UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. AMERISOURCEBERGEN CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; and INTEGRATED COMMERCIALIZATION SOLUTIONS, LLC, Defendants.	Jury Trial Demanded Civ. A. No._____

COMPLAINT

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The United States of America brings this civil enforcement action against AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and Integrated Commercialization Solutions, LLC (collectively, "Defendants") for their violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* ("Controlled Substances Act" or "CSA"). In support of this complaint, the United States alleges as follows:

INTRODUCTION

1. The opioid epidemic has had profound and devastating effects on this country and its citizens. This action seeks to hold Defendants civilly liable for their role in this epidemic.

2. Because of their significant potential for diversion and abuse, opioids and other controlled substances are regulated by the CSA and the implementing regulations issued by the Drug Enforcement Administration ("DEA").

3. In order to prevent controlled substances from being diverted for illegal uses, the CSA requires wholesalers that distribute controlled substances to pharmacies and other customers to monitor their customers' controlled-substance orders.

4. A controlled-substance order that has an unusual size, deviates substantially from a normal pattern, has an unusual frequency, or carries other indicia of suspicion must be reported to DEA unless the distributor conducts an investigation that dispels all suspicion. If suspicion remains after an investigation, or if no investigation is undertaken, the distributor must report the order to DEA, regardless of whether the distributor fills the order.

5. This legal obligation requires distributors either to look into their customers' orders if there is suspicious activity and resolve the suspicion or to alert DEA to their customers' suspicious behavior.

6. AmerisourceBergen Corporation, one of the largest and highest-earning companies in the country, has for years violated this critical responsibility in distributing controlled substances to customers across the country.

7. Defendants violated their obligation to report suspicious orders in multiple ways.

8. Defendants repeatedly refused or negligently failed to report suspicious orders placed by pharmacy customers that Defendants had reason to know were allowing opioids and other controlled substances to be diverted into illegal channels. This includes instances in which Defendants knew that opioids they distributed were likely being sold in pharmacies' parking lots for cash but they continued to supply those pharmacies with huge amounts of opioids anyway. It also includes an instance in which an AmerisourceBergen Corporation employee identified specific problematic customers of a pharmacy and raised the question of whether they were "drug addict[s]" who were feeding their opioid addictions with drugs obtained from the pharmacy, but Defendants continued to flood the pharmacy with massive quantities of opioids for years after. Two of the customers whom the employee identified later died of drug overdoses shortly after buying opioids from that pharmacy.

9. On numerous occasions, Defendants failed to report to DEA opioid and other controlled-substance orders that Defendants themselves confirmed were so suspicious that they could not be shipped.

10. In even more instances, Defendants failed to report opioid and other controlled-substance orders that were flagged for review by their own order monitoring systems as bearing signs of suspicion, but for which Defendants failed to dispel suspicions through investigations.

11. Finally, on many occasions, Defendants failed to report suspicious orders that their faulty electronic order monitoring algorithms did not flag for review. Defendants' order

monitoring systems were deeply deficient in both design and implementation—flagging only a tiny fraction of customers' highly unusual controlled-substance orders and ultimately enabling diversion of controlled substances, which fueled the country's opioid epidemic. Indeed, in the midst of the opioid epidemic, AmerisourceBergen Corporation intentionally altered the order monitoring system for its largest subsidiary, Defendant AmerisourceBergen Drug Corporation, in a way that dramatically reduced the number of controlled-substance orders reviewed by employees.

12. Defendants have for years flouted their legal obligations and prioritized profits over the well-being of Americans. The United States brings this suit to hold Defendants accountable for their egregious failure to report suspicious orders and their role in contributing to the opioid epidemic.

PARTIES

13. Plaintiff is the United States of America.

14. Defendant AmerisourceBergen Corporation ("ABC") is a corporation incorporated in the State of Delaware, with its principal place of business in the Eastern District of Pennsylvania.

15. Defendant AmerisourceBergen Drug Corporation ("ABDC") is a corporation incorporated in the State of Delaware, with its principal place of business in the Eastern District of Pennsylvania.

16. Defendant Integrated Commercialization Solutions, LLC ("ICS") is a California limited liability company. It is the successor to Integrated Commercialization Solutions, Inc., which converted to a limited liability company on March 31, 2017. The pre-conversion and post-conversion corporate entities are both referred to herein as "ICS."

17. Defendants ABDC and ICS are subsidiaries of ABC, and they are subject to ABC's ultimate control in certain relevant respects, as described below.

18. ABC, as the parent company based in Pennsylvania, provides various shared personnel and services utilized by all Defendants, including ABC's Corporate Security and Regulatory Affairs Department ("CSRA"), which has responsibility for certain aspects of Defendants ABDC and ICS's CSA compliance.

19. According to CSRA's charter, CSRA is administered under the authority of ABC's legal department, and it takes direction from ABC's Board of Directors and ABC's Ethics Committee.

20. Defendants have repeatedly represented that ABDC and ICS rely on ABC's officers or executives to serve as their officers or executives.

JURISDICTION AND VENUE

21. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1345, and 1355(a), and 21 U.S.C. §§ 842(c)(1) and 843(f)(2).

22. This Court has personal jurisdiction over ABC because ABC's principal place of business is in Pennsylvania, ABC is doing business in Pennsylvania, and the United States' claims against ABC arise out of and relate to ABC's activities in Pennsylvania.

23. This Court has personal jurisdiction over ABDC because ABDC's principal place of business is in Pennsylvania, ABDC is doing business in Pennsylvania, and the United States' claims against ABDC arise out of and relate to ABDC's activities in Pennsylvania.

24. This Court has personal jurisdiction over ICS because ICS is doing business in Pennsylvania, and because ICS purposefully directed its activities at Pennsylvania, the home of ABC, whose CSRA handled and exercised control over certain aspects of ICS's CSA compliance functions. CSRA also implemented enterprise-wide policies that governed ICS's CSA

compliance and its reporting of suspicious orders of controlled substances. And under policies implemented by both ABC and ICS, CSRA was responsible for reporting suspicious orders received by ICS. This litigation relates to activities that Pennsylvania-based ABC performed for ICS and/or activities that ICS directed at Pennsylvania by relying on CSRA to report suspicious orders and perform certain other CSA compliance functions. Moreover, there was a manifestation that ABC would act for ICS with respect to certain aspects of CSA compliance and with respect to suspicious-order reporting, and ICS and ABC each accepted the understanding that Pennsylvania-based ABC, acting through CSRA personnel, was responsible for and in control of those undertakings. Alternatively, the Court has pendent jurisdiction over ICS because the United States' claims arise from a common nucleus of operative facts, and the exercise of pendent jurisdiction serves the interests of judicial economy, convenience, and fairness.

25. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1395(a) and 21 U.S.C. § 843(f) because each Defendant resides in, can be found in, and does business in this District, because a substantial part of the events or omissions giving rise to the claims occurred in this District, and because claims accrued in this District.

BACKGROUND

I. DEFENDANTS' OBLIGATIONS UNDER THE CSA

A. Controlled substances generally

26. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for abuse. Controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use to treat patients, their abuse potential, and the likelihood

they will cause dependence if abused. A drug becomes a "controlled substance" when it is added to one of these five schedules.

27. Schedule I controlled substances have a high potential for abuse and have no currently accepted use in medical treatment in the United States. There is also a lack of accepted safety for use of these substances under medical supervision. 21 U.S.C. § 812(b)(1). Heroin, for instance, is a Schedule I controlled substance.

28. The remaining schedules—Schedules II through V—are relevant to this case. The drugs in these schedules have legitimate medical purposes when used properly and require a prescription, with certain exceptions. *See* 21 U.S.C. § 829; 21 C.F.R. §§ 1306.11, 1306.21, 1306.26. By definition, all scheduled drugs are susceptible to abuse, either alone or in combination with other substances.

29. Schedule II includes controlled substances that have "a high potential for abuse"; that, if abused, "may lead to severe psychological or physical dependence"; but that nonetheless have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2). Schedule II includes, among other substances, opioids such as oxycodone, hydrocodone, and methadone, and stimulants such as amphetamine. *See* 21 C.F.R. § 1308.12.

30. Schedule III includes controlled substances that have "a potential for abuse less than the drugs or other substances in schedules I and II"; that, if abused, "may lead to moderate or low physical dependence or high psychological dependence"; but that nonetheless have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3).

31. Schedule IV includes controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule III"; that, if abused, "may lead to limited

physical dependence or psychological dependence relative to the drugs or other substances in schedule III"; but that nonetheless have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(4). Schedule IV includes, among other substances, alprazolam (commonly sold under the brand name Xanax), diazepam (commonly sold under the brand name Valium), and lorazepam (commonly sold under the brand name Ativan). *See* 21 C.F.R. § 1308.14.

32. Schedule V includes controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule IV"; that, if abused, "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV"; but that nonetheless have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(5).

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

33. The CSA seeks to prevent diversion and abuse of controlled substances. To accomplish this goal, the CSA establishes a closed system for regulating and monitoring controlled substances, under which it is unlawful to distribute or dispense any controlled substance, except in a manner authorized by law.

34. The CSA and its implementing regulations govern every step in the handling of controlled substances, from their production in a manufacturing facility to their distribution to a pharmacy or other purchaser, and from their prescription by a medical practitioner to their dispensing by a pharmacy filling a prescription for a patient.

35. The system is "closed" in that each part of the supply chain—including manufacturers, distributors, prescribers, and pharmacies—must register with DEA and comply with the CSA and its implementing regulations. *See* 21 U.S.C. §§ 822(a) and 823(f).

36. Entities that register with DEA (known as "registrants") agree to comply with the CSA and its implementing regulations, and may manufacture, distribute, prescribe, or dispense controlled substances only to the extent authorized by their registration and the law. *See* 21 U.S.C. §§ 822(a)–(b), 823(f).

C. Distributors must abide by certain legal obligations when they receive controlled-substance orders from customers

37. The CSA defines a "distributor" as a person or an entity that delivers (other than by administering or dispensing) a controlled substance. 21 U.S.C. § 802(11).

38. The CSA defines "delivery" as the "actual, constructive, or attempted transfer of a controlled substance." *See* 21 U.S.C. §§ 802(8), (11).

39. Defendants ABDC and ICS are distributors of controlled substances within the meaning of the CSA.

40. Distributors of controlled substances are required by the CSA to register with DEA and to maintain effective controls against the diversion of controlled substances for illegitimate uses. *See*, *e.g.*, 21 U.S.C. § 823(b)(1); *see also* 21 C.F.R. § 1301.71(a).

41. A distributor that fails to maintain effective controls against diversion may have its DEA registration(s) revoked and thus lose its ability to distribute controlled substances. *See* 21 U.S.C. §§ 823(b)(1), (e)(1), 824(a)(4).

42. Distributors are a critical part of the "closed" system of regulating and delivering controlled substances because they are the connective link between the manufacturers of pharmaceutical products and the retail pharmacies, hospitals, and other entities at which individuals fill prescriptions for pharmaceutical products.

43. Distributors have a unique understanding of controlled-substance usage and trends because they monitor and maintain the supply chain.

1. Distributors must report suspicious orders of controlled substances, including but not limited to orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency

44. It is unlawful for a distributor to distribute a controlled substance "[e]xcept as authorized" by the CSA. 21 U.S.C. § 841(a).

45. The CSA provides the Attorney General with broad authority to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b); *see also* 21 U.S.C. § 821. The Attorney General has issued numerous regulations establishing an extensive regulatory regime governing controlled substances. *See* 21 C.F.R. §§ 1300.01–1321.01.

46. Regulations promulgated by the Attorney General to implement the CSA have long required each distributor to design and operate a system to identify suspicious orders of controlled substances, and to report suspicious orders to DEA.

47. 21 C.F.R. § 1301.74(b) provides: "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform [DEA] of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

48. "Suspicious orders," however, are not limited to those three non-exclusive categories. A controlled-substance order is also suspicious if it has one or more indicia of suspicion other than unusual size, unusual pattern, or unusual frequency.

49. "A pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern, or frequency[,]" so "orders placed by a pharmacy which engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious." *In re Masters*

Pharm., Inc., 80 Fed. Reg. 55418, 55477 (Drug Enf't Admin. 2015), *pet. for review denied sub nom. Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

50. Thus, "a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices." *Id.* at 55478.

51. On October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the "SUPPORT Act"), which codified these existing regulatory requirements into the CSA's statutory text. Since the effective date of the SUPPORT Act, the CSA statutory language has obligated each distributor to design and operate a system to identify suspicious orders of controlled substances, and to report suspicious orders to DEA. *See* 21 U.S.C. § 832(a). The relevant provision mandates that "[e]ach registrant shall (1) design and operate a system to identify suspicious orders for the registrant; (2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and (3) upon discovering a suspicious order or series of orders, notify [DEA]." *Id.*

52. The SUPPORT Act also incorporates the regulatory language defining a "suspicious order." The CSA states that a "suspicious order" includes but is "not limited to (A) an order of a controlled substance of unusual size; (B) an order of a controlled substance deviating substantially from a normal pattern; and (C) orders of controlled substances of unusual frequency." 21 U.S.C. § 802(57).

53. Both prior to, and after, the enactment of the SUPPORT Act, upon discovering an order with one or more indicia of suspicion, a distributor was and always has been required to

report the order to DEA, unless the distributor investigates the order and dispels all suspicion relating to the order.

54. If, and only if, the distributor dispels all suspicion through an adequate investigation may the distributor determine that the order is not suspicious and need not be reported to DEA.

55. If a distributor does not dispel all suspicion through an investigation, then the distributor must report the order to DEA.

56. These obligations apply to each suspicious order a distributor receives, whether or not the distributor fills the order.

57. One purpose of the suspicious order reporting requirement is to provide DEA investigators in the field with information regarding potential illegal activity in an expeditious manner.

2. Failure to report a suspicious order is punishable by a civil penalty and injunctive relief

58. It is unlawful for any person "to refuse or negligently fail to make, keep, or furnish any record, report, notification, . . . or information required under this subchapter." 21 U.S.C. § 842(a)(5). A person who refuses or negligently fails to make a required suspicious order report to DEA is thus liable for a civil penalty and injunctive relief. 21 U.S.C. §§ 842(c), 843(f).

