasonable inference that diversion occurred at those pharmacies. Further, the evidence established that pill mill doctors were a substantial contributor to the opioid epidemic and that many people who abuse opioids obtain prescriptions from prescribers. See Gayle Tr. at 74:17–

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

75:3; 92:8–92:15; Lo Decl. ¶ 22; Keyes Decl. ¶ 81, 82, 88. As an example, thirty-one prescribers—all of whom were subject to disciplinary action stemming from improper prescribing—wrote 161,696 opioid prescriptions that were filled at Walgreens pharmacies from 2006 to 2020. See P-18323a; Catizone Decl. ¶¶ 73–86. Multiple times, Walgreens pharmacists in San Francisco raised concerns about the legitimacy of the prescriptions written by these prescribers, but Walgreens pharmacies nevertheless continued to fill their prescriptions—in some cases even after disciplinary proceedings had been initiated against the prescriber. See supra I.C.7. This evidence further demonstrates the reasonableness of the inference that significant volumes of illegitimate prescriptions were written in and near San Francisco and filled at Walgreens pharmacies in San Francisco.

The nature and severity of the opioid epidemic in San Francisco also supports the inference that illegitimate prescriptions were being written and filled in the city. Over the course of little more than a decade, the volume of prescription opioids and rates of opioid misuse and addiction increased significantly. See supra I.A.2 & I.A.3. The growing rates of addiction and the presence of unscrupulous doctors bolsters the inference that illegitimate prescriptions were being written and filled in the city. The evidence presented at trial makes clear that Walgreens, the dominant retail pharmacy chain in San Francisco, which had a history of failing to comply with federal regulations, filled a significant volume of illegitimate opioid prescriptions. In so doing, Walgreens contributed directly to opioid diversion and made the opioid epidemic in San Francisco worse than it otherwise would have been.

#### II. **CONCLUSIONS OF LAW**

Plaintiff proved that Walgreens is liable for substantially contributing to the public nuisance—the ongoing opioid epidemic—in San Francisco. A nuisance is "[a]nything which is injurious to health . . . or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property." Cal. Civ. Code § 3479. A public nuisance "affects at the same time an entire community or neighborhood, or any considerable number of persons." Id. § 3480.

Plaintiff is authorized to bring this action for abatement of a public nuisance existing within San Francisco. Cal. Civ. Code § 3494. To succeed on its public nuisance claim at trial, Plaintiff had the burden of proving by a preponderance of the evidence that Walgreens had knowledge that its unreasonable conduct caused a substantial interference with a right common to the public. See People v. ConAgra Grocery Prod. Co., 17 Cal. App. 5th 51, 78–112 (2017). Plaintiff carried its burden.

#### A. Unreasonable Conduct with Knowledge

Plaintiff proved that Walgreens engaged in unreasonable conduct by dispensing hundreds of thousands of red flag opioid prescriptions without due diligence in violation of 21 C.F.R. § 1306.04(a). In addition, Plaintiff proved that Walgreens failed to implement an effective suspicious order monitoring system in violation of 21 C.F.R. § 1301.74.

Even though Walgreens engaged in two forms of unreasonable conduct, the Court's finding of liability rests on Walgreens' violation of 21 C.F.R. § 1306.04(a). This is because of the direct link from dispensing to diversion. The suspicious orders that Walgreens distribution centers failed to identify were sent to Walgreens pharmacies. Walgreens contributed to opioid diversion when its pharmacies filled red flag prescriptions without due diligence. Because Walgreens' distribution centers did not ship opioids to pharmacies outside of Walgreens, there is no link to additional harm. The diversion happened at Walgreens pharmacies.

#### 1. Unreasonable Conduct

Conduct encompasses any action that "assist[s] in creating a system that causes" an interference with a public right. City of Modesto Redevelopment Agency v. Superior Court, 119 Cal. App. 4th 28, 40–41 (2004); Restatement (Second) of Torts § 821B; see also ConAgra, 17 Cal. App. 5th at 79. Conduct is unreasonable if it violates a statute, ordinance, or administrative regulation. In re Firearm Cases, 126 Cal. App. 4th 959, 987 (2005); Ileto v. Glock Inc., 349 F.3d 1191, 1210 (9th Cir. 2003). Conduct is also unreasonable if "the gravity of the harm outweighs the social utility of the defendant's conduct." San Diego Gas & Electric Co. v. Superior Court, 920 P.2d 669, 697 (1996).

Under the public nuisance safe harbor, "[n]othing which is done or maintained under the express authority of a statute can be deemed a nuisance." Cal. Civ. Code § 3482.

