

## **INTRODUCTION**

1. The following Statement of Facts is incorporated by reference as part of the deferred prosecution agreement (the “Agreement”) between the United States Attorney’s Office for the Southern District of New York (the “Office”) and Rochester Drug Co-operative, Inc. (“RDC”).

2. The parties agree and stipulate that the information contained in this Statement of Facts is true and accurate.

## **OVERVIEW**

3. RDC is a regional wholesale drug cooperative, headquartered in Rochester, New York, that distributes, among other things, controlled substances to independently owned pharmacies in several states. During the relevant time period, RDC was the fourth largest wholesale distributor in New York and one of the nation’s ten largest distributors, with over 1,300 pharmacy customers and over \$1 billion in revenue.

4. RDC’s conduct, as described herein, violated Title 21, United States Code, Sections 841 and 846, because RDC distributed controlled substances to pharmacies that it knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes, and Title 18, United States Code, Section 371, and Title 21, United States Code, Section 842(a)(5) and (c)(2)(A), because RDC sought to obstruct and obscure U.S. Drug Enforcement Administration (“DEA”) oversight of the company’s practices, including by misrepresenting to the DEA the company’s due diligence practices and knowingly failing to file suspicious order reports with the DEA regarding some of RDC’s customers’ suspicious orders.

5. Specifically, from at least in or about January 2012, up to and including in or about March 2017, RDC violated the federal narcotics laws by distributing controlled substances – including opioids such as oxycodone and fentanyl – to pharmacy customers that RDC knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes. Among other things, RDC dispensed controlled substances to pharmacy customers that its own compliance department had concluded displayed “red flags” associated with diversion of controlled substances, including, but not limited to, dispensing large quantities of highly-abused controlled substances, purchasing little else besides those controlled substances, dispensing controlled substances in quantities consistently higher than accepted medical standards, accepting a high percentage of cash from patients purchasing controlled substances, dispensing to out-of-area patients, filling prescriptions issued by practitioners who were on RDC’s “watch list” or under DEA investigation, or being terminated by another distributor. Nonetheless, despite these warnings, RDC continued to sell controlled substances – including oxycodone and fentanyl – to these customers, opened new accounts without conducting due diligence before opening, and delayed or avoided terminating pharmacy customers that RDC knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes.

6. Additionally, during the same period, RDC made false statements to the DEA regarding its program for maintaining controls against the diversion of controlled substances. Specifically, since at least 2007, RDC was aware that it was required by law to maintain a program to guard against diversion of controlled substances by its customers, and that RDC needed to report

to the DEA those orders and customers that appeared suspicious. RDC repeatedly represented to the DEA that it had standard operating procedures for conducting due diligence on customer accounts and reporting suspicious orders to the DEA. These statements were untrue. Rather, RDC opened new accounts for pharmacy customers without first conducting due diligence on the pharmacies; released orders of controlled substances to pharmacies that RDC believed were dispensing those controlled substances for other than legitimate medical purposes; increased order limit thresholds so that pharmacies could increase the amounts of controlled substances they were ordering from RDC; shipped orders that RDC's compliance program deemed to be suspicious; and knowingly failed to report suspicious orders to the DEA. During the relevant time period, from 2012 until 2017, RDC's senior management, including the company's chief executive officer ("Executive-1"), were involved in and directed such conduct, and concealed RDC's practices from the DEA, the company's primary regulator.

### **THE CONTROLLED SUBSTANCES ACT'S REQUIREMENTS**

7. The Controlled Substances Act ("CSA") regulates the manufacturing, distribution, and use of substances that have a detrimental effect on public health and welfare. *See* 21 U.S.C. § 801, *et seq.* Under Title 21, United States Code, Section 841(a)(1), it is illegal to distribute a controlled substance except where an individual or entity is expressly authorized "to possess, manufacture, distribute, or dispense [controlled] substances . . . in conformity with the other provisions" of the CSA. 21 U.S.C. § 822. This form of licensure, which is referred to as a DEA registration, is required for a doctor, pharmacist, distributor, manufacturer, or other practitioner to prescribe or otherwise handle prescription controlled substances.

8. The CSA also gives the DEA the authority to administer and regulate the legitimate manufacturing, prescribing, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs, along with civil and criminal

penalties for transactions outside the legitimate chain. *See* 21 U.S.C. §§ 878, 880. As part of its grant of authority under the CSA, the DEA promulgates regulations, which are codified in the Code of Federal Regulations, to prevent the diversion of controlled substances from legitimate channels. Additionally, in order to investigate activity related to the unlawful distribution of controlled substances effectively, the DEA conducts audits, reviews distribution data provided by wholesalers, obtains reports of suspicious activity from distributors and manufacturers, and utilizes other law enforcement techniques to detect the diversion of controlled substances.

9. To combat the high potential for abuse of certain controlled substances, the CSA and DEA implementing regulations create a distribution monitoring system for those authorized to handle controlled substances, at the heart of which are registration, tracking, and reporting requirements. The CSA mandates strict adherence to a number of these requirements by any person or entity that distributes controlled substances.

10. Under the CSA, as a registered distributor, RDC is required to maintain “effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). Additionally, DEA regulations provide that distributors are required to maintain effective controls and procedures to guard against theft and diversion of controlled substance. *See* 21 C.F.R. § 1301.71. In determining whether a distributor has implemented such effective controls, the DEA looks to whether the distributor has implemented the physical and operational security requirements outlined in 21 C.F.R. §§ 1301.72-1301.76. Among the physical and operation security requirements described in that section is the requirement that a person or entity that distributes controlled substances must report suspicious orders of controlled substances. *See* 21 C.F.R. § 1301.74(b). Specifically, distributors of controlled substances must design and operate a system to disclose suspicious orders of controlled

substances, and report any discovered suspicious orders to the DEA. *See id.* Suspicious orders include “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*

11. RDC was aware of these obligations. In 2006 and 2007, the DEA sent letters to all DEA-registered distributors of controlled substances, including RDC, that discussed the requirements of 21 C.F.R. § 1301.74(b) and contained guidance for the identification and reporting of suspicious orders to the DEA (the “DEA Letters”). Specifically, on or about September 27, 2006, RDC received a letter from the DEA “to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem [the] nation [was] facing.” In that letter, the DEA reminded RDC of its obligation to “report suspicious orders of controlled substances,” as defined in 21 C.F.R. § 1301.74(b), to the DEA, and “exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” Additionally, on or about December 27, 2007, RDC received another letter from the DEA “to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b).” In that letter, the DEA stated that the “regulation clearly indicates that it is the sole responsibility of the registrant to design and operate [a system to disclose to the registrant suspicious orders of controlled substances].” That letter concluded that “registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion.”

