IN THE CIRCUIT / SUPERIOR COURT FOR MARION COUNTY, INDIANA

STATE OF INDIANA,

Plaintiff,

vs.

CARDINAL HEALTH, INC., MCKESSON CORPORATION, and AMERISOURCEBERGEN DRUG CORPORATION,

Defendants.

Cause No. 49D07-1910-PL-044323

Jury Trial Demanded

COMPLAINT

TABLE OF CONTENTS

The State of Indiana, through its Attorney General, Curtis T. Hill, Jr., brings this suit against opioid distributors Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation for violations of the Indiana Deceptive Consumer Sales Act, negligence, creating a public nuisance, and unjust enrichment, and seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief. In support of its Complaint, the State asserts:

PRELIMINARY STATEMENT

1. Few contest that prescription opioids have caused a public health epidemic across the State of Indiana and the nation, but many people are not aware of the key players who had a critical role in creating and sustaining this devastating crisis. This Complaint addresses three companies whose distribution of opioids, and whose failure to monitor, detect, and report diversion, allowed the epidemic to spread exponentially around the country and in Indiana.

2. While less visible to the general public than pharmacies or drug manufacturers, pharmaceutical distributors play a key role in preventing drug abuse and diversion. A distributor acts as a "middle man" between a drug manufacturer and the ultimate dispenser of the drug, which may be a hospital, pharmacy, or other healthcare facility. Distributors purchase prescription drugs and other medical products directly from the manufacturers, stores them in warehouses and distribution centers across the country, and processes and delivers orders placed by drug dispensers.

3. Because of the risks inherent in the distribution of prescription opioids, each of the participants in this supply chain has important legal responsibilities intended to protect against misuse and diversion of these dangerous drugs.

4. The "Big Three" distributors—Cardinal Health ("Cardinal"), McKesson Corporation ("McKesson"), and AmerisourceBergen Drug Corporation (AmerisourceBergen") (collectively "Defendants")–corner the pharmaceutical distribution market. These three distributors are among the top Fortune 500 companies, earning hundreds of billions of dollars in annual revenue. The Big Three also have a commanding share of the Indiana opioids market: together they were responsible for about [redacted]% of the prescription opioid market in the State between 2008 and 2014.

5. These three companies played an integral role in the explosion of the opioid crisis and profited from that role. The State brings this lawsuit against these distributors for failing to fulfill their most fundamental legal duties, in violation of Indiana statutory and common law.

6. Just the presence of prescription opioids in the State represents a risk that must be managed. Prescription opioids—including fentanyl, oxycodone, hydrocodone, and combination drugs—are controlled substances. They have a high potential for abuse and misuse; can cause serious injury, including severe psychological or physical dependence; and, therefore, are highly regulated. Equally significant, prescription opioids are subject to diversion away from legitimate medical, research, and scientific channels to unauthorized use and illegal sales. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." Prescription opioids are diverted away from legitimate medical channels in a variety of ways, but the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that, for most people who misuse opioids, the source of their drugs can typically be found in the excess

supply of prescription drugs in the community, beyond what is needed for legitimate medical purposes.

7. By law, distributors—who are the gatekeepers in the prescription opioid supply chain—have strict obligations to monitor and control the sales of prescription opioids to prevent diversion. The federal Drug Enforcement Administration ("DEA") recognized: "[D]istributors 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 …." Therefore, "it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances." Consequently, both federal and Indiana state law impose important requirements on distributors to ensure they fulfill this critically-important role in the prescription opioid supply chain.

8. Indiana's common law imposes a general duty to exercise the degree of care that a reasonably prudent person / business would exercise under similar circumstances. That duty is informed by the statutory and regulatory requirements that Indiana law imposes on distributors. These include, but are not limited to, the requirements to:

- provide and maintain effective controls and procedures to guard against theft and diversion of controlled substances, 856 Ind. Admin. Code § 2-3-30(a);
- implement appropriate inventory management and control systems to prevent and allow detection and documentation of diversion, Ind. Code § 25-26-14-17(9);
- employ persons with appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements, Ind. Code § 25-26-14-20; and

- comply with all applicable federal laws and regulations, Ind. Code § 25-26-14-17(6).

9. Defendants violated their duties under Indiana law to prevent diversion by selling ever-increasing quantities of prescription opioids in Indiana and ignoring the mounting evidence that opioid sales—nationally, and within the State—were far out-pacing legitimate need. Indeed, through their willingness to supply whatever quantities of opioids pharmacies ordered, the Defendants normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout Indiana communities. This over-supply of opioids flowed into Indiana through two primary channels. First, prescription opioids flowed unchecked into the State from Defendants' excessive sales to Indiana pharmacies—far beyond what was needed for legitimate medical needs. Second, over-supply came to Indiana through illegal channels from other states, including those where "pill mills" stocked with opioids supplied by Defendants poured millions of prescription opioids into illicit channels. Indiana, as the crossroads of America, rests within regions where opioid distribution and abuse far outpaced the national trends.

10. Ultimately, Defendants' inadequate systems to monitor, detect, and prevent diversion enabled the excessive sales of opioids to Indiana pharmacies. Defendants not only designed flawed systems; they failed to adhere to even their own minimal and deficient standards. And these flawed systems fell short of the distributors' statutory and regulatory obligations and common law duty under Indiana law in a variety of different ways, as set forth in detail in this Complaint.

11. Defendants relied on sales-volume-based "thresholds" to detect suspicious orders (i.e., orders of unusual size, deviating substantially from a normal pattern, or of unusual

frequency). These thresholds were caps set for each pharmacy's aggregate monthly opioid orders based on certain factors. If a pharmacy's order exceeded its threshold, that was an indication of potential diversion, and Defendants were supposed to flag, stop, and investigate the order. These thresholds should have served as an important tool in detecting and preventing illegal orders. However, the thresholds were flawed in their design and implementation: not only did they fail to detect all suspicious orders, but they were also set at improperly high levels and were inadequately enforced.

12. Specifically, Defendants set their baseline thresholds far too high—permitting pharmacies to order truly excessive amounts of opioids with little or no functional safety check to catch suspicious orders. And Defendants routinely increased the thresholds or found other ways to ship orders without conducting an appropriate investigation, canceling the order, or reporting the pharmacy to the DEA and the State, as required by law.

13. Additionally, Defendants designed and implemented anti-diversion systems that were wholly inadequate and failed to satisfy their core legal duties as distributors of controlled substances under Indiana law. Defendants not only understaffed their anti-diversion compliance programs, but they provided inadequate training to those they employed. Moreover, AmerisourceBergen, Cardinal, and McKesson inappropriately relied on front-line sales personnel to implement and enforce their anti-diversion programs. These sales personnel had a conflict of interest, because their compensation structure rewarded increased sales. There was no compliance incentive for sales personnel to report their own pharmacy customers for placing excessive orders of opioids.

14. As a result of their flawed systems, Defendants systematically failed to notify regulators about the increasing indications of widespread diversion that should have been

apparent from their own distribution and sales data, as well as additional data they acquired from third-party databanks. Rather than utilizing the wealth of data they possessed to prevent and curtail the diversion of opioids, Defendants used the data to target potential customers and strategize ways to increase their market share, allowing them to profit from the rising tide of opioid misuse and abuse.

15. Defendants' systematic failures to report suspicious volumes and patterns of prescription opioid sales—as they were required to do under Indiana and federal law—allowed the opioid epidemic to grow, unchecked, for years.

16. Compounding Defendants' failures to identify and prevent diversion, all three companies actively engaged in marketing designed to increase the sale of opioids. Defendants promoted opioids to pharmacies and, in some instances, even to prescribers and consumers—working alongside opioid manufacturers to affirmatively drive the demand for prescription opioids.

17. Defendants' promotion and marketing of prescription opioids—particularly when viewed in the context of their obligations (and failures) to prevent and control diversion—constituted deceptive, unfair, and/or abusive acts or practices in the context of consumer transactions, in violation of Indiana's Deceptive Consumer Sales Act ("DCSA"). Through these marketing activities, Defendants echoed and reinforced the deceptive, unfair, and/or abusive prescription opioid marketing that the drug manufacturers were disseminating through many different channels nationwide, and in Indiana. Further, some of Defendants' marketing materials misrepresented the benefits of opioids or omitted the serious risks posed by opioid use. These marketing activities, together with the overwhelmingly deceptive branded and unbranded marketing that drug manufacturers disseminated through other channels, encouraged and

normalized over-prescribing of prescription opioids and effectively shifted the medical consensus regarding opioid prescribing and dispensing, nationally and in Indiana, in ways that will take years to undo.

18. Defendants also promoted prescription savings clubs and programs to increase opioid sales by eliminating cost barriers otherwise associated with the initiation of brand-name opioid therapy—an unfair and abusive practice under the DCSA. These discount programs subsidized or eliminated the out-of-pocket cost of these drugs, making them more accessible to Indiana consumers and effectively providing free or inexpensive samples of highly addictive substances. These programs also encouraged long-term use of prescription opioids—indeed, many of the savings cards had **no limit** on the number of times they could be used by the same patient—despite the fact that no good evidence existed to support long-term use of opioids.

19. Defendants actively concealed their misconduct by failing to identify and prevent diversion and in promoting and marketing opioids. In sworn testimony, on their own websites, and in other public statements, Defendants told the public that their anti-diversion programs were thorough, effective, and vigorously enforced. And Defendants vowed that they had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any opioids. These were all false statements. The State has learned from its investigation, after reviewing documents only recently made available, that Defendants' systems to identify and report suspicious orders were seriously inadequate; that Defendants continue to misrepresent the quality, purpose, and key components of their programs; and that Defendants engaged in deceptive, unfair, and/or abusive marketing of prescription opioids.

20. Defendants have continuously and routinely violated Indiana 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 legitimate and necessary use. The consequences for Indiana and its citizens have been devastating.

21. The effects of the opioid epidemic in Indiana 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 Defendants 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 Indiana's citizens.

PARTIES

23. The Attorney General of Indiana is charged with the responsibility for enforcing the State laws at issue, including the Deceptive Consumer Sales Act. The Attorney General also has standing on behalf of the State as *parens patriae* to protect the health and well-being, both physical and economic, of its residents and its municipalities. Opioid use and abuse have substantially affected a significant segment of the population of Indiana.

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

25. Cardinal, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Indiana. Cardinal operates 22 distribution centers that are currently licensed to ship controlled substances into and within Indiana. Cardinal distributed opioids to Indiana pharmacies that were, in turn, purchased by Indiana consumers and governmental agencies. In

addition to distributing opioids, Cardinal marketed and promoted opioids nationally and in Indiana.

26. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in Irvine, Texas.

27. McKesson, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Indiana. McKesson operates 16 distribution centers that are currently licensed to ship controlled substances into and within Indiana. McKesson distributed opioids to Indiana pharmacies that were, in turn, purchased by Indiana consumers and governmental agencies. In addition to distributing opioids, McKesson marketed and promoted opioids nationally and in Indiana.

28. Defendant AmerisourceBergen Drug Corporation is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

29. AmerisourceBergen, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Indiana. AmerisourceBergen operates 11 distribution centers that are currently licensed to ship controlled substances into and within Indiana, including a drug distribution center located in Whitestown, Indiana. AmerisourceBergen distributed opioids to Indiana pharmacies that were, in turn, purchased by Indiana consumers and governmental agencies. In addition to distributing opioids, AmerisourceBergen marketed and promoted opioids nationally and in Indiana.

JURISDICTION AND VENUE

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

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

32. Several Cardinal affiliates and/or subsidiaries also are registered to do business in Indiana, with CT Corporation System, located at 150 West Market Street, Suite 800, Indianapolis, IN 46204, as their registered agent.

33. McKesson is registered to do business in Indiana, with Corporation Service Company as its registered agent, located at 135 North Pennsylvania Street, Suite 1610, Indianapolis, IN 46204.

34. AmerisourceBergen is registered to do business in Indiana, with CT Corporation System, located at 150 West Market Street, Suite 800, Indianapolis, IN 46204, as its registered agent.

35. Venue is proper in this Court, pursuant to Indiana Trial Rule 75(A)(10), because Plaintiff's claims arose, in part, in Marion County, and Defendants do business there, including distributing opioids within the county. In addition, this case is brought by the State of Indiana, a governmental entity whose principal offices are located in Marion County, Indiana.

FACTUAL ALLEGATIONS

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

36. Cardinal, McKesson, and AmerisourceBergen are licensed to distribute prescription drugs in Indiana, 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 per year.

37. Distribution of controlled substances comes with substantial duties. 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.

38. Indiana'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.

39. 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"), has acknowledged that distributors' responsibilities to detect and prevent diversion of controlled substances arise from

statutory and regulatory responsibilities as well as from the obligations that attach to "responsible members of society."

40. The duty of care imposed under Indiana common law is reasonably informed by Indiana's statutes and regulations, which impose a variety of legal obligations on wholesale distributors.

41. Indiana law requires wholesale distributors to be licensed by the Indiana Board of Pharmacy (the "Board").[1] Indiana's wholesale drug distributor statute and the Board's administrative rules impose a host of duties on wholesale distributors that are designed to protect public health and safety.[2] To receive a license, a distributor must attest to the Board that it has implemented and will maintain a range of requirements.[3] In particular, licensed wholesale distributors in Indiana must:

- employ personnel with "appropriate education or experience to assume responsibility for positions related to compliance with [wholesale distribution] licensing requirements," Ind. Code § 25-26-14-20;
- implement appropriate inventory management and control systems to prevent and allow detection and documentation of diversion, Ind. Code § 25-26-14-17(9); and
- adopt, maintain, and adhere to written security policies, Ind. Code § 25-26-14-17(4).

42. Indiana law also imposes duties of care on controlled substance distributors that parallel the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.*, and its implementing regulations. Indiana law subjects registrants to the same record-keeping requirements imposed by federal law.[4] Registrants must also "provide and maintain effective

[1] Ind. Code § 25-26-14-14(a)(2); 856 Ind. Admin. Code § 2-3-2.
[2] Ind. Code § 25-26-14; 856 Ind. Admin. Code, art. 3.
[3] Ind. Code § 25-26-14-17.
[4] Ind. Code § 35-48-3-7.

controls and procedures to guard against theft and diversion of controlled substances."[5] To meet this requirement, registrants must comply with sections 2-3-30 through -35 of Title 856 of the Indiana Administrative Code, which include the requirement that registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and report those suspicious orders to the Board.[6]

43. Indiana law also imposes duties of care on controlled substance distributors that are co-extensive with those imposed under the federal CSA and its implementing regulations, but that are independently enforceable under state law. Indiana law requires: (1) that distributors maintain operations "in compliance with all federal legal requirements applicable to wholesale drug distribution;" Ind. Code § 25-26-14-17(6); and (2) that distributors dealing in controlled substances register with the DEA and "comply with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances," Ind. Code § 25-26-14-17(10).

44. Congress designed the CSA "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States." The CSA carries out this goal by creating a "closed system" of distribution in which every entity that handles controlled substances—including manufacturers, distributors, and dispensers—does so pursuant to a registration with the DEA.[7]

45. The distributors' role is central to the efficacy of the CSA's regulatory system. As the DEA has explained, "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."

[5] 856 Ind. Admin. Code § 2-3-30(a).
[6] 856 Ind. Admin. Code § 2-3-33.
[7] 21 U.S.C. §§ 821-823.

46. Under the CSA, a registered distributor must "provide effective controls and procedures to guard against theft and diversion of controlled substances."[8] Diversion occurs when controlled substances move out of legitimate medical, scientific, and industrial channels.[9] In Indiana, "legitimate medical channel" is narrowly defined as the possession and use by a patient of a narcotic (opioid) prescription drug with a valid prescription for that drug, written by a practitioner acting in the course of the practitioner's professional practice for a "legitimate medical purpose." Any other type of delivery, possession, or use is prohibited by Indiana law and thus outside a legitimate medical channel.

47. 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 of any suspicious orders.[10] The duty to monitor, identify, and report suspicious orders is referred to as the "Reporting Requirement."

48. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[11] This list is not exhaustive,[12] and the DEA has provided extensive guidance on the identification and reporting of suspicious orders.

49. The DEA has advised distributors that:

- they "should consider the totality of the circumstances when evaluating an order for controlled substances";
- 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"; and

[8] 21 C.F.R. § 1301.71 (a).
[9] 21 U.S.C. § 823(b), (e).
[10] 21 C.F.R. § 1301.74(b).
[11] 21 C.F.R. § 1301.74(b).
[12] *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206, 221 (D.C. Cir. 2017).

- signs of potential diversion 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."

50. Defendants were aware of DEA's guidance.

51. In addition to requiring a distributor to monitor, identify, and report suspicious orders, Indiana and federal law also require a distributor to prevent the shipment of suspicious orders to customer pharmacies, a duty referred to as the "Shipping Requirement."[13]

52. The DEA has explained the scope of the Shipping Requirement to distributors on multiple occasions. Before shipping an order that has raised a suspicion, a distributor must "conduct an independent analysis … to determine whether the controlled substances are likely to be diverted from legitimate channels." 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.[14] The independent investigation must be sufficient to dispel all of the red flags that gave rise to the suspicion.[15]

53. Even the HDA, Defendants' lobbying organization, expressly acknowledged the Shipping Requirement in 2008, when 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.