#### a. 21 C.F.R. § 1306.04(a)

Plaintiff proved that Walgreens violated 21 C.F.R. § 1306.04(a). Section 1306.04(a) states:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a).

"The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself." Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, Decision and Order, 77 FR 62316-01, 2012 WL 4832770, at \*62341 (Oct. 12, 2012); Top RX Pharmacy, Decision and Order, 78 FR 26069-01, 2013 WL 1838477, at \*26082 (May 3, 2013) (citing cases). And "[t]he DEA has, in fact, found pharmacy-level responsibility for failing to properly monitor the dispensing practices of pharmacists[.]" Cherokee Nation v. McKesson Corp., No. CIV-18-056-RAW, 2021 WL 1200093, at \*6 (E.D. Okla. Mar. 29, 2021).

The CSA's corresponding responsibility requirement requires pharmacists and pharmacies to identify and resolve objective signs "arising during the presentation of a prescription" that create "a reasonable suspicion that the prescription is not, on its face, legitimate." <u>United States v. City Pharmacy, LLC</u>, No. 3:16-CV-24, 2017 WL 1405164, at \*4 (N.D.W. Va. Apr. 19, 2017); <u>Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy</u>, Decision and Order, 83 FR 10876-01, 2018 WL 1252035, at 10896 (March 13,

2018).

To prove a violation of the corresponding responsibility, a plaintiff must show that (1) a pharmacy dispensed a controlled substance, (2) "a red flag was or should have been recognized at or before the time the controlled substance was dispensed," and (3) "the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance." Holiday CVS, L.L.C., 77 FR 62316-01, 2012 WL 4832770, at \*62341. Prescriptions with unresolved red flags cannot be dispensed. See City Pharmacy, LLC, No. 3:16-CV-24, 2017 WL 1405164, at \*4.

At trial, Plaintiff proved that Walgreens pharmacies violated 21 C.F.R. § 1306.04(a) for fifteen years. This is unreasonable conduct sufficient to support a public nuisance claim. The CSA and its implementing regulations strike a bargain with registrants. In exchange for the privilege of dispensing powerful controlled substances, pharmacies are required to take reasonable steps to prevent those substances from being diverted and harming the public. In connection with this system, § 1306.04(a) requires pharmacies to take reasonable steps to prevent the dispensation of illegitimate prescriptions. Walgreens failed to fulfill this duty.<sup>28</sup> The evidence established that it was more likely than not that Walgreens pharmacies failed to perform due diligence on opioid prescriptions for fifteen years. From 2006 to 2020, Walgreens San Francisco pharmacies were presented with over 1,200,000 red flag prescriptions. The evidence showed that Walgreens pharmacists only resolved a fraction of the red flags present in these prescriptions before dispensing them. There is no social utility in violating a federal regulation designed to protect the public from harm. See In re Firearm Cases, 126 Cal. App. 4th at 987. Walgreens' fifteen-year

<sup>&</sup>lt;sup>28</sup> The Court previously held that "[p]ublic nuisance claims require the existence of a duty." <u>City & Cnty. of San Francisco v. Purdue Pharma L.P.</u>, 491 F. Supp. 3d 610, 669 (N.D. Cal. 2020). Upon further consideration, the authority cited by the Court stands for the narrower proposition that engaging in lawful though potentially "risky" behavior does not support a nuisance claim without a showing that the harms produced by the behavior outweigh the benefits, and that there is link between the behavior and a significant interference with a public right. <u>See In re Firearm Cases</u>, 126 Cal. App. 4th at 988. This clarification is not necessary to the Court's conclusions of law, which rest on the holding that Walgreens violated the duty imposed by § 1306.04(a).

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

violation of § 1306.04(a) is unreasonable conduct sufficient to support a public nuisance claim.

#### 2. Knowledge

California's public nuisance claim has a knowledge requirement. But the California Supreme Court has not squarely addressed the extent to which a plaintiff must prove that a defendant has knowledge of the harm resulting from its unreasonable conduct. The California Court of Appeal articulated the knowledge requirement clearly in People v. ConAgra Grocery Prod. Co., 17 Cal. App. 5th 51, 83–86 (2017).

In ConAgra, the California Court of Appeal held that to prove that a defendant acted with the requisite knowledge, a plaintiff must show that the defendant acted "with knowledge of the hazard" that the defendant's conduct would create. ConAgra, 17 Cal. App. 5th at 84. The ConAgra court explained that acting "with knowledge of the hazard" requires that the evidence be sufficient to support an inference that a defendant "must have known" that its conduct contributed to the alleged harm, not simply that it "should have known." Id. at 84–85. A plaintiff may "rely exclusively on circumstantial evidence" to prove that a defendant "must have known" that their conduct substantially contributed to a public nuisance. See id.

