quality, purpose, and key components of their programs; and that Defendants unfairly and deceptively marketed prescription opioids.

20. Defendants have continuously and routinely violated Vermont law, taking advantage of the dramatic rise in opioid prescribing and profiting heavily from the sale of prescription opioids that they knew, or should have known, were being diverted from the legitimate and necessary uses. The consequences have devastated the lives of many Vermonters and will reverberate in Vermont for years to come.

21. The effects of the opioid epidemic in Vermont have been profound: increased health care costs; premature death and disability; lost productivity during prime work years; increases in drug-related crime and incarceration; and the consequential devastation of households and extended families. These predictable outcomes have created a full-blown public health crisis.

22. The State now asks the Court to hold Cardinal and McKesson accountable for their conduct for the damage they have caused, the costs they have imposed on the State, and the burdens they have placed on Vermont's citizens.

PARTIES

23. Plaintiff the State of Vermont brings this action, by and through its Attorney General, Thomas J. Donovan Jr., who is authorized to represent the State in all civil matters at common law and as allowed by statute. 3 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the Consumer Protection Act and all regulations promulgated thereunder. 9 V.S.A. § 2458.

24. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have substantially affected a significant segment of the population of Vermont.

25. Defendant Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio.

26. Cardinal, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. Cardinal operates 18 wholesale drug outlets that are currently licensed to conduct business in Vermont. Cardinal distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, Cardinal marketed and promoted opioids—including, on information and belief, in Vermont.

27. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in San Francisco, California.

28. McKesson, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. McKesson operates 30 wholesale drug outlets that are currently licensed to conduct business in Vermont. McKesson distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, McKesson marketed and promoted opioids—including, on information and belief, in Vermont.

JURISDICTION AND VENUE

29. The State brings this action exclusively under Vermont law. The State does not assert any claims arising under federal law.

30. The Court has personal jurisdiction over Cardinal and McKesson because they regularly transacted business in Vermont, including by distributing opioids to pharmacies throughout the State; purposely directed business activities, including, on information and belief, marketing activities, into Vermont; had employees who operated in Vermont; and engaged in unlawful practices in Vermont.

31. McKesson is registered to do business in Vermont, with Corporation Service Company as its registered agent, located at 100 North Main Street, Suite 2, Barre, VT 05641. Several Cardinal affiliates and/or subsidiaries also are registered to do business in Vermont, with either Corporation Service Company, located at 100 North Main Street, Suite 2, Barre, VT 05641, or CT Corporation System, located at 17 G W Tatro Dr., Jeffersonville, VT 05464, as their registered agent.

32. Venue is proper in this Court, pursuant to 9 V.S.A. § 2458(a), because Defendants do business in Chittenden County, including distributing opioids within the county.

FACTUAL ALLEGATIONS

I. Vermont Law Imposes on Defendants a Duty to Prevent the Misuse, Abuse, and Diversion of Controlled Substances.

33. Cardinal and McKesson are licensed to distribute prescription drugs in Vermont, including prescription opioids, which are designated as controlled substances due to their high potential for abuse. A license to distribute controlled substances is valuable—it allows Defendants to participate in a tightly controlled, national market valued at more than $7 billion annually for opioids alone.

34. Distribution of controlled substances comes with a substantial duty. Distributors are obligated to take steps to provide effective controls and procedures to guard against theft and diversion of controlled substances, as a critical part of a regulatory system designed to combat drug abuse. These obligations are a crucial component of the State's efforts to protect the public health, welfare, and safety by regulating access to potentially dangerous controlled substances.

35. Vermont's common law imposes a general duty to exercise the degree of care that a reasonably prudent person / entity would exercise under similar circumstances. The scope of this duty of care is determined by the foreseeability of the consequences of the acts or omissions. It is foreseeable that distributing vast amounts of highly addictive prescription opioids into the State, while simultaneously promoting higher sales of these drugs and failing to take reasonable steps to minimize their illegitimate use, could result in widespread misuse, abuse, diversion, and serious injury.

36. Defendants acknowledge that their status as wholesale distributors of controlled substances subjects them to common law duties of care. For example, Defendants' professional lobbying association, the Healthcare Distribution Alliance ("HDA") acknowledges that distributors' responsibilities to detect and prevent diversion of controlled substances arise from the obligations that attach to "responsible members of society."[8]

37. The duty of care imposed under Vermont common law is reasonably informed by Vermont's statutes and regulations, which impose a variety of legal obligations on wholesale distributors that are designed "to promote, preserve, and protect the public health, safety, and welfare."[9]

[8] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), ECF No. 1607110, 2016 WL 1321983 at *3.
[9] 26 V.S.A. § 2021.