[13] *Masters*, 861 F.3d at 221.
[14] *Id.* at 212-13.
[15] *Id*.

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

54. Despite their duty to prevent the diversion of opioid drugs, Defendants did not attempt 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 effectively implement their anti-diversion programs, rendering them both deficient on their face and unenforced in practice.

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

56. All three Defendants' anti-diversion programs relied on aggregate 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.

57. Defendants 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.

58. Defendants sent unwarranted volumes of prescription opioids into Indiana, disregarding the obvious signs that diversion was occurring and that a serious health crisis was developing. Based on information currently available to the State, during the time period 2008 through 2014:

- **Cardinal** shipped [redacted] dosage units of opioids into Indiana, equivalent to more than [redacted] prescription opioid pills for every man, woman, and child in the State.
- **McKesson** shipped [redacted] dosage units of opioids into Indiana, equivalent to more than [redacted] prescription opioid pills for every man, woman, and child in the State.
- **AmerisourceBergen** shipped [redacted] dosage units of opioids into Indiana, equivalent to more than [redacted] prescription opioid pills for every man, woman and child in the State.

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

• • • CARDINAL • • •

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

60. 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. Cardinal's written anti-diversion policies are contained in standard operating procedures, many of which were first implemented in [redacted] The main components of Cardinal's program purported to include:

- [redacted]

- [redacted]
- [redacted] and
- [redacted]

61. 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 Cardinal's bottom line.

62. The anti-diversion system that these policies created had several significant design defects that rendered it ineffective, as set forth in sections 1-6. Moreover, Cardinal's various anti-diversion policies were not coordinated within the context of a consistent, unified policy to prevent the diversion of controlled substances. As a result, employees with one set of responsibilities in Cardinal's anti-diversion program were unaware of the requirements of other parts of the program, even when such understanding and coordination was required to effectively implement those policies.

1. Due diligence policies for onboarding new pharmacy customers were facially inadequate.

63. 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—rather, they presupposed that the pharmacies were operating properly and in good faith. These policies fell short of satisfying Cardinal's legal duties.

64. 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.

65. As written, Cardinal's policies were insufficient to determine whether new pharmacy customers were involved in diversion. Those policies provided Cardinal's sales representatives—[redacted]—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 [redacted] Cardinal also did not require a site visit before beginning to ship opioids to a new pharmacy customer, further evidence of Cardinal's failure to fulfill its broader duty to guard against diversion.

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

67. Cardinal's onboarding policies also allowed employees to approve new pharmacy customers with no mechanism to ensure review and approval by a supervisor. [redacted]

68. These inadequacies in the onboarding process have prevented Cardinal from ensuring the legitimacy of controlled substance purchases by new pharmacy customers.

2. By exclusively relying on unreasonably high thresholds, Cardinal failed to identify and report suspicious orders.

69. Cardinal's suspicious order monitoring system relied on thresholds—monthly ordering limits—to identify opioid orders that required review. But Cardinal set its thresholds at unreasonably high levels, 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.

70. 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.

71. Fearing that any [redacted] Cardinal set its thresholds at unreasonably high levels from approximately December 2007 through 2012.

72. 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.

73. 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]

[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 228.54 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.

74. 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 [redacted] which ignores and abdicates Cardinal's own independent duty to identify and report suspicious orders and guard against diversion.

75. [redacted] In many cases, Cardinal's thresholds were even higher: [redacted] Cardinal's oxycodone thresholds for [redacted] Cardinal justified the disproportionate thresholds at these pharmacies on the theory that

the hospitals or other institutions they serve [redacted] Yet Cardinal acknowledged that [redacted] These inflated thresholds ensured that Indiana pharmacies would not trigger a threshold event, even if they ordered significantly greater-than-usual volumes of opioids.

76. Only when confronted with enforcement actions by the DEA and DOJ in 2012, *see infra* at Part V.A, [redacted] making clear just how inflated Cardinal's threshold formulas had been previously. For example, [redacted] in Mishawaka, Indiana [redacted]

77. 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

[redacted] for the size or demographics of the population served by a pharmacy, nor the total number of pharmacies within the same service area.

78. From approximately December 2007 through 2012, Cardinal's thresholds 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 [redacted]

79. 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 Indiana, or that had a minimal opioid portfolio, would nevertheless be permitted to order unnecessarily large quantities of opioids merely because that pharmacy was part of a retail pharmacy chain. In one example, [redacted] Lowell, Indiana [redacted]

80. Throughout the entire period from approximately December 2007 to [redacted], 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 [redacted]

81. Because of these fundamental design flaws and Cardinal's exclusive reliance on volume-based, aggregate monthly thresholds to trigger investigation of orders, Cardinal's threshold-based system has been ineffective at identifying suspicious orders. From approximately December 2007 to [redacted], 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 aggregate monthly threshold. By design, this system was too simplistic. As a result, Cardinal failed to review individual orders of unusual size that did not exceed the aggregate thresholds, and it further failed to identify orders that were potentially suspicious for other reasons, such as unusual frequency or pattern.

82. Cardinal has known of this fundamental flaw in its system since 2008. [redacted]

[redacted]

83. 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, in violation of Cardinal's duties under Indiana law.

3. Cardinal helped pharmacies avoid threshold events.

84. Cardinal has been aware of [redacted] From approximately December 2007 through 2012, Cardinal's official policy prohibited disclosure of specific threshold levels to pharmacies to prevent pharmacies from attempting to evade review. In the words of Cardinal's Director of Investigations:

[redacted]

85. However, Cardinal also wanted to prevent threshold events from occurring. 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.

86. During the earliest stages of [redacted] 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 [redacted] a pharmacy when the pharmacy's controlled substance orders reached a certain percentage of its threshold. [redacted] 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 201[redacted] —threshold events dropped by 37%.

87. After 2012, Cardinal became even more aggressive about helping pharmacies to avoid threshold events and evade review. From approximately [redacted] to [redacted]

[redacted] Sales representatives had multiple tools available to review a pharmacy customer's thresholds and accruals, [redacted]

88. Further undermining the threshold system, Cardinal's [redacted] Pharmacies selected [redacted] However, instead of [redacted] Cardinal's anti-diversion investigator [redacted]

89. [redacted]

[redacted]

90. Even after Cardinal finally did implement [redacted], it continued to [redacted] For example, Cardinal's policy [redacted] Cardinal's policy also allows [redacted]

4. Cardinal's system was designed to avoid adequately investigating, blocking, and reporting orders triggered by threshold events.

91. 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] (2) required minimal due diligence before fulfilling held orders; (3) allowed pharmacies that exceeded a threshold for one opioid drug family[16] to continue ordering opioids from other drug families; and (4) used a monthly accrual period, [redacted]

[16] A "drug family" is a group of opioids that share the same narcotic ingredient. For example, OxyContin and Percocet are in the same drug family with generic oxycodone, while opioids containing hydrocodone are in a different drug family.

[redacted] 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.

92. From approximately 2013 to the present, [redacted]

93. Cardinal knew this practice was in violation of its duty to prevent diversion and intentionally hid it from the DEA. [redacted]

94. 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 policy limited its due diligence review 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, [redacted]

95. From approximately 2013 to the present, [redacted]

96. 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 2008 through 2012, Cardinal policy allowed distribution center supervisors, "based upon [their] knowledge and experience," to release these orders of interest without any further review, oversight, or documentation. 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.

97. 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 other types of opioids. From approximately December 2007 to [redacted], Cardinal has set separate thresholds for each drug family, meaning that once an order triggered a threshold for a particular drug family, subsequent orders

of opioids in the same drug family also were supposed to be held pending review, interrupting the pharmacy's supply of all opioids in that drug family. However, under this policy, a threshold event relating to one drug family would not impact or interrupt a shipment of opioids belonging to another drug family. Thus, even when a pharmacy's order exceeded a threshold for opioids in one drug family, and was held for investigation, Cardinal could continue shipping opioids in other drug families to that pharmacy, even though the "threshold event" indicated that the pharmacy could be a source of opioid diversion.

98. Additionally, 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 [redacted]

99. For example, on April 14, 2016, [redacted] This practice appears to have been routine. In the State's examination of records relating to Cardinal's opioid sales to just 28 of its more than 800 Indiana pharmacy customers, it found that between December 2012 and August 2017, [redacted]

[redacted]

100. 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 "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," [redacted] 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, and allowing them to apply subjective rather than objective standards, 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.

101. Cardinal's process for investigating pharmacies was inadequate to detect diversion of opioids. 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. This routine due diligence should have served a complementary role to the electronic order monitoring, providing an independent check on pharmacies. However, Cardinal relied on threshold events in its electronic order monitoring system to trigger most site visits. This meant that if pharmacies avoided triggering threshold events, they were unlikely to receive a site visit that might reveal other evidence of diversion. 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.

102. Cardinal's anti-diversion program relies heavily on its sales force—rather than compliance personnel—to investigate the sales employees' own pharmacy customers. Cardinal referred to its sales force as the company's [redacted]

103. During site visits, 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 one type of suspicious activity without further investigation.

104. 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 orders. [redacted] —rather than as a way to identify customers placing potentially suspicious orders. Where pharmacies had extreme increases in opioid sales—15 percent or more per month—sales employees visited the pharmacies to assess them 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." Unless the pharmacy requested a threshold increase or the salesperson reported outward signs of diversion, no further action was taken [redacted]

105. Cardinal's sales employees' anti-diversion duties conflicted with their compensation incentives. Cardinal expected its sales employees to [redacted] Cardinal also gave sales representatives [redacted] Reporting a pharmacy as a diversion risk could damage a sales representative's relationship with the pharmacy customer, potentially resulting in decreased sales or losing the pharmacy as a customer altogether. [redacted]

[redacted]

106. When Cardinal did conduct full site visits using anti-diversion investigators, those visits [redacted]

6. Cardinal failed to take into account information about suspicious prescribers.

107. Cardinal failed to implement a system for storing and sharing information about suspicious prescribers and—as a result—failed to use this information to inform its due diligence of new and existing pharmacy customers. Cardinal [redacted] yet nevertheless failed to implement policies and procedures to collect and use that information to stop distributing opioids to pharmacies that were filling prescriptions from "pill mills."

108. In stark contrast to Cardinal's representations that its anti-diversion program is continually improving, Cardinal has actually reduced the amount of prescriber information it collects from pharmacies. Prior to 2013, [redacted]

109. Even when Cardinal collected prescriber information for a particular pharmacy, [redacted] As a result, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged as likely sources of diversion.

110. [redacted] By the time all four Wagoner Clinic doctors and other clinic employees were charged with a total of 95 felony counts of dealing in controlled substances, in April 2013, they had written more than 125,000 prescriptions and had been linked to the overdose deaths of more than two dozen patients.

111. [redacted]

[redacted]

112. [redacted]

113. Even after identifying pill mill prescribers [redacted], Cardinal failed to follow up and investigate the pharmacies that were filling these prescribers' prescriptions. [redacted] Between December 2015 and February 2018, [redacted]

114. [redacted] Jay Joshi, of Munster, Indiana, a top-ten prescriber

of controlled substances statewide who pleaded guilty to federal drug charges related to opioid-prescribing; Dale Economan, of Marion County, who issued more controlled substance prescriptions than any hospital group in Indiana, was linked to six overdose deaths between 2011 and 2015, and was charged with seven counts of dealing in narcotics; James Hanus, of South Whitley, Indiana, who prescribed the third-greatest amount of controlled substances in Indiana over a 20-month period in 2015 and 2016 and pleaded guilty to dealing in controlled substances; Paul Madison, of Michigan City, Indiana, whose Illinois license was revoked for running a cash-only pill mill; and James Ranochak, of Fort Wayne, Indiana, who was indicted on federal charges for conspiracy to commit healthcare fraud and distributing a controlled substance.

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

115. 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 threshold. Cardinal also allowed large chain pharmacies to operate independently, under their own set of rules—including by allowing chain pharmacies to carry out investigations of their own suspicious orders with no oversight from Cardinal. In each of these ways, Cardinal undermined its already-ineffective anti-diversion program, violating its legal duties and resulting in increasing and undetected diversion of opioids.

1. Cardinal understaffed its anti-diversion department.

116. Wholesale distributors of controlled substances have a duty under Indiana common law, statutes, and regulations to employ personnel with "appropriate education or experience to assume responsibility for positions related to compliance with licensing

requirements" for the distribution of pharmaceuticals. Ind. Code § 25-26-14-20. Cardinal breached that duty by failing to staff enough well-trained individuals on its anti-diversion team.

117. Despite having [redacted] distinct pharmacy customers that order controlled substances nationwide—[redacted] of which order opioid drugs—Cardinal employed only **two people** devoted to anti-diversion prior to 2007. Following the DEA's 2007 enforcement action against Cardinal, it increased the anti-diversion group, initially hiring 24 compliance officers. These compliance officers, however, were not responsible for analyzing threshold events or investigating pharmacies, but instead were tasked with "various compliance measures" that applied specifically to distribution centers, [redacted] By 2014, there were only around [redacted] employees responsible for Cardinal's anti-diversion functions.

118. Cardinal's failure to staff a sufficient number of properly trained investigators prevented it from conducting necessary investigations of its pharmacy customers. [redacted]

119. [redacted]

120. These staffing failures have had real-world consequences in Indiana. Cardinal's internal documents confirm that, [redacted] Indiana retail pharmacy customers [redacted] Indiana [redacted]

121. The compliance personnel that Cardinal did hire were not qualified to implement Cardinal's compliance policies and were not adequately trained to carry out their anti-diversion responsibilities. [redacted] Cardinal relied on administrative assistants with no specialized training or experience to carry out anti-diversion responsibilities, including promoting one such administrative assistant to roles responsible for onboarding new pharmacy customers and investigating threshold events [redacted]

122. Cardinal also failed to provide adequate training to its compliance personnel. Cardinal expected its anti-diversion employees to learn through informal "on-the-job" [redacted] training. [redacted] As a result, Cardinal's key compliance employees [redacted]

2. Cardinal raised thresholds, failed to report flagged orders, and shipped orders, without conducting a diligent investigation.

123. Cardinal has admitted that it did not report all suspicious orders of controlled substances to the DEA. For example, from approximately December 2007 through 2012, Cardinal only reported orders that were so egregious that they led Cardinal to terminate a pharmacy's ability to order controlled substances altogether. Under this system, Cardinal's Aurora, Illinois, and St. Louis, Missouri, distribution centers, which service Indiana, [redacted] In fiscal year 2011, Cardinal reported just 47 total suspicious orders to the DEA from its 24 distribution centers **nationwide**. That same year, Indiana's opioid-related overdose death rate reached 5.6 deaths per 100,000 persons, eight times greater than it had been in 2000; that rate has more than doubled since, rising to 12.6 deaths per 100,000 persons in 2016, the most recent year for which data are available.

124. On several occasions, Cardinal shipped suspicious opioid orders to Indiana pharmacies without conducting any investigation to determine whether to report and cancel the order, in direct violation of its duties under Indiana law. For example, [redacted] in Hartford City [redacted] In violation of Cardinal's duty, this notation provides no indication of whether Cardinal visited or otherwise contacted the pharmacy to inquire about these orders; whether the pharmacy provided any

response that would justify the threshold events; or whether Cardinal engaged in any form of investigation whatsoever to ensure the legitimacy of these orders.

125. Similarly, over three days in December 2012, Cardinal's monitoring system [redacted] These cursory notations similarly provide no indication that Cardinal ever conducted any form of investigation to determine the legitimacy of the orders, as required by Indiana law.

126. In some cases, Cardinal responded to an order that exceeded a threshold by improperly and [redacted]

127. For example, [redacted] Washington, Indiana [redacted] These notations provide no indication of whether Cardinal contacted the pharmacy, received a response, or engaged in any other manner of investigation to ensure the legitimacy of the order or the need for a threshold increase, in violation of Cardinal's duty under Indiana law. [redacted]

128. In other instances, when a pharmacy placed an order that exceeded a threshold, [redacted]

129. For example, [redacted]

[redacted]

130. In some instances, Cardinal's failure to report suspicious orders resulted from [redacted]

131. Even where Cardinal reported suspicious orders to the DEA, Cardinal failed to report all such orders to the State, as required by law. Between July 2012 and September 2017, [redacted]

[redacted]

132. In all, an initial review of data derived from Cardinal's suspicious order monitoring system indicates that, [redacted]

3. Cardinal filled pharmacy orders for opioids after it had already identified related orders as suspicious.

133. Cardinal also violated its duty under Indiana law by continuing to ship opioids to pharmacies, even when it had previously identified suspicious orders from those pharmacies, without first resolving those suspicions through investigation.