59. These statutory provisions apply to both registrants and to persons responsible for a registrant's compliance with the CSA. *See United States v. Ahmad*, Civ. A. No. 15-181, 2016 WL 11645908, at *3-4 (E.D. Ark. May 2, 2016), *aff'd sub nom.*, *United States v. United Pain Care, Ltd.*, 747 Fed. Appx. 439 (8th Cir. 2019); *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310, 313-14 (E.D. La. 1990), *aff'd*, 925 F.2d 120 (5th Cir. 1991).

60. Between January 1, 2014 and November 2, 2015, the CSA provided a maximum civil penalty of $10,000 for each refusal or negligent failure to file a required report. *See* 21 U.S.C. § 842(c)(1)(A), (B).

61. The maximum civil penalty increased to $16,864 per-violation, due to regulatory adjustments reflecting increases in cost of living, effective November 3, 2015. 28 C.F.R. § 85.5.

62. Effective October 24, 2018, the SUPPORT Act distinguishes between penalties for non-opioid-related reporting violations and opioid-related reporting violations. The maximum penalty for non-opioid violations occurring on or after October 24, 2018 remains $16,864 per violation. *See* 21 U.S.C. § 842(c)(1)(B)(i); 28 C.F.R. § 85.5. But the maximum penalty for refusing or negligently failing to report a suspicious order of opioids (as defined in 21 U.S.C. § 802(18)) is $109,374 for each violation occurring on or after October 24, 2018. *See* 21 U.S.C. § 842(c)(1)(B)(ii); 28 C.F.R. § 85.5.

II. DEFENDANTS' CONTROLLED-SUBSTANCE BUSINESSES

A. ABC distributes drugs through a network of subsidiaries

63. ABC is one of the largest pharmaceutical distribution companies in the United States.

64. ABC is also one of the ten largest companies in the country by revenue. For the fiscal year that ended on September 30, 2022, ABC reported revenues of more than $238 billion, with gross profits of just under $8.3 billion.

65. ABC distributes pharmaceuticals, including controlled substances, to thousands of customers throughout the United States.

66. ABC operates through a network of subsidiaries, including Defendants ABDC and ICS. It is these subsidiaries, not ABC itself, that serve as the DEA registrants for Defendants' various drug distribution centers.

67. Defendant ABDC is the DEA registrant for at least 25 distribution centers.

68. ABDC's distribution centers are in the following localities: Bethlehem, Pennsylvania; Romeoville, Illinois; Lockbourne, Ohio; Kansas City, Missouri; Shakopee, Minnesota; Williamston, Michigan; Buford, Georgia; Roanoke, Texas; Sugar Land, Texas; Orlando, Florida; Mansfield, Massachusetts; Morrisville, North Carolina; Glen Allen, Virginia; North Amityville, New York; Newburgh, New York; Corona, California; Denver, Colorado; Honolulu, Hawaii; Phoenix, Arizona; Sacramento, California; Salt Lake City, Utah; Des Moines, Washington; Olive Branch, Mississippi; Whitestown, Indiana; and Louisville, Kentucky.

69. Defendant ABDC has also been the registrant for at least nine other distribution centers since January 1, 2014, but those registrations are now retired.

70. Defendant ICS is the DEA registrant for at least three distribution centers.

71. ICS's distribution centers are in Reno, Nevada; Brooks, Kentucky; and Lockbourne, Ohio.

72. Defendants ABDC and ICS are, and at all relevant times to this action were, subsidiaries of ABC and subject to ABC's control in certain relevant respects, and they are and were at all relevant times registered with DEA to distribute opioids and other controlled substances.

73. Thus, Defendants ABDC and ICS are and were "registered distributor[s] of opioids" for purposes of 21 U.S.C. § 842(c)(1)(B)(ii).

B. Defendants sell huge quantities of controlled substances, and controlled substances are a significant source of revenue for Defendants

74. Each year, Defendants collectively receive tens of millions of orders for controlled substances from customers across the country.

75. As part of this controlled-substances business, Defendants distribute billions of dosage units of opioids annually.

76. For example, in 2020 alone, ABDC sold customers in the United States:

a. more than 2.3 billion dosage units of hydrocodone products;

b. more than 100 million dosage units of fentanyl products; and

c. more than one billion dosage units of oxycodone products, including more than 60 million oxycodone 30mg tablets.

77. Many of Defendants' customers are retail pharmacies that dispense prescription drugs to the public.

78. These retail pharmacy customers include both chain pharmacies with up to thousands of locations across the United States, as well as independent pharmacies that have only one or a small number of locations and typically operate in a limited geographic region.

79. Beginning around 2010, Defendants, with the help of an outside consulting company, Consulting Firm 1,[1] implemented a sales and marketing strategy focused on increasing their sales to independent pharmacies, which were particularly lucrative customers for Defendants, and which sometimes lacked diversion controls and could facilitate diversion of controlled substances into illegal channels.

80. Documents reviewed by the government to date indicate that throughout the period from January 1, 2014 to the present (together with any future periods in which Defendants engage in unlawful conduct, the "relevant period"), Defendants often sold controlled substances,

[1] This Complaint refers to non-party individuals by their initials and non-party entities with pseudonyms such as "Pharmacy 1" and "Distributor 1." An appendix identifying all referenced individuals and entities will be provided to Defendants.

including opioids, at much higher profit margins than other products, particularly to independent pharmacy customers.

81. For example, when ABDC sold oxycodone 30mg tablets to two Walgreens stores between 2013 and 2018, ABDC earned profit margins that were many times larger than the profit margins it earned from other drugs.

82. And ABDC earned about double those profit margins selling the same oxycodone products to certain independent pharmacy customers for a portion of the same period.

83. In some instances, Defendants' high margins on controlled substances were solely responsible for any profits they earned from independent pharmacy customers.

84. For example, from 2012 through 2020, ABDC earned large gross profit margins on its controlled-substance sales to a Gainesville, Florida independent pharmacy (discussed further *infra* ¶¶ 387-403), while it lost money on its overall sales to the pharmacy of non-controlled-substance products.

85. Similarly, from 2013 through 2020, ABDC earned large gross profit margins from controlled-substance sales to a Lakewood, Colorado independent pharmacy (discussed *infra* ¶¶ 404-431), while at the same time losing money on its overall non-controlled-substance sales to the same pharmacy.

86. Additionally, because many retail pharmacies prefer to purchase all or almost all pharmaceuticals from the same distributor, Defendants' willingness to supply customers with controlled substances was often essential to Defendants' ability to contract with and maintain customers.

C. ABC has, at all relevant times, been responsible for certain aspects of the other Defendants' CSA compliance

87. Throughout the relevant period, personnel responsible for ABDC's and ICS's CSA compliance, including maintenance of effective controls against diversion, were part of or affiliated with CSRA, which was also responsible for filing suspicious order reports on behalf of ABDC and ICS.

88. According to ABC's representations to DEA and its own records, including CSRA's charter, CSRA had enterprise-wide authority for CSA compliance by ABC subsidiaries, including Defendants ABDC and ICS.

89. During the relevant period, CSRA reviewed new customers' applications to buy controlled substances from ABDC and ICS.

90. Likewise, throughout much or all of the relevant period, before ABDC or ICS could begin selling controlled substances to a new customer, Defendants' policies required approval from a CSRA Director of Diversion Control, who worked out of ABC's corporate headquarters.

91. CSRA also was responsible for identifying CSA compliance concerns with existing ABDC and ICS customers and for terminating sales of controlled substances to customers engaged in suspicious practices.

92. Further, CSRA leadership was responsible for notifying ABDC and ICS customers of CSRA's decisions to terminate sales to the customers on behalf of ABDC and ICS.

93. CSRA leadership provided such notification through letters written on ABC letterhead and addressed from ABC's corporate headquarters.

94. CSRA leadership also, in some instances, sent similar letters on ABC letterhead to DEA notifying DEA of alleged terminations of controlled-substance sales to customers.

95. CSRA additionally was responsible for Defendants' suspicious order reporting to DEA.

III. DEFENDANTS' CSA COMPLIANCE PROGRAMS SUFFERED FROM SERIOUS SYSTEMIC DEFECTS THAT ENABLED SIGNIFICANT CSA VIOLATIONS

96. In 2007, DEA suspended ABDC's Orlando, Florida distribution center from selling controlled substances, after DEA determined that ABDC had distributed over 3.8 million dosage units of hydrocodone to rogue Internet pharmacies that were diverting hydrocodone.

97. The suspension followed a series of letters from DEA to ABDC and other distributors emphasizing that distributors are required to report suspicious orders of controlled substances and to avoid filling suspicious orders that might be diverted, pursuant to the obligation to maintain effective controls against diversion.

98. In the Order suspending the Orlando distribution center's registration, DEA determined that ABDC had shipped hydrocodone orders with suspicious characteristics to several rogue Internet pharmacies and that in supplying those pharmacies, ABDC had failed to maintain effective controls against diversion.

99. DEA further determined that ABDC's Orlando distribution center's continued registration would constitute an imminent danger to public health and safety because of the substantial likelihood that ABDC, acting through the distribution center, would continue to supply pharmacies that diverted controlled substances.

100. Following the suspension, ABDC reached a settlement with DEA that took effect on June 22, 2007.

101. Pursuant to the settlement, ABC implemented new compliance policies for ABDC and its other subsidiaries.

102. These compliance policies involved both a suspicious order monitoring program component and a "Know Your Customer" component, which was supposedly designed to prevent Defendants from servicing customers engaged in suspicious controlled-substance practices.

103. ABDC represented to DEA that its new suspicious order monitoring program would enable ABDC to detect suspicious orders of controlled substances, report suspicious orders to DEA pursuant to 21 C.F.R. § 1301.74(b), and to reject and not ship suspicious orders.

104. Defendants' policies and representations gave the appearance of compliance, but their programs suffered from serious defects in practice, which caused Defendants to violate the CSA on a massive scale.

A. Defendants grossly underfunded their CSA compliance programs

105. Defendants' compliance problems started with ABC's gross underfunding of CSA compliance programs.

106. As alleged above, CSRA and its "Diversion Control" team exercised responsibility for CSA compliance functions for ABDC and ICS throughout the relevant period. That responsibility extended to issues relating to diversion control and suspicious order reporting.

107. CSRA was tasked with vetting thousands of customers, reporting to DEA which of Defendants' hundreds of millions of controlled-substance orders were suspicious, and preventing the diversion of the billions of opioid dosages units and other controlled substances Defendants sold each year as the opioid epidemic intensified.

108. But despite this immense responsibility, ABC dedicated a minuscule fraction of its resources to the Diversion Control team and CSRA in general.

109. In 2014, for example, CSRA's overall budget was around $4 million, and much of that funding was spent on matters unrelated to suspicious order reporting and diversion control.

110. Also in 2014, ABDC alone sold more than one billion dosage units of oxycodone and more than three billion dosage units of hydrocodone.

111. The $4 million CSRA budget for 2014 was significantly less than what ABC spent on taxicabs that same year; less than half of what ABC spent on its CEO's compensation; less than a third of what ABC spent on office supplies and forms; and less than a fifth of ABC's payments for phone bills and credit card fees.

112. While CSRA's budget increased somewhat over the years, it remained underfunded throughout the relevant period.

113. In 2019, for example, the combined salaries for Diversion Control employees totaled roughly $2.1 million.

114. That represents about 0.001% of the roughly $180 billion in revenue that ABC earned that year, and less than a fifth of ABC's CEO's compensation for the same year.

115. This persistent underfunding of CSA compliance functions undermined all aspects of ABC's compliance operations, including the Know Your Customer programs and suspicious order monitoring programs for Defendants ABDC and ICS, as well as other ABC subsidiaries that sold and distributed controlled substances.

116. Defendants' failure to dedicate adequate resources to their compliance functions during the relevant period was particularly unreasonable because of the ongoing opioid epidemic, which Defendants knew was being fueled by the diversion of the same prescription drugs they sold by the billions.

B. Defendants adopted, but did not adequately implement, Know Your Customer policies, which facilitated Defendants' servicing of problematic customers

117. CSRA implemented Know Your Customer policies for both ABDC and ICS following the 2007 settlement with DEA, as purported means to assess new customers' suitability to purchase controlled substances from Defendants and to comply with Defendants' CSA obligations to prevent diversion.

118. The Know Your Customer programs, in theory, generally required prospective customers to complete due diligence questionnaires.

119. For many customers, that questionnaire was what ABC referred to as a "Form 590," although Defendants sometimes allowed chain customers to submit truncated due diligence documentation, and Defendant ICS sometimes used a modified version.

120. The Form 590 was designed to identify commonly recognized "red flags" that a potential customer might be engaged in diversion.

121. As ABC recognized, widely accepted red flags that controlled substances sent to a pharmacy may be diverted include if a pharmacy:

a. dispenses unusually large quantities of oxycodone and other opioids;

b. dispenses a high percentage of oxycodone 30mg tablets as compared to other oxycodone formulations, since oxycodone 30mg is recognized as the most commonly diverted and abused formulation of oxycodone;

c. accepts an unusually large percentage of cash transactions for controlled-substance prescriptions;

d. purchases controlled substances from multiple distributors, since doing so can enable a pharmacy to hide unusual controlled-substance purchasing from suppliers;

e. fills prescriptions for which the patient and/or prescriber are not located near the pharmacy;

f. fills large numbers of "cocktails"—combinations of controlled substances that are subject to abuse, such as the combination of an opioid, benzodiazepine, and muscle relaxant;

g. regularly has long customer lines or customers loitering; and/or

h. dispenses large numbers of controlled-substance prescriptions written by prescribers known to engage in problematic practices.

122. Through Form 590s and similar documents, Defendants requested information relevant to identifying these red flags, including anticipated purchases of certain high-risk drugs, percentages of controlled and non-controlled substance sales, percentages of prescriptions filled for controlled substances, the identity of top opioid prescribers, the pharmacist-in-charge's disciplinary history, end-users' payment methods (cash, insurance, credit, etc.), and whether the prospective customer was purchasing controlled substances from, or had had its controlled-substance purchases terminated by, another distributor.

123. Knowing a customer's anticipated purchases of certain high-risk drugs should have given Defendants an important baseline for judging the customer's future purchasing quantities and patterns for those drugs.

124. Further, in addition to requiring pharmacy customers to complete Form 590s and similar forms, ABDC's Know Your Customer program also purportedly required sales personnel to visit prospective pharmacy customers, take pictures of the interiors and exteriors of the pharmacies, and record written descriptions of the premises in Defendants' files.