38. Vermont law requires wholesale distributors to be licensed by the Vermont Board of Pharmacy (the "Board"). The Board's administrative rules impose a host of duties on wholesale distributors that are designed to protect public health and safety. To receive a license, a distributor must attest to the Board that it has implemented and will maintain a range of requirements. In particular, licensed wholesale distributors in Vermont must:

- "employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs," 20-4 Vt. Code R. § 1400:17.5;
- equip their facilities with security systems suitable to protect against diversion, 20-4 Vt. Code R. § 1400:17.8; and
- adopt, maintain, and adhere to written security policies, 20-4 Vt. Code R. § 1400:17.20.

39. Vermont law also imposes duties of care on controlled substance distributors that are co-extensive with those imposed under the federal Controlled Substances Act (21 U.S.C. § 801 *et seq.*) and its implementing regulations, but that are independently enforceable under state law. Vermont law requires: (1) that distributors maintain operations "in compliance with all federal requirements applicable to wholesale drug distribution;" 26 V.S.A. § 2068(9); (2) that distributors comply with all "applicable federal, state, and local laws and rules," 20-4 Vt. Code R. § 1400:17.23; and (3) that distributors dealing in controlled substances "register with the [DEA], and …. comply with all applicable state, local, and DEA requirements," 20-4 Vt. Code R. § 1400:17.25.

40. Congress designed the federal Controlled Substances Act ("CSA") "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States."[10] The CSA carries out this goal by creating a "closed system" of distribution in which every entity that

[10] 1 H.R. Rep. No. 91–1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

handles controlled substances—including manufacturers, distributors, and dispensers—does so pursuant to a registration with the DEA.[11]

41. The distributors' role is central to the efficacy of the CSA's regulatory system. As the DEA has explained, "[b]ecause distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances … from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses."[12]

42. Under the CSA, a registered distributor must "provide effective controls and procedures to guard against theft and diversion of controlled substances."[13] Diversion occurs when controlled substances move out of legitimate medical, scientific, and industrial channels.[14] In Vermont, "legitimate medical channel" is narrowly defined as the possession and use by a patient of a narcotic (opioid) prescription drug in accordance with the directions of the patient's licensed health care provider, whose prescription has been dispensed by a licensed pharmacist. Any other type of dispensing,[15] possession, or use is prohibited by Vermont law[16] and thus outside a legitimate medical channel.

43. In particular, distributors must "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and must report to the DEA the discovery

[11] 21 U.S.C. §§ 821-823.
[12] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.
[13] 21 C.F.R. § 1301.71.
[14] 21 U.S.C. § 823(b).
[15] "Dispense" is defined to include "leave with" and "give away." 18 V.S.A. § 4201(7).
[16] Any possession, administering, or dispensing not specifically authorized under Chapter 84 (the Vermont controlled substances act) is prohibited by 18 V.S.A. § 4205. *See also* 18 V.S.A. § 4216.

of any suspicious orders.[17] The duty to monitor, identify, and report suspicious orders is referred to as the "Reporting Requirement."

44. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.[18] This list is not exhaustive,[19] and the DEA has provided extensive guidance on the identification and reporting of suspicious orders.

45. The DEA has advised distributors that:

- they must "consider the totality of the circumstances when evaluating an order for controlled substances";[20]
- monitoring only the volume of controlled substance orders is insufficient to guard against diversion because if an order "deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious";[21] and
- signs that might be indicative that a pharmacy is engaged in diverting controlled substances, include "[o]rdering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs," and ordering controlled drugs "in quantities disproportionate to the quantity of non-controlled medications ordered."[22]

46. Defendants were aware of DEA's guidance.

47. In addition to requiring a distributor to monitor, identify, and report suspicious orders, Vermont law also requires a distributor to prevent the shipment of suspicious orders to customer pharmacies, a duty referred as the "Shipping Requirement."[23]

48. The DEA has explained the scope of the Shipping Requirement to distributors on multiple occasions.[24] Before shipping an order that has raised a suspicion, a distributor must

[17] 21 C.F.R. § 1301.74(b).
[18] 21 C.F.R. § 1301.74(b).
[19] *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206, 221 (D.C. Cir. 2017).
[20] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[21] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).
[22] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[23] *Masters*, 861 F.3d at 222.