In ConAgra, the court held that the plaintiff presented sufficient evidence to establish that the defendants acted with the requisite level of knowledge because the record "indicated that the defendants had learned about the harms and hazards of lead exposure by the 1920s, yet still promoted its lead products." ConAgra, 17 Cal. App. 5th at 85. There, the court found that the defendants must have known that lead paint posed a serious risk of harm to children because defendants received publications from congressional hearings and trade associations detailing the hazards of lead paint. Id. at 87. This evidence was sufficient to show that defendants "must have known" about the harms that would result from promoting lead paint for interior use. See id. 85–87.

Applying ConAgra here, Plaintiff proved that Walgreens "must have known" of the

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

28

harms that would result from violating its regulatory duties for over a decade.<sup>29</sup> The CSA and its implementing regulations reflect the dangers posed by the controlled substances that Walgreens dispenses. The regulations that apply to Walgreens were put in place precisely because of the harms that result when opioids are diverted. Based on the regulatory scheme alone, it is reasonable to infer that Walgreens "must have known" that failing to prevent diversion of opioids would result in harm in San Francisco. Beyond the regulatory scheme, Walgreens received ample notice of the harms caused by opioid diversion. In 2006, the DEA sent distributors of controlled substances, including Walgreens, a letter stating that "[a]s each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country." P-00035 at 00005. The letter was one part of a broader public awareness campaign that began in the mid-2000s to alert DEA registrants to the rapidly growing nationwide opioid epidemic. Three years after the letter was sent, the DEA found that a Walgreens pharmacy filled "prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice in contravention of 21 C.F.R. § 1306.04(a)." P-20642 at 00002. Three years after that, the DEA initiated enforcement actions against several more Walgreens pharmacies based on findings that the pharmacies "consistently failed" to exercise their corresponding responsibility. P-19716 at 00001, 00009, 00016.

Throughout the 2010s, Walgreens executives recognized the harms that result from the abuse of prescription drugs. In 2012, Polster attended a DEA presentation discussing the severe harms that the diversion of prescription opioids was inflicting across the country. Polster, June 2, 2022, Trial Tr. at 2375:12–18. Polster circulated the takeaways among the "highest levels" at Walgreens. Id. The DEA presentation warned, among other things, that "more Americans abuse prescription drugs than the number of: cocaine,

<sup>27</sup> 

<sup>&</sup>lt;sup>29</sup> As in its order on the motions to dismiss, the Court does not decide whether California law incorporates an actual knowledge requirement because the facts proved at trial satisfy the actual knowledge requirement. See City & Cnty. of San Francisco., 491 F. Supp. 3d at 673.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

hallucinogen, heroin, and inhalant abusers combined!!!" P-19656 at 00009 (cleaned up). That same year, a Walgreens executive delivered an internal presentation on how the "new hot topic in the news is the epidemic America has: 'Prescription Pain Drug Abuse.'" See P-20639 at WAG-MDL-01013473. A few years later, Walgreens executives continued to recognize that "[p]rescription drug abuse is a serious social and health problem." WAG-MDL-03189.00002. Viewed as a whole, the evidence presented at trial established that Walgreens "must have known" that violating its regulatory obligations to prevent diversion of opioids would substantially contribute to the opioid epidemic in San Francisco.

#### В. **Factual and Legal Causation**

"The elements of a cause of action for public nuisance include ... causation." See Melton, 183 Cal. App. 4th at 542. A plaintiff must prove factual causation, which requires proving that a defendant's conduct was a "substantial factor in bringing about" the nuisance. ConAgra, 17 Cal. App. 5th at 101. Additionally, a plaintiff must establish that the defendant's wrongful conduct was not "too remote from the current hazard to be its 'legal cause,'" i.e., proximate causation. Id. at 103.

#### 1. **Factual Causation**

Unreasonable conduct must be a substantial factor in contributing to the public nuisance. ConAgra, 17 Cal. App. 5th at 101; Citizens for Odor Nuisance Abatement v. City of San Diego, 8 Cal. App. 5th 350, 359 (2017). "The substantial factor standard is a relatively broad one, requiring only that the contribution of the individual cause be more than negligible or theoretical. Thus, a force which plays only an 'infinitesimal' or 'theoretical' part in bringing about injury, damage, or loss is not a substantial factor, but a very minor force that does cause harm is a substantial factor." ConAgra, 17 Cal. App. 5th at 101 (citations and internal quotations omitted).