12. From in or about 2006 up to and including 2017, RDC was also advised by DEA agents, contracted compliance auditors, speakers at industry conferences, and attorneys of the

obligations imposed on distributors to maintain effective controls against the diversion of controlled substances.

### **THE OPIOID EPIDEMIC**

13. Since before RDC received the DEA Letters in 2006 and 2007 citing the nationwide “prescription drug abuse problem,” and continuing for at least the next decade, the United States saw a dramatic rise in the use and abuse of oxycodone and fentanyl, two highly addictive, narcotic-strength opioids. These opioids, both of which are distributed by RDC, are used to treat severe and chronic pain conditions, such as post-operative pain, serious back and orthopedic injuries, as well as pain associated with certain forms of cancer and other terminal illnesses. Oxycodone, which is dispensed as a pill, and fentanyl, which is dispensed as a patch or spray, can only be obtained from pharmacies with a prescription written by a treating physician, or other authorized health care practitioner.

14. RDC’s compliance department and senior management were well-aware of the highly addictive qualities and frequent abuse of opioids such as oxycodone and fentanyl, which abuse can lead to opioid dependence, addiction, and the use of illicit narcotics such as heroin. Indeed, in October 2014, an RDC sales representative shared a report from the National Institute of Health with Executive-1, the chief operating officer (“Executive-2”), and other employees in RDC’s compliance and sales department, which found that “[t]he United States is in the midst of a prescription drug abuse epidemic as addiction, overdoses and deaths associated with medical drug use have risen dramatically.” RDC’s own employees also circulated data from the Center for Disease Control (“CDC”), the DEA, and other trade publications relating to the rampant abuse of opioids in the United States. According to a CDC report distributed within RDC’s compliance department, prescription drug overdoses kill more than one American every hour, and opioid-

related deaths have reduced the average life expectancy in the United States. Between 1999 and 2017, nearly 400,000 people in the United States died from an opioid overdose. This number is on the rise; since 2015, there have been 28% more opioid related deaths in the United States. Thus, the rise in the use and abuse of opioids has, according to government data shared within RDC, resulted in the deaths of hundreds of thousands of individuals. The dramatic increase in opioid abuse has had significant collateral consequences: millions of children nationwide have a parent who suffers from opioid substance abuse and the cost of opioid treatment is a substantial financial strain on the Medicare and Medicaid programs.

15. RDC was aware of the opioid epidemic, its costs, and law enforcement's focus on preventing the diversion of controlled substances. For example, between 2012 and 2017, Executive-1, Executive-2, and the chief compliance officer (the "Compliance Officer"), among others, were routinely copied on emails discussing the opioid epidemic, and the prosecution of pharmacists for running "pill mills," and doctors for their unlawful prescribing habits. RDC was also aware that law enforcement authorities were looking to distributors, like RDC, to assist in detecting and identifying pharmacies and doctors whose dispensing and prescribing practices were contributing to the opioid epidemic. For instance, in February 2012, following the public announcement of the DEA's investigation into another distributor for violations of the CSA, Executive-1 advised his senior management team, including Executive-2 and the Compliance Officer, that RDC "need[s] to stay very low profile" to avoid drawing "media" attention "with regards to [its] distribution of controlled drugs."

#### **THE GROWTH IN SALES BY RDC OF CONTROLLED SUBSTANCES**

16. Despite the emerging consensus about the opioid epidemic, and the steady rise in opioid-related deaths, RDC's controlled substances sales grew dramatically over the relevant time

period. Beginning in 2012, RDC's total sales grew considerably, in large part due to its rapid expansion of controlled substance sales. Specifically, in 2012, RDC distributed 4,743,500 tablets of oxycodone and, in 2013, it distributed 4,442,900 tablets of oxycodone. Those oxycodone sales numbers increased dramatically over the next three years: in 2014, RDC distributed 24,031,500 tablets; in 2015, the company distributed 44,306,430 tablets; and in 2016, it distributed 42,233,650 tablets. Similarly, RDC's distribution of fentanyl grew at an exponential rate: in 2012, it distributed 63,497 dosages; in 2013, that figure increased to 660,213 dosages; in 2014 and 2015, RDC distributed, respectively, 2,287,896 and 2,377,479 dosages; and in 2016, RDC distributed 1,316,115 dosages. Over the same period of time, the percentage of RDC's revenues from sales from controlled substances listed on Schedule II of the CSA increased from 5.3% in 2012 to 10.5% in 2015. It was also during this period that RDC added larger, higher volume pharmacy customers – customers that purchased increasing amounts of controlled substances. As a result, from fiscal year 2012 through fiscal year 2016, controlled substances represented approximately 14.6 percent of RDC's revenues, for a total of approximately \$1.2 billion in controlled substances sales.