"conduct an independent analysis … to determine whether the controlled substances are likely to be diverted from legitimate channels."[25] That independent analysis must be thorough and must include certain steps, including: (1) requesting information from the pharmacy that placed the order; (2) documenting the pharmacy's explanation for the order; and (3) engaging in any additional follow-up necessary to determine the legitimacy of the order.[26] The independent investigation must be sufficient to dispel all of the red flags that gave rise to the suspicion.[27]

49. Even the HDA, Defendants' lobbying organization, expressly acknowledged the Shipping Requirement in 2008, where it advised distributors that they "should not ship to the customer any units" of a potentially suspicious order without conducting a "fully documented" investigation to determine whether the order is legitimate.[28]

II. Defendants Violated Their Obligations to Prevent the Misuse, Abuse, and Diversion of Prescription Opioids.

50. Despite their duty to prevent the diversion of opioid drugs, neither Cardinal nor McKesson attempted to create formal anti-diversion programs to fulfill their duty until 2007. And even then, the programs they designed failed to meet their legal obligations to detect, prevent, and report diversion. Defendants also failed to fully implement these anti-diversion programs, rendering them both deficient on their face and unenforced in practice.

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[24] *See, e.g., Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01, 36,500 (DEA July 3, 2007) (holding that a distributor violated its duty by shipping suspicious orders without first conducting a due diligence investigation); Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51) (providing that a distributor must "exercise due care in confirming the legitimacy of all orders prior to filling").

[25] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).

[26] *Masters Pharm., Inc.*, 861 F.3d at 212-13.

[27] *Masters Pharm., Inc*., 861 F.3d at 212-13.

[28] *HDA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, available as Attachment 1 to "Prescription Drug Diversion: Combatting the Scourge," Hearing before the Subcommittee on Commerce, Manufacturing & Trade of the U.S. House of Representatives Committee on Energy and Commerce (112th Cong., 2d Session) (March 1, 2012) at 216, 227, 230 (hereinafter "HDMA Industry Compliance Guidelines"), available at https://archive.org/details/gov.gpo.fdsys.CHRG-112hhrg80861.

51. Cardinal and McKesson each designed anti-diversion programs that allowed them to continue shipping ever-increasing and excessive quantities of opioids into Vermont without conducting the required due diligence into their pharmacy customers or notifying law enforcement of ordering volumes and patterns that were indicative of diversion.

52. Both Defendants' anti-diversion programs relied on monthly, volume-based order "thresholds" for each pharmacy customer as the purported trigger for identifying potentially suspicious orders. Their systems failed to identify all orders of unusual size, frequency, and pattern, in violation of Defendants' duties to identify, report, and prevent shipment of all suspicious orders.

53. Cardinal and McKesson each designed and implemented their anti-diversion programs in a way that manipulated and reduced the likelihood of "threshold events," which in turn allowed them to avoid conducting appropriate investigations of their pharmacy customers. Defendants were motivated to minimize threshold events because they wanted to avoid losing customers.

54. Cardinal and McKesson pumped unwarranted volumes of prescription opioids into Vermont, disregarding the obvious signs that diversion was occurring and that a serious health crisis was developing. Based on information currently available to the State, McKesson shipped 75,333,960 dosage units of opioids into Vermont from 2008 through 2014. That is equivalent to more than 120 prescription opioid pills for every man, woman, and child in the State. Based on the same data, Cardinal shipped 40,078,061 dosage units of opioids into Vermont during the same time frame, equivalent to about 64 opioid pills for every man, woman, and child in the State.

55. Defendants' failure to create and implement effective anti-diversion programs, in violation of their duty under Vermont law, resulted in the distribution of excessive quantities of dangerous and addictive prescription opioids into Vermont, facilitating an epidemic of opioid abuse, misuse, and diversion that was both foreseeable and inevitable.

A. Cardinal designed a monitoring system that failed to monitor, identify, report, and prevent the fulfillment of suspicious orders.