134. Cardinal sometimes did this by cancelling (also referred to as "cutting") an order that exceeded a threshold and allowing the pharmacy to place a subsequent, often smaller order for the same drug family (that would not trigger a threshold event). [redacted]

135. [redacted]

136. Cardinal engaged in this practice in Indiana. For example, [redacted]

137. Still worse, Cardinal knew that this pharmacy was likely a source of diversion and continued distributing opioids to it anyway. [redacted]

138. On other occasions, Cardinal canceled and reported to the DEA pharmacy orders that hit a threshold, but nevertheless immediately resumed shipping opioids to the pharmacy whose order or orders Cardinal had just reported as suspicious. For example, one Connersville pharmacy's opioids orders [redacted]

139. In an initial analysis of Cardinal's suspicious order and transactional data for 28 of Cardinal's more than 800 Indiana pharmacy customers, the State determined that on [redacted] between December 2012 and September 2017, [redacted]

140. Cardinal also failed to address patterns of suspicious orders that persisted over time. Even where Cardinal did cancel specific pharmacy orders and report them as suspicious, it routinely failed to investigate, suspend, or terminate those pharmacy customers, and instead allowed them to continue buying opioids. Cardinal's failure extended to pharmacies that repeatedly submitted suspicious orders, sometimes over a period of years.

141. Cardinal knew that continuing to supply these pharmacies with opioids violated its duty to prevent diversion. [redacted]

[redacted]

142. Between 2012 and 2017, Cardinal [redacted]

[redacted]

4. Cardinal applied different, even looser rules to its chain pharmacy customers.

143. Cardinal's anti-diversion program treated its national chain pharmacy customers with kid gloves. Chain pharmacies were Cardinal's biggest customers: in 2008, sales to Chain Pharmacy #1 and Chain Pharmacy #3 alone made up approximately 41% of Cardinal's revenue. To keep them happy, Cardinal allowed its chain pharmacy customers to operate under a special set of rules, effectively abdicating its legal duties to prevent diversion to the very entities it was supposed to be monitoring.

144. In early 2008, [redacted] Cardinal complied with all of these demands.

145. Cardinal cannot abdicate its anti-diversion duties by delegating them to another player in the opioid distribution chain. To the contrary, Cardinal's duty to prevent diversion exists regardless of whether its customers are small, independent pharmacies or part of a large chain. As early as 2009, the DEA specifically admonished Cardinal for treating chain pharmacies differently from independent pharmacies. During a DEA review of Cardinal's Massachusetts distribution center, Cardinal was unable to produce any diligence files for its chain pharmacy customers. When the DEA pressed Cardinal for the reason no diligence files existed for these pharmacies, Cardinal admitted that it was because Cardinal only communicated with chain pharmacies' corporate loss prevention departments and did not undertake any independent investigation of the individual pharmacies' conduct. The DEA told them at the time that "due diligence investigations must be performed on all customers, chain pharmacies included," and that those due diligence responsibilities included site visits.

146. Cardinal nevertheless continued to exempt its chain pharmacy customers from Cardinal's monitoring programs until approximately May 2012. During that period, Cardinal failed to conduct site visits at any of its large chain pharmacy customers. [redacted]

147. When Cardinal did hold orders from a chain pharmacy that hit a threshold, instead of independently investigating the potentially suspicious orders, Cardinal merely asked the chain pharmacy's corporate headquarters for an explanation. Cardinal relied entirely on the corporate office's response, conducted no investigation of its own, and did not even make contact with the

individual pharmacy that placed the potentially suspicious order. In doing so, Cardinal knowingly abdicated one of its core legal duties and improperly relied on chain pharmacies to investigate and report their own suspicious activity—something that creates an obvious conflict and is improper on its face.

148. This improper reliance had predictable results. [redacted]

149. Cardinal even permitted permanent threshold increases for a specific pharmacy based solely on the explanation provided by the pharmacy's corporate headquarters. Even after Cardinal began more strictly reviewing threshold changes from chain pharmacies, it still applied a special set of rules: [redacted]

150. Cardinal exempted certain chain pharmacy orders from its anti-diversion program entirely. Many national pharmacy chains also act as distributors, receiving orders from their own stores and shipping from their own warehouses. In the case of at least one of Cardinal's national chain customers, [redacted]

151. Cardinal's differential treatment of its chain pharmacy customers also extended to its new customer on-boarding process. Cardinal's on-boarding process for new, independent pharmacies included collecting a variety of "know your customer" data, including whether the pharmacy filled prescriptions for out-of-state patients, the pharmacy's expected usage for certain products, and whether there were local pain clinics in proximity to the pharmacy. In contrast, for new chain pharmacy customers, Cardinal collected only information about the chain's number of stores, anticipated drug usages, and internal diversion programs. [redacted] Cardinal's failure to gather and maintain this know-your-customer data prevented it from being able to determine accurately whether orders placed at specific chain pharmacies might be suspicious or otherwise indicative of diversion.

152. [redacted]

153. By employing a less rigorous onboarding process for chain pharmacies and by allowing its chain pharmacy customers to conduct their own suspicious order investigations,

Cardinal was able to appease its largest customers and continue shipping excessive quantities of opioids into Indiana without interruption.

● ● ● **McKESSON** ● ● ●

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

154. McKesson failed to design an anti-diversion program to fulfill its obligations under Indiana law to detect, prevent, and report diversion. McKesson's anti-diversion program did not require adequate due diligence of new pharmacy customers; allowed artificially high thresholds to be set based on poor data and metrics; permitted the company to proactively inform/warn pharmacy customers of their thresholds to avoid investigations; and authorized threshold manipulation to support increased opioid sales.

155. In addition to designing an inadequate program, McKesson failed to even fully implement its program, as discussed in Section D below. Consequently, McKesson's anti-diversion program, like those of Cardinal and AmerisourceBergen, was both poorly designed and unenforced in practice.

156. In response to a 2008 settlement agreement with the DEA and DOJ, McKesson created an anti-diversion program called the Controlled Substance Monitoring Program ("CSMP"). McKesson's CSMP was supposed to implement the following components: (1) due diligence procedures for onboarding new pharmacy customers and monitoring existing customers; (2) maximum monthly threshold limits, or order limits, on the amount of prescription opioids pharmacy customers could order; (3) and a three-tiered investigatory and reporting process to identify and report suspicious orders of prescription opioids that exceeded these thresholds.

157. The CSMP's three-tiered investigatory procedures were supposed to be triggered by any order that exceeded a threshold. During the initial investigation of an excessive order, termed a Level 1 review, McKesson was supposed to contact the pharmacy customer to determine the reason for the excessive order, and conduct additional analysis and investigation, such as reviewing the pharmacy customer's sales patterns. If the Level 1 review indicated that the opioid order was "reasonable," the pharmacy could obtain approval for a threshold increase. If the Level 1 review was not "conclusive," the CSMP required two more levels of investigation by various McKesson personnel before reporting it to the DEA. It was only after a Level 3 review that the order was supposed to be reported to the DEA and deemed "suspicious."

158. To administer and oversee the CSMP in 2008, McKesson appointed one Director of Regulatory Affairs ("DRAs") for [redacted] The DRAs' duties included approving new pharmacy customers, approving threshold increase requests, and overseeing and conducting investigations of existing pharmacy customers.

159. Sales personnel and Distribution Center Managers were also charged with core anti-diversion responsibilities, including gathering information, conducting diligence investigations, and reporting suspicious activity, [redacted]

160. McKesson distributed drugs to Indiana pharmacies primarily through [redacted] distribution centers: [redacted]

1. Due diligence policies for onboarding new pharmacy customers were facially inadequate.

161. Under the first component of the CSMP, McKesson was supposed to investigate new pharmacy customers before supplying them with prescription opioids, through a process

termed "onboarding." However, the design of McKesson's customer onboarding procedures under the CSMP was inadequate to evaluate pharmacies for diversion risk and determine whether they should be supplied with opioid drugs.

162. First, McKesson assigned its sales representatives, who [redacted] responsibility for conducting a site visit, collecting information on the pharmacy, and filling out a questionnaire as part of the new customer investigation. However, the questionnaire used by these sales representatives did not contain a [redacted] In addition, McKesson improperly relied on certain pharmacy customers [redacted]

163. A McKesson sales representative who was the primary point of contact with numerous Indiana pharmacies acknowledged that [redacted] In fact, this sales representative admitted that if his Indiana [redacted]

164. McKesson's new customer investigatory procedures also failed to comply with onboarding directives developed by its own industry group, the HDA. In an internal email circulated in [redacted]

[redacted] The DRA informed the rest of the regulatory team that [redacted]

165. McKesson also routinely failed to fill out and file updated pharmacy questionnaires. For example, a [redacted] Indiana [redacted] including Indiana pharmacies, [redacted]

166. Through 2017, McKesson's onboarding policies were even more lax for its largest chain pharmacy customers. [redacted] But even from [redacted], the CSMP only required an [redacted]

2. Unreasonably high threshold levels allowed McKesson to avoid identifying and reporting suspicious orders.

167. The intended purpose of McKesson's threshold system, the second component of the CSMP, was to provide an "automatic block" to prevent pharmacies from obtaining opioids in

an amount that exceeded their monthly limit. An order that exceeded the limit, and that was subsequently blocked, was sometimes termed a threshold event, [redacted] or "incursion" by McKesson. Under the CSMP, a pharmacy customer's order could be unblocked after it exceeded a threshold only if: (1) [redacted] (2) [redacted] or (3) [redacted] thereby allowing the pharmacy to once again [redacted]

168. Although thresholds were the cornerstone of the CSMP, from 2008 through 2013, McKesson routinely used improper metrics and set thresholds at artificially high levels. When it began creating thresholds in 2008, McKesson's first step was to calculate [redacted] During the same time frame—in 2008—McKesson entered into an agreement with the DEA and DOJ to settle claims based on its failure to monitor and report suspicious orders across the country. Nevertheless, [redacted]

169. On top of these inflated averages, McKesson's threshold-setting procedures [redacted] Further, McKesson personnel retained discretion to [redacted]

170. From at least [redacted] through [redacted] McKesson's thresholds failed to take into account [redacted]

[redacted] such as the volume of prescription opioids supplied by other distributors to the same pharmacy or to other pharmacies in the same region, [redacted]

171. McKesson was aware that thresholds set in this manner were improperly inflated, and yet took no action for years. The DRA responsible for the North Central Region, which services Indiana, acknowledged in a [redacted]

172. These artificially high thresholds thwarted McKesson's ability to monitor and identify suspicious orders in Indiana. For example, [redacted] From [redacted] through [redacted] By consistently setting thresholds well above a pharmacy's typical monthly ordering quantity, McKesson's system ensured that pharmacies did not exceed their thresholds unless they ordered many multiples of their monthly average opioid orders. As a result, McKesson's pharmacy customers were able to place unusually large and suspicious orders without triggering any investigation or review.

173. Only after significant pressure from the DEA and DOJ [redacted] did McKesson begin implementing [redacted]

[redacted] demonstrating how inflated those pharmacies' previous thresholds had been. For example, [redacted] Indiana pharmacies, [redacted] In addition, multiple Indiana pharmacies [redacted]

174. But even after 2013, McKesson continued to use the previous improper threshold-setting procedures. [redacted]

175. McKesson also [redacted] In [redacted] And [redacted]

176. [redacted]

[redacted]

[redacted]

3. McKesson's CSMP improperly permitted advance warnings and inappropriate disclosures to pharmacy customers to assist in evading the threshold system.

177. Although McKesson's CSMP mandated that [redacted] it also included a loophole to permit McKesson to alert pharmacies when they approached their monthly thresholds to prevent a threshold breach. As one employee explained in designing this loophole, [redacted]

178. Similarly, McKesson focused on how to provide assurances to pharmacy customers that the threshold system would not get in the way of sales. For example, McKesson employees discussed their concern about [redacted]

179. The threshold warning loophole was written directly into the CSMP manual, which noted that [redacted] The CSMP manual also stated [redacted]

180. Additionally, McKesson permitted pharmacies to request a permanent or temporary increase in their thresholds to avoid a threshold event. This, combined with threshold

warnings, enabled pharmacies to avoid having their orders blocked and allowed McKesson to evade investigatory and reporting requirements mandated by Indiana law.

181. McKesson even went so far as to [redacted] Such alerts were sometimes provided by [redacted] McKesson directed customer service personnel to provide these [redacted] in order to [redacted]

182. By 2014, under pressure from renewed DEA and DOJ investigations, McKesson [redacted] However, [redacted] To this day, [redacted]

4. McKesson manipulated thresholds to support increased opioid sales.

183. When the CSMP was created, requests for threshold changes by pharmacy customers were supposed to be [redacted] However, in the face of ever-increasing prescription opioid sales, and as the opioid crisis ballooned, McKesson not only improperly disclosed threshold information to pharmacy customers, as discussed above, but also actively [redacted]

[redacted]

184. For a pharmacy to obtain a threshold increase, the CSMP required submission of a Threshold Change Request ("TCR") form. Threshold increases could be permanent or temporary. The completed TCR form was supposed to include a documented justification for the increase based on information gathered by McKesson sales personnel or Distribution Center Managers, [redacted]

185. McKesson routinely and improperly [redacted] For years, McKesson's DRAs [redacted] In some instances, if a pharmacy called in to request a threshold increase after receiving [redacted]

186. This approach allowed McKesson's pharmacy customers to receive large quantities of opioids. For example, in [redacted] indicating that McKesson granted threshold increases well in excess of the maximum threshold set to prevent diversion.

187. To manipulate thresholds, McKesson sales personnel also actively advocated on behalf of customers to obtain threshold increases instead of fulfilling their duties to monitor

customers for diversion. For example, [redacted]

188. Information to justify threshold change requests was often merely collected [redacted]

189. In [redacted], the DRA for the North Central Region called attention to these improper threshold procedures: [redacted] Consistent with that statement, McKesson commonly increased thresholds without appropriate justification and without adequate investigation. These problems were nationwide and systemic. For example, from [redacted] through [redacted]

[redacted]

190. Although a particular pharmacy's [redacted] was not in and of itself a sufficient justification to increase thresholds in most cases, in the North Central region, which serviced Indiana, [redacted]

191. Mirroring these systemic and nationwide problems, diligence records for pharmacies in Indiana show [redacted] in Randolph County, Indiana [redacted] Clark County, Indiana [redacted]

192. McKesson also increased customers' thresholds to even higher levels than requested without adequate justification. Customers in McKesson's North Central region, which includes Indiana, would routinely receive [redacted] the requested increase [redacted] The same day, several other North Central pharmacies also received [redacted] The documented rationale for these increases were that the pharmacies were [redacted]

193. McKesson personnel even took it upon themselves to initiate threshold increases without waiting for pharmacies to make the request—and then failed to file any documentation at all. In one alarming example in [redacted], a DRA from the North Central Region provided [redacted]

194. In another example, one pharmacy in LaPorte County, Indiana received a [redacted]

195. In another example, [redacted], which distributes opioids to Indiana, [redacted]

[redacted] Notably, preemptive threshold increases were often granted [redacted]

196. In [redacted], in response to McKesson [redacted]

197. In yet another example, [redacted]. In justifying this broad increase, one McKesson employee suggested that McKesson [redacted] In response, McKesson employees improperly [redacted]

198. McKesson personnel also improperly [redacted]

199. The result of McKesson's systematic manipulation of thresholds was evident in Indiana. A sample of pharmacies investigated by the State shows [redacted]

[redacted] an Indiana pharmacy's [redacted]

200. These practices should have stopped in [redacted]

201. Although McKesson did cut thresholds in 2014, it often quickly increased them again. For example, McKesson cut one Indiana pharmacy's [redacted]

202. The threshold system, [redacted] never served its purpose. McKesson did not set and then [redacted] thresholds. The thresholds did not meaningfully restrict McKesson's customers from obtaining excessive opioid drugs.

Instead they were used to accommodate whatever pharmacy customers wanted to purchase, or [redacted]

203. The result was a consistent pattern of excessive opioid sales in Indiana. Scott County, Indiana is an illustrative example. The 2010 U.S Census listed the county population as 24,181, making it the sixty-fourth most populous of Indiana's 92 counties. McKesson's transactional records for [redacted] Scottsburg, Indiana, population 6,747. [redacted] town of Austin, Indiana, with a population of just 4,295. Together, [redacted], the transactional records show more than [redacted]

5. McKesson's CSMP inappropriately relied on sales representatives and distribution center employees for key anti-diversion functions.

204. McKesson knew that [redacted] Thus, a critical component of McKesson's duty was to investigate and monitor its pharmacy customers to guard against diversion.