125. CSRA could also request dispensing data from pharmacies and send outside auditors to conduct site visits with existing customers about which CSRA developed concerns.

126. Defendants represented the Know Your Customer programs as alleged central components of their broader compliance efforts both internally and in presentations to government entities.

127. And, in theory, if Defendants had scrupulously followed their policies and made effective use of information obtained through the Form 590s and other due diligence, the Know Your Customer programs could have put Defendants on stronger foundations for CSA compliance.

128. But the Know Your Customer programs suffered from significant defects in implementation, as alleged further below.

1. ABC allowed sales personnel—who were incentivized to recruit and retain customers—to conduct due diligence rather than compliance personnel

129. For much of the relevant period, Defendants generally tasked sales representatives, rather than CSRA personnel, with collecting Form 590s, communicating with prospective customers about the forms, and conducting in-person visits and other alleged new-customer due diligence.

130. These same sales representatives also often received incentive compensation for bringing on new customers and maintaining existing customers.

131. Identifying diversion problems that might prevent sales to new customers was thus contrary to sales representatives' own professional and financial interests.

132. This conflict of interest undermined the effectiveness of the Know Your Customer programs by increasing the likelihood that red flags would be ignored or not detected.

2. In violation of their own policies, Defendants did not obtain the diligence information necessary to assess the possible risks associated with prospective customers

133. CSRA also often failed to follow the policies required by the Know Your Customer programs.

134. CSRA regularly allowed ABC's subsidiaries to supply customers that had not submitted Form 590s or for which ABC had not conducted the associated due diligence.

135. In fact, an internal audit conducted in May 2016 found that CSRA lacked required Form 590s or related due diligence information for thousands of ABDC customers.

136. After that audit, CSRA began a "590 Validation Project" aimed at obtaining missing or incomplete Form 590s.

137. But the project was such a low priority that it was only 10 percent complete by July 2017, and less than 60 percent complete by January 2019.

138. CSRA's Vice President for Corporate Security and Diversion Control, D.M., emphasized to sales personnel in 2017 that the failure to obtain Form 590s exposed ABC and ABDC to regulatory and legal risks. Nevertheless, he and CSRA did not make obtaining completed Form 590s a priority.

139. Further, even when Defendants did actually collect Form 590s, CSRA often allowed customers to omit key information such as anticipated purchase quantities of high-risk drugs and percentages of controlled substances, critically compromising the forms' utility for spotting red flags.

3. Defendants ignored, or failed to address, red flags of diversion and other problems, including when alleged diligence information conflicted with a customer's actual practices

140. In addition to conducting inadequate diligence at the outset of a customer relationship, Defendants failed to adequately monitor their customers' business practices, which

meant Defendants regularly continued to sell controlled substances to customers engaged in suspicious practices.

141. Defendants regularly allowed customers to order much greater quantities of controlled substances, including opioids, than their Form 590s projected.

142. This enabled customers whose controlled-substance ordering and dispensing practices raised red flags to evade scrutiny.

143. Moreover, as is addressed further below, even when a prospective customer's Form 590 raised obvious and unresolved red flags, CSRA often permitted ABDC and ICS to begin selling controlled substances to the customer anyway.

144. And though CSRA did sometimes request dispensing data and send auditors to existing customers whose ordering raised red flags, CSRA used these tools with only a small number of Defendants' more than 20,000 annual customers.

145. Furthermore, as set forth in detail below, CSRA often failed to act on information it obtained in a timely manner.

146. In the instances when CSRA did use dispensing data and audits to confirm suspicions that customers might be facilitating diversion, CSRA often allowed ABDC and ICS to continue selling controlled substances to those customers for months or even years.

147. In sum, regardless of what the Know Your Customer programs' policy documents said on paper, Defendants' poor implementation of their policies caused Defendants to distribute controlled substances to numerous customers engaged in suspicious practices and resulted in Defendants' failure to identify problematic issues with many of their customers.

148. As a result, following the implementation of the programs, Defendants continued to fill and not report controlled-substance orders from customers who presented glaring red flags of diversion, as alleged in detail below.

C. ABC designed ABDC's Order Monitoring Program to flag for review only orders that exceeded certain statistical thresholds

149. After the 2007 settlement with DEA, in addition to the Know Your Customer programs, ABC also created computer-based order monitoring programs for ABDC, supposedly to enable ABC and ABDC to detect and report suspicious orders of controlled substances.

150. ABDC and ICS utilized different and separate order monitoring systems.

151. As described further below, both programs had significant deficiencies, which resulted in numerous CSA violations.

1. ABDC's original Order Monitoring Program applied high thresholds for identifying suspicious orders, and CSRA sometimes raised thresholds upon request

152. In 2007, ABC implemented the Controlled Substance/Listed Chemical Order Monitoring Program ("OMP") to review controlled-substance orders placed with ABDC.

153. A central feature of OMP was its use of computer-based algorithms designed to flag and hold orders with certain indicia of suspicion for human review and potential reporting to DEA.

154. ABC designed OMP's algorithms to flag and hold for review only orders that exceeded statistical "thresholds."

155. OMP divided controlled substances into groups that CSRA called "drug families," and divided customers into "customer peer groups" of small, medium, large, and extra large based on dollar volume.

156. OMP then set thresholds for each group that represented the maximum amount of drugs in a particular drug family that a customer could purchase during a 30-day period before triggering scrutiny.

157. Typically, a customer's default threshold within OMP was set at roughly three times the customer's peer group's average total orders for a 30-day period.

158. OMP's algorithms were supposed to automatically flag and hold orders exceeding those thresholds so that employees could review the orders and determine whether they could be cleared as non-suspicious or needed to be rejected and reported to DEA.

159. Thus, for example, if a customer's 30-day threshold for products in the "oxycodone solid" drug family was set at 33,300 dosage units, the customer could order up to 33,300 units of oxycodone solid in a 30-day period, and those orders would be shipped automatically without any automated electronic mechanism requiring review and potential reporting to DEA. But if the customer placed an order for drugs in the oxycodone solid drug family that pushed its 30-day ordering above the 33,300-dosage-unit threshold, then that order would be flagged and held for review.

160. Thus, a customer's orders were typically not even reviewed, much less reported, unless the customer placed orders for controlled substances in a given drug family in an amount that was 300% more than its peers' average orders.

161. Furthermore, CSRA could raise a customer's thresholds upon request. For such customers, ABDC automatically shipped even orders that dramatically exceeded the approximately 300% default threshold without review.

162. As a result of ABC's design decisions and these ad hoc threshold adjustments, OMP flagged and held for review less than 1% of controlled-substance orders placed with ABDC.

2. ABDC's original Order Monitoring Program relied exclusively on numerical order thresholds and did not monitor for other suspicious practices

163. While numerical thresholds can be an important part of an effective suspicious order monitoring program, ABC's implementation of OMP and its over-reliance on high thresholds ensured that significant numbers of suspicious orders would not be reviewed or reported to DEA.

164. ABC provided no automated mechanism to flag for human review and potential reporting suspicious orders that did not exceed OMP's thresholds and therefore were not flagged by the OMP algorithms.

165. This meant that ABDC regularly shipped orders to customers whom CSRA had notice were engaged in suspicious practices, including customers CSRA knew were likely facilitating diversion of controlled substances, without any opportunity for CSRA to review or to report those orders.

166. Indeed, even in instances where CSRA had decided to cut off a customer's supply of controlled substances due to suspected diversion, OMP allowed the customer to keep placing controlled-substance orders, which ABDC automatically shipped and did not report as suspicious.

167. The lack of an automated mechanism to review and report orders that did not exceed OMP's thresholds was a particularly serious problem with respect to orders placed by customers with suspicious business practices and customers whose opioid-ordering thresholds had been increased.

168. Such customers were able to order highly unusual amounts of controlled substances without those orders being flagged for review.

D. Beginning in 2014, ABC created a revised order monitoring program that sharply cut the number of suspicious-order reports to DEA

169. In 2014, in the midst of the ongoing opioid epidemic, ABC began working to replace OMP with a revised order monitoring program ("ROMP").

170. Rather than endeavoring to fix the defects described above, ABC intentionally designed ROMP with new algorithmic thresholds that would flag *fewer* controlled-substance orders to be held and reviewed, and in turn dramatically *reduce* the number of suspicious orders reported to DEA.

171. ABC retained an outside consulting organization, Consulting Firm 2, to assist with its redesign of OMP.

172. Consulting Firm 2 started in 2014 by assessing and making recommendations regarding ABC's purported CSA compliance processes.

173. After interviewing more than 20 employees and visiting distribution centers, Consulting Firm 2 found significant problems with ABC's order monitoring and reporting, as well as CSRA's practices generally.

174. Consulting Firm 2 told ABC that ABC faced risks as a result of those problems.

175. ABC then engaged Consulting Firm 2 to modify OMP and implement ROMP.

176. Consulting Firm 2 quickly came to understand that a suspicious order monitoring system must, *inter alia,* identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

177. ABC also knew that, to comply with the law, ROMP would need to identify, *inter alia,* orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency, so that ABC and ABDC could report suspicious orders to DEA.

178. Despite this clear knowledge of Defendants' legal obligations, ABC deliberately designed ROMP in a way that failed to flag many statistically unusual orders.

1. ROMP flagged only orders that were both unusual in size and pattern or of extraordinarily unusual pattern

179. Contrary to its legal obligations, ABC designed ROMP to flag only orders that were unusual in both size *and* pattern, or that deviated in the extreme from a normal ordering pattern.

180. ROMP replaced OMP's single algorithmic threshold with three different thresholds.

181. The first threshold was the customer order parameter, or "COP" threshold. The COP threshold was based on a customer's own ordering history for a particular drug family. When ABDC received an order, ROMP's algorithms evaluated the order against the COP threshold and determined whether the customer's order was unusual compared to that customer's historical purchasing for the same drug family. In practice, the COP threshold identified orders that were of highly unusual size.

182. The second threshold was the cumulative 30-day-trailing "TRD" threshold, which was similar to the original OMP's threshold. When ABDC received an order, ROMP evaluated the order with the TRD threshold and determined whether the order was unusual based on the customer's last 30 days of orders for the ordered drug family, as compared to a peer group of customers' average purchasing of the same drug family. The TRD threshold was designed to

flag 30-day ordering patterns that qualified as outliers compared to peer customers' ordering patterns. In practice, the TRD threshold identified substantially abnormal ordering patterns.

183. The final threshold was the "TRD+" threshold. The TRD+ threshold was typically calculated by multiplying the TRD threshold by a factor of up to 10. Thus, whereas the TRD threshold identified unusual ordering patterns, the TRD+ threshold identified extremely abnormal ordering patterns.

184. Critically, ROMP flagged only controlled-substance orders that failed two or more of these three thresholds.

185. This "dual-trigger" requirement flagged for human review and potential reporting to DEA only orders of both unusual size *and* pattern (COP and TRD) or orders of extremely unusual ordering pattern (TRD and TRD+).

186. Orders that exceeded only the COP threshold due to their unusual size or only the TRD threshold due to their substantially abnormal pattern were not flagged by ROMP and instead automatically shipped to customers without reporting to DEA.

187. Thus, by design, ROMP allowed orders that ABC's own algorithms had identified as being of unusual size or deviating substantially from a normal pattern to ship without any review or opportunity for reporting to DEA.

188. Additionally, ROMP had no algorithm to flag orders of unusual frequency.

189. In fact, as part of ROMP's development, Consulting Firm 2 had considered basic algorithms to identify orders of unusual frequency, explaining that ABC could simply establish a threshold for a number of monthly orders and flag orders that exceed that threshold.

190. Consulting Firm 2 explained that, for example, if a customer placed 34 orders per month on average, ABC could set the customer's frequency threshold at 2–3 times that number (68 or 102 orders per month) and flag all orders that exceeded that threshold.

191. But ABC failed to include such an algorithm or any other frequency test in ROMP.

192. As a result, suspicious orders of unusual frequency were automatically filled without any review or opportunity for reporting to DEA, as were suspicious orders of unusual size or suspicious orders deviating substantially from a normal pattern that exceeded only one of ROMP's thresholds.

193. And as with OMP, ROMP included no automated mechanism that triggered review of orders with non-statistical indicia of suspicion, such as orders that were suspicious based on the customer who placed them.

194. Such suspicious orders automatically shipped without any required review or potential reporting to DEA.

195. Further, as with OMP, CSRA retained the ability to increase a customer's thresholds upon request, which could allow even suspicious orders that exceeded two of ROMP's default or original thresholds for a customer to be shipped automatically without required review or potential reporting.

2. ABC designed ROMP recognizing it would flag fewer orders for review and report fewer orders to DEA

196. ROMP's exceedingly narrow parameters for flagging suspicious orders were no accident.

197. OMP had imposed financial and customer-relation costs on ABC and ABDC. In 2013 and 2014, OMP flagged less than 1% of controlled-substance orders for review, but still

delayed shipment of thousands of orders. And in each of those two years, ABC and ABDC filed more than 35,000 suspicious order reports with DEA.

198. Each rejected order hurt ABC's revenue. Moreover, each delayed or rejected order jeopardized business relationships with customers.

199. Each order ABC reported to DEA also put its customers at risk of regulatory action that could, in turn, impact ABC's profits.

200. ABC designed ROMP fully recognizing that it would flag and report fewer orders than OMP.

201. ROMP did in fact flag a much smaller percentage of orders than OMP, clearing the way for many more controlled-substance orders—including suspicious controlled-substance orders—to be processed without any required human review.

202. For example, ABC's internal analyses found that in 2017, ROMP's algorithms flagged only about 0.29% of orders.

203. In that year and each of the subsequent two years, more than 99.5% of controlled-substance orders placed with ABDC were automatically filled and were not reviewed or reported regardless of whether indicia of suspicion were present.

204. After ROMP was implemented, ABC applauded its success in flagging fewer orders and preventing customer complaints.

205. For instance, when ABC and Consulting Firm 2 discussed ROMP shortly after it was introduced, D.M., CSRA's Vice President for Corporate Security and Diversion Control, applauded the fact that flagged orders dropped significantly under ROMP.

206. ABC's decision to redesign ROMP in a way that substantially reduced the number of suspicious order reports—and to even celebrate its success in doing so—was not reasonable in the context of the ongoing opioid epidemic and significant diversion of controlled substances.