56. Following a series of investigations in 2006 and 2007 by state and federal law enforcement into Cardinal's anti-diversion monitoring practices, *see infra* at Part V.A, Cardinal created an anti-diversion program that purported to monitor, identify, report, and prevent the shipment of suspicious controlled substance orders. The main components of Cardinal's program purported to include:

- conducting a due diligence review before onboarding new pharmacy customers;
- setting thresholds, or order limits, to restrict the number / volume of opioids a pharmacy could order each month;
- utilizing an electronic system to hold orders that exceeded thresholds, termed "threshold events," pending further review by Cardinal's anti-diversion staff; and
- conducting regular site visits of existing customers to uncover evidence of suspicious activity.

57. In actuality, Cardinal's four-pronged system was designed to ensure that its pharmacy customers would receive a steady stream of opioids and that anti-diversion duties would never interfere with the Cardinal's bottom line.

1. Cardinal's due diligence policies for onboarding new pharmacy customers were facially inadequate.

58. Cardinal's anti-diversion policy required review of potential new pharmacy customers before onboarding them to ensure that customers purchasing opioids from Cardinal were not engaged in diversion. However, Cardinal's customer onboarding policies were

inadequate because they did not allow Cardinal to independently assess a pharmacy's risk of diversion.

59. From approximately December 2007 through 2012, Cardinal's process for approving new pharmacy customers seeking to order opioids was limited to (1) receiving a customer survey with basic information about the pharmacy's business; (2) receiving an agreement signed by the pharmacy pledging compliance with DEA regulations; and (3) confirming that the pharmacy and its employees were registered with the DEA and relevant state regulatory entities.

60. As written, Cardinal's policies were insufficient to determine whether new pharmacy customers were involved in diversion. Those policies provided Cardinal's sales representatives—who had a financial incentive, due to their compensation structure, to bring on new customers—with responsibility for collecting relevant documents and completing the survey for the customer. Cardinal did not require an independent inquiry into whether other distributors were providing controlled substances to the pharmacy, nor did it require the pharmacy to provide [redacted] preventing Cardinal from investigating the doctors whose prescriptions the pharmacy was filling. Cardinal also did not require site visits at a new pharmacy customer before beginning to ship opioid drugs to it, further evidence of Cardinal's failure to fulfill its broader duty to guard against diversion.

61. To this day, Cardinal's new customer approval review policy relies [redacted] Cardinal still does not [redacted]

[redacted] These inadequacies prevent Cardinal from ensuring the legitimacy of controlled substance purchases by new pharmacy customers.

2. Unreasonably high "thresholds" made it possible for Cardinal to avoid identifying and reporting suspicious orders.

62. Cardinal's suspicious order monitoring system relied on thresholds to identify opioid orders that required review. But Cardinal relied on unreasonably high thresholds, which minimized the number of flagged orders, and allowed Cardinal to avoid investigating or reporting its pharmacy customers when they placed ever-increasing or otherwise suspicious orders for opioids.

63. Cardinal designed its system so that, if an opioid order exceeded a pharmacy's pre-set monthly threshold limit, the order would be held pending review. Moreover, under Cardinal's system, subsequent orders of opioids in the same drug family (i.e., opioids sharing the same narcotic ingredient) also were supposed to be held pending review, interrupting the pharmacy's supply of all opioids in that drug family.[29]

64. However, Cardinal systematically set thresholds at inappropriately high levels to minimize the number of threshold events, to avoid order delays, and to prevent disruption of Cardinal's revenue stream and pharmacy customer satisfaction. Cardinal (1) used unreasonably high sales figures to set thresholds, (2) allowed chain pharmacies with their own anti-diversion programs to have even *higher* thresholds; and (3) set thresholds without accounting for critical factors that the DEA had explained it was required to consider and that would have allowed Cardinal to detect diversion.

65. Fearing that any "aggressive limits will cause … [c]ustomer backlash," Cardinal set its thresholds at unreasonably high levels from approximately December 2007 through 2012.

[29] For example, OxyContin and Percocet are in the same drug family with generic oxycodone, while hydrocodone is a different drug family.

66. Cardinal categorized pharmacy customers based on order volume (small, medium, and large) and business class (e.g., retail pharmacies, hospitals, and long-term care facilities). Cardinal then averaged the monthly quantity of each opioid drug family [redacted] for a given pharmacy size and type, and then **tripled** the monthly average to create the threshold amount. Cardinal's thresholds thus allowed its pharmacy customers to order **three times** the average volume of opioid drugs ordered by pharmacies of similar size and type before triggering any suspicious order review.