The substantial factor test subsumes "but for" causation. Rutherford, 16 Cal. 4th at 969. It also addresses situations "involving independent or concurrent causes in fact." See id. Conduct may substantially contribute to a nuisance even where there are "independent or concurrent causes in fact." See id. If a defendant's conduct operated concurrently with

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

other forces to produce the harm, it is a substantial factor, so long as "the injury, or its full extent, would not have occurred but for that conduct." In re Ethan C., 54 Cal. 4th 610, 640 (2012); see also City of Modesto, 19 Cal. App. 5th at 158 ("[T]he plaintiff need only introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result.") (citations and internal quotations omitted).

"Although a finding of causation may not be based on mere speculation or conjecture, such finding may be predicated on reasonable inferences drawn from circumstantial evidence." City of Modesto, 19 Cal. App. 5th at 153 (quoting Smith v. Lockheed Propulsion Co., 247 Cal. App. 2d 774, 780 (1967)). "Direct proof of each link in a chain of causation is not required." Id.

California courts have repeatedly held that causation may be reasonably inferred from circumstantial evidence in the context of mass torts. In ConAgra, plaintiff filed a public nuisance claim against manufacturers of lead paint, alleging that the manufacturers promoted the use of lead paint for the interior of homes and buildings, despite knowing of the health hazards that it posed, thereby contributing to a public nuisance in California. ConAgra, 17 Cal. App. 5th at 66. On appeal, defendants argued that plaintiffs failed to prove causation because there was no direct evidence of any customer using lead paint because they believed it was safe based on defendants' marketing. Id. at 102–03. The Court of Appeal rejected the argument. It held that "there was plenty of evidence that defendants' affirmative promotions of lead pain for interior residential use played at least a 'minor' role in creating the nuisance that now exists." <u>Id.</u> at 102–03. The evidence established that defendants engaged in multi-year marketing campaigns, aimed at window and door manufacturers as well as consumers, and promoted the use of lead paint for residential interiors. Id. Based on the length of the marketing campaigns and the volume of marketing materials, the Court of Appeal held that "the trial court could reasonably infer that at least some of those who were targets of these recommendations heeded them. That is all that the substantial factor test requires." Id. at 103.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

In City of Modesto, the plaintiffs sued manufacturers of dry-cleaning equipment, alleging that they improperly instructed dry-cleaners that dry-cleaning chemicals could be safely released into the environment; in fact, the dry-cleaning chemicals polluted the local water supply and created a public nuisance.<sup>30</sup> 19 Cal. App. 5th at 136–42. During a bench trial, plaintiffs offered evidence that for several decades, the manufacturers "took affirmative steps directed toward the improper discharge of solvent wastes" by providing guidance to dry-cleaners to discharge polluted water into sewers. Id. at 147-50. Despite the significant volume of evidence, the trial court ruled that plaintiffs failed to prove liability because they did not prove that a drycleaner "relied on" the manufacturers' guidance or that a dry-cleaner relying on the guidance "caused the contamination." Id. at 150-51.

The Court of Appeal reversed. It held that plaintiffs were not required to prove a "chain of causation" with "direct evidence." Id. The court explained: "We do not agree that the substantial factor test of causation requires the kind of incontrovertible linkage proposed by defendants." Id. at 152. The court held that "circumstantial evidence of sufficient substantiality from which reasonable inferences can be drawn will support a finding of causation in fact." Id. at 153 (citation omitted). The court held that plaintiffs' evidence of manufacturers' multi-year instructions to dry-cleaners to dispose of solvent waste in sewers—despite being aware of the dangers the waste posed—could support a finding of liability, even without direct evidence that any specific dry-cleaner followed a manufacturer's advice. See id. 152-58. The court vacated the trial court's ruling on causation and remanded the case with directions to apply the correct causation standard.

23

24

25

26

27

28

<sup>&</sup>lt;sup>30</sup> While the primary claim in <u>City of Modesto</u> was brought under the Polanco Act—which "involves cleanup of the release of hazardous substances"—the Court of Appeal applied nuisance law principles to interpret the Act's provisions, explaining that "environmental legislation by which government exercises its traditional power to regulate public nuisances should be construed in light of common law principles bearing on nuisance." <u>City of Modesto</u>, 19 Cal. App. 5th at 145. Accordingly, the legal principles discussed in <u>City of Modesto</u>—which are drawn almost exclusively from nuisance case law—are equally applicable to a nuisance claim. See id. at 145–49 ("The critical inquiry [was] whether the defendants' actions, taken as a whole, created or assisted in the creation of the nuisance.") (cleaned up).

Id. at 159.