E. The human review element of the ABDC order monitoring program was grossly insufficient

207. The problems with the order monitoring programs that ABC designed for ABDC did not stop with ABC's over-reliance on thresholds that failed to flag large categories of suspicious orders for review or potential reporting.

208. CSRA also implemented an ineffective human review process, which caused ABC and ABDC to not report vast numbers of flagged orders for which reviewers never dispelled suspicion.

209. As discussed, the CSA requires distributors to maintain effective controls against the diversion of controlled substances.

210. The CSA and its implementing regulations specifically require that, upon identifying, *inter alia*, an order of unusual size, an order deviating substantially from a normal pattern, or an order of unusual frequency, a distributor must report the order as suspicious to DEA unless the distributor performs an adequate investigation that dispels all suspicion associated with the order.

211. If all suspicion is not dispelled, then the distributor must file a suspicious order report with DEA.

212. The orders flagged by OMP's and ROMP's algorithms unquestionably met the statutory and regulatory meaning of suspicious, since OMP and ROMP were designed to identify only those orders that met thresholds for particularly unusual size and pattern, constituting a limited subset of orders that meet the statutory and regulatory definition of suspicious.

213. ABC's written policies required order reviewers to review each and every flagged order for suspicion and take certain investigative steps, then make a determination whether the order (1) could be shipped or should be rejected, and (2) needed to be reported to DEA.

214. ABC's policies required that any order reported to DEA as suspicious would also be rejected. However, they allowed reviewers to reject an order but not report the order to DEA as suspicious.

215. ABC's policies directed its order reviewers to document their review of each flagged order and justify their decisions whether to ship or reject the order and whether to report the order to DEA in designated fields in ABC's databases.

216. Following the implementation of ROMP, order reviewers were also required to select applicable "adjudication reason codes" from a drop-down menu.

217. Subsequent policy amendments clarified that for controlled substances that ABC categorized as "high risk," order reviewers were required to record comments specific to each order review and their rationale for releasing any flagged order.

218. But, while ABC purported to require its reviewers to conduct documented investigations sufficient to dispel suspicion before making the determination that a flagged order need not be reported, ABC did not do so in practice, due to a variety of defects with CSRA's review process and ABC's deficient resource allocations for CSA compliance.

1. For a portion of the relevant period, ABC tasked insufficiently trained distribution center personnel—not compliance personnel—with reviewing many suspicious orders, including opioid orders

219. From before 2014 to late 2017, ABC policies allowed distribution center personnel (*i.e.*, ABDC warehouse employees, not CSRA staff) with minimal training to review and clear for shipment orders of controlled substances that had been flagged by OMP or ROMP but that ABC categorized as "low or medium risk."

220. Many of these drugs were in fact highly dangerous, as ABC improperly categorized commonly abused opioids such as fentanyl as "low or medium risk."

221. Consulting Firm 2 notified ABC in 2015 that ABC did "not have a policy to determine which associates(s) at [its] distribution center[s] [were] responsible for reviewing orders[,]" and that as a result, the haphazardly assigned distribution center employees brought "no consistency" to flagged order reviews.

222. Consulting Firm 2 warned ABC that these problems created "a significant risk area because the company needs to be compliant with DEA regulations and able to explain and defend their decisions."

223. ABC nevertheless authorized these personnel to clear highly unusual, flagged orders of dangerous controlled substances for shipment.

2. Even when flagged orders were reviewed by alleged compliance personnel, ABC devoted inadequate resources towards that task, resulting in cursory, if not non-existent, reviews

224. Throughout the relevant period, ABC's underfunding of CSRA meant that the Diversion Control team—the CSRA unit with primary responsibility for suspicious order reviews and reporting—was grossly understaffed.

225. From before 2014 through around late 2017, members of the Diversion Control team were responsible for reviewing flagged orders of "high risk" controlled substances, as well as other flagged orders for which distribution center personnel determined they could not dispel suspicion.

226. After a policy change in late 2017, the Diversion Control team became primarily responsible for reviewing all flagged orders of controlled substances.

227. Accordingly, the Diversion Control team was responsible for reviewing tens of thousands or hundreds of thousands of orders per year.

228. Despite this immense responsibility, for a significant part of the relevant period, the Diversion Control team had only around five or six dedicated order reviewers, and even those employees were able to spend only a portion of each workday reviewing flagged orders.

229. The enormous volume of ABC's controlled-substance sales meant that each of these handful of employees needed to adjudicate dozens or hundreds of orders per day, allowing them to spend just a few minutes or seconds reviewing each flagged order.

230. For example, one Diversion Control team member's 2014 annual performance evaluation reflected that he reviewed approximately 43,200 orders in a single year—a feat he achieved by regularly reviewing roughly 240 orders in a single workday.

231. And this employee—like others—often had to cram all these daily order reviews into just a few hours, resulting in alleged reviews of very unusual orders for highly addictive controlled substances that lasted just seconds.

232. Indeed, the employee's performance review reflects that he spent less than half of his work time reviewing suspicious orders.

233. Accordingly, the employee has admitted that he frequently completed his review of a flagged order and decided not to report it to DEA in about 45 seconds.

234. ABC's data show that order reviews were often even quicker than that. For example, ABC's data show that on or about February 10, 2015, a different Diversion Control team reviewer cleared a series of flagged controlled-substance orders placed by numerous different pharmacies for 59,000 dosage units of oxycodone, OxyContin, hydrocodone, and Vicodin to be shipped and not reported, all within the span of two minutes and 45 seconds.

3. ABC's order reviewers did not have access to information and did not receive adequate training needed to conduct investigations

235. In addition to lacking the time to investigate orders properly, CSRA order reviewers also lacked essential resources, information, and training.

236. For example, ABC's stated policy required every CSRA review of every flagged order to begin with an examination of the current Form 590 for the customer who placed the flagged order.

237. But, as noted above, CSRA often did not have completed Form 590s for its customers. *See supra* Section III(B). Without Form 590s providing basic information about customers, ABC's order reviewers could not take the first and most basic investigatory step required by ABC's policies.

238. ABC's policies also required CSRA reviewers to take other investigatory steps for each flagged order, and only after completion of those investigatory steps did ABC's policies permit an order reviewer to decide whether to release an order and document his or her decision for doing so.

239. But ABC, ABDC, and CSRA regularly violated these policies by releasing orders without conducting investigations, and by recording reasons for releasing and not reporting orders that did not reflect suspicion-dispelling investigations.

240. Moreover, while ABC often had access to a wealth of customer data, it typically failed to make all of this data available to CSRA.

241. For example, even though some of ABC's customers were serviced by multiple ABC subsidiaries, and even though CSRA was responsible for preventing diversion for all subsidiaries, ABC did not generally make one subsidiary's customer information available to employees reviewing orders placed by that same customer with another subsidiary.

242. This deficiency left order reviewers (both at the distribution center level and at the Diversion Control team level) operating in the dark as to a portion of ABC's sales to a particular customer.

243. As Consulting Firm 2 put it, the "left hand [didn't] know what the right hand [was] doing," and there was "no coordination of order monitoring between" ABC's various subsidiaries.

244. CSRA and members of the Diversion Control team also often lacked backgrounds in diversion control issues, and they were given little formal training.

245. One Diversion Control employee stated she did not recall receiving any training on suspicious orders, and she described ABC's training on other topics as quick and scant.

246. Predictably, given the lack of training, resources, and time, CSRA personnel reported to Consulting Firm 2 that they felt "overwhelmed by the volume of activities they [were] required to perform, the administrative demands of their position[s] and the lack of direction that they [were] provided."

247. As a result of these pervasive issues, at most, CSRA's supposed order investigations typically consisted only of an order reviewer quickly scanning over what little information ABC made immediately available.

248. Reviewers typically did not, for instance, contact the relevant customer or take any other real suspicion-dispelling steps.

249. Based on these cursory reviews, ABC's order reviewers cleared and did not report an extremely high percentage of flagged orders throughout the relevant period.

250. The percentage of highly unusual, flagged orders that ABC did not report to DEA reached well over 99 percent in 2017.

251. That year, two years into ROMP's implementation, ABC and ABDC filed fewer than 350 suspicious order reports for orders placed with ABDC—an approximately 99% drop from 2014.

252. By comparison, in 2017, ABC's two major competitors respectively filed about 200,000 and 40,000 suspicious order reports.

F. The compliance program for ICS suffered similar defects

253. ABC maintained a common policy that required all its subsidiaries, including ABDC and ICS, to maintain order monitoring programs.

254. Pursuant to ABC's enterprise-wide policy, ICS developed an electronic order monitoring program that was separate and distinct from the order monitoring programs established for ABDC.

255. This program was in place from before the beginning of the relevant period until November 2019 or around then.

256. ICS's electronic order monitoring program only monitored orders that ICS received electronically. It did not monitor hard-copy orders that ICS received from customers, and ICS routinely cleared suspicious hard-copy orders without conducting suspicion-dispelling investigations or reporting the orders to DEA.

257. Like the ABDC order monitoring programs discussed above (OMP and ROMP), ICS's electronic order monitoring program used statistical thresholds to flag unusual controlled-substance orders for review.

258. Orders that breached ICS's thresholds were placed on what ICS referred to as "51 holds."

259. Under ICS's policies, orders that breached thresholds and were placed on 51 holds were designated as suspicious, and human reviewers (who were CSRA representatives)

were supposed to take certain steps to investigate those orders and attempt to either dispel suspicions or reject the orders and report them to DEA.

260. ICS's policies stated that CSRA was required to file suspicious order reports with DEA relating to suspicious orders of controlled substances received by ICS.

261. As with ABDC, the individuals responsible for reviewing the suspicious orders identified by ICS's order monitoring programs routinely cleared them for shipment without conducting or documenting suspicion-dispelling investigations.

262. Until 2018, ICS's policies categorically provided that controlled-substance orders placed by customers who were themselves distributors were not suspicious.

263. This rule has no basis in the law, and as a result of it, ABC and ICS repeatedly refused or negligently failed to report suspicious orders received from ICS's distributor customers for which ABC and ICS did not dispel suspicion.

264. That includes suspicious orders received from Distributor 1, which admitted to unlawful distribution of opioids as part of a deferred prosecution agreement, and whose CEO was convicted of conspiring to distribute opioids unlawfully.

265. And though the ICS policy provided that suspicious orders from pharmacy customers should be reported if suspicion was not dispelled, that policy was consistently ignored.

266. In fact, from the beginning of the relevant period until at least July 2018, ABC and ICS did not file a *single* suspicious order report with DEA for an order placed with ICS.

267. During that time, ICS received numerous suspicious orders, including from customers with suspicious business practices, one of which is described below as an example of ABC's and ICS's egregious misconduct.

268. In or around November 2019, ICS rolled out a new suspicious order monitoring program that it developed with the help of a third party, which ABC retained on ICS's behalf.

269. Under the programs that ICS utilized before, during, and after November 2019, ICS routinely received suspicious orders of controlled substances that ABC and ICS refused or negligently failed to report to DEA despite not having conducted suspicion-dispelling investigations.

270. ABC's and ICS's reporting failures involve orders that their order monitoring programs identified as unusual and suspicious, as well as orders that ICS's order monitoring programs cleared without flagging and holding for review.

IV. DEFENDANTS VIOLATED THE CSA BY REFUSING OR NEGLIGENTLY FAILING TO REPORT SUSPICIOUS ORDERS OF CONTROLLED SUBSTANCES

271. As a result of the flaws in the design and implementation of their compliance programs, as detailed above, each Defendant violated 21 U.S.C. § 842(a)(5) by refusing or negligently failing to report suspicious orders to DEA on numerous occasions during the relevant period.

272. Defendants' violations fall into four broad and non-exclusive categories: (1) failures to report orders that were suspicious because of indications that the customers placing the orders likely were facilitating diversion of controlled substances; (2) failures to report suspicious orders that breached Defendants' thresholds and were flagged, and which Defendants' reviewers rejected because they recognized that they could not dispel the suspicions raised by the orders; (3) failures to report suspicious orders that breached Defendants' thresholds and were flagged for review, but which Defendants cleared to be shipped and not reported without dispelling all suspicions; and (4) failures to report other suspicious orders that Defendants' faulty algorithms did not flag. Certain violations fall into more than one of these categories.

273. Defendants' violations were at least negligent in light of the pervasive problems identified above with Defendants' compliance programs, including the minimal resources and training that Defendants devoted to suspicious order monitoring and reporting, their failures to comply with their own Know Your Customer policies and their otherwise deficient due diligence practices, and the flawed order monitoring programs that Defendants implemented, all in the context of the opioid epidemic.

A. Defendants violated the CSA by failing to report suspicious orders placed by customers Defendants had notice were likely facilitating diversion

274. Each Defendant violated 21 U.S.C. § 842(a)(5) on numerous occasions by refusing or negligently failing to report controlled-substance orders that were suspicious because, *inter alia*, the Defendant had notice that the customer placing the order was potentially facilitating the diversion of controlled substances.

275. A few examples of Defendants' conduct with such customers are included below to illustrate Defendants' conduct with such customers more generally.

276. These examples illustrate the spectrum of the common deficiencies in Defendants' CSA compliance and suspicious order monitoring and reporting practices—from the poor implementation of their Know Your Customer programs; to the failure of OMP, ROMP, and ICS's order monitoring programs on many occasions to flag orders that unquestionably were suspicious; to the failure of Defendants' personnel to perform adequate suspicion-dispelling investigations for orders flagged by OMP, ROMP, and ICS's order monitoring programs; to each Defendant's failure to report suspicious orders that were either flagged by Defendants' algorithms or were suspicious because of other indicia of diversion.

277. Importantly, in the examples below, there were numerous occasions where Defendants confirmed that orders were suspicious, but Defendants kept shipping and time and again refused or negligently failed to report the suspicious orders to DEA.

1. Pharmacy 1 (Fort Lee, NJ)

278. Pharmacy 1 was a closed-door, mail-order independent pharmacy in Fort Lee, New Jersey.

279. From February 2016 through February 2020, Defendants collectively sold huge amounts of controlled substances to Pharmacy 1.

280. On or about August 3, 2022, Pharmacy 1 pleaded guilty in the District of New Jersey to conspiring to violate the CSA by illegally selling opioids distributed by Defendants ABDC and ICS. Pharmacy 1 also surrendered its DEA registration in or around June 2021 based on the same conduct.