17. The growth in RDC's revenues from 2012 through 2016 directly benefited RDC's largest purchasers of controlled substances. Specifically, RDC is a stock cooperative with approximately 310 shareholders, including RDC's largest pharmacy customers. On an annual basis, RDC makes distributions, called "patronage dividends," to its shareholder pharmacy customers, which are calculated based on the amount of drugs and other products that the pharmacy purchased from RDC during a year. Accordingly, the pharmacies that purchase the most from RDC receive the largest dividend payments each year. For example, for fiscal year 2015, RDC's total patronage dividend distributions were \$31,068,406. In the same year, RDC's largest



customer, based in Woodbury, New York (“Pharmacy-1”) – which was also one of nation’s largest dispensers of Subsys, a highly-addictive fentanyl spray, – received a dividend of \$10,567,921.

18. RDC’s increase in controlled substance sales – and the corresponding increase in the distribution of controlled substances – also benefited Executive-1, whose compensation was directly tied to RDC’s pre-patronage dividend earnings. Specifically, beginning with a nine-year contract in 2005, RDC paid Executive-1 an annual base salary of several hundred thousand dollars, plus a substantial bonus based on RDC pre-patronage dividend earnings and/or cash flow. Under a five-year contract renewal in 2014, the bonus was approximately 2.5 percent of RDC’s adjusted net earnings – which was calculated before RDC’s dividend was paid, and before state and federal taxes – as well as an additional bonus of one percent of RDC’s net cash flow, until Executive-1 retired as CEO in 2017. As a result of this arrangement, in 2012, Executive-1 received approximately \$660,093 in total compensation; in 2013, he was paid approximately \$739,833; in 2014, he was paid approximately \$960,214; in 2015, he was paid approximately \$1,529,633; in 2016, he was paid approximately \$1,501,018; and in 2017, the year he retired as CEO, Executive-1 was paid approximately \$1,238,651. Executive-1’s bonuses, which were never fully disclosed to the board of RDC or its shareholders, increased in amount as RDC’s sales of controlled substances grew, which created a significant monetary incentive to bring on new customers that posed significant risks under the CSA.

### **RDC’S DIVERSION OF CONTROLLED SUBSTANCES**

#### **RDC’s Policies and Procedures Regarding the Diversion of Controlled Substance**

19. Since at least 2011, RDC has had policies regarding the company’s procedures for preventing the diversion of controlled substances to illegitimate channels. Consistent with the CSA and DEA implementing regulations, those policies set forth due diligence to be conducted by

RDC's compliance department to identify "red flags" of diversion of controlled substances to illegitimate channels. Those policies, which were amended from time to time during the relevant period, identified "red flags" that "indicate that a pharmacy may be dispensing controlled substances for other than legitimate medical purposes" to individuals who were diverting or abusing the substances. Those "red flags" included, among other things, pharmacies that were "[d]ispensing highly-abused controlled substances" in large quantities, purchasing "only controlled substances and little else," "[d]ispensing quantities consistently higher than accepted medical standards," "[a]ccepting a high percentage of cash from patients," "[d]ispensing to out-of-area or out-of-state patients," and "[f]illing controlled substance prescriptions issued by practitioners acting outside the scope of their medical practice or specialty."

20. RDC's compliance department had primary responsibility for RDC's fulfillment of its obligations under the CSA. Up until March 2017, the compliance department was supervised by RDC's Compliance Officer, who reported directly to Executive-1 and Executive-2. After November 2013, the compliance department was staffed by one or more compliance specialists, who were tasked principally with reviewing orders and dispensing data, and field auditors, who were tasked principally with visiting pharmacies to conduct due diligence. As part of its due diligence on customer accounts, RDC's compliance staff reviewed pharmacies' DEA registrations, licenses, and account applications; the field auditors visited the pharmacies; and the compliance specialists reviewed the pharmacies' dispensing data to look for the "red flags" identified in RDC's policies. RDC's compliance staff also maintained what was referred to as a "watch list," "exclusion list," or "do not fill list" of physicians who had been arrested, investigated by state or federal government agencies, subject to state administrative proceedings, or whom RDC compliance personnel had identified as engaging in suspicious prescribing practices. RDC's

compliance specialists were trained that customer due diligence included, among other things, reviewing dispensing data to see if pharmacies were filling prescriptions written by suspect physicians on the compliance department's "watch list."

21. RDC's senior management, including Executive-1 and Executive-2, were involved in compliance decision-making and were aware of RDC's legal obligation to maintain effective controls against diversion. Specifically, on multiple occasions, the Compliance Officer, other RDC employees, RDC's counsel, contracted compliance consultants, and law enforcement officers apprised Executive-1 and Executive-2 of the company's obligations under the CSA. For example, on or about February 3, 2014, a compliance consultant instructed the company's senior management, including Executive-1 and Executive-2, that "[a]s a distributor, [the company] need[ed] to comply with the DEA 'Know-Your-Customer' Due Diligence policy," which requires RDC to collect and analyze customers' controlled substances dispensing data in order to prevent diversion. The compliance consultant further warned that the company could be placed in the DEA's "cross-hairs . . . because of [its] willful blindness and deliberate ignorance." The compliance consultant explained that RDC could be in legal jeopardy by distributing controlled substances to customers "that are dispensing controlled substances not for legitimate medical purposes, accepting controlled substances prescriptions from bad doctors or accepting 'cash' only for bad prescriptions."

22. RDC also notified its customers of its obligation under the CSA to maintain effective controls against the diversion of controlled substances to illegitimate channels, and to identify the "red flags" that RDC represented it looks for in reviewing customers' orders.

### **RDC Failed to Provide Necessary Resources to CSA Compliance**

23. Despite RDC's obligation to maintain effective controls against the diversion of controlled substances, it failed to properly staff or provide sufficient resources to its compliance department, which was tasked with maintaining those controls against diversion. In 2012, the only individuals in the compliance department were the Compliance Officer, who had no prior experience or training in compliance, and an administrative assistant. Gradually, RDC hired additional employees, but up until 2017, RDC only had a handful of employees working in the compliance department, many of whom had little or no background in compliance.