Here, Plaintiff presented "circumstantial evidence of sufficient substantiality" to permit reasonable inferences that "support a finding of causation in fact." See City of Modesto, 19 Cal. App. 5th at 152. Plaintiff proved that Walgreens—the largest dispenser of opioids in San Francisco—flouted its regulatory obligation to prevent opioid diversion from 2006 to 2020. During this period, opioid abuse was rampant throughout the city, unscrupulous doctors wrote significant volumes of suspect opioid prescriptions, and Walgreens pharmacies filled tens of thousands of the prescriptions written by these doctors. Walgreens San Francisco pharmacies received over 1,200,000 red flag opioid prescriptions, yet they performed due diligence for less than 5% of these prescriptions before dispensing them. The evidence presented at trial supports a reasonable inference that Walgreens dispensed large volumes of illegitimate opioid prescriptions and that it made the opioid epidemic in San Francisco worse than it otherwise would have been.

Throughout the trial, Walgreens repeatedly made the point that Plaintiff did not directly prove that Walgreens San Francisco pharmacies dispensed any illegitimate prescriptions. That argument fails because, as explained above, California law is crystal clear that "[d]irect proof of each link in a chain of causation is not required." See City of Modesto, 19 Cal. App. 5th at 153. Indeed, in light of the overwhelming evidence presented at trial, it is difficult to take seriously the argument that the failure to identify specific illegitimate prescriptions is fatal to Plaintiff's case.<sup>31</sup> Walgreens gave short shrift to its regulatory obligations for fifteen years, and its pharmacies failed to perform due

<sup>&</sup>lt;sup>31</sup> Indeed, because Walgreens' wrongful conduct took place over fifteen years, circumstantial evidence is almost certainly more persuasive than direct evidence would have been. To proceed by direct proof, Plaintiff would have had to trace each individual illegitimate prescription to each unscrupulous prescriber, show that a Walgreens pharmacy filled the illegitimate prescription, and show that the illegitimate prescription caused harm. And even if Plaintiff had successfully proved up these causal chains, such evidence would have been rightly criticized by Walgreens as de minimis. But the substantial factor test does not require "the kind of incontrovertible linkage proposed by" Walgreens. See City of Modesto, 19 Cal. App. 5th at 152. Under the substantial factor test, Plaintiff "need only introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result." See id. at 158 (citation and internal quotations omitted). Plaintiff did so here.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

diligence on hundreds of thousands of red flag prescriptions, many of which were written by suspicious prescribers that Walgreens' own pharmacists warned the company about. Based on the evidence presented at trial, it is unimaginable that many of the red flag prescriptions were not diverted. The aggregate evidence that Plaintiff presented at trial was not only adequate to establish Walgreens' culpability—it was devastating.

#### The Orange County and West Virginia Cases are Factually a.

In two recent decisions involving the nationwide opioid litigation, two separate courts held that the plaintiffs in those cases failed to prove causation. In November 2021, after a multi-month bench trial, judgment was entered in favor of various opioid manufacturer defendants in the Superior Court of California County of Orange. People v. Purdue Pharma L.P., No. 30201400725287CUBTCX, 2021 WL 5227329, at \*2 (Cal. Super. Nov. 01, 2021) ("Orange County case"). In July 2022, after another multi-month bench trial, judgment was entered in favor of various opioid distributors in the Southern District of West Virginia. See City of Huntington v. Amerisource Bergen Drug Corp., No. CV 3:17-01362, 2022 WL 2399876, at \*1 (S.D.W. Va. July 4, 2022) ("West Virginia case"). Walgreens was not a party to either case. Neither case involved a pharmacy defendant that dispensed opioids. The facts of both cases are materially distinguishable from the facts proven here. The cases do not help Walgreens.

Neither the Orange County case nor the West Virginia case involved a pharmacy defendant alleged to have violated a federal regulation by failing to consistently perform due diligence on opioid prescriptions over a fifteen-year period. The Orange County case centered on the allegation that various opioid manufacturers engaged in false and misleading marketing that deceived prescribers, causing them to write large numbers of "medically unnecessary" prescriptions.<sup>32</sup> Orange County Case, 2021 WL 5227329, at \*7. The West Virginia case involved allegations that three opioid distributors failed to identify

<sup>&</sup>lt;sup>32</sup> Plaintiff brought claims against several opioid manufacturers in this case, but those claims have been settled or stayed.

and halt suspicious opioid orders and instead shipped the suspicious orders to pharmacies where they were subsequently diverted. <u>See</u> West Virginia Case, 2022 WL 2399876, at \*13.