281. Prior to February 2016, Pharmacy 1 purchased its controlled substances from two distributors that were not ABC subsidiaries, Distributor 1 and Distributor 2.

282. By November 2015, Distributor 2 was rejecting controlled-substance orders from Pharmacy 1 due to their suspiciousness.

283. Distributor 2 expanded its investigation of the pharmacy on or around December 30, 2015.

284. The very next day, Pharmacy 1 completed an application to start buying opioids from Defendant ICS.

285. Pharmacy 1 first sent its application to Virtual Manufacturer 1, a company that marketed and supplied opioids and other drugs. Virtual Manufacturer 1 is not, and at all times relevant to this action was not, registered with DEA to distribute controlled substances, so

Virtual Manufacturer 1 contracted with ICS to have ICS distribute Virtual Manufacturer 1's drugs.

286. Virtual Manufacturer 1 marketed and sold two opioids that it wanted ICS to distribute to Pharmacy 1: levorphanol and Abstral. Both are highly dangerous and addictive controlled substances.

287. Abstral is especially dangerous and addictive. It is a sublingual fentanyl tablet, and it is approved only for treatment of breakthrough cancer pain in adults. Even then, Abstral is medically indicated only for patients who have demonstrated tolerance to another opioid therapy.

288. Abstral bears an FDA-required label warning: "ABSTRAL exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death."

289. Pharmacy 1 submitted two Form 590s to ICS, each of which contained obvious red flags. The Form 590s showed that:

a. more than 60% of Pharmacy 1's purchases would be controlled substances, a very high percentage that is indicative of diversion;

b. Pharmacy 1 wanted to make monthly purchases of large amounts of fentanyl products, which are some of the most dangerous and addictive Schedule II controlled substances; and

c. Pharmacy 1 was purchasing controlled substances from at least two other distributors, which would prevent ABC and ICS from seeing the full scope of Pharmacy 1's purchasing.

290. Despite all these red flags, CSRA's Director of Diversion Control, E.C., authorized ICS to begin making sales to Pharmacy 1.

291. The CSRA Director's email approving Pharmacy 1 did not include any questions, analysis, or comment. It merely said "Approved. Thx."

292. Due to Pharmacy 1's suspicious ordering practices, Distributor 2 stopped selling controlled substances to Pharmacy 1 on February 4, 2016.

293. Just before that termination took effect, on or around February 1, 2016, ICS started serving as a distributor for Pharmacy 1.

294. ABC and ICS handled Pharmacy 1's application on a rush basis so that the pharmacy could avoid running out of controlled substances after being terminated by Distributor 2.

295. Pharmacy 1 quickly began purchasing far more controlled substances from ICS than its Form 590 projected. Although Pharmacy 1's Form 590 said that it would purchase about 75 bottles of the opioid levorphanol per month, by mid-2016, it was ordering and receiving more than 400 bottles per month.

296. Throughout this period, ICS knew that Pharmacy 1 was also purchasing large amounts of levorphanol from Distributor 1 as well.

297. CSRA personnel noticed Pharmacy 1's increased ordering, but they merely required Pharmacy 1 to request an increase to its thresholds for fentanyl products to allow its levorphanol orders to be processed without being flagged.

298. Despite Pharmacy 1 ordering more than four times as much levorphanol as it had said it would, ABC and ICS did not report to DEA any of Pharmacy 1's orders placed with ICS in 2016.

299. In August 2016, as its opioid orders with ICS were skyrocketing, Pharmacy 1 also applied to start purchasing controlled substances from ABDC, in addition to ICS.

300. Like Pharmacy 1's application to purchase drugs from ICS, Pharmacy 1's application to purchase drugs from ABDC was also subject to CSRA's review and approval.

301. Again, Pharmacy 1's application contained numerous red flags, which CSRA personnel noted in internal communications.

302. CSRA personnel expressed concern that Pharmacy 1's orders were anticipated to be over 60% controlled substances, that some of its customers and top prescribers were from out of state, that it was buying the same drugs from multiple distributors, that it had given vague answers and non-responses to questions, and that its owner operated a similar pharmacy very nearby.

303. Nonetheless, CSRA overlooked these red flags, and CSRA Director E.C. approved ABDC to sell opioids and other controlled substances to Pharmacy 1 in September 2016.

304. Throughout its relationship with Pharmacy 1—through both ABDC and ICS—ABC failed to coordinate its order monitoring across its subsidiaries, contributing to many suspicious orders going unreported.

305. Between at least September 2016 and June 2018, both ABDC and ICS sold Pharmacy 1 opioids that CSRA considered to be in the same drug families. Purchasing the same controlled substances from the two ABC subsidiaries allowed Pharmacy 1 to evade each subsidiary's order monitoring thresholds.

306. When CSRA Director E.C. realized that ABC had allowed Pharmacy 1 to buy the same types of opioids from ICS and ABDC, he acknowledged that CSRA "should have blocked" Pharmacy 1 from buying controlled substances from ABDC that the pharmacy was already buying through ICS, and he asked other CSRA personnel "[h]ow did we miss this?".

307. After CSRA approved controlled-substance sales to Pharmacy 1 through ABDC, the pharmacy quickly began ordering very significant quantities of controlled substances from ABDC, again creating more suspicion within CSRA.

308. In April 2017, CSRA Director E.C. noted that Pharmacy 1's purchases through ABDC to that point were almost all fentanyl.

309. A CSRA Diversion Control employee also raised concerns about Pharmacy 1's large and growing ordering of oxycodone from ABDC as early as May 2017, by which time ROMP had already flagged multiple orders that Pharmacy 1 placed with ABDC for oxycodone.

310. That employee, who lived and worked in California, explained to a supervisor that despite noticing the large increase in oxycodone ordering, she was hesitant to report Pharmacy 1's opioid orders as suspicious to DEA: "I mean I would rather not report someone if it isn't necessary and it is hard for me to 'know the customers' on the east coast. Lol."

311. Between February 2017 and March 2018, ABDC received hundreds of controlled-substance orders from Pharmacy 1, about a fifth of which were so unusual that they were flagged by ROMP.

312. ABC and ABDC filed no suspicious-order reports relating to Pharmacy 1 during this period.

313. By May 2, 2018, CSRA personnel recommended terminating all controlled-substance sales to Pharmacy 1.

314. CSRA's Vice President for Corporate Security and Diversion Control, D.M., explained a few of the huge red flags that led to this recommendation in an email to Pharmacy 1's pharmacist-in-charge: "[Pharmacy 1] purchased 77.3% controlled substances from AmerisourceBergen during the time period October 1, 2017 to December 31, 2017"; Pharmacy 1

was "purchasing oxycodone from 2 wholesalers, hydrocodone from 2 wholesalers and fentanyl products from 5 wholesalers"; "61% of RXs dispensed [were] controlled substance RXs"; and Pharmacy 1 purchased massive amounts of highly-dangerous and addictive drugs, with "Levorphanol, Subsys [another fentanyl product,] and oxycodone products" being the "#1, #3, and #4 most overall dispensed drug[s] by Rx from [Pharmacy 1.]"

315. But even after the May 2, 2018 recommendation to terminate Pharmacy 1 as a controlled-substance customer, CSRA allowed ABDC and ICS to keep selling dangerous opioids and other controlled substances to Pharmacy 1 for more than three months.

316. And Defendants filed almost no suspicious order reports with DEA for Pharmacy 1's orders.

317. Indeed, during the entire multi-year period that ABDC and ICS sold opioids to Pharmacy 1, ABC and ABDC filed just four suspicious order reports for a group of oxycodone and hydromorphone orders placed with ABDC on or about April 16, 2018.

318. ICS filed no suspicious order reports relating to Pharmacy 1.

319. In fact, outside those orders on or about April 16, 2018, Defendants never filed a single suspicious order report with DEA for Pharmacy 1, even though ROMP and ICS's order monitoring program flagged hundreds of Pharmacy 1's orders and CSRA employees recognized that Pharmacy 1's business model and practices were highly suspicious.

320. Eventually, on or about May 17, 2018, CSRA Vice President D.M. sent Pharmacy 1 a purported termination letter on ABC letterhead and addressed from ABC's Pennsylvania corporate headquarters. The letter stated that ABC was "proceeding with the termination of sales of all controlled substances . . . to both your ABDC and ICS accounts."

321. But Defendants did not actually terminate controlled-substance sales to Pharmacy 1 at that time.

322. After CSRA sent Pharmacy 1 the alleged termination letter on behalf of both ABDC and ICS, Virtual Manufacturer 1 promptly stepped in and told ABC to continue distributing controlled substances to Pharmacy 1.

323. ABC obliged, and CSRA allowed both ABDC and ICS to continue direct sales to Pharmacy 1.

324. Top ICS executives reacted favorably to CSRA's decision, writing in email communications: "Great News!" "Nice!" and "SELL….SELL….SELL!!!!!".

325. Following the May 2018 termination letter, Defendants ABDC and ICS continued to fill and not report Pharmacy 1's opioid orders, despite the patent grounds for suspicion that CSRA had identified.

326. At one point in July 2018, a CSRA manager wrote: "[Pharmacy 1] is trying to order outside of their normal order pattern, [and Pharmacy 1] has been doing this since they received notice from ABC Diversion Control."

327. The CSRA manager also indicated that she would report Pharmacy 1's orders as suspicious. But she did not.

328. CSRA did eventually terminate ABDC's and ICS's direct controlled-substance sales to Pharmacy 1 on or about July 26, 2018.

329. CSRA Vice President D.M. sent a letter to DEA on ABC letterhead asserting that Defendants had "terminated the sale of all controlled substances" to Pharmacy 1 through both ABDC and ICS.

330. But ICS set up a secret back-door channel to continue selling controlled substances including opioids to Pharmacy 1 through another distributor, Distributor 3, even after this supposed termination took effect.

331. The proxy distributor relationship allowed ABC and ICS to surreptitiously maintain Pharmacy 1 as a profitable customer.

332. To create this back channel, ICS obtained multiple Form 590s from Distributor 3, which it submitted to CSRA Director E.C. and another CSRA Director, S.H., on August 7, 2018.

333. ICS business personnel, including Vice President G.L., were very concerned with "expediting" the approval of Distributor 3's Forms 590 by ABC, leading multiple CSRA employees to contact E.C. directly. E.C. responded in less than two hours after receiving Distributor 3's Forms 590, saying "I spoke w/ [CSRA Director S.H.] and neither of us have any concerns. Requests are approved."

334. Between August 7, 2018 when CSRA approved the new Form 590s for Distributor 3, and February 11, 2020, Distributor 3 placed hundreds of orders with ICS for levorphanol, Abstral, and the fentanyl nasal spray "Lazanda."

335. Some ICS/CSRA personnel knew and explicitly discussed that Distributor 3 was placing those orders to supply the drugs to Pharmacy 1.

336. Nonetheless, ICS and ABC did not file suspicious order reports for any of the suspicious orders that Distributor 3 placed for Pharmacy 1.

337. CSRA Vice President D.M. has since admitted that this scheme of setting up a proxy distributor to distribute the same products to Pharmacy 1 was no better than ICS continuing to service Pharmacy 1 directly.

338. In all, ABC and its subsidiaries made more than $130 million from direct and indirect sales of Virtual Manufacturer 1's products to Pharmacy 1.

339. Each Defendant committed a separate CSA violation each time it refused or negligently failed to file a suspicious order report for a suspicious Pharmacy 1-bound controlled-substance order received after the Defendant had notice of Pharmacy 1's suspicious controlled-substance practices.

340. These unreported suspicious orders include, for example, an order for fentanyl lozenges that Pharmacy 1 placed with ABDC on or about June 28, 2017, which was flagged by ROMP, and which a distribution center employee cleared to be shipped and not reported, with the only recorded justification being the false comment "Low Risk" and the selection of the adjudication reason code connoting "Product not typically subject to diversion or abuse."

341. They also include an order for oxycodone that Pharmacy 1 placed with ABDC on or about June 11, 2018, which exceeded ROMP's TRD threshold, but which ABDC shipped without review.

342. They further include an order of Abstral 800mcg that Distributor 3 placed with ICS on or about November 6, 2018, which ICS shipped to Distributor 3 and did not report.

2. Pharmacy 2 (Trenton, NJ)

343. Pharmacy 2 was an independent pharmacy in Trenton, New Jersey.

344. From the beginning of the relevant period through July 2016, ABDC sold extraordinary quantities of controlled substances to Pharmacy 2, including millions of opioid pills, while failing to conduct due diligence and failing to report numerous suspicious orders.

345. During that time, Pharmacy 2's co-owner and employees purchased controlled substances from ABDC, and then knowingly diverted the drugs to street-level dealers and other cash-paying customers who did not have legitimate prescriptions.

346. These actions resulted in a DEA order suspending Pharmacy 2's registration in 2017.

347. In May 2022, Pharmacy 2's co-owner, who also served as its pharmacist-in-charge, was indicted in the District of New Jersey for conspiracy to violate the CSA by illegally distributing opioids, including oxycodone.

348. CSRA failed to conduct minimal due diligence on Pharmacy 2 before ABDC began to send it huge amounts of oxycodone and other controlled substances.

349. CSRA accepted a Form 590 from Pharmacy 2 that listed illegible and incomprehensible amounts of oxycodone, hydrocodone, and methadone, in the sections related to anticipated purchasing.

350. CSRA also overlooked that Pharmacy 2 had left important sections of its Form 590 blank, including areas seeking information about (a) whether Pharmacy 2 had written policies for filling prescriptions; (b) the percentage of Pharmacy 2's prescriptions that were for controlled substances; (c) Pharmacy 2's process for verifying prescriptions; and (d) whether Pharmacy 2 participated in the New Jersey state prescription monitoring program.

351. Despite these defects, CSRA allowed ABDC to sell massive volumes of controlled substances to Pharmacy 2.

352. By 2014, Pharmacy 2 was ordering highly unusual amounts of opioids from ABDC.

353. On or about August 22, 2015, a CSRA Director observed that Pharmacy 2 "order[ed] oxycodone products every day," the pharmacy appeared to be aware of its OMP thresholds, and it appeared to be structuring its ordering to avoid being flagged by OMP.

354. After highlighting Pharmacy 2's suspicious ordering patterns, CSRA sent an outside auditor to conduct a site visit on or about September 2, 2015.