205. Nevertheless, McKesson's regulatory personnel only conducted site visits [redacted] The DRA for the North Central Region, for example, only tried to visit [redacted] As a result, McKesson's sales team, the same group charged with and compensated for

increased sales, was considered [redacted]

206. Essential components of McKesson's affirmative anti-diversion investigations were also left in the hands of [redacted] For example, sales or distribution center personnel were required to [redacted]

207. McKesson's anti-diversion program thus relies heavily on McKesson's sales force—rather than compliance personnel—to investigate their own pharmacy customers. [redacted]

208. A fundamental conflict of interest existed between the sales force's mandate to increase sales and their regulatory duties. [redacted]

[redacted] McKesson expected its sales employees [redacted]

209. 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. [redacted]

210. If McKesson blocked suspicious orders or stopped doing business with a pharmacy, sales employees would [redacted]

211. McKesson was well aware of the conflict between the regulatory and sales duties required of its sales and distribution center personnel, and yet took no meaningful action to rectify that flaw. In [redacted]

212. McKesson's monitoring policies were so inadequate that one [redacted]

6. McKesson failed to identify and take action against suspicious prescribers.

213. The problem of pill mills and over-prescribing physicians directly affected Indiana. For example, Dr. Jaime Guerrero, an anesthesiologist who practiced in Louisville, Kentucky, and in Jeffersonville, Indiana, pled guilty in January 2016 to unlawful distribution or dispensing of controlled substances without a legitimate medical purpose and beyond the bounds of professional medical practice, among other crimes.

214. Similarly, Dr. Tristan Stonger was arrested in January 2017, and subsequently charged with 55 felony charges in connection with operating a pill mill. Dr. Stonger's Pain Management Centers of Indiana had offices in Peru, Bloomington, and Indianapolis. In November 2017, Dr. Stonger pled guilty to five charges.

215. Both Dr. Guerrero and Dr. Stonger wrote prescriptions for Indiana residents that were filled at Indiana pharmacies. Moreover, regulatory documentation identifies both [redacted]

[redacted] pharmacy customers in Indiana.

216. [redacted] In fact [redacted]

217. Dr. Stonger was noted as the source for [redacted]

218. These issues were not new; Indiana pill mills and over-prescribing physicians were in the news years earlier for inappropriate controlled substances prescription practices. Despite this, McKesson affirmatively chose not to [redacted] Similarly, McKesson did not [redacted] Even when McKesson did [redacted] In [redacted], McKesson's head of compliance [redacted]

219. One pharmacy customer [redacted] and requested that McKesson [redacted]

220. In [redacted], McKesson [redacted]

221. In [redacted], McKesson also [redacted] Thus, McKesson consistently failed to use prescriber data when it was provided, then purposefully blinded itself to knowledge of suspicious prescribers whose prescriptions were consistently filled at multiple Indiana pharmacies.

222. McKesson also had unique access to prescriber information, but utilized the information to increase profits rather than identify dangerous doctors. [redacted]

[redacted]

223. [redacted]

224. Although McKesson had the ability to obtain top prescriber information and the capacity to analyze it for potential problematic prescribers and identify pill mills, there is little evidence it regularly sought such information, and even less that it attempted to identify problematic prescribers. Instead, as noted above, McKesson backed away from its responsibility and stopped asking if pharmacies received [redacted] Instead, it left the task of identifying dangerous prescribers to individual pharmacies, which had neither the ability to gather information beyond their own prescribers, nor McKesson's ability to analyze broad sets of information. In doing so, McKesson abdicated its role and failed to fulfill its legal responsibilities to the State.

D. McKesson failed to adhere to the terms of its anti-diversion program.

225. In addition to its failure to design an effective anti-diversion program, McKesson also systemically failed to implement the flawed components of the CSMP in Indiana and nationwide. McKesson consistently understaffed its anti-diversion department, inhibiting its ability to carry out diligent investigations of its opioid drug pharmacy customers; failed to report or otherwise diligently investigate all orders that exceeded a set threshold; and allowed large

chain pharmacies to conduct their own diligence investigations and police themselves with little to no oversight by McKesson.

1. McKesson understaffed and undertrained its anti-diversion department.

226. Like the other Defendants, McKesson's lack of attention to its compliance duties is clear from the limited resources it invested into its regulatory affairs personnel department.

[redacted] DRAs were the only [redacted] responsible for [redacted] In the North Central region, which included Indiana, a single DRA was responsible for [redacted]

227. Given that volume, the DRA responsible for Indiana [redacted] This means the DRA responsible for monitoring Indiana pharmacies was visiting less than [redacted]% of his assigned pharmacies per month. At this rate, it would take over [redacted] years to complete a single visit to each of the pharmacies for which the DRA was responsible. This understaffing occurred even though McKesson knew that federal regulators did not have the resources to monitor the nation's pharmacies, [redacted]

228. In [redacted] McKesson's DRAs complained of [redacted] One DRA likened asking for more

resources to [redacted]

229. In addition to this understaffing, neither full-time anti-diversion personnel nor front-line sales employees were sufficiently trained on McKesson's legal obligations to prevent diversion. One sales employee [redacted] Similarly, a former McKesson employee stated that even after [redacted] of working in the Regulatory Affairs Department, he did not have [redacted] did not recall [redacted] did not understand the [redacted], and stated [redacted] Yet another former employee, a sales representative responsible for working with Indiana pharmacies, testified that he could not remember McKesson ever [redacted] This same sales representative testified that despite the central role of sales personnel in the CSMP, he was not familiar with the term [redacted]

230. While McKesson incentivized sales personnel to increase sales, little or no effort was focused on [redacted] For example, McKesson did not provide information about [redacted] following multiple DEA investigations into McKesson's failure to adequately monitor suspicious orders.

2. McKesson failed to conduct investigations of suspicious orders to detect and prevent diversion.

231. The CSMP implemented a three-tiered investigatory process that was supposed to identify orders that were suspicious and facilitate reporting to the DEA but consistently failed to do so. For independent pharmacies and smaller chains, McKesson required [redacted]

232. In practice, however, McKesson conducted some investigations into orders that exceeded threshold limits, termed Level 1 reviews, in name only and failed to meet even the low bar required by the CSMP. McKesson also used threshold breach investigations as an opportunity to [redacted]

233. Critically, Level 1 reviews did not [redacted] In many instances, [redacted] In other instances, [redacted] For example, when a threshold event triggered a Level 1 review for a pharmacy [redacted]

[redacted]

234. McKesson's employees were also left to [redacted]

235. McKesson also failed to standardize the interview questions for investigatory site visits and interviews. The DRA for the North Central region, which services Indiana, noted that he created his own [redacted] Despite directing employees to consider various red flags, McKesson had no standard policy or practice for evaluating red flags until mid-[redacted] And deciding whether to stop supplying a pharmacy with opioid drugs, or to escalate a review to Level 2, was largely left to the discretion of [redacted]

236. An internal McKesson audit from [redacted] of four distribution centers, [redacted], which supplied many Indiana pharmacies, confirmed [redacted] In many cases, McKesson personnel [redacted] At the Washington Court House distribution center, [redacted]

[redacted]

237. These were not isolated incidents, but rather part of a systemic and nationwide problem. [redacted]

238. Even opioid manufacturers considered McKesson's anti-diversion investigations to be inadequate. [redacted]

239. In the course of investigating McKesson's conduct, the State reviewed a sample of McKesson due diligence files for Indiana pharmacies that further revealed serious flaws in McKesson's investigatory and record-keeping practices. [redacted]

240. In a [redacted]

241. In other instances, Washington Court House Distribution Center employees responsible for conducting Level 1 reviews of Indiana pharmacies merely filed boilerplate documentation for the file with no evidence of any investigation into the circumstances underlying the threshold violation. Instead, [redacted]

242. In one particularly egregious example, an Indiana pharmacy's regulatory file contains [redacted]

243. McKesson's anti-diversion investigatory system was used to generate documentation for the files rather than provide any meaningful oversight to detect diversion.

3. McKesson failed to report flagged orders and shipped orders without conducting an appropriate investigation.

244. McKesson already has admitted that it failed to report all the suspicious orders that it should have to the DEA. For example, in its 2017 settlement agreement with the DEA and

DOJ, McKesson acknowledged that suspicious orders did not get flagged in the system and it did not identify and report all the suspicious orders it should have between 2008 and 2014, a period in which McKesson shipped more than [redacted] total dosage units of opioids to Indiana pharmacies.

245. McKesson also failed to report and block orders in Indiana [redacted] from Indiana pharmacies [redacted] despite profiting from and shipping more than [redacted] opioid dosage units into Indiana during this period. For example, on or about [redacted] pharmacy in Spencer County, Indiana, [redacted] While it was supposed to trigger a Level 1 review of the threshold event, [redacted] Instead, [redacted] McKesson's sample regulatory and hardcopy files produced for review contain no records detailing any [redacted], in violation of its duty to investigate whether the order was suspicious.

246. On [redacted] pharmacy in Franklin County, Indiana, [redacted]

[redacted] Again, McKesson's sample regulatory and hardcopy files produced for review contain no records detailing any [redacted], in violation of its duty to investigate whether the order was suspicious.

247. On [redacted] pharmacy in Jefferson County, Indiana, [redacted] and hardcopy files produced for review contain no records detailing any [redacted] in violation of its duty to investigate whether the order was suspicious. [redacted]

248. [redacted] pharmacy in Spencer County, Indiana, [redacted] and hardcopy files produced for review contain no records detailing any [redacted], in violation of its duty to investigate whether the orders were suspicious. [redacted]

[redacted]

249. McKesson's [redacted]

[redacted]

250. For example, [redacted], a pharmacy in Dekalb County, Indiana [redacted]

[redacted]

251. Such practices were not limited to Indiana—they were a symptom of McKesson's systemic anti-diversion failures. Often McKesson failed to report any suspicious orders until [redacted]

[redacted] Only after the DEA [redacted]

[redacted]

252. [redacted]

253. In [redacted] clear red flags for the presence of diversion. Although it had never previously reported a suspicious order from the [redacted] McKesson claimed [redacted] it was reported to the DEA on the basis that it was a [redacted] rather than having [redacted]

254. Further demonstrating its systemic problems, McKesson also failed to [redacted] In addition to the exponential [redacted] increases [redacted] The owner of these pharmacies and dozens of other participants were later convicted on charges related to a drug trafficking conspiracy. The pharmacies in question were located in Michigan, Indiana's neighbor to the north, and a state that was also in McKesson's North Central Region.

255. McKesson also failed to block or report orders that represented significant multiples of the average monthly orders [redacted]

256. On several occasions, McKesson also violated its duty under Indiana law by cancelling (or [redacted]) an order that exceeded a threshold and allowing the pharmacy to place a subsequent, often smaller order for the same drug (that would not trigger a threshold event). This was also termed a [redacted]

257. McKesson acknowledged that [redacted]

258. For example, [redacted] a McKesson employee noted that he had advised a La Porte, Indiana pharmacy [redacted] The next day [redacted]

[redacted]

4. McKesson applied different, even looser, rules to its chain pharmacy customers.

259. McKesson wholly abdicated its responsibility to investigate threshold events triggered by orders from its large chain pharmacy customers, in violation of its duties under Indiana law. McKesson's pharmacy customers were typically divided into "ISM" or "ISMC" (independent, small, and medium size pharmacies) and larger chains identified as RNAs (Retail National Accounts). When an ISM pharmacy exceeded a threshold, [redacted] However, if a Retail National Account pharmacy did the same, McKesson [redacted]

260. McKesson relied [redacted]

261. McKesson personnel responsible for liaising with RNAs [redacted] The RNAs simply had to acknowledge they [redacted] McKesson allowed its chain customers to serve [redacted]

[redacted] For chain customers that wanted a threshold increase, [redacted]

262. In addition, McKesson did not have standard operating procedures to evaluate the RNA customer compliance programs upon which McKesson purportedly relied. For example, [redacted]

263. McKesson's abandonment of its duty allowed McKesson to both maintain profitable business relationships with large chain customers and continue shipping massive quantities of prescription opioids into Indiana without interruption.

264. McKesson's uniform policy of special treatment for chain pharmacies was also evident [redacted] agreement [redacted] Chain Pharmacy #1, [redacted]

265. McKesson also approved permanent bulk threshold change requests to chains without appropriate reasons or documentation. A permanent threshold increase was provided to [redacted] Chain Pharmacy #1's [redacted]

266. In yet another example, McKesson [redacted] Chain Pharmacy #1 without any justification or documentation at all. Chain Pharmacy #1 has [redacted] Indiana locations [redacted] McKesson records reflect [redacted] One McKesson employee aptly described the chain as [redacted] [redacted] Chain Pharmacy #1 [redacted] Chain Pharmacy #1 [redacted] Chain Pharmacy #1 [redacted]

267. Regulatory files reveal that McKesson representatives [redacted] chain pharmacy customers [redacted] This pattern was repeated in multiple chains with

substantial presence in Indiana. For instance, permanent [redacted] for at least two Indiana locations of Chain Pharmacy #2 [redacted] The Retail Sales Manager's notes for each threshold increase indicate that the [redacted] McKesson again reached out in [redacted] for another Chain Pharmacy #2 location. [redacted]

268. [redacted] McKesson created a [redacted]

269. The pattern repeated. On [redacted], McKesson again sent a [redacted] Later that day, the pharmacy responded by requesting that McKesson [redacted] The only documentation provided by McKesson [redacted] The pharmacy did not provide

McKesson with any [redacted]

270. This pattern was also apparent with other McKesson chain pharmacy customers. In [redacted], for example, McKesson emailed another large chain pharmacy [redacted] The only justification provided for the [redacted]

271. McKesson also permitted and approved drastic increases in opioid thresholds at some chain pharmacies. For example, [redacted] Chain Pharmacy #2 [redacted] Lake County, Indiana [redacted]

272. Threshold increases led to significant volumes of opioids reaching Indiana communities. [redacted] Chain Pharmacy #2 location in Porter County, Indiana. [redacted] McKesson did not cite the elevated [redacted] but rather that the store appeared to be [redacted] McKesson did not take any further action and continued supplying the pharmacy.

• • • **AMERISOURCEBERGEN** • • •

E. AmerisourceBergen designed a flawed monitoring system.

273. Following the DEA's 2007 enforcement actions, AmerisourceBergen created an anti-diversion program called the Order Monitoring Program ("OMP") that purported to monitor, identify, report, and prevent the shipment of suspicious controlled substance orders. AmerisourceBergen's Corporate Security and Regulatory Affairs Department was responsible for administering the OMP.

274. The OMP was flawed in its design. Specifically, it failed to require adequate due diligence of new pharmacy customers; set artificially high thresholds for those customers, was based on poor data and metrics; improperly warned pharmacy customers when they were approaching their thresholds to avoid shipping delays and investigations; and permitted threshold manipulation to support increased opioid sales.

275. To meet DEA's regulatory requirements, AmerisourceBergen's OMP was supposed to implement the following components: (1) "Know Your Customer" due diligence,

which required investigations of new pharmacy customers; (2) establishment of thresholds (i.e., order limits), to restrict the volume of opioid drugs that a pharmacy could order each month and prevent the shipment of orders that exceeded thresholds; (3) investigation of orders that exceeded thresholds, to identify and report orders that were deemed suspicious to the DEA; and (4) customer monitoring, [redacted]

276. Pharmacy customer orders that exceeded thresholds were supposed to be held and blocked until completion of an initial review; these were sometimes called "Orders of Interest." Once a pharmacy customer's threshold was exceeded, subsequent orders of opioids from the same drug family (opioids sharing the same narcotic ingredient) were also to be blocked pending completion of the review.

277. Employees at AmerisourceBergen's [redacted] performed initial investigations. Between [redacted] employees with responsibility for reviewing potentially suspicious orders that exceeded thresholds. Despite their critical role in AmerisourceBergen's anti-diversion program, [redacted] Their training was also inadequate. [redacted] at a distribution center that serviced Indiana [redacted]

278. Although [redacted] were supposed to "Know [their] Customer," [redacted] which was central to the company's "Know Your Customer" due diligence. [redacted] was a pharmacy questionnaire that surveyed pharmacy

customers for information about their business, including information about [redacted] disciplinary history, customer payment methods, what percentage of the pharmacy's prescription volume was made up of controlled substances, [redacted] and top prescribers of opioids, among other questions. Though the [redacted] requests information about prescribing physicians, AmerisourceBergen did not perform independent searches on those prescribers as part of its new customer investigations.

279. [redacted] were supposed to analyze potential suspicious orders and determine [redacted] made that determination simply based on [redacted] Instead of requiring a rigorous investigation, AmerisourceBergen instructed [redacted] Releasing orders [redacted] were also supposed to [redacted]

280. Orders [redacted] would be [redacted] based on the results [redacted]

[redacted] Orders that were [redacted]

281. In addition to requiring investigation of threshold breaches, AmerisourceBergen's OMP purported to [redacted] if AmerisourceBergen employees [redacted]

1. AmerisourceBergen had inadequate due diligence when onboarding new pharmacy customers.

282. AmerisourceBergen knew that, [redacted] This due diligence was supposed to [redacted] However, AmerisourceBergen's customer onboarding policies failed to independently assess a pharmacy's risk of diversion.