In both cases, the courts held that the plaintiffs' theories of liability involved extended chains of causation that the plaintiff failed to prove. In the Orange County case, the plaintiffs' theory of liability required proof that the defendants' marketing contained false and misleading statements about the safety and efficacy of opioids, that these statements reached prescribers, and that the falsehoods in the statements caused prescribers to write medically unnecessary prescriptions (i.e. prescriptions that the prescribers wrote because they were deceived into believing that opioids are safer and more effective than they actually are). See Orange County Case, 2021 WL 5227329, at \*8–9. The Orange County court held that plaintiffs failed to prove this claim because they offered "no evidence of medically inappropriate prescriptions caused or induced by any allegedly false or misleading marketing and promotion by Defendants[.]"<sup>33</sup> Id. at 10.

In the West Virginia case, the plaintiffs' theory of liability required them to prove that defendants failed to maintain adequate systems to identify suspicious opioid orders, that defendants shipped suspicious opioid orders to pharmacies in violation of their duty to halt the orders, and that the suspicious orders that they should have halted were subsequently diverted at the pharmacy level. See West Virginia Case, 2022 WL 2399876, at \*13–25. As an initial matter, the court ruled that the plaintiffs did not prove that any of the defendants failed to implement systems to identify suspicious orders. Id. ("Plaintiffs did not prove that defendants failed to maintain effective controls against diversion and

<sup>&</sup>lt;sup>33</sup> The Orange County case is consistent with <u>ConAgra</u> and <u>City of Modesto</u>. The Orange County court did not hold that plaintiffs were required to prove causation with direct evidence. <u>See</u> Orange County Case, 2021 WL 5227329, at \*11. Rather, the Orange County court ruled that plaintiffs had failed to carry their burden of introducing sufficient evidence to prove a causal connection between the defendants' conduct and resulting harm. <u>See id.</u> at \*10–11.

Northern District of California

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

design and operate sufficient SOM systems to do so.").<sup>34</sup> In addition, the court ruled that plaintiffs failed to "identify a single pharmacy customer of defendants that was engaged in diversion." Id. at 34. In other words, even if defendants failed to halt suspicious opioid orders, there was no evidence that those orders caused any harms because there was no evidence that any of the pharmacies that received the orders improperly dispensed them. See id.<sup>35</sup>

The case that Plaintiff presented against Walgreens does not suffer similar evidentiary shortcomings. In the West Virginia case, the court found that the evidence established that the distributor defendants complied with their obligation to identify and halt suspicious orders. West Virginia Case, 2022 WL 2399876, at \*13-25. In contrast, the evidence here established that Walgreens' distribution centers failed to implement and maintain effective systems for monitoring suspicious orders. Further, unlike the West Virginia defendants, Walgreens dispensed the prescription opioids that its distribution centers shipped to its pharmacies. And the evidence established that for fifteen years, Walgreens San Francisco pharmacies failed to perform adequate due diligence and dispensed hundreds of thousands of red flag prescriptions. The link between Walgreens' violation of its regulatory duties and the resulting harm is direct. Walgreens pharmacies that fill illegitimate prescriptions contribute directly to opioid diversion. In the Orange County case, the court found that there was "no evidence of medically inappropriate prescriptions" caused by the defendants' marketing. See Orange County Case, 2021 WL 5227329, at \*10. The causal link that Plaintiff had to prove here is much shorter. Plaintiff had to show that Walgreens' unreasonable noncompliance with CSA regulations resulted

25

26

27

28

<sup>23</sup> 24

<sup>&</sup>lt;sup>34</sup> Indeed, much of the evidence showed that the DEA considered the distributor defendants' suspicious order monitoring systems to be well above board. See West Virginia Case, 2022 WL 2399876, at \*29–35.

<sup>&</sup>lt;sup>35</sup> On August 4, 2022, Plaintiff filed a statement of recent decision with an order issued by the West Virginia Mass Litigation Panel on August 3, 2022 ("WVMLP order"). See Statement of Recent Decision (dkt. 1576). While the WVMLP order both disagrees with and distinguishes the West Virginia case, it involves claims brought in West Virginia state court under West Virginia state law. See Ex. A (dkt. 1576–1) at 26–37. As such, the Court does not consider the WVMLP order here.