355. The auditor quickly confirmed the suspicious nature of Pharmacy 2's controlled-substance ordering.

356. The auditor reported that Pharmacy 2's "due diligence procedures are insufficient for the amount of opioid, benzodiazepine and codeine based cough medication controlled substance prescriptions being filled by [the pharmacy]." The auditor further reported that the pharmacist-in-charge did not appear to understand her legal obligations and that 50% of the pharmacy's controlled-substance sales were for oxycodone—a serious red flag.

357. As a result, the auditor "recommended that ABC curtail shipments of all opioids, all benzodiazepines and schedule 5 cough syrups."

358. But ABDC continued filling Pharmacy 2's controlled-substance orders and not reporting the orders to DEA as suspicious even after receiving the auditor's report.

359. By late 2015, Pharmacy 2 had grown to be ABDC's largest customer for oxycodone solids in New Jersey.

360. Subsequently, in every month between March 2016 and July 2016, ABDC shipped more oxycodone to Pharmacy 2 than it had shipped to Pharmacy 2 in any month in any of the prior three years.

361. CSRA eventually terminated controlled-substance sales to Pharmacy 2 on or about September 21, 2016, but not before ABDC sent Pharmacy 2 enormous amounts of opioids and other controlled substances.

362. Specifically, between September 2015, when the auditor recommended that CSRA curtail opioid sales to Pharmacy 2, and September 2016, when ABDC stopped selling

controlled substances to Pharmacy 2, ABDC shipped Pharmacy 2 more than 1,000,000 dosage units of opioids.

363. During the same period, ABC's algorithms under OMP and ROMP flagged many orders placed by Pharmacy 2. Order reviewers cleared dozens of those orders to be filled and not reported to DEA, despite the serious and unresolved issues with Pharmacy 2's controlled-substance practices.

364. ABC and ABDC committed a separate CSA violation each time they refused or negligently failed to file a suspicious order report for a suspicious controlled-substance order received from Pharmacy 2 after ABC and ABDC had notice of Pharmacy 2's suspicious controlled-substance practices.

365. These unreported suspicious orders include, for example, an order for 400 oxycodone 30mg tablets that Pharmacy 2 placed with ABDC on or about August 23, 2015, which was flagged by OMP, but which a CSRA Diversion Control employee cleared to be shipped and not reported, with the only recorded justification being the comment "high risk | Approved as compliant, within customer's typical purchase history."

366. They also include an order for 400 dosage units of oxycodone 30mg tablets that Pharmacy 2 placed with ABDC on or about January 8, 2016. The order exceeded ROMP's TRD threshold, but ABDC shipped it anyway without review or reporting by ABC or ABDC.

3. Pharmacy 3 (Beckley, WV)

367. Pharmacy 3 was an independent pharmacy located in Beckley, West Virginia. ABDC sold huge quantities of controlled substances to Pharmacy 3 from at least the beginning of the relevant period to 2020.

368. In June 2021, Pharmacy 3, its sister pharmacy, and their owner reached a settlement with the Department of Justice relating to their filling of illegitimate prescriptions for controlled substances from 2015 to 2020.

369. Pharmacy 3 started buying controlled substances from ABDC in 2012.

370. In January 2015, CSRA personnel observed red flags associated with Pharmacy 3's and its sister pharmacy's purchases of controlled substances.

371. On or about January 28, 2015, CSRA sent its outside auditor an email identifying Pharmacy 3 as a "potential candidate[] to receive an on-site visit from [the auditor.]"

372. On or about January 29, 2015, the auditor advised CSRA that the auditor had already visited Pharmacy 3 on behalf of Distributor 2, and that Distributor 2 subsequently terminated its relationship with Pharmacy 3. The auditor also informed CSRA that Pharmacy 3 had been "dispensing significant amounts of opiate narcotics in 2011."

373. CSRA did not take any action based on this information.

374. The auditor visited Pharmacy 3 on behalf of ABC and ABDC on or around February 11, 2015. The auditor then prepared a report of the visit that the auditor submitted to ABC on or about February 22, 2015.

375. The auditor's report confirmed that Pharmacy 3 was not only flooding ABDC with suspicious orders, but also facilitating diversion. Some of the auditor's observations are summarized below:

a. A retired deputy sheriff who worked as an armed security guard at Pharmacy 3 told the auditor that he had "witnessed numerous drug deals in the parking lot after customers have filled there [sic] 'Oxy[codone] RX'";

b. The security guard also told the auditor that Pharmacy 3 had customers who were "drug addicts" and "drug dealers," and that the security guard had observed people getting out of cars in Pharmacy 3's parking lot with "wad[s] of money" and then exchanging cash for prescriptions;

c. Pharmacy 3's pharmacist-in-charge told the auditor that at least 50% of its sales were for controlled substances, with its "top" drugs being oxycodone, hydrocodone, and alprazolam, three highly diverted controlled substances;

d. Pharmacy 3's pharmacist-in-charge admitted that the pharmacy provided controlled substances to customers who had "attempted to have [their] prescriptions filled at over 20 different pharmacies[,]" but whose prescriptions no other pharmacy would fill;

e. Pharmacy 3 did not "verify customers and their prescriptions," and it did not check that "the prescriptions were validated through the state [prescription drug monitoring] system"; and

f. Pharmacy 3 was "filling excessive and unusual amounts of controlled substances."

376. Three months after CSRA received this extremely damning report about Pharmacy 3, on May 5, 2015, a CSRA Director recommended that ABC and ABDC "consider severing the pharmacy's ability to purchase controlled substances" in light of the auditor's findings and other issues with the pharmacy.

377. But despite its knowledge of "numerous drug deals" in Pharmacy 3's parking lot, and all the other glaring red flags, ABDC continued to supply Pharmacy 3 with a steady stream of opioids and other controlled substances.

378. ABDC did so even after then-Senior Director for Corporate Security and Diversion Control D.M. sent Pharmacy 3 a letter on or about June 12, 2015 explaining that CSRA intended to suspend all sales of controlled substances to Pharmacy 3.

379. CSRA did not actually suspend Pharmacy 3's controlled-substance purchasing until on or about December 5, 2015, and shortly thereafter, it reversed course and allowed ABDC to start supplying Pharmacy 3 with controlled substances again.

380. Between CSRA's June 12, 2015 letter and when ABC and ABDC temporarily cut off controlled-substance sales to Pharmacy 3 on or about December 5, 2015, Pharmacy 3 placed numerous orders for controlled substances with ABDC, and ABDC shipped nearly 500,000 dosage units of controlled substances to Pharmacy 3, including more than 100,000 oxycodone tablets.

381. ABC and ABDC did not report any of these orders as suspicious even though they considered Pharmacy 3's business practices and ordering activities to be so suspicious that they warranted terminating Pharmacy 3 as a controlled-substance customer.

382. CSRA Vice President D.M. has admitted that ABDC should not have filled thousands of Pharmacy 3's controlled-substance orders because ABDC should have stopped all controlled-substance sales to Pharmacy 3 immediately upon receiving reports of drug deals in Pharmacy 3's parking lot, which he aptly described as the reddest of red flags.

383. In total, between receiving notice of drug deals in Pharmacy 3's parking lot and the termination of controlled-substance sales to Pharmacy 3 in December 2015, ABDC received

over a thousand suspicious orders from Pharmacy 3 that ABC and ABDC refused or negligently failed to report to DEA.

384. ABC and ABDC committed a separate CSA violation each time they refused or negligently failed to file a suspicious order report for a suspicious Pharmacy 3 controlled-substance order after they had notice of Pharmacy 3's suspicious practices.

385. These unreported suspicious orders include, for example, an order for 500 oxycodone 30mg tablets that Pharmacy 3 placed with ABDC on or about March 2, 2015, which was flagged by OMP, but which a CSRA Diversion Control employee cleared, with the only recorded justification being the comment "retail Phcy | Approved as compliant, within customer's purchase history."

386. They also include an order for 1,000 dosage units of hydrocodone that Pharmacy 3 placed with ABDC on or about October 20, 2015, which was not flagged and which ABDC shipped without review.

4. Pharmacy 4 (Gainesville, FL)

387. Pharmacy 4 is an independent pharmacy located in Gainesville, Florida. ABDC sold huge quantities of controlled substances to Pharmacy 4 from the beginning of the relevant period to December 2019.

388. Pharmacy 4 regularly had orders flagged by OMP and ROMP between June 2014 and September 2018, but ABC and ABDC did not file suspicious-order reports relating to any controlled-substance orders that Pharmacy 4 placed during that period.

389. In May 2017, Pharmacy 4's orders became so suspicious that CSRA Diversion Control personnel raised concerns to CSRA's management. They determined that Pharmacy 4 was an extreme outlier for orders of controlled substances and identified serious red flags, including that:

a. Pharmacy 4 was selling 37% of its prescriptions for cash;

b. Pharmacy 4's overall purchases were more than 51% controlled substances; and

c. 95% of one of Pharmacy 4's top prescriber's prescriptions were for a Schedule III opioid, and that prescriber's patients paid for 97% of those prescriptions in cash.

390. As a result, CSRA personnel expressed concerns related to Pharmacy 4's due diligence process, and they suggested that an outside auditor visit Pharmacy 4.

391. The auditor conducted a site visit of Pharmacy 4 on or around June 21, 2017. The auditor prepared a report dated June 29, 2017.

392. The auditor's report concluded that Pharmacy 4 was an account of concern based on several findings that raised serious red flags:

a. Pharmacy 4 was responsible for "monotonous[*i.e.*, mountainous]" amounts of "controlled substances and commonly abused/diverted controlled substances (including oxycodone, hydromorphone, benzodiazepines, hydrocodone)";

b. A billing clerk and a Pharmacy 4 pharmacist reported "that several incidents have occurred on the lot of [Pharmacy 4] involving customers apparently making hand-to-hand exchanges on the pharmacy parking lot with non-customers after filling a prescription";

c. Pharmacy 4 was "purchasing approximately 50% controlled substances by dosage unit from AmerisourceBergen and dispensing approximately 32% controlled substances by number of prescriptions";

d. Pharmacy 4 was "dispensing combinations of controlled substances that are known to be a high risk for abuse/diversion"; and

e. Pharmacy 4 was "not consistently using effective controls to prevent diversion and/or abuse of controlled substances."

393. Despite the auditor's findings and CSRA's concerns about Pharmacy 4, ABDC continued to service Pharmacy 4 uninterrupted.

394. And ABC and ABDC did not file a suspicious-order report with DEA for any of the thousands of orders that Pharmacy 4 placed in the 11 months after the auditor submitted his report.

395. CSRA finally sent Pharmacy 4 a termination letter on May 25, 2018, but the so-called termination was very short lived.

396. CSRA blocked controlled-substance sales to Pharmacy 4 on or around May 29, 2018, then it reinstated controlled-substance sales to the pharmacy just 17 days later, on June 22, 2018.

397. Shortly after ABDC resumed selling opioids and other dangerous drugs to Pharmacy 4, a CSRA employee unsurprisingly observed that Pharmacy 4's purchases went "right back to where they were originally and caused concern[.]"

398. Despite CSRA recognizing that Pharmacy 4 had resumed the same suspicious-ordering practices that had led CSRA to briefly terminate ABDC's controlled-substances sales to Pharmacy 4 in June 2018, ABDC sold controlled substances to the pharmacy at the same or increased levels for the next 18 months, until CSRA eventually terminated Pharmacy 4 as a controlled-substance customer on or about December 6, 2019.

399. During those 18 months, ABDC received thousands more controlled-substance orders from Pharmacy 4, but ABC and ABDC did not report any of those orders to DEA.

400. From June 29, 2017, when ABC and ABDC received notice of drug sales in Pharmacy 4's parking lot, through their second termination of Pharmacy 4 in December 2019, ABC and ABDC refused or negligently failed to report to DEA thousands of suspicious orders from Pharmacy 4, including dozens of suspicious orders that were flagged by ROMP, and thousands of other suspicious orders that were not flagged by ROMP.

401. ABC and ABDC committed a separate CSA violation each time they refused or negligently failed to file with DEA a suspicious order report for a suspicious Pharmacy 4 controlled-substance order after they had notice of Pharmacy 4's suspicious practices.

402. The unreported suspicious orders include, for example, multiple orders for nearly 1,900 dosage units of a Schedule III opioid that Pharmacy 4 placed with ABDC on or about January 2 and 3, 2018, which were flagged by ROMP, but which a CSRA Diversion Control employee cleared to be shipped and not reported to DEA. These unreported orders were cleared with no comment or other justification besides the selection of adjudication reason codes connoting that the orders were purportedly within acceptable patterns and parameters.

403. They also include, for example, an order for 500 dosage units of oxycodone 30mg tables that Pharmacy 4 placed with ABDC on or about February 6, 2019, which order exceeded ROMP's TRD threshold, but which ROMP's dual-trigger algorithms failed to flag, and which ABDC shipped without review.

5. Pharmacy 5 (Lakewood, CO)

404. Pharmacy 5 was an independent pharmacy in Lakewood, Colorado.

405. ABDC sold huge quantities of controlled substances to Pharmacy 5 from the beginning of the relevant period to 2020.

406. The pharmacy closed in July 2020 and voluntarily surrendered its DEA registration in August 2020.

407. Before it became a customer of ABDC, Pharmacy 5 purchased drugs from another large drug distributor, Distributor 4. However, Distributor 4 became concerned with the extraordinary volume of Pharmacy 5's Schedule II controlled-substance purchases and regularly refused to fill orders.

408. When Pharmacy 5 complained to Distributor 4 and threatened to find another distributor if its orders were not filled, Distributor 4 told Pharmacy 5 to look elsewhere.

409. Pharmacy 5 reached out to ABDC and specifically told ABDC about Distributor 4's unwillingness to fill its Schedule II controlled-substance orders.

410. ABDC sales representatives told Pharmacy 5 that ABDC would love to have its business. The sales representatives also assured Pharmacy 5 that ABDC would give the pharmacy the drugs it wanted, including all its desired Schedule II controlled substances, and that it would not scrutinize Pharmacy 5's orders.