24. In addition, from at least 2013 through 2016, Executive-1 complained to senior management, including Executive-2 and the Compliance Officer, about the financial burden of compliance efforts. For example, in March 2015, Executive-1 wrote to the Compliance Officer and Executive-2 that "[I] can't believe how much we have stuck in this compliance thing . . . Remember we don't know if we are wrong or right and there is NO return on what we are doing." Likewise, in July 2015, Executive-1 wrote to senior management that the company would not "be adding any more help" to its compliance department, despite the growth in sales by RDC of controlled substances. In addition, in August 2016, Executive-1 wrote to Executive-2 and the Compliance Officer that Executive-1 was "pissed at the BS we deal with on the DEA business now and the adverse effects it has had on business over the past three years." Even after RDC's outside counsel confronted Executive-1 in 2014 and 2015 about the compliance department having insufficient resources, Executive-1 refused to hire the number of employees requested by the Compliance Officer and recommended by outside consultants.

25. As a result of Executive-1's staffing decisions, RDC's compliance department lacked the training and resources to effectively monitor RDC's sales of controlled substances, and on many occasions shipped orders of controlled substances without conducting due diligence.

**RDC's Distribution of Controlled Substances to Pharmacies Engaged in Illicit Activity**

26. Throughout the relevant period, RDC routinely distributed controlled substances – including opioids such as oxycodone and fentanyl – to pharmacy customers that displayed “red flags” associated with diversion of controlled substances. RDC's compliance department, and in many cases RDC's senior management, knew, should reasonably have known, and intentionally avoided confirming that those pharmacy customers were diverting controlled substances to illegitimate channels.

27. From at least 2012 through 2016, for over one hundred customers, RDC's compliance department identified “red flags” of unlawful distribution of controlled substances, but nonetheless continued to ship controlled substance orders to those customers. Indeed, in a September 2014 memorandum by RDC's outside legal counsel to Executive-1, which was prepared following meetings with the compliance department's staff and shared with Executive-2, RDC's legal counsel estimated that “approximately 125 pharmacy customers currently require further due diligence” to ensure they were dispensing controlled substances in compliance with the law.

28. Specifically, RDC's compliance department observed the following types of “red flags” – all of which were listed in RDC's due diligence policies – associated with RDC's pharmacy customers' dispensing:

a. Many of RDC's customers – including some of RDC's largest customers – were purchasing and dispensing large quantities of highly-abused controlled substances, and little

else. In particular, the majority of the purchases made by Pharmacy-1, RDC's largest customer during the relevant period, were for controlled substances, including oxycodone and fentanyl. Pharmacy-1 was RDC's largest Subsys purchaser. Additionally, Pharmacy-1 was a large purchaser of oxycodone; not only did Pharmacy-1 purchase at least twenty percent more oxycodone than any other RDC customer, but the size of those purchases grew at an exponential rate. For instance, between October 2012 and October 2013, Pharmacy-1 went from purchasing approximately 70,000 units of oxycodone per month to over 200,000 units per month. Similar patterns of ordering growth continued into 2016. RDC's compliance department, including the Compliance Officer, flagged Pharmacy-1's ordering as suspicious on multiple occasions, stating, for instance, "We can have all the documentation in the world, but I personally feel this is too high for RDC and I think we should not allow them to exceed 80,000 units a month." Similarly, toward the end of 2013, based on dispensing information provided by the compliance department, Executive-2 told Executive-1 that he was "very concerned with the growth of Subsys at [Pharmacy-1]" and his "gut feeling is the risk is to [sic] great versus the reward" and "that [Pharmacy-1] could potentially become a real problem for RDC." Notwithstanding these concerns, RDC continued to supply Pharmacy-1 with oxycodone and fentanyl until approximately June 2017. RDC's concern about the quantities of controlled substances its customers were ordering was not limited to Pharmacy-1. Rather, for multiple other pharmacies, RDC's compliance department regularly noted to senior management, including Executive-1, Executive-2, and the Compliance Officer, customers that were predominantly buying large quantities of highly-abused controlled substances.

b. Certain RDC customer pharmacies were dispensing quantities of controlled substances that were consistently higher than accepted medical standards. This included, in

particular, prescriptions for thirty-day supplies of 180 or more oxycodone 30-milligram tablets, which are the most commonly diverted and abused form of oxycodone. For example, RDC's compliance department found that two pharmacies located in New York City that shared the same owner were, among other things, distributing high monthly dosages of oxycodone 30-milligram tablets, leading RDC's compliance department to conclude that the pharmacies exhibited "red flags" indicating that they were likely engaged in illicit activity. Indeed, as one of RDC's contracted field auditors told Executive-2, the Compliance Officer, and others, the dispensing at those pharmacies was "very high and the average dispensed is like a stick of dynamite waiting for [the] DEA to light the fuse." RDC's compliance staff made similar observations about dispensing for multiple other pharmacy customers. Nevertheless, RDC continued to supply some of those pharmacies distributing high monthly dosages of oxycodone even after RDC's compliance department identified the "red flag" in the pharmacies' dispensing data.

c. Certain RDC customer pharmacies were accepting cash from a large percentage of patients obtaining highly-abused controlled substances, such as oxycodone and fentanyl. Patients paying in cash for controlled substances is a "red flag" of diversion because cash transactions can be concealed from detection by insurance companies, state regulators, and law enforcement. The DEA and outside auditors repeatedly informed RDC throughout the relevant period that pharmacies that accepted more than ten percent of its payments for controlled substances in cash were exhibiting a "red flag" of diversion of controlled substances. During that same time period, RDC's compliance department identified multiple customers who accepted cash payments that greatly exceeded the ten percent threshold, and RDC continued to distribute controlled substances to those customers. For example, in September 2014, a member of RDC's compliance department determined that a pharmacy customer of RDC in Pittsburgh, Pennsylvania ("Pharmacy-2") was

distributing large quantities of suboxone – an opioid used to treat opioid addiction, which is also frequently abused – and that approximately sixty percent of the suboxone prescriptions filled were paid for in cash. When RDC’s compliance department contacted Pharmacy-2, the pharmacy explained that ninety-five percent of its cash-paying customers were from a neighboring state with prescribing limits that caused them to travel across the border, which was itself a “red flag” of diversion. One of RDC’s consulting field auditors raised the issue with Executive-1, noting that this was “a DEA investigation in the making,” but while Executive-1 agreed that it was not “going to end well,” RDC did not cease doing business with Pharmacy-2. Instead, after one of RDC’s auditors visited the pharmacy, the clinic that was referring individuals to Pharmacy-2 started “insuring” its cash-paying customers so that the percentage of prescriptions paid for in cash at Pharmacy-2 decreased. But despite such manipulation, RDC did not investigate Pharmacy-2 further and did not terminate Pharmacy-2 as a customer until May 2018, when RDC learned that Pharmacy-2 was under investigation for diversion of controlled substances.