283. From approximately [redacted], AmerisourceBergen's process for approving new pharmacy customers was supposed to consist of [redacted]

284. Existing AmerisourceBergen customers, [redacted] were [redacted] For example, one Indiana pharmacy that AmerisourceBergen supplied [redacted]

[redacted]

285. Demonstrating an additional flaw in its program, AmerisourceBergen sales personnel—[redacted]

286. Further, from [redacted], AmerisourceBergen's onboarding process did not require [redacted] Although AmerisourceBergen requested that customers [redacted] AmerisourceBergen still does not require potential pharmacy customers to [redacted]

287. AmerisourceBergen's onboarding process also did not require [redacted] even though AmerisourceBergen [redacted] Until very recently, AmerisourceBergen's onboarding policy stil[redacted]

288. AmerisourceBergen also routinely failed to adhere to its nominal onboarding procedures. For example, [redacted]

[redacted]—AmerisourceBergen established [redacted]

289. Only in [redacted] did AmerisourceBergen begin remediating these deficiencies. [redacted] Yet an AmerisourceBergen [redacted] reminded sales employees that these compliance duties, [redacted]

290. The result was predictable. [redacted]

291. AmerisourceBergen also [redacted] its chain pharmacy customers—which AmerisourceBergen [redacted] as any pharmacy with [redacted] AmerisourceBergen's most recent Standard Operating Procedure [redacted] Despite instituting a measure of onboarding due diligence requirements [redacted] AmerisourceBergen [redacted]

[redacted]

292. This [redacted] left holes in the diligence process. For example, in 2013, Chain Pharmacy #3 [redacted]; this was the same year that Chain Pharmacy #3 paid a record $80 million fine to the DEA / DOJ for alleged violations of the Controlled Substances Act. Despite this, AmerisourceBergen still did not [redacted]

2. Unreasonably high thresholds prevented identification and reporting of suspicious orders

293. From its inception, AmerisourceBergen's threshold system was designed to avoid impacting sales rather than identify suspicious orders. One AmerisourceBergen employee admitted that thresholds were designed [redacted] Consequently, AmerisourceBergen systematically set thresholds at inappropriately high levels to minimize the number of threshold events, avoid order delays, and prevent disruption of AmerisourceBergen's revenue stream.

294. [redacted] AmerisourceBergen then [redacted]

[redacted] In other words, AmerisourceBergen [redacted] —meaning a pharmacy would have to [redacted] before triggering any suspicious order review.

295. In January 2009, default thresholds for hydrocodone were set at [redacted] AmerisourceBergen knew that these thresholds were [redacted] because they were set at a level that they [redacted][17]

296. Moreover, the [redacted] on which AmerisourceBergen relied were inflated even before AmerisourceBergen [redacted] to set the final thresholds. [redacted] for its thresholds, AmerisourceBergen used [redacted] during which opioid sales, and diversion of opioids to non-medical use, were already at dangerously excessive levels. In 2006, for example, pharmacies dispensed a record 174 million opioid prescriptions nationwide—equivalent to 72.4 prescriptions per 100 persons nationally and a 185% 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 2007, opioid prescribing increased further, reaching 75.9 prescriptions per 100 persons. AmerisourceBergen acknowledged that [redacted] that formed the basis of its threshold calculations could allow customers [redacted] The baseline threshold [redacted]

[17] [redacted]

[redacted] AmerisourceBergen reached a settlement with the DOJ and DEA for alleged failures to maintain effective anti-diversion controls at their Florida distribution center.

297. From at least [redacted], AmerisourceBergen's thresholds also failed to [redacted]

298. Furthermore, [redacted] thresholds were based on a [redacted] Consequently, a customer with [redacted] effectively multiplying the quantity of opioids they could purchase before breaching any thresholds.

299. Following increased DEA enforcement activity directed at distributors, AmerisourceBergen's excessively high thresholds [redacted] However, this resulted in [redacted] —indicating just how inflated and ineffective AmerisourceBergen's thresholds were for the most commonly diverted opioids. In early [redacted], two Indiana pharmacies' thresholds for [redacted]

[redacted] another [redacted]

[redacted]

300. [redacted] AmerisourceBergen also revised its threshold-setting procedures in 2015. While demonstrating the company's awareness of the flaws in its own program, the new procedures were still poorly designed and failed to remedy many of the problems exhibited by the previous system.

301. First, the revised system [redacted] [18] The revised system also was supposed to [redacted] However, AmerisourceBergen chose to [redacted]

302. Rather than a single threshold, the new system implemented two [redacted] [19]

[redacted]

[18] [redacted]

[19] [redacted]

[redacted] In effect, this new system only blocked orders if they were [redacted] in violation of the duties required under Indiana law.

303. The revised OMP threshold system also purported to implement a "fail-safe" [redacted]

304. The 2015 revised system also continued setting thresholds excessively high. From 2015 [redacted] AmerisourceBergen improperly [redacted] As a result, even after AmerisourceBergen revised its threshold program, unless a pharmacy [redacted] or [redacted]

[redacted] blocked and investigated.

305. In addition to setting these inflated values, AmerisourceBergen implemented other workarounds to avoid setting off diversion detection. The revised system als[redacted]

306. These excessively high thresholds thwarted the OMP's ability to monitor and identify suspicious orders in Indiana. In essence, the thresholds were rendered meaningless in all but the most extreme circumstances. For example, in [redacted], AmerisourceBergen's hydrocodone thresholds were sometimes [redacted] From [redacted] through [redacted], hydrocodone thresholds were sometimes [redacted] As an example of the impact of these excessively high thresholds, one Indiana pharmacy dispensed [redacted] That pharmacy was located in Floyd County, Indiana which has a population only of about 77,000. During this time, AmerisourceBergen [redacted]

307. By consistently setting thresholds well above a pharmacy's typical monthly ordering quantity, AmerisourceBergen's pharmacy customers did not exceed their thresholds

unless they ordered [redacted] of prescription opioids [redacted] and they were able to place unusually large and suspicious orders without triggering any investigation or review.

3. AmerisourceBergen provided advance warnings and inappropriate disclosures to pharmacy customers that were approaching their monthly thresholds

308. AmerisourceBergen knew that communicating a threshold limit to a customer [redacted] As noted by one AmerisourceBergen employee, disclosing the threshold to a customer [redacted]

309. Despite that policy, from [redacted], AmerisourceBergen routinely provided customers with information about when they could [redacted]

310. Through [redacted], AmerisourceBergen's diversion control employees were [redacted] AmerisourceBergen's employees tasked with diversion control would [redacted]

[redacted] For example, a pharmacy might have an oxycodone threshold of 500 dosage units [redacted] If the customer ordered 200 dosage units on October 1, and 300 dosage units on October 15, [redacted] Sometimes, if a pharmacy customer's order exceeded a threshold, [redacted] An AmerisourceBergen [redacted]

311. In [redacted] AmerisourceBergen determined that [redacted] stated that [redacted]

312. Instead, customer service employees at AmerisourceBergen became responsible for routinely providing customers with [redacted]

[redacted] When a customer called regarding a held order, the customer would receive [redacted]

313. It was not until [redacted] that AmerisourceBergen finally made it a policy that employees [redacted]

4. AmerisourceBergen routinely increased thresholds without adequate due diligence.

314. Beyond merely assisting pharmacy customers in avoiding orders that would breach a threshold, AmerisourceBergen also proactively pushed customers to request threshold increases, independently increased threshold levels without requests from pharmacy customers, and created policies that allowed orders in excess of thresholds to be quickly released to customers without due diligence. AmerisourceBergen thus turned its OMP threshold system into a sales tool to ensure that customers received steady supplies of opioids rather than a compliance tool to avoid diversion.

315. To obtain a threshold increase, the pharmacy customer [redacted] was supposed to [redacted]

[redacted]

316. [redacted] the CSRA Department was supposed to [redacted]

[redacted] Effective [redacted] due diligence was supposed to include [redacted]

317. AmerisourceBergen routinely granted threshold increases without proper justifications and without adequate due diligence. For example, as to one pharmacy,

AmerisourceBergen increased thresholds by [redacted]

AmerisourceBergen raised another customer's threshold [redacted] For yet another customer, AmerisourceBergen provided a threshold increase [redacted] AmerisourceBergen increased thresholds for another account [redacted]

318. In another case, AmerisourceBergen increased a pharmacy's threshold [redacted]

319. In addition, in [redacted], with no valid justification, AmerisourceBergen implemented [redacted]

[redacted] In internal communications, the rationale provided for this change was [redacted] None of these justifications were sufficient to grant a threshold increase based on OMP directives.

320. In addition, [redacted] AmerisourceBergen account managers routinely [redacted]

321. AmerisourceBergen knew that [redacted] Consequently, threshold increase requests were supposed to [redacted] Yet, in 2012, AmerisourceBergen increased oxycodone thresholds [redacted]

322. An AmerisourceBergen document titled [redacted] showed other ways that the company tried to subvert and work around its own OMP, further undermining an already flawed system. This document revealed [redacted]

[redacted]

AmerisourceBergen's priority was thus to ensure that its customers did not come under investigation rather than comply with its duties under Indiana law.

323. As an extra incentive to increase business purchases from AmerisourceBergen, the protocol for increasing thresholds was [redacted] However, AmerisourceBergen only chose to classify an account as having [redacted]

324. In other instances, thresholds were ignored altogether. For example, in December 2010, a distribution center manager [redacted] As AmerisourceBergen personnel acknowledged in an internal communication, [redacted]

325. In [redacted], AmerisourceBergen changed the policies by which threshold increases were requested [redacted]

326. However, AmerisourceBergen continued its practice of ignoring its own rules. In January 2017, AmerisourceBergen increased thresholds [redacted]

[redacted]

327. The threshold system, an essential component of AmerisourceBergen's OMP, thus never served its purpose. AmerisourceBergen did not set and then maintain thresholds. The thresholds did not meaningfully restrict AmerisourceBergen's customers from obtaining an excessive amount of opioid drugs, but instead were used to accommodate whatever pharmacy customers wanted to purchase, or were set so high that they never triggered any review.

328. The result was a consistent pattern of excessive opioid sales in Indiana. Between November 2014 and November 2015, a pharmacy in Floyd County, Indiana [redacted] in Lawrence County, Indiana, AmerisourceBergen [redacted] And in [redacted], AmerisourceBergen [redacted] in Clark County, Indiana [redacted] Notably, these statistics only account for AmerisourceBergen shipments, and do not account for additional opioids supplied to these towns by other distributors such as Cardinal and McKesson.

F. AmerisourceBergen failed to adhere to the terms of its own anti-diversion program.

329. Not only did AmerisourceBergen design a deficient OMP, it systemically failed to implement the components of its program in Indiana and nationwide. Specifically, AmerisourceBergen understaffed its anti-diversion department; undertrained employees responsible for monitoring and investigating suspicious orders; failed to diligently investigate all

suspicious orders and report them to the DEA; and allowed large chain pharmacies to conduct their own diligence investigations and police themselves with little to no oversight by AmerisourceBergen.

1. AmerisourceBergen understaffed and undertrained its anti-diversion employees

330. AmerisourceBergen failed to provide adequate training and guidance for employees at nearly every level of its anti-diversion program and left out core anti-diversion measures. While one AmerisourceBergen diversion investigator [redacted] In essence, AmerisourceBergen relied on its employees' subjective judgment when conducting investigations rather than providing them with clear, objective criteria to identify suspicious orders.

331. In addition, the same AmerisourceBergen diversion investigator [redacted] Similarly,

[redacted]

332. One of AmerisourceBergen's [redacted], who was responsible for first-level review and investigation of potentially suspicious orders at a distribution center, described her training as [redacted]

333. Compounding this weakness, the training that was provided to AmerisourceBergen employees was [redacted] AmerisourceBergen's Director for Diversion Control admitted that [redacted]

334. In addition to failing to adequately train and provide its employees with standard operating procedures, AmerisourceBergen also severely understaffed its anti-diversion department. In approximately [redacted] when AmerisourceBergen's diversion control program was implemented, AmerisourceBergen only had [redacted] who were responsible for [redacted] In addition, they and their investigators were tasked with [redacted] In fact, a March 2008 presentation included [redacted]

[redacted]

335. As a result of this understaffing, AmerisourceBergen argued that their sales employees' [redacted] Sales and distribution center employees were consequently charged with [redacted] In fact, sales employees [redacted] In short, AmerisourceBergen chose to design a compliance system in which sales employees' [redacted]

336. AmerisourceBergen's chronic understaffing also led to issues of capacity and staff burnout. For example, the diversion investigator [redacted]

337. AmerisourceBergen's problems with undertraining and understaffing were further apparent in a [redacted] assessment of AmerisourceBergen's anti-diversion practices. [redacted]:

[redacted]

2. AmerisourceBergen failed to adhere to critical components of its anti-diversion program.

338. As discussed above, the Form 590 pharmacy questionnaire is a core part of AmerisourceBergen's anti-diversion program. These questionnaires provide drug distributors with essential information about a pharmacy, its business, the top prescribing physicians, and other information critical to evaluate pharmacy orders.

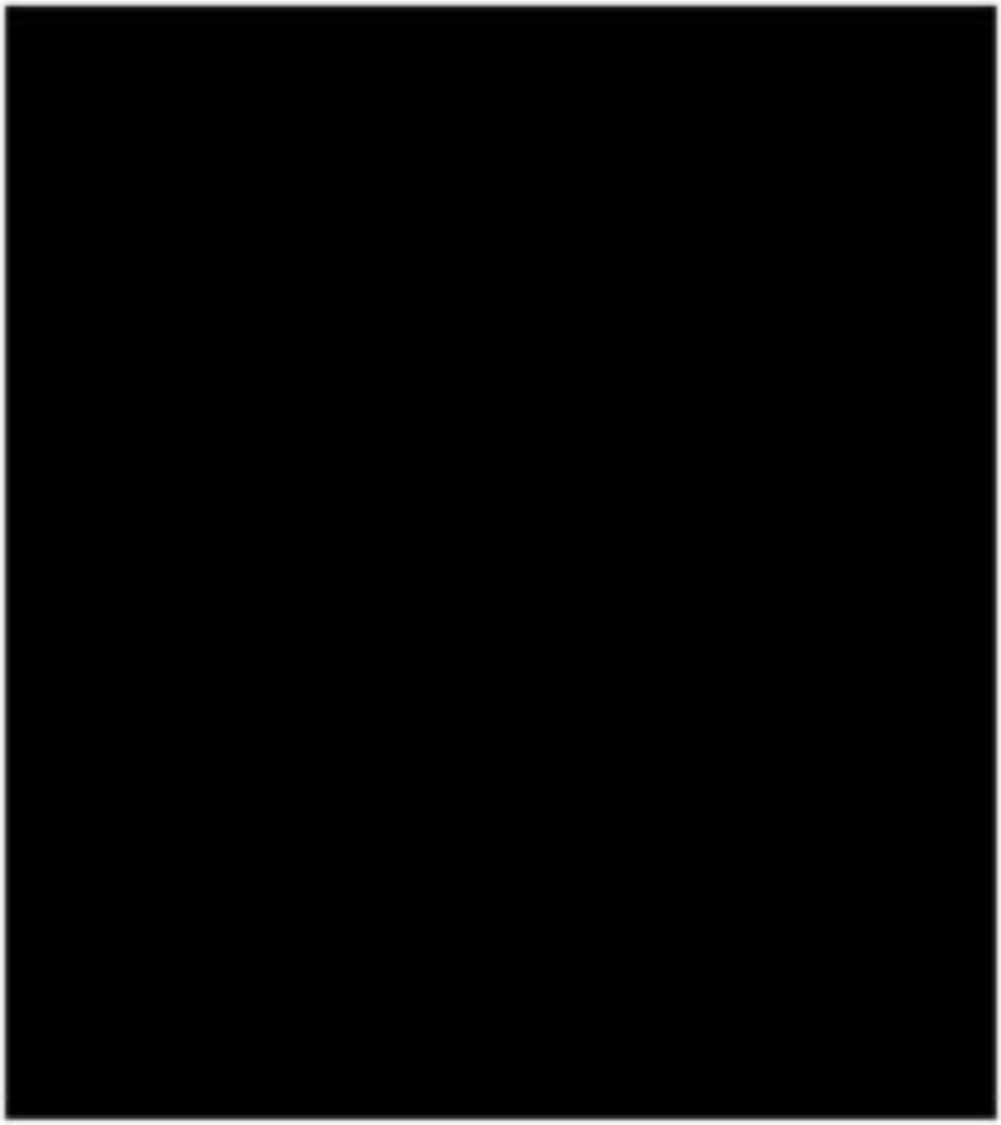
339. An [redacted] diversion control training presentation [redacted]

340. [redacted]

341. [redacted]

342. The distribution centers serving Indiana pharmacies [redacted]

343. AmerisourceBergen documents identify [redacted]



344. Based on AmerisourceBergen's data,

Together, these AmerisourceBergen distribution centers supplied of opioid orders to the company's Indiana customers.