411. ABDC began servicing Pharmacy 5 in mid-2013 and sold it huge quantities of controlled substances.

412. By 2015, Pharmacy 5 was ABDC's largest purchaser of oxycodone 30mg tablets in all of Colorado.

413. In January 2015, a CSRA employee wrote D.M. and other Diversion Control management, advising that Pharmacy 5 had "been on [her] radar for months" and that she found its oxycodone purchasing especially concerning. She noted that Pharmacy 5 was purchasing more oxycodone than large, nationally-recognized hospitals, and that ABC had increased

Pharmacy 5's OMP thresholds to allow it to order very large volumes of oxycodone without the orders being flagged for review.

414. The same CSRA employee analyzed Pharmacy 5's dispensing practices as well. She identified eleven patients for whom she questioned the legitimacy of their prescriptions, noting that she wondered about those patients: "is this a drug addict/illegitimate patient based on the combos and quantities of drugs?".

415. At least two of those patients later died from drug overdoses.

416. One died of combined drug toxicity from oxycodone, fentanyl, alprazolam, and gabapentin three days after filling prescriptions for oxycodone 30mg, fentanyl, and alprazolam at Pharmacy 5.

417. The other died of toxic opiate overdose within weeks after filling prescriptions for multi-week supplies of oxycodone 30mg, methadone, and alprazolam at Pharmacy 5.

418. After identifying these and other customers she thought might be using Pharmacy 5 to fuel addictions, the CSRA employee circulated her dispensing analysis to D.M. and E.C. The analysis identified numerous red flags, including:

a. large percentages of customers paying for controlled substances in cash;

b. significant numbers of customers receiving combinations of controlled substances that are known to be dangerous and used for illegitimate purposes;

c. customers traveling long distances to fill prescriptions; and

d. oxycodone making up nearly half of all of Pharmacy 5's controlled-substance purchases.

419. As a result of this analysis, CSRA sent an outside auditor to conduct an on-site assessment of Pharmacy 5 in April 2015. The auditor who conducted the assessment called senior CSRA management shortly thereafter to tell them that Pharmacy 5 was a mess and that its pharmacist would fill anything.

420. The auditor's assessment also confirmed the already-identified red flags and found new ones, including that Pharmacy 5 failed to conduct due diligence when filling prescriptions, and it filled prescriptions for practitioners who were on a "no fill list" at another local pharmacy.

421. Based on the auditor's assessment and other suspicious information, CSRA sent a letter to Pharmacy 5 on June 22, 2015 stating that ABDC would suspend all controlled-substance sales to Pharmacy 5.

422. But CSRA never actually suspended or terminated controlled-substance sales to Pharmacy 5 or otherwise took significant action.

423. Instead, CSRA reversed course after Pharmacy 5 submitted letters from doctors asking ABDC to keep supplying Pharmacy 5 with controlled substances.

424. One of those doctors is currently serving a federal prison sentence for his role in a pharmaceutical kickback scheme.

425. Subsequently, CSRA continued to receive information that confirmed that Pharmacy 5's orders and business practices were highly suspicious.

426. For example, after a CSRA investigator analyzed pain clinics whose prescriptions were filled by Pharmacy 5, she informed D.M. that many of the pain clinics' prescriptions raised red flags because the clinics were located far away from Pharmacy 5, because there were

numerous pharmacies that were closer to the clinics than Pharmacy 5, and because many of the clinics were staffed by doctors with disciplinary records.

427. A manufacturer whose controlled-substance products ABDC distributed separately raised concerns with ABC that Pharmacy 5 was the sixth-largest recipient in the United States of the manufacturer's high-strength, immediate-release oxycodone, which caused the manufacturer concern because it would expect far lower quantities for a pharmacy like Pharmacy 5.

428. ABC and ABDC did not report to DEA a single suspicious order from Pharmacy 5 after April 2015, even though ABDC received over 10,000 controlled-substance orders from Pharmacy 5 during that time.

429. ABC and ABDC committed a separate CSA violation each time they refused or negligently failed to file with DEA a suspicious-order report for a suspicious Pharmacy 5 controlled-substance order after they had notice of Pharmacy 5's suspicious practices.

430. These unreported suspicious orders include, for example, an order for 600 dosage units of methadone that Pharmacy 5 placed with ABDC on or about February 4, 2019. That order was flagged by ROMP, but a CSRA Diversion Control employee cleared it for shipment, with no comment or other justification besides the selection of the adjudication reason code "Within acceptable range of customers established order pattern."

431. They also include, for example, an order for 400 dosage units of oxycodone 30mg tablets that Pharmacy 5 placed with ABDC on or about October 11, 2019, which order exceeded ROMP's TRD threshold, but which ABDC shipped without review.

B. Defendants violated the CSA by failing to report flagged suspicious orders that Defendants' reviewers confirmed were suspicious and therefore rejected

432. Defendants further violated 21 U.S.C. § 842(a)(5) on numerous occasions by refusing or negligently failing to report to DEA controlled-substance orders that were flagged for review and that Defendants concluded could not be shipped because their reviewers could not dispel suspicion regarding the orders.

433. As alleged above, the CSA requires a distributor to report, *inter alia*, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency to DEA, unless the distributor dispels the suspicion raised by the orders' unusualness.

434. This includes orders of unusual size, pattern, or frequency that a distributor determines it cannot ship because it cannot dispel the suspicion associated with the orders.

435. On multiple occasions, ABC represented to DEA that ABC and its subsidiaries abided by this requirement, telling DEA that "rejected orders are also reported to the DEA as suspicious."

436. But this was not true. In fact, for a significant portion of the relevant period, ABC's written guidance to order reviewers directed them to reject all flagged orders for which they could not dispel suspicion, but to report a rejected suspicious order only if the reviewer determined that the ordered controlled substance was more likely than not being diverted.

437. And even after ABC stopped providing this guidance in writing, the practice continued.

438. As a result, in numerous instances in which order reviewers rejected flagged ABDC orders because they could not dispel suspicion associated with those orders, ABC and ABDC nevertheless did not report the orders to DEA.

439. A significant number of these instances in which orders were rejected for shipment by reviewers because suspicion could not be dispelled, but the orders were not reported to DEA, occurred on or after October 24, 2018.

440. Orders that were rejected due to their suspiciousness but that ABC and ABDC nonetheless failed to report include, for example, an order for 600 oxycodone 30mg tablets placed with ABDC by Pharmacy 4 on or about August 18, 2015, which a CSRA reviewer rejected but did not report to DEA despite noting that the order was for a "high risk family [and] over consumption high risk item not compliant."

441. They also include an order for 600 oxycodone 30mg tablets placed with ABDC by Pharmacy 5 on or about April 24, 2014, which a CSRA reviewer rejected but did not report to DEA, despite a note by the reviewer stating "investigate | Order Quantity Exceeds threshold; not to release."

442. Each time ABC, ABDC, or ICS refused or negligently failed to report to DEA a flagged order that a reviewer rejected because he or she could not dispel suspicion, they violated 21 U.S.C. § 842(a)(5).

C. Defendants violated the CSA by failing to report flagged suspicious orders for which they did not dispel suspicion

443. Defendants further violated 21 U.S.C. § 842(a)(5) on at least hundreds of thousands of occasions by refusing or negligently failing to report to DEA controlled-substance orders that Defendants' order monitoring programs' thresholds flagged for human review and that Defendants shipped even though their reviewers did not dispel suspicion.

444. As noted, Defendants' order reviewers operated under intense time pressures and without support, resources, or training.

445. As a result, Defendants' order reviewers regularly cleared flagged orders to be shipped and not reported after only cursory reviews of a few seconds or minutes, without actually dispelling the suspicion flagged by Defendants' algorithmic thresholds.

446. The little documentation that Defendants maintained relating to purported order reviews confirms Defendants' failure to dispel the suspicions surrounding at least hundreds of thousands of highly unusual, flagged orders that were not reported to DEA.

447. For example, that limited documentation shows that Defendants' investigations were inadequate, and the flagged orders should have been reported, because, *inter alia*: (1) the recorded comments provide "demonstrably false" or "implausible" reasons for allegedly dispelling suspicion (*Masters*, 861 F.3d at 218–19); (2) the recorded comments lack any justification whatsoever for dispelling suspicion, indicating that no investigations even occurred (*Masters*, 861 F.3d at 218 (finding that "the lack of documentation was evidence that the [investigation] never took place")); or (3) the recorded comments otherwise evince, at best, a cursory and pro forma review.

448. Below are a few non-exclusive examples of Defendants' practices of clearing orders without reporting them to DEA as suspicious even though Defendants did not conduct investigations sufficient to dispel all suspicions relating to the orders.

1. Suspicious flagged ABDC orders falsely cleared as not subject to diversion or abuse

449. In tens of thousands of instances in which ABC and ABDC reviewers cleared highly unusual orders placed with ABDC for commonly abused controlled substances like hydrocodone and fentanyl, the only comments recorded indicate that the orders were cleared because those drugs allegedly are not subject to diversion or abuse.

450. Such orders include, for example, the previously mentioned June 28, 2017 order for fentanyl lozenges that Pharmacy 1 placed with ABDC, which was flagged by ROMP, and which a distribution center employee cleared to be shipped and not reported, with the only recorded justification being the comment, "Low Risk" and the selection of the adjudication reason code "Product not typically subject to diversion or abuse."

451. They also include, for example, an order for fentanyl patches placed with ABDC by Pharmacy 5 on or about January 25, 2019, which a CSRA reviewer approved to be shipped and not reported, with the only recorded justification being the selection of the adjudication reason code "Product not typically subject to diversion or abuse."

452. It is demonstrably false that fentanyl is not subject to diversion or abuse.

453. This group of orders also includes, for example, an order for a Schedule III opioid placed with ABDC by Pharmacy 6, a Clay County, Tennessee independent pharmacy customer, on or about February 16, 2017.

454. The order was flagged for review by ROMP, but a CSRA reviewer cleared the order to be shipped and not reported to DEA, with the only recorded justification being the comment "New" and the selection of the adjudication reason code "Product not typically subject to diversion or abuse."

455. The fact that a pharmacy is a "new" customer is not a legitimate justification for not reporting its suspicious order to DEA.

456. Pharmacy 6's pharmacist-in-charge in February 2017 pled guilty to criminally conspiring to violate the CSA. He has admitted, *inter alia*, that from October 2015 through early February 2019, he was engaged in a conspiracy with Pharmacy 6's owner and others to

intentionally and without authority distribute and dispense prescriptions for opioids that he knew were not for legitimate medical purposes.

457. Reviewers clearing the fentanyl and other opioid orders described above on the manifestly false basis that those opioids are not subject to diversion or abuse demonstrates ABC's and ABDC's failure to dispel suspicion regarding those orders and their disregard of their obligations under the CSA.

458. The same is true of many thousands of analogous orders that ABC's and ABDC's reviewers cleared to be shipped and not reported based on the false justification that dangerous controlled substances were supposedly not subject to diversion or abuse.

2. Suspicious flagged ABDC orders cleared as typical

459. Similarly, in over one hundred thousand instances in which ABC and ABDC cleared highly unusual, flagged ABDC orders for shipment, the only comments recorded indicate that the orders were cleared because they were "within normal ordering" or otherwise typical.

460. These were implausible conclusions, because OMP's and ROMP's algorithms flagged only orders that were highly atypical.

461. Such orders include, for example, the previously mentioned order for 400 oxycodone 30mg tablets that Pharmacy 2 placed with ABDC on or about August 23, 2015, which was flagged by OMP, but which a CSRA Diversion Control employee cleared to be shipped and not reported, with the only recorded justification being the comment "high risk | Approved as compliant, within customer's typical purchase history."

462. They also include the order for 990 dosage units of a Schedule III opioid that Pharmacy 4 placed with ABDC on or about January 2, 2018, which was flagged by ROMP, but which a CSRA Diversion Control employee cleared to be shipped and not reported with no

comment or other justification besides the selection of the adjudication reason code "Within acceptable range of customers established order pattern."

463. They also include, for example, an order for 600 dosage units of oxycodone 30mg placed with ABDC by Pharmacy 7, a Media, Pennsylvania independent pharmacy customer, on or about April 21, 2021.

464. The order was flagged for review by ROMP, but a CSRA Diversion Control employee approved the order to be shipped and not reported, with the only recorded justification being the comment "Order quantity/frequency is consistent" and the selection of the adjudication reason code "Within acceptable range of customers established order pattern."

465. In November 2021, the pharmacist-in-charge of Pharmacy 7 was arrested for illegally providing controlled substances, including oxycodone 30mg, to drug-dependent women in return for sex acts. In 2022, he pled guilty to counts of, *inter alia*, administering, dispensing, delivering, gifting, or prescribing a controlled substance outside the course of professional practice. Pharmacy 7 and its pharmacist-in-charge also separately agreed to pay a consent judgment of $750,000 to settle civil CSA claims brought by the United States in relation to the same pills-for-sex scheme.

466. Suspicious orders erroneously cleared as typical also include, for example, an order for promethazine and codeine syrup placed with ABDC by Pharmacy 8, a Chicago, Illinois hospital pharmacy customer, on or about September 28, 2017.

467. That order was flagged by ROMP because it exceeded the COP threshold by more than 260% and the TRD threshold by more than 1,000%.

468. Nonetheless, a CSRA reviewer approved the order to be shipped and not reported to DEA, with the only recorded justification being the comment "high risk drug family |" and the

selection of the adjudication reason code "Within acceptable range of customers established order pattern."

469. This explanation that the order was "within acceptable range" makes no sense on its face, and it demonstrates the reviewer's failure to conduct due diligence.

470. Indeed, nearly a year and over a dozen of flagged promethazine and codeine syrup orders later, a different CSRA employee realized that promethazine and codeine syrup was being diverted from Pharmacy 8.

471. The CSRA reviewer clearing the September 28, 2017 promethazine and codeine syrup order on the manifestly false basis that this highly unusual order was somehow typical demonstrates ABC's and ABDC's failure to dispel suspicion regarding that order.

472. The same is true with the three other order examples provided above and with many thousands of analogous orders that CSRA reviewers likewise cleared to be shipped and not reported based on similarly inapplicable justifications.

3. Suspicious flagged ABDC orders cleared without justification

473. In tens of thousands of additional instances in which ABC and ABDC cleared highly unusual, flagged ABDC orders for shipment without reporting the orders to DEA, either no reviewer comment was recorded, or the only recorded comment is an entirely non-informative phrase such as "approved for release."