d. RDC’s compliance department also identified multiple pharmacy customers that were filling prescriptions for patients who had traveled from great distances – including from different states – to fill prescriptions for controlled substances. The fact that a pharmacy fills prescriptions for patients who have traveled from long distances – and likely passed by pharmacies that are close and more convenient – is a “red flag” of diversion because it indicates that pharmacies local to the patients refused to fill the patients’ prescriptions. As was the case with Pharmacy-2, RDC distributed controlled substances to customers that had a significant number of customers traveling from great distances to obtain controlled substances, and continued to distribute to those customers even after RDC’s compliance department had identified the “red flag” and reported it to the Compliance Officer and senior management.



e. RDC's compliance department also noted, in reviewing dispensing data, that pharmacy customers were filling prescriptions issued by practitioners who were prescribing controlled substances outside the scope of their medical practice or specialty, on RDC's "watch list," or under DEA investigation. Indeed, RDC supplied multiple pharmacies that filled prescriptions written by physicians who were under DEA investigation and were later prosecuted and convicted for diverting controlled substances, including Dr. Robert Terdiman, Dr. Kevin Lowe, Dr. Rogelio Lucas, Dr. Ernesto Lopez, Dr. Martin Teshler, and Dr. David Taylor, among others. All of these physicians were flagged on RDC's watch list, and yet RDC continued to distribute controlled substances to pharmacies that had filled prescriptions they wrote.

29. The concerns RDC's compliance department expressed about the dispensing of numerous pharmacy customers and the "red flags" of diversion were conveyed to RDC's senior management, including Executive-1. Specifically, the Compliance Officer regularly apprised RDC's senior management of compliance problems with particular pharmacies by email, and also at regular in-person meetings (and later, during the relevant period, on telephone calls) with Executive-1 and Executive-2. Additionally, and taken together, the number of "red flags" associated with RDC customers prompted various employees and managers at RDC to conclude that there were substantial and pervasive compliance issues with RDC's customers. Indeed, in January 2013, RDC's head of sales commented to Executive-1, Executive-2, and the Compliance Officer that "we have some VERY suspicious customers due to their buying" and "[i]f anyone other than [the Compliance Officer] were to look [at] the reports" it would be a "scary story." RDC employees, including Executive-2 and the Compliance Officer, frequently expressed similar sentiments about RDC's customers to Executive-1.

30. Nonetheless, despite the fact that RDC routinely observed “red flags” surrounding the dispensing of multiple customers, the company – at the direction of Executive-1 – largely ignored these warning signs, continued to distribute controlled substances to customers that were illegitimately dispensing these narcotics, and refused to terminate or cut off sales of controlled substances to those customers. Executive-1 made the decisions not to terminate RDC’s relationship with customers that RDC’s compliance department determined were likely diverting controlled substances. Executive-1 instructed RDC’s employees to “educate and work with [its] customers” instead of cutting them off. In fact, and as reflected in an email the Compliance Officer sent to Executive-1, if RDC were to determine that it needed “to stop selling to even one store,” the Compliance Officer would “always consult with [Executive-1] first.” Consistent with that understanding, the Compliance Officer consulted with Executive-1 on the possible cessation of business with customers. The compliance department was always guided by the directions of senior management and, in particular, Executive-1. In general, the guidance Executive 1 provided was to work with a customer and not terminate the relationship.

31. As a result of RDC’s senior management’s directives, RDC rarely terminated its relationships with pharmacy customers, and continued to supply customers with controlled substances for months or years after encountering substantial evidence that the drugs those pharmacies dispensed were being used illicitly. For instance, despite the “red flags” identified by RDC’s compliance department, RDC did not terminate its relationship with Pharmacy-1, Pharmacy-2, or several other problematic pharmacy customers until at least 2017. That was, in part, because RDC’s senior management directed the compliance department to work with RDC’s problematic customers – in particular, customers who were shareholders, board members, or owed debts to RDC – and not terminate them. In total, from 2012 through February 2017, RDC only

terminated its relationship with seventeen of its 1,300 pharmacy customers, and in multiple cases, the reason for termination was not compliance related.

32. In almost every case, RDC terminated its relationship with pharmacy customers for compliance reasons only when the customer refused to comply with RDC's requests or when a continued relationship with the customer exposed RDC to immediate legal consequences. For example, in March 2015, if not earlier, RDC's compliance department identified a New York City pharmacy ("Pharmacy-3"), which was one of RDC's largest customers and an RDC shareholder, as a "large concern of RED FLAG diversions [sic]." Those "red flags" identified by the compliance department included dispensing a large amount of oxycodone and Subsys; more than thirty percent of payments in cash; filling prescriptions written by doctors who were under investigation by the DEA; routinely exceeding its controlled substance order thresholds; and filling prescriptions for patients coming from out-of-state. Specifically, in March 2015, following an onsite visit at the pharmacy, one of RDC's compliance auditors noted that Pharmacy-3 was "really bad with prescribers we do not care for." Those concerns continued for months even as RDC continued to distribute controlled substances to Pharmacy-3. For instance, in September 2015, one of the employees in RDC's compliance department noted that Pharmacy-3 "continue[s] to fill for cash and doctors who are suspicious and have been warned against" and concluded that Pharmacy-3 was "a risk . . . and shouldn't be a customer." Another RDC employee around the same time described the dispensing at Pharmacy-3 as "evil," and in October 2015, one of RDC's compliance auditors again noted "the previously communicated concerns of the RDC Compliance Team regarding the pharmacy's filling [] of questionable controlled substances prescriptions written by several physicians." Despite concerns from RDC's compliance personnel about Pharmacy-3, RDC continued supplying the pharmacy until November 2015. Indeed, just weeks