67. Moreover, the averages on which Cardinal relied were inflated even before Cardinal tripled them to set the final thresholds. As the baseline for its thresholds, [redacted]—a time period during which opioid sales, and diversion of opioids to non-medical use, were already at dangerously excessive levels. In 2007, for example, pharmacies dispensed 228.43 million opioid prescriptions nationwide—at the time, the highest number ever recorded—equivalent to 75.9 prescriptions per 100 persons and a 243% percent increase compared to opioid prescription levels in 1996, the year OxyContin ER, an extended release formulation of oxycodone, was launched with an aggressive marketing campaign. In 2008, opioid prescribing increased further, reaching 78.2 prescriptions per 100 persons.

68. From approximately December 2007 through 2012, Cardinal's system granted even higher thresholds to pharmacies that maintained their own anti-diversion or loss-prevention programs. Cardinal permitted these higher thresholds based on the flawed premise that "[its] role in the customer's anti-diversion decreases as the customer ability increases,"[30] which ignores and abdicates Cardinal's own independent duty to identify and report suspicious orders and guard against diversion.

[30] CAH_MDL2804_02953792 at 3–4.

69. Cardinal's records confirm that, as of April 2012, oxycodone thresholds for Cardinal's Vermont retail pharmacy customers were frequently four, five, or six times higher than the pharmacies' average monthly oxycodone purchases from the previous twelve months. Cardinal's oxycodone thresholds for its Vermont "institutional retail" pharmacies, such as those in proximity to a hospital, were even more disproportionate to the pharmacies' actual oxycodone purchases. Cardinal justified the disproportionate thresholds at these pharmacies on the theory that the hospitals or other institutions they serve are "less risky because of the vertical integration of the system, which includes the hospital's own risk management."[31] Yet Cardinal acknowledged that not all "institutional" pharmacies were connected to a hospital; some were over a mile away from a hospital; and many served non-hospital patients. Through these inflated thresholds, Cardinal ensured that Vermont pharmacies would not trigger a threshold event, even if they ordered significantly greater-than-usual volumes of opioids.

70. Only when confronted with enforcement actions by the DEA and DOJ in 2012, *see infra* at Part V.A, did Cardinal begin reforming its threshold formulas to more accurately reflect pharmacies' actual order volumes. These changes resulted in drastic reductions in pharmacy thresholds, making clear just how inflated Cardinal's threshold formulas had been previously. For example, [redacted] in Chittenden County, Vermont [redacted]

[31] CAH_MDL2804_01891921 at 4, 8.

[redacted]

71. Additionally, Cardinal's threshold calculations failed to incorporate critical factors necessary to make the thresholds a meaningful tool for monitoring suspicious orders. Despite the DEA's guidance that a suspicious order monitoring system should account for factors including the geographic location of its pharmacy customers, Cardinal's thresholds have never accounted for the size or demographics of the population served by a pharmacy, nor the total number of pharmacies within the same service area.

72. From approximately December 2007 through 2012, Cardinal's thresholds also did not account for the possibility that pharmacies were receiving opioids from multiple distributors. Cardinal also sometimes set its thresholds without considering pharmacies' actual prescription volumes. If a retail independent pharmacy did not provide Cardinal with its dispensing data, Cardinal automatically provided the pharmacy with generic "mid-level" threshold limits rather than demand the information or conduct an investigation. Cardinal did this to reduce the number of threshold events experienced by new pharmacy customers, which had been assigned "small" threshold limits under a former policy governing thresholds for new pharmacy customers.

73. Cardinal's thresholds for chain pharmacies—retail pharmacies owned by a common parent company and operating under the same name with multiple locations—were based on a standard threshold for the entire chain. Thus, a pharmacy serving a small community in Vermont, or that had a minimal opioid portfolio, could nevertheless be permitted to order unnecessarily large quantities of opioids merely because that pharmacy was part of a retail pharmacy chain. In one instance, [redacted]

[redacted] Windham County, Vermont [redacted]

[redacted]

74. Throughout the entire period from approximately December 2007 to the present, Cardinal's thresholds have failed to account for the quantity of opioids distributed and dispensed in a given geographic region. Despite easily accessible state and regional (1) distribution data, (2) prescribing data, (3) market share data, and (4) population data, some of which is also available at the county- and census tract-level, and all of which [redacted] [redacted] see *infra* Section IV.B, Cardinal's thresholds did not account for opioid distribution, opioid prescribing, its own market share, or the population of a given geographic area. Cardinal failed to take this critically important geolocation data into account even after [redacted]