345. Despite being the company's [redacted] AmerisourceBergen had [redacted]

346. Specifically, [redacted] supplied by AmerisourceBergen's [redacted]

347. The failures were even worse [redacted] serviced by AmerisourceBergen's [redacted] More than [redacted] supplied by AmerisourceBergen's [redacted]

348. Finally, nearly [redacted] supplied by AmerisourceBergen's [redacted]

349. In summary, a significant number of [redacted] served by AmerisourceBergen's [redacted] As a result of these deficiencies, [redacted]

350. [redacted] Scott County, Indiana. [redacted]

351. [redacted] this Scott County pharmacy [redacted]

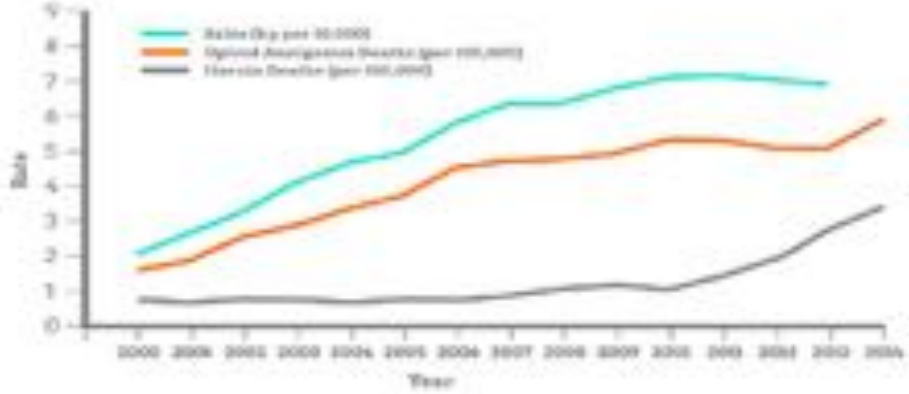
352. [redacted] a pharmacy located in Lawrence County, Indiana. [redacted]

353. [redacted] opioid sales and opioid deaths both

rose on nearly parallel tracks. [redacted]

[redacted]

PRESCRIPTION PAINKILLER SALES AND AGE-ADJUSTED RATES FOR DRUG-POISONING DEATHS, BY TYPE OF DRUG: UNITED STATES, 2000–2014



3. AmerisourceBergen failed to act on information that should have triggered, at a minimum, an investigation

354. [redacted]

[redacted] AmerisourceBergen [redacted]

355. But gathering data was insufficient. Although the reports and information that AmerisourceBergen generated should have triggered scrutiny [redacted]

[redacted]

356. [redacted] pharmacies located in Floyd County, Clark County, and Wayne County, Indiana [redacted]

357. [redacted] the Floyd County pharmacy [redacted] Indiana independent pharmacy with the [redacted]

358. [redacted] Floyd County pharmacy [redacted]

359. [redacted] the pharmacy in Clark County, Indiana, [redacted]

360. [redacted] Floyd County pharmacy [redacted]

361. The Clark County pharmacy [redacted] —a county with a [redacted]

362. [redacted] Despite this, [redacted]

[redacted]

Floyd County [redacted]

[redacted]

363. [redacted] Wayne County, Indiana. [redacted] Around the March 2018 time period, Wayne County also ranked [redacted] for overdose deaths, with a two-year average overdose death rate of [redacted]

364. [redacted]

365. [redacted] One such drug combination—the "Trinity" or "Trinity Cocktail"—includes an opioid, a benzodiazepine (indicated for the management of anxiety disorder or the short-term relief of symptoms of anxiety), and carisoprodol (a muscle relaxant). All three of these drugs are controlled substances, and the combination creates an extremely addictive "high" and poses significant risks of central nervous system and respiratory depression, which could lead to death. [redacted]

366. As evidenced by internal documents, [redacted]

367. [redacted]

368. [redacted]

369. AmerisourceBergen continued to [redacted]

370. [redacted]

371. The State has found no evidence to date that [redacted] resulted in any AmerisourceBergen investigation of these or other Indiana pharmacies. [redacted] the combination of the three drugs—known to have such dangerous side effects when taken in combination—[redacted]

4. AmerisourceBergen failed to conduct diligent investigations of suspicious orders to detect and prevent diversion

372. As discussed above, the OMP required AmerisourceBergen to investigate whenever a pharmacy ordered a volume of opioids that exceeded its monthly threshold. However, AmerisourceBergen consistently failed to conduct investigations that were sufficiently diligent and that would reliably detect and prevent diversion.

373. First, threshold breaches that involved what AmerisourceBergen classified as [redacted]

374. [redacted] further details the systemic and nationwide failures in AmerisourceBergen's anti-diversion practices. For example, the [redacted]

375. While AmerisourceBergen provided its anti-diversion employees with [redacted]

[redacted]

376. [redacted]

377. In addition to threshold breaches, AmerisourceBergen also failed to investigate pharmacy customers that triggered other red flags independent of threshold breaches, such as [redacted] In fact, when one diversion investigator was asked [redacted]

378. Ignoring red flags had real-world consequences. For example, California's Board of Pharmacy brought disciplinary charges against [redacted] pharmacy [redacted], Script Life Pharmacy, based on more than a dozen violations between 2011 and 2012, including dispensing controlled substances without a prescription. The pharmacy owner and pharmacist-in-charge agreed to pay $200,000 to settle those claims. News accounts and press releases documented the pharmacy's settlement with the state in March 2016. [redacted]

379. AmerisourceBergen's analyses showed that [redacted] Despite the fact that controlled substance ratios and prior discipline are important red flags for diversion, AmerisourceBergen [redacted]

380. Likewise, in Indiana, AmerisourceBergen failed to investigate pharmacies with obvious red flags. The Floyd and Clark County pharmacies [redacted] AmerisourceBergen's records show that [redacted] Among all Indiana pharmacies [redacted]

381. Despite these obvious red flags, [redacted] Floyd County [redacted] In [redacted] criminal search warrants were served on one of the pharmacy's top prescriber of controlled substances; in [redacted], a warrant was executed on the pharmacy [redacted]

382. [redacted] Floyd County pharmacy. [redacted]

383. [redacted]

384. [redacted] As to one top Indiana prescriber, [redacted] a local article published in December 2014 about [redacted] As described in the article, [redacted] or one of his Nurse Practitioners was alleged to be responsible for eight drug overdose deaths between 2008 and 2013. No other reference to these news reports was found in the regulatory documents provided to the State, which indicates that AmerisourceBergen did not [redacted]

385. As to another of the pharmacy's top prescribers, [redacted]

386. Data for another of the pharmacy's top prescribers, [redacted]

387. Disregard for potential bad doctors was commonplace for AmerisourceBergen. Beginning in at least [redacted]

388. [redacted][20]

[20] Though Floyd County, Indiana is located in close proximity to Kentucky, it is over 100 miles away from the borders of the next-closest states, Ohio and Tennessee.

[redacted]

[redacted] In any event, such an inquiry and request for additional information should have been raised years earlier, instead of after an [redacted] flagged the pharmacy as a problem. And there is no indication that AmerisourceBergen made any real inquiry into this pharmacy between [redacted]

[redacted]

389. Despite the [redacted] findings as well as the warrants issued against the pharmacy and one of its top prescribers, a [redacted]

[redacted]

5. AmerisourceBergen failed to report suspicious orders.

390. In addition to failing to adequately investigate suspicious orders, AmerisourceBergen [redacted]

391. [redacted]

392. In [redacted], AmerisourceBergen documents indicate that it identified [redacted] orders of interest [redacted], but reported only [redacted]

393. By [redacted], AmerisourceBergen identified [redacted] orders of interest from [redacted] customers in Indiana. [redacted] customers accounted for [redacted] of those orders. However, AmerisourceBergen only [redacted]

394. In [redacted] AmerisourceBergen identified [redacted] orders of interest from [redacted] customers but only [redacted]

395. In [redacted] AmerisourceBergen identified [redacted] orders of interest, including [redacted], yet it reported only [redacted]

396. The table below reflects overall AmerisourceBergen reporting trends in Indiana for certain opioids it considered [redacted]

AmerisourceBergen: High and Medium Risk Indiana Opioid Orders Reported To DEA

[redacted]

Table based on AGO analysis of AmerisourceBergen data

397. These numbers not only show [redacted] From [redacted] the number of opioid orders that Indiana customers placed with AmerisourceBergen [redacted], but the number of orders of interest that AmerisourceBergen flagged [redacted] And the percentage of orders that AmerisourceBergen reported to the DEA in [redacted] was approximately [redacted]

[redacted] The percentage of orders that AmerisourceBergen reported to the DEA in [redacted]

[redacted]

398. From [redacted] the number of Indiana customers that AmerisourceBergen reported to the DEA [redacted] The table below summarizes AmerisourceBergen data. The percentage of customers that AmerisourceBergen reported to the DEA [redacted]

[redacted]

CUSTOMERS REPORTED TO THE DEA
[redacted]

6. AmerisourceBergen failed to block orders that exceeded thresholds and released orders that should have been flagged for further investigation.

399. AmerisourceBergen also violated its own OMP by failing to block pharmacy purchases that breached thresholds. For instance, in [redacted] AmerisourceBergen's CSRA Department reviewed [redacted] pharmacies, whose conduct required AmerisourceBergen to [redacted] One [redacted] recommendation arose due to [redacted]

[redacted]

[redacted]

400. As recently as [redacted] indicating a system-wide compliance failure. For example, [redacted] Indiana was not alone, this pattern was evidenced in other states [redacted]

401. A two-year summary of [redacted] illustrates the scope of Indiana orders that [redacted] but which were nevertheless released [redacted] Chain Pharmacy #3 [redacted]

7. AmerisourceBergen applied even less stringent rules for its chain pharmacy customers.

402. AmerisourceBergen [redacted] AmerisourceBergen justified this [redacted] on the basis that [redacted]

403. In practice, this meant that AmerisourceBergen would not [redacted]

404. In addition to [redacted], AmerisourceBergen [redacted] For example, AmerisourceBergen [redacted] Chain Pharmacy #3 [redacted] AmerisourceBergen even [redacted] Chain Pharmacy #3 [redacted]

405. If an AmerisourceBergen employee attempted to initiate investigations of potentially suspicious orders from chain pharmacies, [redacted] For example, when one employee [redacted] Chain Pharmacy #3 and Chain Pharmacy #4 [redacted]

[redacted]

406. [redacted] of large chain pharmacy orders were [redacted] For example, [redacted] Chain Pharmacy #3's [redacted] activity [redacted]

407. [redacted] illustrates the impact of delegating supervision authority to large chain pharmacies. [redacted] to Chain Pharmacy #3 locations in Indiana, [redacted]

408. The result of AmerisourceBergen's deference to national retail accounts was [redacted] Chain Pharmacy #3 locations in Indiana [redacted]

[redacted]

Chain Pharmacy #3 orders in Indiana [redacted]

III. Defendants Engaged in the Deceptive, Unfair, and/or Abusive Marketing of Prescription Opioids.

409. Defendants' contributions to the opioid epidemic are not limited to their escalating sales and failure to design and implement policies that effectively prevented diversion. Defendants' internal documents confirm that they actively promoted prescription opioids to prescribers and pharmacists. Through these marketing activities, they built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

410. Defendants' promotion and marketing of prescription opioids constitutes an unfair and abusive practice under Indiana's DCSA, in the context of their legal duties as licensed distributors of controlled substances and their failure to implement adequate systems to detect, prevent, and report diversion. Their marketing of prescription opioids ranged from [redacted]—to [redacted], disseminated through marketing channels over which they had unique control, as well as promotion and/or administration of prescription savings clubs and programs designed to encourage initiation and long-term use of branded prescription opioids. Through these marketing activities, Defendants built upon and reinforced the opioid manufacturers' deceptive, misleading, and highly successful marketing campaign to promote prescription opioid use.

411. Defendants' roles in marketing prescription opioids were at odds with their core responsibilities as licensed distributors of controlled substances. These marketing efforts were

intended to increase opioid sales, which would thereby increase the supply of opioids in the community and increase abuse and diversion, further undermining Defendants' already insufficient diversion prevention systems.

412. Defendants profited in two ways from their marketing activities: (1) they were paid by the drug manufacturers to promote their prescription opioids, and/or (2) they were paid from increases in pharmacy drug sales that resulted from these marketing efforts.

413. Defendants focused their marketing efforts on pharmacists because they knew—as did the opioid manufacturers—that pharmacists, as the last healthcare professionals to see patients before medication is dispensed, occupy a unique position of influence over both prescribers and consumers. Particularly over the last few decades, the typical pharmacist's role has evolved from rote dispensing of prescriptions to actively advising on drug therapies.

414. In a 2010 survey by the National Community Pharmacists Association ("NCPA"), pharmacists reported interacting with other health care professionals regarding patients' drug therapy an average of 7.1 times per day. Eighty-one percent of the surveyed pharmacists reported recommending changes to patients' drug regimens, with physicians accepting 73% of those recommendations. Nearly all (93%) of the surveyed pharmacists reported, for example, recommending changes from branded to generic drugs, with physicians accepting 80% of those recommendations.

415. Cardinal has expressly acknowledged [redacted] One Cardinal marketing proposal emphasized to an opioid manufacturer client that [redacted] Cardinal's

proposal advised the drug company that [redacted].”

416. Opioid manufacturers that used Defendants' marketing services also knew that pharmacists are key to ensuring that prescriptions are converted to sales. Purdue, for example, asserted in a [redacted] In 2015, when Purdue launched its extended-release hydrocodone product, Hysingla, it [redacted] Purdue also noted that [redacted]

417. Purdue and other manufacturers worked hand-in-glove with Defendants to promote their products—through the distributors—to pharmacies and pharmacists. For example, [redacted]

418. The targeting of pharmacists by Defendants in their marketing activities was particularly problematic because of Defendants' existing and often long-term business relationships with pharmacies—with whom Defendants shared a legal responsibility to prevent diversion. Defendants were in a unique and trusted position in the controlled substances supply chain from which they could have spoken truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have taken no position about the benefits and risks of opioids, and simply filled orders and shipped drugs.

Instead, Defendants abused their unique position for profit, by contributing to the chorus of deception surrounding opioids.

419. To engage in the promotion of controlled substances at all, under the circumstances detailed in this Complaint, was a dereliction of Defendants' duties to prevent opioid diversion. Through these marketing activities, Defendants contributed to and reinforced the deceptive and misleading marketing messages that healthcare providers received about opioids through other channels. Moreover, much of the Defendants' marketing content was deceptive, because it either affirmatively misrepresented the benefits and risks of prescription opioids, or it omitted important information about the risks of prescription opioids. Defendants knew or should have known that these marketing messages—particularly those that misrepresented or omitted material information about the potential for diversion or risks of addiction associated with prescription opioids—were deceptive. Through their deceptive, unfair and/or abusive conduct, Defendants put Indiana consumers at increased risk of harm from the escalating and largely unchecked distribution and sale of prescription opioids, increased availability and diversion of opioids to non-medical use in Indiana, and increased misuse and addiction that has created an epidemic of health problems, overdose, and death in Indiana.

A. Cardinal's Opioids Marketing.

420. Cardinal has actively sought to increase the sale of opioids nationwide, including in Indiana, by marketing these dangerous and addictive drugs to pharmacists and prescribers, and even directly to consumers, contrary to its public claim that it merely serves as a secure delivery service for transporting medications from warehouse to pharmacy. Cardinal not only offers marketing services to its drug manufacturer clients, it incentivizes and encourages manufacturers to use these marketing channels as a way of building their business and increasing sales of prescription opioids.

421. Increased drug sales benefit Cardinal. [redacted]

422. Cardinal offers a range of marketing services to its drug manufacturer clients. [redacted] For many manufacturers, the cost of Cardinal's marketing services is [redacted]

423. [redacted]

424. [redacted] A year later, Purdue and three of its current and former executives pled guilty to federal criminal charges connected to their misleading marketing of OxyContin, paying $600 million in fines and other payments. [redacted]

425. As another example, [redacted] By late 2013, INSYS had publicly announced that it was under federal investigation and had received a subpoena from the U.S. Department of Health and Human Services inquiring into INSYS's sales and marketing practices relating to SUBSYS. [redacted] Since then, the founder and four executives of INSYS were convicted in May 2019 of federal racketeering conspiracy offenses

relating to the company's payments of kickbacks to prescribers and fraud on Medicare and private insurance programs related to SUBSYS. Thereafter, INSYS agreed that it would pay $225 million and one of its operating units would plead guilty to several counts of mail fraud, in settlement of related civil and criminal claims against the company, and it filed for bankruptcy protection days later.

426. From at least 2010 to 2017, Cardinal's marketing team routinely [redacted]

427. Cardinal also offered manufacturers the opportunity to [redacted]

428. Cardinal did not simply [redacted] it also [redacted]

429. Cardinal's marketing programs were not [redacted]

430. Through Cardinal's marketing programs, it disseminated the drug manufacturers' promotional messages about opioids nationally and into Indiana. It did so with the knowledge that engaging in these types of marketing to promote controlled substances was problematic and should be avoided. These marketing activities constituted an unfair and abusive business practice, under the circumstances detailed in this Complaint, as discussed in section 1 below. Moreover, at least some of the marketing materials that Cardinal disseminated were deceptive, as discussed in section 2 below.

1. Cardinal engaged in an unfair and abusive business practice by marketing prescription opioids through a variety of marketing programs.

431. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally and in Indiana. These marketing activities constituted an unfair and abusive business practice, under the circumstances detailed in this Complaint.

432. ***Direct-to-Consumer Marketing.*** Cardinal has marketed drugs directly to consumers through [redacted] To manufacturers, Cardinal describes this program, [redacted] To pharmacies, Cardinal explains that [redacted]

433. There is ample evidence that this type of marketing is effective. A 2014 audience-research study conducted by Nielsen found 74% of PHN viewers indicated advertisements are

more believable when viewed in a pharmacy; 49% of viewers surveyed indicated that they felt encouraged to discuss a product or brand they had seen on the network with their pharmacist; 48% indicated that after seeing advertisements on PHN, they felt motivated to discuss those products or brands with their physicians; and 13% of consumers who have seen advertisements on PHN have purchased those products or brands.

434. As John Disher, Cardinal's Senior Manager for Marketing and Business Development, said in 2014: "This study again confirms that consumers consider advertising messages on Pharmacy Health Network to be informative and highly credible, and that ads on our network drive action, by encouraging consumers to talk with their pharmacists and physicians about products they see on our network … As our network continues to receive a positive response from advertisers and consumers alike, we look forward to expanding the number of stores and advertisers that participate in the program."

435. In fact, additional studies show that, as of November 2015, Cardinal's PHN was proven to increase sales of advertised products.

436. [redacted] Beyond these examples, it is clear that [redacted]

[redacted]

437. ***Direct Mail Marketing.*** Cardinal promoted opioids through [redacted]

[redacted]

438. [redacted]

[redacted]

439. ***Email Marketing.*** Cardinal has also [redacted]

[redacted]

440. [redacted]

[redacted]

441. Cardinal claims that through [redacted] Cardinal specifically promotes its ability to [redacted] In its own words, Cardinal advertises that its "commercial team helps to position [a manufacturer's] product for success by identifying physicians who treat unique patient populations, understanding prescriber behavior and driving engagement."

442. From 2010 through at least 2015, Cardinal used [redacted]

443. From at least 2012 through 2017, Cardinal frequently used [redacted]

444. ***Marketing in Customer Newsletters.*** Cardinal has also offered opioid marketing through [redacted]

445. [redacted]

446. Drug manufacturers can purchase [redacted]

447. Cardinal used [redacted] including pharmacists in Indiana, from at least 2009 through 2017.

448. ***Telemarketing.*** Cardinal offers its manufacturer clients the option of purchasing [redacted]

449. [redacted]

450. One telemarketing script [redacted]

451. ***Advertisements on Ordering Platform.*** Cardinal also runs drug advertisements on [redacted]

452. Cardinal offers drug manufacturers the options of [redacted]

[70] Controlled substances—including opioids—are divided into Schedules, depending on their potential for abuse. Schedule III drugs have a potential for abuse that is lower than drugs in Schedules I and II, and abuse of these drugs may lead to moderate or low physical dependence or high psychological dependence.

[71] [redacted]

[redacted]

453. [redacted]

[redacted]

454. ***Pharmacy Rebates.*** Cardinal further encourages purchases of opioids through its

[redacted]

455. [redacted]

[redacted]

456. ***Auto-Shipments.*** Cardinal also offered an auto-ship program called "[redacted]" as a marketing service. [redacted]

[redacted]

457. [redacted]

2. Cardinal deceptively marketed opioids.

458. In addition to being an unfair and abusive business practice, some of Cardinal's marketing content was also deceptive. These marketing messages—like other opioid marketing messages disseminated in the medical community by opioid manufacturers—contained deceptive statements about the benefits of particular opioids or misleading omissions about the serious risks associated with them.

459. Cardinal's deceptive and misleading marketing of opioids contributed to—and built upon—the deceptions that drug manufacturers were disseminating through other channels.

460. Cardinal disseminated certain opioid advertisements that contained deceptive statements regarding the risk of addiction, abuse, and diversion posed by these drugs. For example, [redacted] This advertisement was sent to [redacted]

[23] Schedule II controlled substances are so-categorized because they have a high potential for abuse, which may lead to severe psychological and physical dependence.

[redacted]

461. Moreover, many of Cardinal's opioid advertisements failed to disclose the serious risks associated with opioids or to provide "fair balance" in their representation of the risks and benefits of the drugs. For example, [redacted] Likewise, Cardinal disseminated advertisements promoting opioids without mentioning any of the drugs' risks—providing, at most, [redacted] These advertisements failed to provide "fair balance" and had material omissions, which rendered them misleading to their intended recipients, in violation of the Deceptive Consumer Sales Act.

462. Cardinal disseminated advertisements that were not clearly labeled as paid advertising content and would reasonably have been mistaken by Cardinal's pharmacy customers as neutral informational content provided by Cardinal.

463. Through these and other advertisements, Cardinal took advantage of its unique position of trust as a distributor of controlled substances to promote opioids in deceptive and misleading ways. On information and belief, Cardinal knew that these advertisements—particularly those that misrepresented the risk of diversion for, or addictive potential of, prescription opioids—were deceptive, because of its experience in the pharmaceutical industry and its own heightened duties, as a distributor, when handling controlled substances. Moreover, when engaging in pharmaceutical marketing, Cardinal knew or should have known about the

attendant legal obligations, including the obligation to provide "fair balance" and adequately disclose the risks associated with the drugs it was promoting.

B. McKesson's Opioids Marketing.

464. McKesson actively sought to increase the sale of opioids by directly participating in marketing these dangerous, addictive, and misuse- and abuse-prone drugs, in collaboration with the manufacturers.

1. McKesson engaged in an unfair and abusive business practice by marketing prescription opioids.

465. Through its marketing programs, McKesson disseminated drug manufacturers' promotional messages about opioids nationally, including in Indiana. These marketing activities constituted an unfair and abusive business practice, under the circumstances detailed in this Complaint.

466. McKesson claims to have had a policy of not [redacted] Despite that policy, [redacted], McKesson's marketing team identified [redacted]

467. [redacted]

468. ***Auto-Shipments.*** Specifically, McKesson promoted prescription opioids through its [redacted] program. This marketing program identified [redacted]

469. McKesson described [redacted]

(emphasis in the original).

470. The prescription opioids McKesson promoted and auto-shipped (including to Indiana pharmacies) through [redacted] include the following:

Opioid	Manufacturer	Approximate Date
[redacted]		

471. McKesson charged manufacturers $[redacted] program. McKesson eventually [redacted] McKesson lamented that it would "[redacted]" and would need to [redacted]

472. ***Email Marketing.*** McKesson also promoted opioids through the [redacted] programs, which sent [redacted] McKesson described [redacted]

McKesson promoted [redacted]

473. The prescription opioids that McKesson marketed through [redacted] include the following:

Opioid	Manufacturer	Approximate Date
[redacted]		

474. McKesson charged manufacturers between $[redacted] $[redacted] **for each** [redacted]

475. ***Fax Marketing.*** McKesson promoted opioids through its [redacted] program, which sent [redacted] McKesson described [redacted] as having the ability to distribute [redacted]

476. The prescription opioids that McKesson promoted through [redacted] include the following:

Opioid	Manufacturer	Approximate Date
[redacted]		

477. McKesson charged manufacturers between $[redacted] $[redacted] per [redacted] campaign.

478. ***Advertisements on Ordering Platform.*** McKesson [redacted] McKesson touted [redacted] McKesson boasted that more than [redacted] of its pharmacy customers accessed

[redacted] and [redacted]% of its independent pharmacy customers accessed the portal [redacted]

479. The prescription opioids that McKesson promoted through [redacted] include the following:

Opioid	Manufacturer	Approximate Date
[redacted]		

480. McKesson charged between $[redacted] $[redacted] per [redacted] on [redacted]

481. ***Direct Mail Marketing.*** McKesson used its [redacted] program to promote opioids [redacted] McKesson promoted [redacted]

482. McKesson used the [redacted] program to promote opioids. For example, in [redacted] McKesson [redacted] nationally, [redacted] According to the agreement between McKesson and [redacted] the estimated cost for [redacted] per [redacted]

483. [redacted] Calling it a [redacted] McKesson offered its [redacted] to provide a way for pharmacists to [redacted] focused on promoting [redacted]

[redacted] McKesson billed the program as providing [redacted]

484. Through the program, [redacted]

485. As part of the program, [redacted]

486. McKesson touted the [redacted] as a proven way to [redacted]

487. [redacted]

2. McKesson deceptively marketed opioids.

488. In addition to being an unfair and abusive business practice, some of McKesson's marketing content was also deceptive. The opioid advertisements that McKesson disseminated were deceptive and misleading because they failed to disclose the serious risks of addiction,

abuse, and diversion associated with opioids. The advertisements failed to provide "fair balance" of the risks and benefits of opioid use.

489. McKesson's deceptive and misleading marketing of opioids contributed to—and built upon—the deceptions that drug manufacturers were disseminating through other channels.

490. For example, [redacted] The advertisement emphasized that [redacted] (emphasis in original). Yet nowhere does the advertisement mention the risk for addiction and dependence from the opioid ingredient in the drug.

491. McKesson disseminated other advertisements [redacted]

492. Finally, in [redacted] Purdue's now-defunct website, TeamAgainstOpioidAbuse.com. [redacted] a Purdue website that is known to have spread misleading information regarding the effectiveness of abuse-deterrent properties of certain opioid formulations.

493. Through these and other advertisements, McKesson took advantage of its unique position of trust, as a distributor of controlled substances, to promote opioids in deceptive ways. On information and belief, McKesson knew or should have known that these advertisements—particularly those that misrepresented the risk of diversion for, or addictive potential of,

prescription opioids—were deceptive, because of its own heightened duties, as a distributor, when handling controlled substances. Moreover, when engaging in pharmaceutical marketing, McKesson knew or should have known about the attendant legal obligations, including the obligation to provide "fair balance" and adequately disclose the risks associated with the drugs it was promoting.

C. AmerisourceBergen's Opioids Marketing.

494. AmerisourceBergen not only fueled the opioid epidemic with its sales and failure to design and implement policies that effectively prevented diversion, but the company actively promoted prescription opioids to pharmacists.

495. AmerisourceBergen expressly stated that the purpose of its marketing efforts was to [redacted] Indeed, AmerisourceBergen's marketing efforts were intended to increase opioid sales, which would thereby increase the supply of opioids in the community and increase abuse and diversion, further undermining AmerisourceBergen's already insufficient anti-diversion system.

496. Through various marketing programs, [redacted] These marketing activities constituted an unfair and abusive business practice, under the circumstances detailed in this Complaint.

497. AmerisourceBergen promoted [redacted]

498. Not only did AmerisourceBergen profit from its marketing activities [redacted]. AmerisourceBergen was actually [redacted]

[redacted] Under this [redacted] AmerisourceBergen [redacted]

499. AmerisourceBergen knew it was uniquely positioned to market opioids. As AmerisourceBergen recognized [redacted] And AmerisourceBergen used its unique position to [redacted]

500. ***Elevate Provider Network*** AmerisourceBergen [redacted] Elevate Provider Network, AmerisourceBergen explained:

[redacted]

501. One way the Elevate Provider Network [redacted] on [redacted]

502. A second way the Elevate Provider Network [redacted] with the goal of enrolling patients in a program that would fill all of their medications at the same time each month [redacted]

503. AmerisourceBergen touted the Elevate Provider Network as a proven way to "increase adherence," thereby increasing revenue to the pharmacy via increased refills of prescriptions, stating: "Over 40% of Elevate member pharmacies have top 20% performance in one or more adherence measures."

504. The Elevate Provider Network [redacted] the Good Neighbor Pharmacy program, which provided a host of additional business and marketing services to independent pharmacies. The Good Neighbor Pharmacy program was also [redacted] AmerisourceBergen thus both promoted opioids for pharmacy purchase, and assisted pharmacies in increasing their prescription sales and patient adherence.

505. At least [redacted] Indiana pharmacies participated in the Elevate Provider Network, including pharmacies in Floyd County and Clark County, Indiana.

506. ***Email Marketing.*** AmerisourceBergen also promoted opioids through its [redacted]

507. AmerisourceBergen advertised [redacted] ability to reach [redacted] active retail accounts and approximately [redacted] members [redacted] in Indiana.

508. AmerisourceBergen charged manufacturers $[redacted] for each [redacted] $[redacted] for each additional [redacted]

509. Around [redacted], AmerisourceBergen provided [redacted]

510. ***Customer Communication Portal.*** [redacted]

511. [redacted]

AmerisourceBergen charged Covidien $[redacted] for [redacted] open access to The LINK, [redacted] Covidien's [redacted]

512. AmerisourceBergen also signed a marketing agreement [redacted]

513. [redacted]

514. Around [redacted], AmerisourceBergen promoted [redacted] AmerisourceBergen offered [redacted] a monthly subscription [redacted] for $[redacted] per [redacted]

515. ***Ordering Platform.*** [redacted] AmerisourceBergen charged [redacted] $[redacted] for [redacted]

516. Around [redacted], AmerisourceBergen engaged with [redacted] an opioid.

[redacted]

517. ***Print Advertising & Editorial Marketing.*** [redacted]

[redacted]

518. [redacted]

[redacted]

519. [redacted]

[redacted] AmerisourceBergen published [redacted]

[redacted]

520. AmerisourceBergen also offered [redacted]

[redacted]

521. ***Direct Mail.*** AmerisourceBergen also [redacted]

[redacted]

522. AmerisourceBergen described its direct mail advertising as having the capability to [redacted] AmerisourceBergen promoted this marketing program by highlighting [redacted]

D. Defendants helped to initiate and facilitate long-term opioid use by promoting prescription savings cards and programs.

523. All three Defendants also engaged in unfair and abusive business practices by promoting prescription savings clubs and programs that offered discounted opioids. These clubs and programs were directed at patients and encouraged and supported both initiation and long-term use of prescription opioids.

524. Opioid manufacturers drive initiation and long-term use of their drugs through the distribution of promotional prescription "savings cards" (a/k/a prescription "discount cards") to consumers. Savings cards reduce or eliminate the out-of-pocket cost of these drugs, thus reducing or eliminating any financial obstacles to initiating or continuing long-term treatment with expensive, brand-name drugs—including brand-name opioids. Similar discounts are also offered through savings clubs and programs that provide discounts at the point-of-sale.

525. Cardinal promoted and disseminated savings cards through [redacted] for opioids. [redacted]

Opioid	Manufacturer	Savings Card Offer	Approx. Year
[redacted]			

526. McKesson administers [redacted] McKesson runs [redacted] A patient may redeem the discount at the point of sale (i.e., a pharmacy) and receive the manufacturer's pre-determined discount off the purchase price of the medication. The pharmacy submits claims to McKesson for the difference, McKesson reimburses the pharmacy, and then McKesson submits those claims to the drug manufacturer for reimbursement.

527. An affiliate of McKesson, [redacted] also administers a similar program [redacted] eliminating the need for patients and pharmacists to submit claims to or through McKesson for reimbursement.

528. In promoting its [redacted]

[redacted]

529. McKesson promoted the following opioids through [redacted]

[redacted]

Opioid	Manufacturer	Savings Card Offer	Approx. Year
[redacted]			

530. As part of AmerisourceBergen's Good Neighbor Pharmacy Program, it offered a Prescription Savings Club to pharmacies' customers. [redacted]

531. In a presentation to its investors in 2009, AmerisourceBergen identified the Savings Club as a way for the company to "Grow Patient and Consumer Base."

532. AmerisourceBergen marketed the Savings Club as a way to increase a pharmacy's overall prescription volume. In one example, [redacted] AmerisourceBergen claimed that [redacted]

533. Additionally, the Savings Club was aimed [redacted] Cash paying customers are of particular concern in the context of opioids transactions. AmerisourceBergen's

own internal training presentations [redacted]

534. The savings clubs and programs that Defendants promoted—and, in the cases of McKesson and AmerisourceBergen, administered—were intended to and did encourage patients to initiate and stay on long-term opioid therapy by making it easier and cheaper to access prescription opioids, even though there are **no studies demonstrating the safety or efficacy of long-term opioid use beyond 12 weeks**. In other words, Defendants' savings cards and programs facilitated long-term use of the drugs, well beyond the duration of treatment for which there was scientific support.

IV. The Foreseeable Consequences of Defendants' Conduct Include Increased Opioid Misuse, Addiction, Diversion, Overdose, and Death in Indiana Communities.

535. Indiana—like many other states—saw an explosion in opioid prescribing between 1996 and 2012 that fueled an escalating public health crisis of opioid overuse, misuse, and abuse over the last decade. The effects of this crisis are reverberating through the State to this day and are expected to continue for decades. One recently-published analysis concluded that, under the status quo, the number of opioid overdose deaths nationwide is projected to increase from 33,100 per year in 2015 to 81,700 deaths per year by 2025.