before RDC terminated Pharmacy-3 as a customer, one of RDC's compliance department employees told two other employees, "I can't tell you not to release orders if [the Compliance Officer] tells you to do so, but I wouldn't let them go over their limits. It makes me sick to my stomach to see they purchased so much from us last month." RDC ultimately terminated the pharmacy only after it refused to cooperate with RDC and, among other things, allow RDC to review its dispensing reports.

**RDC'S MISREPRESENTATIONS TO THE DEA AND  
WILLFUL FAILURE TO FILE SUSPICIOUS ORDER REPORTS**

**RDC's Compliance Policies and Representations to the DEA**

33. At the time RDC received the DEA Letters in 2006 and 2007, it had no system in place to identify or report suspicious orders of controlled substances. After receiving the letters, in 2007 or early 2008, Executive-1 instructed the Compliance Officer to develop a program to identify and monitor suspicious orders. The Compliance Officer consulted Executive-1 and Executive-2, along with other members of RDC's senior management, in designing the suspicious order monitoring program and formulating the accompanying suspicious order monitoring guidance. In or about March 2009, RDC completed its system for identifying suspicious orders and reporting those orders to the DEA. In general, RDC's program identified "orders of interest," which were controlled substance orders that exceeded predetermined ordering thresholds set for a customer. If an identified order was "suspicious" because it was of an unusual size, deviated from a customer's normal pattern of ordering, was of an unusual frequency, or was likely to be diverted from legitimate channels, then RDC's compliance department was required, as part of the program, to report the order to the DEA and not ship the order to the customer. In or about June 2009, the DEA visited RDC as part of a regularly-scheduled audit, and at that time, RDC showed the DEA

its computer system for identifying suspicious orders and explained its suspicious order reporting procedure, including that it would report to the DEA all orders that it had identified as suspicious.

34. At the June 2009 audit, and at subsequent visits by, in conversations with, and in letters to the DEA, RDC represented to the DEA that it had a standard operating procedure relating to conducting due diligence on customer orders. For instance, in a March 2012 letter to the DEA, RDC stated that it was using a system to monitor its sales of controlled substances, and as part of its program, “any order that [was] placed and would go over the customer’s usage . . . would be stopped” until “proper documentation from [the] customer [was] obtained.” Again, in or about July 2013, RDC provided to the DEA a copy of its standard operating procedure for identifying suspicious orders.

35. In September 2014, RDC received a legal opinion from its outside counsel, which was sent to Executive-1 and later shared with Executive-2, regarding RDC’s compliance with its legal obligation to identify and report suspicious orders to the DEA. That legal opinion reviewed RDC’s legal obligation, pursuant to 21 C.F.R. § 1301.74(b), to report suspicious orders to the DEA, and recommended, among other things, that RDC make changes to its compliance program. In late 2014, RDC’s outside counsel was tasked with working with RDC, including the Compliance Officer, to draft a revised standard operating procedure for suspicious order reporting. That revised standard operating procedure for conducting customer due diligence and suspicious order monitoring was finalized in or about January 2015. The 2015 policy provided that “[p]rior to selling controlled substances to any customer, RDC must obtain, review, and verify . . . drug dispensing data,” and “will assess whether each prospective . . . customer dispenses controlled substances for legitimate medical purposes.” The policy also identified RDC’s legal requirement to report suspicious orders, pursuant to 21 C.F.R. § 1301.74(b), and provided that “RDC will

review and monitor every controlled substance order to determine whether they are suspicious orders that cannot be filled and must be reported to DEA.” RDC subsequently shared its 2015 policy with the DEA, including in connection with its application for a license to operate a new facility in Fairfield, New Jersey.

36. In November 2016, the DEA conducted an audit of RDC’s facility in Rochester, New York. Following that audit, in January and February 2017, RDC’s customer due diligence and suspicious order reporting policy were revised. At no time between the revision in January 2015 and January 2017 did RDC make any written change to its customer due diligence and suspicious order reporting policy, or notify the DEA of any change in its due diligence and reporting procedures.

#### **The Consent Decree**

37. In or about August 2013, the DEA and the Office initiated an investigation regarding RDC’s failure to file with the DEA automated, comprehensive drug reporting system (“ARCOS”) reports, which are monthly reports of all sales and shipments of controlled substances by a manufacturer or distributor. On July 8, 2015, RDC entered into a consent order in the Southern District of New York (the “Consent Decree”), in which RDC admitted to CSA violations for failing to properly file ARCOS reports with DEA from 2012 to 2014. RDC paid a \$360,000 civil penalty in connection with the Consent Decree, and was required to cure its prior reporting failures by compiling and re-reporting the missing ARCOS data for the DEA. In connection with the negotiations surrounding the Consent Decree, representatives of the DEA and the Office reminded RDC about its obligations under the CSA to, among other things, report suspicious orders to the DEA. Approximately one week after the entry of the Consent Decree, Executive-1

stated in an email to other RDC employees, “I spoke to some stores today about this and they said they completely understand that the DEA is fining everyone and \$360 is a low number.”