## 

# 

# 

## 

## 

### 

### 

### 

## 

# 

# 

# 

# 

## 

## 

## 

## 

### 

# 

## 

# 

## 

Francisco. Ample evidence supports this conclusion.

in the filling of large volumes of illegitimate prescriptions that caused harm in San

### 2. Proximate Causation

Proximate cause involves "various considerations of policy that limit an actor's responsibility for the consequences of his conduct." See Ferguson v. Lieff, Cabraser, Heimann & Bernstein, 30 Cal. 4th 1037, 1045 (2003) (citation omitted). "Because the purported causes of an event may be traced back to the dawn of humanity, the law has imposed additional limitation on liability other than simple causality." See ConAgra, 17 Cal. App. 5th at 104. There "is no bright line demarcating a legally sufficient proximate cause from one that is too remote," People v. Roberts, 2 Cal. 4th 271, 320 fn. 11 (1992), but courts place great emphasis on "foreseeability of harm" in determining whether a proximate cause has been established. Novak v. Cont'l Tire N. Am., 22 Cal. App. 5th 189, 196 (2018); see also Pac. Shores Properties, LLC v. City of Newport Beach, 730 F.3d 1142, 1168 (9th Cir. 2013).

At trial, Plaintiff proved that the numerous forms of harm resulting from Walgreens' unlawful dispensing of illegitimate opioid prescriptions were foreseeable. The risks posed by opioids have been known to medical practitioners for decades and have been codified in the Controlled Substances Act since 1970. The regulatory duties that the CSA imposes on pharmacies to prevent diversion of opioids reflect the danger that opioids pose. "A lack of reasonable care in the handling, distribution, and administration of controlled substances can foreseeably harm the individuals who take them. That's why they're controlled in the first place—overuse or misuse can lead to addictions and long-term health problems." See Dent v. National Football League, 902 F.3d 1109, 1119 (9th Cir. 2018) (citing the CSA).

The evidence at trial established the severity of opioid addiction and the adverse long-term health conditions that can result from prescription opioid abuse. The evidence demonstrated that opioids are highly addictive and have the potential to affect individuals from all walks of life. It further demonstrated the immense challenge of reducing opioid

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

use after a user's brain has downregulated the amount of dopamine it naturally produces in response to the additional dopamine that opioids cause to be released. Opioid abuse can have extremely destructive effects on people's lives, causing them to neglect health, family and work. In extreme cases of addiction, they devote all available time, attention, and resources to obtaining more opioids. There was also persuasive evidence showing how abuse of prescription opioids often leads to the use of illicit opioids, including heroin and fentanyl. As addiction becomes more severe, opioid users tend to seek out stronger, cheaper, and more potent opioids. The cycle of addiction is foreseeable. The negative downstream consequences that flow from opioid abuse—including crime, homelessness, and destruction of city property—are also foreseeable. Given the immense difficulty of reducing opioid use and the severe pain of withdrawal, it is foreseeable that individuals suffering from addiction will experience increasingly adverse life events. The potential for opioids to be abused is a risk of which the government has long warned of and of which Walgreens has long been aware.

Courts in other jurisdictions have expressed concerns about "extending the law of nuisance to the sale or distribution of opioids[.]" See, e.g., West Virginia Case, 2022 WL 2399876, at \*56–59; see also State ex rel. Attorney General of Oklahoma v. Johnson & Johnson, 499 P.3d 719, 730 (Okla. 2021). These courts have reasoned that nuisance law traditionally applies only "in the context of conduct that interferes with public property or resources." See West Virginia Case, 2022 WL 2399876, at \*57; State ex rel. Hunter, 499 P.3d at 727. These courts have also expressed concern that applying "the law of public nuisance to the sale, marketing and distribution of products would invite litigation against any product with a known risk of harm." See West Virginia Case, 2022 WL 2399876, at \*59. Neither point is persuasive here.

Unlike nuisance law in other states, "California law has never imposed such a requirement that there be some form of injury to land or property[.]" See Ileto, 349 F.3d at 1213 ("[T]he district court's determination that a nuisance must be associated with property is contrary to clearly established California law."). Indeed, "California common

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

law consistently has defined nuisance in broad terms that encompass injuries to health, or acts that are 'indecent or offensive to the senses' or obstructions to the free use of property in any manner that might interference with the 'comfortable enjoyment of life or property." Id. (quoting Acuna, 929 P.2d at 615). Further, this case does not raise concern that "floodgates" of litigation will open against a company that sells any product with a known risk of harm. Plaintiff's case against Walgreens is not based on dispensing controlled substances with known risks of harm—it is based on Walgreens' fifteen-year violation of federal regulations that were put in place to prevent the controlled substances that Walgreens dispenses from causing harm. See Ileto, 349 F.3d at 1214–15. Walgreens' conduct in dispensing opioids—not the opioids themselves—is the fundamental cause of the harm here.