[redacted]

[redacted]

75. Because of these fundamental design flaws and Cardinal's exclusive reliance on volume-based thresholds to trigger investigation of orders, Cardinal's threshold-based system has been ineffective at identifying suspicious orders. From approximately December 2007 to the present, Cardinal's system has relied exclusively on these thresholds to trigger investigation of pharmacy orders. Cardinal's monitoring system was originally "primarily focused on volume," and even after Cardinal began considering additional factors in 2011—pharmacy ordering patterns and frequency—Cardinal only reviewed those factors when an investigation of an order was "triggered" by exceedance of the volume-based threshold. By design, this system is too simplistic for Cardinal to reliably identify orders that are potentially suspicious for other reasons, such as unusual frequency or pattern.

76. Because of the flaws in Cardinal's design of—and exclusive reliance on—these improperly high volume-based thresholds, Cardinal's suspicious order monitoring system was and is insufficient to identify, review, and report suspicious orders as Cardinal is required to do under applicable law.

3. Cardinal manipulated its policies to help pharmacies prevent threshold events.

77. Cardinal has been aware of attempts by pharmacy customers to "game the system" since the beginning of its suspicious order monitoring program. From approximately December 2007 through 2012, Cardinal's official policy was to not disclose specific threshold levels to pharmacies. However, Cardinal also wanted to prevent threshold events from occurring.

78. Thus, without disclosing a specific threshold to a pharmacy, Cardinal would: (1) alert pharmacies when they were approaching their thresholds, thereby allowing the pharmacies to request a preemptive threshold increase; (2) coach pharmacies on how to avoid triggering review of their orders; and (3) raise thresholds without conducting any investigation into the pharmacy's operations.

79. While in the earliest stages of designing its suspicious order monitoring program, the senior leadership of Cardinal's anti-diversion department emphasized the need to be "proactive in determining if we need to raise the threshold prior to [the pharmacy customer] hitting it" to avoid customer backlash. To meet this need, from approximately December 2008 through 2012, Cardinal tracked pharmacies' proximity to their thresholds—their "threshold accrual"—and used an "early dialogue" process, in which sales representatives were required to "immediately contact" a pharmacy when the pharmacy's controlled substance orders reached a certain percentage of its threshold. Intended "to prevent SOM [Suspicious Order Monitoring]

events" from happening,[32] this process directly subverted the very purpose of the thresholds—alerting Cardinal to potentially suspicious orders. Instead, Cardinal warned pharmacies when they were approaching a potential threshold event so that the pharmacy could request—and Cardinal could grant—a preemptive increase. Cardinal was extremely successful in shielding itself and its pharmacy customers from threshold events: from 2010 to 2011—the first year of the early dialogue intervention program—threshold events dropped by 37%.

80. After 2012, Cardinal became even more aggressive about helping pharmacies to avoid threshold events and evade review. From approximately [redacted] to [redacted] [33] Sales representatives had multiple tools available to review a pharmacy customer's thresholds and accruals, [redacted] [34]

81. Further undermining the threshold system, Cardinal's [redacted]

[32] CAH_MDL2804_02246162 at -197.
[33] CAH_MDL2804_02011099.
[34] Deposition of Todd Cameron, Sept. 26, 2018, CAH_MDL2804_02953369, at 295:5–22.

[redacted][35] Pharmacies selected [redacted] However, instead of investigating these pharmacies during visits, Cardinal's anti-diversion investigator instead provided pharmacy personnel with key information about Cardinal's system for detecting suspicious orders—the metrics that Cardinal uses to track pharmacy order patterns—which they could use to alter the pharmacy's purchasing patterns to avoid further scrutiny.

82. Moreover, Cardinal had no written policy defining the criteria or process for raising a pharmacy customer's threshold until approximately January 15, 2013. Before then, its anti-diversion employees had broad discretion to grant threshold increases whenever they saw fit. In one year from October 2009 to October 2010, Cardinal increased Vermont pharmacy opioid thresholds 19 times. In one instance, Cardinal raised five different opioid thresholds for one pharmacy in a single day, resulting in a combined 200,800 dosage unit increase in the volume of opioids the pharmacy could purchase every month—including a more than 100,000 dosage unit increase for oxycodone. Cardinal's records contain no documentation showing that it conducted any comprehensive investigation to determine the legitimacy of the threshold increases. The only justification for the increases contained in Cardinal's records was the cursory notation that the "data supports quantity ordered."