### **RDC’s Opening of Accounts Without Conducting Due Diligence**

38. In early 2015, after RDC and its outside counsel finalized the revised 2015 due diligence and suspicious reporting policy – which had been created, at least in part, in response to the investigation that led to the Consent Decree – the Compliance Officer presented the policy to the company’s sales team, as well as to Executive-1 and Executive-2. The revised policy represented that RDC would, among other things conduct due diligence on all pharmacies’ dispensing practices before onboarding them as customers. Executive-1 and Executive-2 expressed that they did not favor the new policy because of its effect on the company’s sales representatives. In March 2015, for example, Executive-1 lamented to Executive-2 and the Compliance Officer, among others, that “there is NO return” on the company’s compliance program. Around the same time, Executive-2 echoed that sentiment, telling the Compliance Officer that the new policy was not giving the sales team a “fighting chance” when it came to opening new customer accounts.

39. During the same period, RDC was bringing on new customers that concerned the company’s compliance department. Specifically, shortly before the Compliance Officer announced RDC’s revised customer due diligence and suspicious order monitoring policy in 2015, he complained to other members of the compliance department in an email that “all the new stores we are bringing on have baggage.” That was, according to a compliance department field auditor, at least in part, because “everyone is being cut off by [other distributors] and running over to RDC . . . we are picking up rejects from other distributors.” To that, the Compliance Officer responded, “you are making me sick just reading this,” and another compliance department employee added

that she found herself “literally cringing when we have new accounts now because of how the dispensing has looked.” At the direction of Executive-1, however, the RDC sales team continued to open accounts and begin selling to problematic new customers, some of which had previously had their distribution arrangements with other wholesalers terminated. As a result, RDC’s compliance department experienced delays in authorizing the sale of controlled substances to new customers, because compliance department personnel believed it was necessary to scrutinize new customers’ dispensing data before making any sales.

40. In or about July 2015, after receiving complaints from sales representatives about the length of time it was taking for RDC’s compliance department to approve the opening of new accounts, Executive-1 declared that even though he had “no idea if [a new pharmacy customer] is a good guy or bad guy . . . it is taking too long [to open an account] no matter what the problem is.” Executive-1 added in a subsequent email, “I know we have to do due diligence but we have the tail wagging the dog. . . . this HAS to stop. . . . Do the compliance after opening. And close it if it looks funny.” That same month, Executive-1, Executive-2, and the Compliance Officer, among others, met to discuss revising RDC’s 2015 due diligence and suspicious reporting policy to eliminate the requirement that customer due diligence be conducted before opening an account. After the meeting, RDC made the decision to begin opening accounts without completing due diligence on the pharmacies’ dispensing data, and without changing the policy. The Compliance Officer informed Executive-1 and Executive-2 that RDC should formalize this change in writing and notify the DEA of its change in practice, given that the company had previously represented to the DEA that it was conducting due diligence of all new accounts. However, RDC neither changed its written procedures concerning account opening nor notified the DEA of its change in policy.



41. RDC began distributing controlled substances to new customers without conducting due diligence on the customers' dispensing practices. In multiple cases, after bringing on new customers without conducting due diligence and supplying them with controlled substances for months, RDC discovered significant problems in the dispensing records for those customers – including high dosage opioid prescriptions and accepting a high percentage of cash from patients – that indicated the pharmacies were unlawfully distributing controlled substances.

42. In or about June 2016, Executive-1 again pushed to accelerate the process for opening new accounts. Specifically, on June 5, 2016, Executive-1 emailed Executive-2, the Compliance Officer, and members of RDC's sales team: "Based on recent government change[s] I want to accelerate our account opening process. As soon as our credit managers completely approve our credit app we will open an account right away. We will continue to do our diligence on controls but not before we open the account." The "recent government changes" were, according to Executive-1, that "the government has recently told the DEA to lay off wholesalers . . . and concentrate on fixing the problem with more addiction programs." Executive-2 stated that he agreed with Executive-1 that "we should open the account and then conduct the due diligence review." The Compliance Officer responded that if management made the change, he "would suggest that [the company's counsel] change our [standard operating procedure] to state that . . . we made a change." The Compliance Officer emphasized that because the existing standard operating procedure "states that RDC will conduct a review prior to opening [a new customer] to controls," RDC's change should "be documented so we may show DEA when they are in the next time for an audit."

43. In late June 2016, the Compliance Officer sought the opinions of two of RDC's compliance field auditors – both of whom had prior law enforcement experience – about

Executive-1's proposal to open new customer accounts without conducting due diligence. Those employees told the Compliance Officer that they did not agree with changing RDC's approach to due diligence, and their opinions were conveyed to Executive-1 and Executive-2. Executive-1 responded in an email: "That is bullshit!" and insisted on speaking to the auditors. In a subsequent meeting between Executive-1, Executive-2, and the auditors, Executive-1 told the auditors that opening accounts without conducting due diligence would be the company's policy going forward in light of the government's change in enforcement priorities. The auditors told Executive-1 that the change was a mistake from a compliance standpoint because RDC had an obligation under the CSA to know its customers and guard against diversion.

44. At the direction of Executive-1, however, RDC continued to open new customer accounts without conducting due diligence on prospective customers' dispensing. RDC did not amend its written policies or notify the DEA of its change in its account opening practices. For multiple customers that had accounts opened without conducting due diligence, compliance employees subsequently determined that those customers displayed "red flags" of diversion of controlled substances to illegitimate channels.

#### **RDC's Failure to File Suspicious Order Reports with the DEA**

45. Since at least 2009, RDC has operated a system designed to detect suspicious orders. RDC's automated system was created to identify "orders of interest," which were defined by RDC as controlled substance orders that "exceeded normal purchasing patterns." Normal purchasing patterns were established using monthly threshold "allowable limits" for controlled substances, which were calculated based on a multiple of the pharmacy customer's average purchases of the relevant drug family over the preceding 12 months. Whenever a customer exceeded that "allowable limit" threshold, RDC's system held the order and flagged it as an "order

of interest” for RDC’s compliance staff. RDC’s compliance staff was then responsible for reviewing the held “order of interest,” the pharmacy customer’s dispensing data, and any other documentation provided by the pharmacy prior to releasing an order for shipment, in order to determine whether the order was “suspicious.” While RDC’s policies changed from time to time, they generally provided that an “order of interest” was “suspicious” if it deviated from legitimate business practices or evinced a “red flag” of diversion of controlled substances. The DEA’s regulation concerning the reporting of suspicious orders – which was binding on RDC as a registrant – similarly defined suspicious orders as orders of unusual size, deviating substantially from normal practice, or of unusual frequency. Under RDC’s policies, suspicious orders could not be filled and, pursuant to the DEA regulation, had to be reported to the DEA.