#### C. **Substantial Interference with Public Rights**

Public nuisance law "protect[s] the quality of organized social life." See People ex rel. Gallo, 14 Cal. 4th at 1090. "A public nuisance is one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted up individuals may be unequal." Cal. Civ. Code § 3480. "[P]ublic nuisances are offenses against, or interferences with, the exercise of rights common to the public." People ex rel. Gallo, 14 Cal. 4th at 1103. The California Supreme Court has recognized five categories of public rights that can give rise to a claim for a public nuisance—"the public health, the public safety, the public peace, the public comfort or the public convenience." Id.

Throughout this case, Walgreens has argued that a public nuisance claim requires Plaintiff to identify discrete conduct or conditions that are abatable. See, e.g., Joint Motion for Summary Judgment (dkt. 987-2) at 8-12. Walgreens contends that "every California public nuisance decision" involves "well-defined conduct" like "emitting noxious odors" or "a well-defined hazardous condition" like water pollution or lead paint in home. See id. at 8. Walgreens argues that to be actionable, a nuisance claim must involve discrete conduct or conditions that can be remedied through abatement. See id.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

California courts have repeatedly rejected Walgreens' "ability to abate" argument. See ConAgra, 17 Cal. App. 5th at 109; see also Cnty. of Santa Clara v. Atl. Richfield Co., 137 Cal. App. 4th 292, 306 (2006). "[L]iability for nuisance does not hinge on whether the defendant owns, possesses or controls the property, nor on whether he is in a position to abate the nuisance; the critical question is whether the defendant created or assisted in the creation of the nuisance." Santa Clara, 137 Cal. App. 4th at 306; People v. Purdue Pharma L.P., 2021 WL 8154036, at \*10 (Cal. Super. Mar. 12, 2021) ("The Court declines to limit what qualifies as a nuisance to 'discrete, identifiable conditions' since it is not a requirement in the public nuisance statute or the cases interpreting it.").

Consistent with the case law, California statute broadly defines a nuisance as:

"Anything which is injurious to health, including, but not limited to, the illegal sale of controlled substances, or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property, or unlawfully obstructs the free passage or use, in the customary manner, of any navigable lake, or river, bay, stream, canal, or basin, or any public park, square, street, or highway, is a nuisance."

Cal. Civ. Code § 3479 (emphasis added).

At trial, Plaintiff proved that the opioid epidemic, defined by high rates of opioid abuse, addiction, and overdoses, constitutes a public nuisance. Plaintiff further proved that the opioid epidemic interferes with all five categories of public rights recognized by the California Supreme Court—"the public health, the public safety, the public peace, the public comfort or the public convenience." People ex rel. Gallo, 14 Cal. 4th at 1103. And Plaintiff proved that Walgreens substantially contributed to the opioid epidemic in San Francisco, which has caused widespread harm across the city and interfered with public peace, comfort and convenience.

Plaintiff proved that Walgreens substantially contributed to an opioid epidemic with far-reaching and devesting effects across San Francisco. Abuse of opioids, opioid-related medical conditions, and opioid overdoses have increased markedly in the last twenty years. People suffering from opioid addiction use opioids on streets and in parks throughout the city. Widespread opioid use exacerbates crime and fuels the market for illegal opioids.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Patients suffering from various opioid-related conditions overwhelm the city's hospitals. The challenge of responding to daily calls of opioid overdoses taxes the city's emergency service teams. Many of the victims of opioid overdoses have previously received medical services but continue to battle addiction. The city has created special paramedic teams to respond to the severity of opioid abuse across its neighborhoods. Library staff have received special training on how to administer naloxone in response to opioid overdoses. Libraries have been forced to close after syringe-clogged toilets overflowed. Excrement and refuse attributable to opioid use can be found on streets across the city. The city has had to open new restrooms and syringe disposal sites in an effort to reduce the amount of waste on the streets. Streets, sidewalks, and parks throughout the city have nevertheless been forced closed due to opioid-related hazards. Dozens of syringes have been found in the sandbox at children's playgrounds and in the children's reading area at the city library. City staff have been stuck with syringes, encountered opioid users overdosing, confronted opioid-related violence, and found dead bodies. The effects of the opioid epidemic on San Francisco have been catastrophic. The city has fought hard and continues to do so, but the opioid epidemic, which Walgreens helped fuel, continues to substantially interfere with public rights in San Francisco.

#### III. **CONCLUSION**

For the foregoing reasons, Plaintiff has proven by a preponderance of the evidence that Walgreens substantially contributed to the public nuisance in San Francisco.<sup>36</sup> A subsequent trial will be held to determine the extent to which Walgreens must abate the public nuisance that it helped to create.

#### IT IS SO ORDERED.

Dated: August 10, 2022

CHARLES R. BREYER United States District Judge

<sup>&</sup>lt;sup>36</sup> In light of the findings stated herein, Walgreens' motion for judgment on partial findings is denied.