83. Even after Cardinal finally did implement a threshold increase policy in 2013, it continued to permit threshold increases without conducting legitimate investigations into the propriety of those increases. For example, the policy [redacted]

[35] CAH_MDL2804_00035120 at 1.

[redacted] Cardinal's policy also allows [redacted]

[redacted]

4. Cardinal avoided adequately investigating, blocking, and reporting orders triggered by threshold events.

84. Cardinal designed its suspicious order monitoring system so that when a pharmacy did place an order exceeding a threshold—indicating that the order was potentially suspicious and required further review—Cardinal could resume normal shipments to that pharmacy as quickly as possible. To that end, Cardinal (1) gave pharmacies [redacted] [redacted] (2) required minimal due diligence before fulfilling held orders; (3) allowed pharmacies that exceeded a threshold for one opioid drug family to continue ordering opioids from other drug families; and (4) used a monthly accrual period, which allowed pharmacies whose orders were identified as suspicious and reported to the DEA to resume ordering once the period re-set. Finally, even when Cardinal determined that an order was "unreasonable" and should not be shipped, Cardinal (5) failed to report all such orders to the DEA, as required by law.

85. From approximately 2013 to the present, [redacted] Under this policy, and in violation of its duty, Cardinal failed to investigate, failed to report to the DEA, and shipped orders that exceeded a pharmacy customer's threshold [redacted]

[redacted]

86. When Cardinal did hold a pharmacy's order pending review, Cardinal failed to conduct adequate due diligence to determine whether to cancel the order and report it as suspicious or to release and ship the order. From approximately December 2007 through 2012, Cardinal's diligence review was limited to an online survey completed by the pharmacy responsible for the potentially suspicious order; a "customer profile" that included only basic information about the pharmacy and its opioid drug purchases; and the held order itself. Cardinal did not require a site investigation before releasing an order that exceeded a threshold, and it did not even have a written policy specifying when a site visit was required until 2012.

87. From approximately 2013 to the present, [redacted] This practice has allowed pharmacies to continue receiving increasing quantities of opioid drugs [redacted]

88. Cardinal's suspicious order monitoring system also failed to ensure adequate investigation of orders flagged as potentially suspicious by Cardinal's distribution center employees. Cardinal labeled these potentially suspicious orders as "orders of interest." From approximately December 2007 through 2012, Cardinal allowed distribution center supervisors, "based upon [their] knowledge and experience," to release these orders of interest without any

further review, oversight, or documentation.[36] Only if the supervisor, in his or her sole discretion, decided to hold the order would the order be subject to review by Cardinal's anti-diversion department.

89. Cardinal also designed its thresholds so that "threshold events"—and any resulting hold and investigation of a pharmacy's order—would have as little impact as possible on the pharmacy's ability to continue ordering opioids. From approximately December 2007 to [redacted], Cardinal has set separate thresholds for each drug family, and following a threshold event, only holds orders for drugs in the specific drug family with the threshold exceedance. The logical result of this policy is that a threshold event in one drug family does not impact or interrupt a shipment of opioids belonging to another drug family, despite the indication that the pharmacy could be a source of opioid diversion. [redacted]

90. From approximately December 2007 to [redacted], Cardinal's monthly threshold levels reset with each new monthly accrual period—without accounting for suspicious ordering activity that occurred in the preceding accrual period. This means that pharmacies placing suspicious orders in one accrual period were allowed to continue ordering and receiving the same opioid as soon as their monthly accrual periods reset—with no further review or investigation by Cardinal to ensure that the pharmacies were not engaged in diversion.

91. From approximately December 2007 through 2012, Cardinal also failed to appropriately report suspicious orders to the DEA. Under Cardinal's policy, an employee reviewing a threshold event had the authority to decide whether the excessive order was

[36] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 15, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf

"reasonable" or "unreasonable." Cardinal's policy gave little guidance as to what orders were "reasonable," specifying only that a reviewer should use "applied reasoning" and offering several general factors for consideration, including "seasonal events, natural events, [and] regional prescribing habits." Even though an excessive and unreasonable order would certainly meet the definition of "suspicious" under the controlling regulations, Cardinal would still not report those orders to the DEA unless a Cardinal reviewer also designated those orders as suspicious at the reviewer's own discretion. By building this discretionary process into its anti-diversion system, Cardinal allowed its personnel to limit the number of "suspicious orders" they reported to the DEA, even when those orders were flagged by Cardinal's system because they bore all the hallmarks of a "suspicious order."