46. Despite RDC’s suspicious order reporting policies – which it conveyed to the DEA – and its regulatory obligations, RDC failed to report suspicious orders to the DEA. Specifically, from 2012 through 2016, RDC received and fulfilled over 1.5 million orders for controlled substances from its pharmacy customers, including hundreds of thousands of orders for frequently-abused drugs, such as oxycodone, fentanyl, and hydrocodone. During this period, RDC only reported four suspicious orders to the DEA, notwithstanding senior management’s awareness of the company’s reporting obligations under the CSA. RDC failed to report to the DEA at least two thousand orders of controlled substances made by its pharmacy customers that should have been reported as suspicious pursuant to the criteria set forth in 21 C.F.R. § 1301.74(b) and the guidance contained in letters from the DEA.

47. Many of RDC’s pharmacy customers – including its largest customers – exhibited ordering patterns that generated “orders of interest” and should have resulted in further investigation to determine whether the pharmacies, and/or certain physicians who prescribed drugs

dispensed by the pharmacies, were engaging in opioid diversion. Specifically, through reports that RDC received reflecting the controlled substances that its pharmacy customers had dispensed, on-site visits of its customers, and other sources, RDC internally identified “red flags” suggesting that certain pharmacy customers may have been dispensing controlled substances that were not for legitimate medical purposes. For example, many of RDC’s customers exhibited the following dispensing patterns:

a. A high percentage of the pharmacy’s controlled substance sales, and particularly sales of oxycodone 30-milligram tablets, were paid for in cash as opposed to through insurance.

b. An unusually high proportion of the pharmacy’s overall dispensing consisted of controlled substances.

c. A disproportionate percentage of the pharmacy’s controlled substance purchases were for highly-abused drugs, such as oxycodone 30-milligram tablets or fentanyl patches or spray.

d. The pharmacy filled prescriptions for controlled substances for many patients who lived great distances from the pharmacy.

e. The pharmacy frequently filled prescriptions for quantities or dosages of controlled substances that were higher than accepted medical standards.

f. The pharmacy filled prescriptions for controlled substances written by prescribers on RDC’s internal watch list.

48. Notwithstanding these “red flags” – including in the rare instances when RDC determined that a pharmacy should be terminated as a customer – RDC did not file suspicious order reports with the DEA for orders placed by these pharmacy customers. RDC did not report

suspicious orders because Executive-1 directed that RDC should be “the knight in shining armor” for independent pharmacies, and should work with pharmacies instead of reporting them. Consistent with that direction, the Compliance Officer instructed compliance department employees verbally and in writing on multiple occasions that “we do not turn in a store” merely based on suspicions of wrongdoing by the customer, but rather choose “to educate and work with our customers.”

49. Not only did RDC ignore dispensing patterns and “red flags” associated with orders that should have prompted the filing of reports with the DEA, but RDC’s compliance department – consistent with the directive from Executive-1 and Executive-2 to avoid reporting customers – took steps to prevent reporting of suspicious orders and the future flagging of orders as “orders of interest.” For example, while RDC’s order of interest system identified approximately 8,300 “orders of interest” from 2012 through 2016, RDC did not comply with its own policies after flagging these orders, and instead filled nearly all these “orders of interest” without taking steps to determine whether there was a legitimate explanation for an increase in a pharmacy customer’s order volume. RDC rarely contacted the pharmacy that placed the “order of interest” to obtain the reason for the increased ordering, and regularly failed to obtain updated controlled substance dispensing information from the customer before releasing the order to be shipped. In fact, the compliance department staff was trained to mark flagged orders “not suspicious,” falsely note that “dispensing data supports” the increase in controlled substances orders, and release orders to pharmacies without reviewing the pharmacies’ current dispensing data. The Compliance Officer, at the direction of Executive-1, also released “orders of interest” in the evening or during the weekend for large customers or pharmacies owned by board members, even after the compliance staff had flagged such orders as “suspicious.” For example, in March 2013, when Pharmacy-1

exceeded its order limit for oxycodone, the Compliance Officer wrote to Executive-1 and Executive-2 that while “[t]echnically by our [standard operating procedure] we should make a call and stop selling.” The company, nevertheless, continued to supply controlled substances to the customer.

50. Additionally, in order to prevent the generation of future “orders of interest,” and therefore avoid triggering the requirement to report a suspicious order to the DEA, the company’s compliance department increased the threshold limit of controlled substances a pharmacy could purchase from RDC. Even in the rare instance in which RDC attempted to limit customers’ ordering, RDC did not report suspicious orders by those customers, or the customers themselves, to the DEA. RDC knew that such a practice was contrary to law. For example, in 2012, after attending a conference hosted by the DEA, an RDC employee told Executive-1, Executive-2, and the Compliance Officer that the DEA had stated that “if we currently have stores that are constantly hitting our suspicious order report [threshold] . . . we cannot just simply cut them back, on the drug that is causing the alert. . . . by cutting them back, we are telling the account[] [t]hat a little bit of Diversion, is okay.” Nonetheless, throughout the relevant time period, RDC manipulated customers’ “allowable limit” thresholds but did not report orders.

51. In February 2017, the Civil Division of the Office first served a document request to RDC. In November 2017, the Criminal Division of the Office served a subpoena on RDC. Following receipt of these requests, RDC reported hundreds of suspicious orders to the DEA relating to customers that it has had for years, and has reported at least 400 suspicious order reports in each year since RDC was the subject of an investigation by the Office.