474. Such orders include, for example, an order for 600 dosage units of oxycodone 30mg that Pharmacy 5 placed with ABDC on or about October 9, 2014, which was flagged by ROMP, but which was cleared for shipment, with the only recorded justification being the comment, "Approved as compliant."

475. They also include, for example, an order for oxycodone tablets placed with ABDC by Pharmacy 9, a Clay County, Tennessee independent pharmacy customer, on or about

April 15, 2015. The order was flagged by OMP, but a CSRA reviewer released this order for shipment without reporting, and with the only recorded justification being the comment "Approved for release."

476. Pharmacy 9's pharmacist-in-charge in April 2015 pled guilty to criminally conspiring to violate the CSA. He has admitted, *inter alia*, that from April 2014 through early February 2019, he was engaged in a conspiracy with Pharmacy 9's owner and others to intentionally and without authority distribute and dispense prescriptions for controlled substances including oxycodone that he knew were not for legitimate medical purposes.

477. CSRA's clearing of the April 15, 2015 oxycodone order without any attempted justification demonstrates ABC's and ABDC's failure to dispel suspicion regarding that order, as does similarly deficient documentation for analogous orders.

4. Suspicious flagged ICS orders

478. Likewise, Defendants ABC and ICS refused or negligently failed to report numerous orders that were flagged by ICS's thresholds as suspicious, after performing only cursory reviews, or without performing any reviews at all, and without actually dispelling the suspicion associated with those suspicious orders.

479. Such orders include both suspicious orders placed by pharmacy customers such as Pharmacy 1, which should have been reported pursuant to ICS's policies and the CSA, and suspicious orders placed by distributors, like Distributor 1, which ICS's policies wrongly instructed were not suspicious.

480. They also include, for example, fentanyl orders that Distributor 1 placed with ICS on August 8, 2017 and September 11, 2017, and which ICS's electronic order monitoring system flagged as suspicious, but which ICS promptly cleared for shipment without conducting suspicion-dispelling investigations or reporting the orders to DEA.

481. The specific orders discussed above are included only as examples of the Defendants' unlawful conduct and are not exhaustive.

482. In sum, ABC and ABDC failed to dispel the suspicions raised by numerous flagged orders placed with ABDC, but they refused or negligently failed to report those suspicious orders to DEA nonetheless.

483. Likewise, ABC and ICS failed to dispel the suspicions raised by numerous flagged orders placed with ICS, but they refused or negligently failed to report those suspicious orders to DEA nonetheless.

484. Each time ABC and ABDC refused or negligently failed to report to DEA a flagged ABDC order for which they did not dispel suspicion, they violated 21 U.S.C. § 842(a)(5)

485. Each time ABC and ICS refused or negligently failed to report to DEA a flagged ICS order for which they did not dispel suspicion, they violated 21 U.S.C. § 842(a)(5).

D. Defendants violated the CSA by failing to report suspicious orders that they designed their thresholds not to flag

486. Defendants ABC and ABDC further violated 21 U.S.C. § 842(a)(5) on numerous occasions by refusing or negligently failing to report to DEA controlled-substance orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency, as well as orders bearing other indicia of suspicion, which—by design—were not flagged for review by OMP or ROMP.

487. As explained above, Defendants knew that the CSA and its implementing regulations defined suspicious orders to include, *inter alia,* orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

488. Nonetheless, ABC intentionally designed ROMP to flag for review and potential reporting only orders of both unusual size *and* pattern or orders of extremely abnormal ordering pattern.

489. As a result of this decision and other design decisions with ABDC's order monitoring programs, a huge number of statistically unusual and otherwise suspicious orders placed with ABDC were automatically processed without review or any opportunity for reporting.

490. For example, on or about January 25, 2018, Pharmacy 8 placed a suspicious order with ABDC for 5,760 dosage units of promethazine with codeine syrup, which order exceeded ROMP's TRD threshold by more than 500%.

491. Yet even though ROMP identified this order as having a substantially abnormal pattern compared to the ordering patterns of comparable customers, because this order did not exceed one of ROMP's other two thresholds, it was not flagged for review and potential reporting.

492. As a result, ABDC automatically shipped and did not report this suspicious order, which was placed by a pharmacy where diversion of promethazine and codeine syrup was ongoing.

493. For another example, on or about August 8, 2016, Pharmacy 2 placed a suspicious order with ABDC for drugs in the oxycodone solid drug family. The order pushed Pharmacy 2's 30-day oxycodone solid ordering to 77,900 dosage units and therefore exceeded the peer-based default TRD threshold for that pharmacy's oxycodone solid ordering—28,900 dosage units in a 30-day period—by more than 150%.

494. Further, even though CSRA had manually increased Pharmacy 2's TRD threshold for oxycodone solid significantly above the peer-based default threshold, to 69,617 dosage units in a 30-day period, the order exceeded even the increased TRD threshold.

495. Yet even though ROMP identified this order as having a substantially abnormal pattern compared to the ordering patterns of comparable customers, because CSRA had set Pharmacy 2's TRD+ threshold for the oxycodone solid drug family at an astronomical 696,170 dosage units, and because Pharmacy 2 structured its ordering so as not to exceed the very high COP threshold CSRA had imposed, the order was not flagged for review.

496. As a result, ABDC automatically shipped and did not report this suspicious order, which was placed by a pharmacy that CSRA knew engaged in suspicious practices.

497. For one more example, on or about November 20, 2018, Pharmacy 4 placed a suspicious order for a Schedule III opioid with ABDC. The order pushed Pharmacy 4's 30-day ordering of this Schedule III opioid to 15,000 dosage units and therefore exceeded the peer-based default TRD threshold for that pharmacy's ordering for the drug—1,050 dosage units in a 30-day period—by more than 1,300%.

498. Further, even though CSRA had manually increased Pharmacy 4's TRD threshold for the Schedule III opioid by a factor of more than 14 above the peer-based default threshold, to 14,278 dosage units in a 30-day period, the order exceeded even the massively increased TRD threshold.

499. And even though ROMP identified this order as having a substantially abnormal pattern compared to the ordering patterns of comparable customers, because this order did not exceed one of ROMP's other two thresholds, it was not flagged for review.

500. As a result, ABDC automatically shipped and did not report this suspicious order, which was placed by a pharmacy that CSRA knew exhibited many red flags, notably including the presence of parking-lot drug deals.

501. In many similar instances, ABDC automatically shipped and did not report other orders that its thresholds identified as having an unusual size, pattern, or frequency, but that, by design, its order monitoring program caused to be shipped without any required opportunity for human review and potential reporting.

502. In each such instance that ABC and ABDC refused or negligently failed to report a suspicious order that its thresholds identified as suspicious but that they nonetheless failed to flag for review and potential reporting, ABC and ABDC violated 21 U.S.C. § 842(a)(5).

CLAIM FOR RELIEF

Count I
(Civil Penalties and Injunctive Relief Based on Violations of 21 U.S.C. § 832(a)(3), 21 U.S.C. § 842(a)(5), and/or 21 C.F.R. § 1301.74(b))

503. The United States incorporates by reference each of the preceding paragraphs as if set forth in full.

504. From at least January 1, 2014 through present, each Defendant refused or negligently failed to report to DEA suspicious orders for controlled substances, in violation of 21 U.S.C. § 832(a)(3), 21 U.S.C. § 842(a)(5), and/or 21 C.F.R. § 1301.74(b).

505. Each Defendant violated 21 U.S.C. § 832(a)(3), 21 U.S.C. § 842(a)(5), and/or 21 C.F.R. § 1301.74(b) on multiple occasions, with the precise number of violations to be established at trial.

506. For each violation each Defendant committed, that Defendant is liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(B); 28 C.F.R. § 85.5, and injunctive relief as provided under 21 U.S.C. § 843(f).

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests judgment to be entered in its favor and against each Defendant as follows:

a. Awarding a sum equal to civil penalties up to the maximum amount allowed by law, to be determined by the Court;

b. Granting injunctive relief to address and restrain each Defendant's violations of the law; and

c. Granting the United States such further relief as this Court deems just and proper.

JURY DEMAND

The United States hereby demands a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Respectfully submitted,

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Dated: December 29, 2022

JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
AUSA Anthony D. Scicchitano
U.S. Attorney's Office, 615 Chestnut Street, Suite 1250
Philadelphia, PA 19106 (215) 861-8380

DEFENDANTS

AmerisourceBergen Corporation; AmerisourceBergen Drug Corporation; Integrated Commercialization Solutions, LLC

County of Residence of First Listed Defendant Montgomery County
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
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II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- [x] 1 U.S. Government Plaintiff
- [ ] 2 U.S. Government Defendant
- [ ] 3 Federal Question *(U.S. Government Not a Party)*
- [ ] 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	[ ] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[ ] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
[ ] 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	[ ] 625 Drug Related Seizure of Property 21 USC 881	[ ] 422 Appeal 28 USC 158	[ ] 375 False Claims Act
[ ] 120 Marine	[ ] 310 Airplane	[ ] 365 Personal Injury - Product Liability	[ ] 690 Other	[ ] 423 Withdrawal 28 USC 157	[ ] 376 Qui Tam (31 USC 3729(a))
[ ] 130 Miller Act	[ ] 315 Airplane Product Liability	[ ] 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	[ ] 400 State Reapportionment
[ ] 140 Negotiable Instrument	[ ] 320 Assault, Libel & Slander	[ ] 368 Asbestos Personal Injury Product Liability		[ ] 820 Copyrights	[ ] 410 Antitrust
[ ] 150 Recovery of Overpayment & Enforcement of Judgment	[ ] 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	[ ] 830 Patent	[ ] 430 Banks and Banking
[ ] 151 Medicare Act	[ ] 340 Marine	[ ] 370 Other Fraud	[ ] 710 Fair Labor Standards Act	[ ] 835 Patent - Abbreviated New Drug Application	[ ] 450 Commerce
[ ] 152 Recovery of Defaulted Student Loans (Excludes Veterans)	[ ] 345 Marine Product Liability	[ ] 371 Truth in Lending	[ ] 720 Labor/Management Relations	[ ] 840 Trademark	[ ] 460 Deportation
[ ] 153 Recovery of Overpayment of Veteran's Benefits	[ ] 350 Motor Vehicle	[ ] 380 Other Personal Property Damage	[ ] 740 Railway Labor Act	[ ] 880 Defend Trade Secrets Act of 2016	[ ] 470 Racketeer Influenced and Corrupt Organizations
[ ] 160 Stockholders' Suits	[ ] 355 Motor Vehicle Product Liability	[ ] 385 Property Damage Product Liability	[ ] 751 Family and Medical Leave Act	SOCIAL SECURITY	[ ] 480 Consumer Credit (15 USC 1681 or 1692)
[ ] 190 Other Contract	[ ] 360 Other Personal Injury		[ ] 790 Other Labor Litigation	[ ] 861 HIA (1395ff)	[ ] 485 Telephone Consumer Protection Act
[ ] 195 Contract Product Liability	[ ] 362 Personal Injury - Medical Malpractice		[ ] 791 Employee Retirement Income Security Act	[ ] 862 Black Lung (923)	[ ] 490 Cable/Sat TV
[ ] 196 Franchise				[ ] 863 DIWC/DIWW (405(g))	[ ] 850 Securities/Commodities/ Exchange
				[ ] 864 SSID Title XVI	[x] 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		[ ] 865 RSI (405(g))	[ ] 891 Agricultural Acts
[ ] 210 Land Condemnation	[ ] 440 Other Civil Rights	Habeas Corpus:			[ ] 893 Environmental Matters
[ ] 220 Foreclosure	[ ] 441 Voting	[ ] 463 Alien Detainee		FEDERAL TAX SUITS	[ ] 895 Freedom of Information Act
[ ] 230 Rent Lease & Ejectment	[ ] 442 Employment	[ ] 510 Motions to Vacate Sentence		[ ] 870 Taxes (U.S. Plaintiff or Defendant)	[ ] 896 Arbitration
[ ] 240 Torts to Land	[ ] 443 Housing/ Accommodations	[ ] 530 General		[ ] 871 IRS—Third Party 26 USC 7609	[ ] 899 Administrative Procedure Act/Review or Appeal of Agency Decision
[ ] 245 Tort Product Liability	[ ] 445 Amer. w/Disabilities - Employment	[ ] 535 Death Penalty	IMMIGRATION		[ ] 950 Constitutionality of State Statutes
[ ] 290 All Other Real Property	[ ] 446 Amer. w/Disabilities - Other	Other:	[ ] 462 Naturalization Application		
	[ ] 448 Education	[ ] 540 Mandamus & Other	[ ] 465 Other Immigration Actions		
		[ ] 550 Civil Rights			
		[ ] 555 Prison Condition			
		[ ] 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

- [x] 1 Original Proceeding
- [ ] 2 Removed from State Court
- [ ] 3 Remanded from Appellate Court
- [ ] 4 Reinstated or Reopened
- [ ] 5 Transferred from Another District *(specify)*
- [ ] 6 Multidistrict Litigation - Transfer
- [ ] 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Controlled Substances Act, 21 U.S.C. § 842

Brief description of cause:
Civil complaint for civil penalties and injunctive relief under the Controlled Substances Act

VII. REQUESTED IN COMPLAINT:

- [ ] CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ To be determined at trial

CHECK YES only if demanded in complaint:
JURY DEMAND: [x] Yes [ ] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
Dec 29, 2022

SIGNATURE OF ATTORNEY OF RECORD
/s/ Anthony D. Scicchitano

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 615 Chestnut Street, Suite 1250, Philadelphia, PA 19106

Address of Defendant: 1 W. 1st Avenue, Conshohocken, PA 19428

Place of Accident, Incident or Transaction: 1 W. 1st Avenue, Conshohocken, PA 19428

RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when ***Yes*** is answered to any of the following questions:

1.	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	Yes ☐	No ☑
2.	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	Yes ☐	No ☑
3.	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	Yes ☐	No ☑
4.	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	Yes ☐	No ☑

I certify that, to my knowledge, the within case ☐ **is** / ☑ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 12/29/2022 Anthony D. Scicchitano, AUSA PA 208607

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☑ 11. All other Federal Question Cases
  (Please specify): Controlled Substances Act, 21 U.S.C. § 842

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
  (Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Anthony D. Scicchitano, AUSA, counsel of record *or* pro se plaintiff, do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☐ Relief other than monetary damages is sought.

DATE: 12/29/2022 Anthony D. Scicchitano, AUSA PA 208607

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.