5. Cardinal's sales representatives conducted the majority of site visits, and Cardinal's investigators deferred to the pharmacies they were investigating.

92. Many indicators of diversion, including those listed in Cardinal's policies governing on-site investigations of its pharmacy customers, cannot be identified through electronic order monitoring alone. Thus, a critical component of Cardinal's duty was to conduct regular due diligence reviews of its pharmacy customers, including regular on-site visits, to monitor for and guard against diversion. Despite this, Cardinal relied on threshold events to trigger most site visits. Moreover, Cardinal (1) placed most of the responsibility for conducting site visits on its sales force; and (2) required that its investigators defer to the pharmacies supposedly under investigation.

93. Cardinal's anti-diversion program relies heavily on its sales force—rather than compliance personnel—to investigate the sales employees' own pharmacy customers. The

Cardinal sales force is treated as the company's "boots on the ground and the front line of defense" in its anti-diversion efforts.

94. Cardinal's sales employees look for the more extreme indicators of diversion including long lines, minimal front-end merchandise, and out-of-state license plates in the parking lot. But, from at least June 2009 to March 2013, sales employees only were required to report pharmacy customers that exhibited "two or more" of these indicators, thus allowing Cardinal to continue selling opioids to pharmacies that exhibited suspicious activity without further investigation.

95. From approximately December 2008 through May 2013, Cardinal's sales force monitored pharmacy customers using monthly "Highlight Reports" that identified pharmacies based on increases in their opioid drugs orders. Cardinal presented these Highlight Reports as a way to identify "which customers may be experiencing a change in business"—one of the justifications Cardinal used to raise customer thresholds[37]—rather than as a way to identify customers placing potentially suspicious orders. Where pharmacies had extreme increases in opioid sales—over 15 percent per month—sales employees visited the pharmacies to assess the pharmacy for visible signs of diversion. But where pharmacies had increases in their opioid sales of between 10 and 15 percent, sales employees merely were required to call the pharmacy "to understand the reason for the increased ordering."[38] Unless the pharmacy requested a threshold increase or the salesperson reported outward signs of diversion, no further action was taken. Cardinal's anti-diversion department did not use Highlight Reports to make decisions about whether to report suspicious orders or stop selling to certain pharmacy customers.

[37] *See* CAH_MDL2804_02954214 at 4; Deposition of Jennifer R. Norris, Aug. 7, 2018, CAH_MULTISTATE_0014000, at 269:8–22; CAH_MDL2804_02954268 at 3.
[38] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 13, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf.

96. Cardinal's sales employees' anti-diversion duties conflicted with their compensation incentives. Cardinal expected its sales employees to "build relationships with independent retail pharmacies that will increase account penetration, revenue growth and customer satisfaction" to meet Cardinal's business goals.[39] Reporting a pharmacy as a diversion risk could damage a sales representative's relationship with the pharmacy customer, potentially reducing the sales representative's ability to increase sales to that pharmacy. Cardinal also gave sales representatives performance-based bonuses for selling more drugs and retaining pharmacy customers. In contrast, sales representatives received no financial incentive to monitor pharmacies for signs of diversion, leaving little doubt as to where sales representatives were incentivized to direct their focus and time.

97. When Cardinal did conduct full site visits using anti-diversion investigators, those visits [redacted][40] [redacted] reducing the probability that Cardinal's investigator would find anything suspicious.

B. Cardinal failed to adhere to the terms of its own anti-diversion program.

98. Not only did Cardinal design a seriously deficient anti-diversion program, it also failed to adhere to it. The company consistently has understaffed its anti-diversion department, raised pharmacy thresholds without enough scrutiny of factors relevant to potential diversion, and failed to report or otherwise diligently investigate all orders that exceeded a set threshold. Cardinal also allowed large chain pharmacies to operate independently, under their own set of rules—often by allowing chain pharmacies to carry out their own investigations of suspicious orders with no oversight from Cardinal. In each of these ways, Cardinal undermined its already-

[39] CAH_MDL2804_00618377 at 5, 9.
[40] CAH_MDL2804_02904365, at -380.