536. Despite increased public awareness surrounding the dangers of opioid use, opioid sales only began to meaningfully decline in the State very recently, after nearly two decades of unacceptably and unnecessarily high prescribing levels. In 2012, for example, more than 110 opioid prescriptions were dispensed for every 100 Indiana residents—the equivalent of, on average, more than one opioid prescription for every man, woman, and child in the State. In some parts of Indiana, opioid prescribing rates were even higher at their peak and have been slow to decrease. In Scott County, for example, opioid prescribing peaked in 2008-2012, when

more than 235 opioid prescriptions were dispensed for every 100 residents, each year. In 2017 (the most recent year for which data are available from the CDC) opioid prescribing rates were still well above 100 prescriptions per 100 residents in, for example, Scott County (124.4), Howard County (113.4), Floyd County (115.9), Vanderburgh County (121.5), Knox County (113.1), and Fayette County (103.4).

537. These levels of prescription opioid sales are far higher than required for legitimate medical use. Increased sales and availability of these drugs in Indiana communities have been accompanied by increased abuse and diversion, leading many citizens to misuse opioids, to become addicted to them, and to escalate to the use of heroin and fentanyl. These patterns have led to overdoses and premature death.

538. Increased rates of prescription opioid diversion—and serious public health consequences—were foreseeable consequences of the Defendants' promotion of these opioids and their failure to implement effective systems to detect and prevent diversion of these dangerous drugs.

A. Prescription opioid diversion is widespread in Indiana.

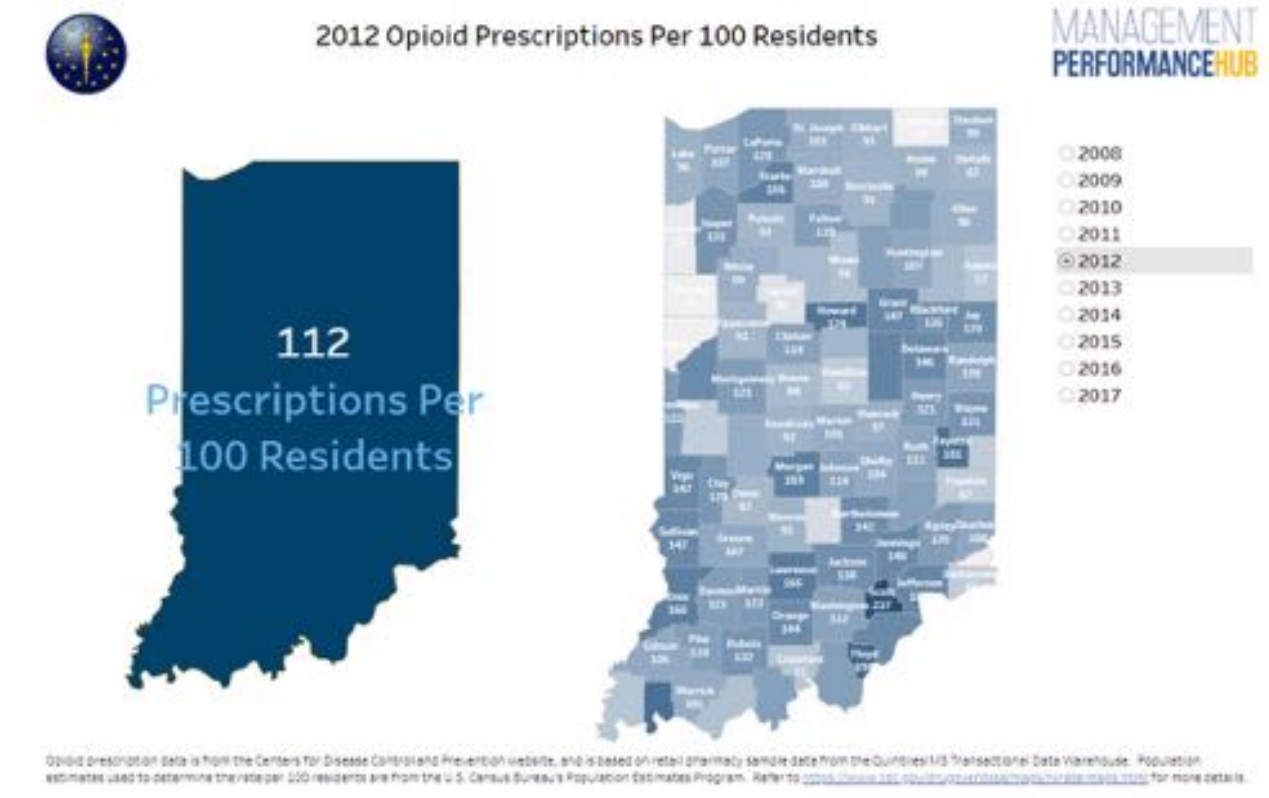
539. Prescription opioids are diverted away from legitimate medical channels in several ways. Some prescription drugs are stolen from warehouses and pharmacies. Some are prescribed to persons posing as medical patients, who then sell the pills to illegal dealers. But the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that the source of their drugs, for most people who misuse opioids, is typically found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

540. More than twenty years ago, when the prescription and sale of opioids were limited to a narrow set of patients who suffered from severe medical conditions and had close

oversight from treating physicians—who had been educated to understand that opioids were dangerous and addictive, and should be prescribed in relatively narrow circumstances—there was little or no excess supply of prescription opioids in communities available for misuse. But when Purdue Pharma introduced its extended-release oxycodone formulation branded as OxyContin ER in 1996, the company launched a massive marketing campaign that changed the landscape of opioid prescribing and over-use for decades to follow. Prescription opioid diversion became a serious problem as over-prescribing rose for less serious conditions—both acute and chronic—and physician oversight and vigilance decreased. This change in culture was driven by aggressive marketing of these drugs—not only by the manufacturers, but also, as it turns out, by distributors like Cardinal, McKesson, and AmerisourceBergen. As a result of this marketing, and the resulting shift in the medical consensus around opioid prescribing, it became common for healthcare providers to prescribe opioids for long-term conditions like chronic lower-back pain, minor injuries like sprains, and post-surgical pain (or even potential pain) from minor procedures, like removal of wisdom teeth. The supply of opioids available in communities across Indiana and the United States ballooned.

541. At the height of excessive opioid prescribing and dispensing, more opioid prescriptions were filled in Indiana each year than there were residents in the State. As noted above, at the peak of over-prescribing in 2012, 112 opioid prescriptions were filled for every 100 residents statewide. In some counties, more than 200 prescriptions were filled for every 100

residents:



Source: NextLevel Recovery Indiana, https://www.in.gov/recovery/1054.htm

542. Excessive opioid supply in Indiana communities over the past two decades has resulted in high rates of prescription opioid misuse in the State. In each of the years 2006 through 2011, for example, around 6% of Indiana citizens 12 and older were estimated to have misused prescription pain relievers in the preceding twelve months. Opioid misuse has been particularly prevalent among young people: in 2013, for example, an estimated 5.7% of teens (ages 12-17) and 12.2% of young adults (ages 18-25) had misused prescription pain relievers in the preceding year.

543. In more recent years, through increased awareness, regulatory efforts, and addiction treatment, the rate of prescription opioid misuse in Indiana has begun to decrease—but

not by enough. Many Hoosiers still struggle with prescription opioid abuse and addiction, and many have escalated to abuse of heroin and other illicit opiates.

B. Defendants knew or should have known that high levels of opioid sales would lead to increased diversion and harm to public health.

544. Because of their place in the closed system of prescription drug distribution, their significant market shares, and their access to extensive opioid dispensing data, Defendants were in a unique position to see that an epidemic of prescription opioid overprescribing and diversion was unfolding.

545. Defendants tracked news coverage of the opioid epidemic as early as [redacted]

546. [redacted], discussing an FDA proposal intended to reduce the misuse and abuse of long-acting painkillers like OxyContin. [redacted]

[redacted]

547. Cardinal personnel continued [redacted]

548. [redacted]

549. [redacted]

[redacted]

550. Cardinal also tracked and circulated articles internally about the abuse and diversion of specific drugs. [redacted]

551. As for McKesson, the company knew of the opioid epidemic as early as 2001. The company admitted [redacted]

552. [redacted]

553. In [redacted], McKesson [redacted]

554. In [redacted]

555. [redacted]

556. AmerisourceBergen was similarly aware of the opioid crisis. As early as 2008, AmerisourceBergen [redacted]

[redacted]

557. [redacted]

[redacted]

558. Specifically, Defendants had access to data [redacted]

IQVIA and Symphony Health provide data analytics to the healthcare industry. IQVIA has a databank of over "600 million non-identified patient records" and prescription drug data "to state, county, zip code or prescriber granularity." In addition, IQVIA provides services that allow corporations such as Defendants to determine where individual products are sold, "granular prescription performance," and "weekly prescription dispensing" through various proprietary databases, such as DDD, Xponent, and National Prescription Audit.

559. Symphony Health offers similarly extensive information, with databases including medical, hospital, and prescription claims data along with "point-of-sale prescription data, non-retail invoice data, and demographic data."

560. McKesson used [redacted]

561. [redacted]

562. Symphony is cited as a [redacted] In addition, [redacted]

Symphony Health provided [redacted]

[redacted]

563. In addition, [redacted]

564. Cardinal likewise had access to [redacted]

565. AmerisourceBergen has also leveraged IQVIA data [redacted] IQVIA has provided AmerisourceBergen with [redacted] IQVIA provided [redacted]

566. AmerisourceBergen's access to IQVIA data included [redacted] which allowed AmerisourceBergen [redacted] AmerisourceBergen also ordered [redacted]

[redacted] IQVIA data allowed AmerisourceBergen to [redacted]

567. Although AmerisourceBergen had access to IQVIA data [redacted] Despite acknowledging that IQVIA data could [redacted] AmerisourceBergen [redacted]

568. Defendants tracked the flow of opioids closely, and understood the connection between increasing opioid sales and diversion. Yet Defendants designed their own diversion control systems to allow the shipment of prescription opioids in quantities that vastly exceeded any plausible medical need in the communities they served without triggering red flags or regulatory reporting. Defendants set excessively high thresholds and then relied on these flawed thresholds as the primary indicator of potential diversion. As detailed in Section II *supra*, they made no attempt to set these thresholds at levels consistent with legitimate medical use of opioids. Instead, initial thresholds were tied to [redacted], which at the time set records for opioid overprescribing. And even then, Defendants routinely permitted, and in fact encouraged, prescription opioid sales that surpassed their excessive thresholds. *See supra* Section II.

569. Defendants knew or should have known that diffuse channels of prescription opioid diversion—including sharing of the drugs with friends and family members—were the most common.

570. Defendants knew or should have known that continuing to promote and market opioids to prescribers, pharmacists, and directly to consumers would lead to increased supply of opioids in Indiana communities and to increased diversion. Defendants were sophisticated purveyors of opioid marketing—they knew how effective Purdue and other manufacturers had been in expanding the use of prescription opioids, and they built opioid marketing services into their distribution contracts with the manufacturers. Overprescribing, driven by reckless and deceptive marketing tactics, was already a well-documented and pervasive problem.

571. Defendants also knew that the marketing of controlled substances in general—and opioids in particular—was a problematic practice. Both Cardinal and McKesson implemented marketing policies and internal guidelines [redacted] of controlled substances. Cardinal's regulatory compliance personnel even understood—[redacted] As early as [redacted] McKesson's [redacted] raise concerns with the DEA and McKesson discontinued [redacted] However, despite the risks associated with this marketing—which both Cardinal and McKesson appear to have known and understood—they continued to market opioids. [redacted]

[redacted]

572. Defendants also knew or should have known that their diversion control systems did not work: their anti-diversion and suspicious order monitoring programs were designed with loopholes to minimize the detection of suspicious orders. Defendants actively helped their pharmacy customers to subvert the systems' protections against diversion, and the protections that did exist were deliberately flawed from the start. It is no surprise that Defendants' anti-diversion systems did not prevent the diversion of prescription opioids, as explained in Section II *supra*.

573. As licensed distributors of controlled substances and giants in the prescription drug distribution industry, Defendants knew or should have known the risks of the controlled substances that they sold and failed to control. Prescription opioids present such serious health risks to consumers, and are so prone to diversion, that the federal government requires drug distributors (like the Defendants) to store them in a locked vault with walls, floors, and ceilings made of "at least 8 inches of reinforced concrete;"[24] to transport them with extensive security precautions;[25] and to sell them only to DEA-registered pharmacies whose orders distributors must carefully monitor and investigate (and report to DEA, if suspicious).[26] Defendants knew and accepted the rules when they entered the marketplace to sell these dangerous controlled substances.

[24] 21 C.F.R. § 1301.72(a)(2)–(3)(i).
[25] *See, e.g.*, 21 C.F.R. §§ 1301.74(e) & 1301.77.
[26] *See supra* Section I.

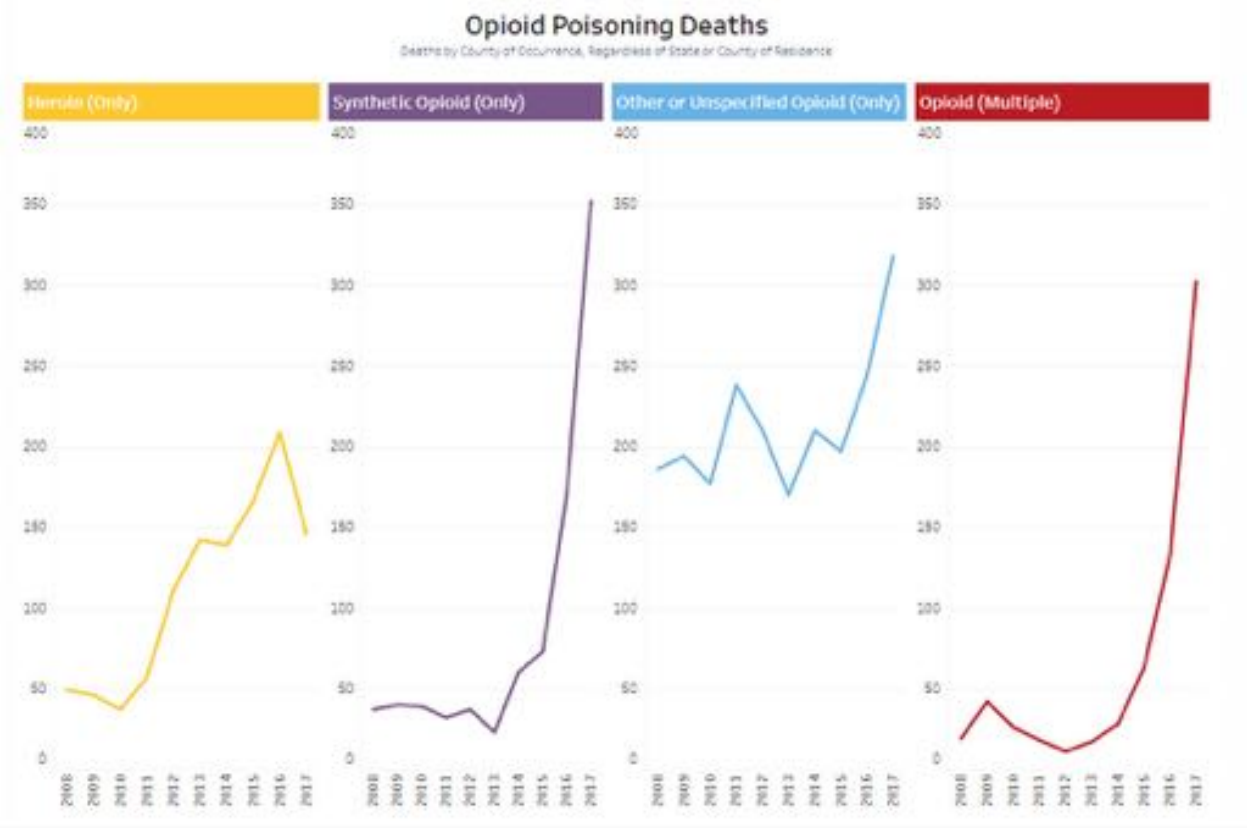
574. The resulting harm—to both Indiana consumers and to the State—was foreseeable to the Defendants and could have been prevented. Defendants instead prioritized profit above their legal responsibilities and the well-being of the public, with devastating results.

C. Indiana has suffered the devastating effects of prescription opioid diversion.

575. Widespread prescription opioid diversion—and the resulting epidemic of addiction—have caused devastating consequences for Indiana and its citizens.

576. Scientific evidence demonstrates the close link between opioid prescriptions and opioid abuse. A 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse," with compelling data for extended release oxycodone (*i.e.*, OxyContin). The most common source of opioids that are abused is, directly or indirectly, through physicians' prescriptions. This high volume of opioid use and diversion leads to increased incidence of dependence and addiction—a significant public health problem in Indiana.

577. One of the most devastating consequences of opioid diversion and abuse has been the skyrocketing rate of overdose deaths. The leading cause of drug overdoses in Indiana is prescription opioids: "Indiana loses more citizens to prescription opioid overdoses annually than to cocaine and heroin combined." In Indiana, there were 757 opioid-overdose deaths in 2016—reflecting a 73% rise since just 2014. Year-over-year increases are continuing despite efforts by the State and the CDC to reduce prescribing and educate consumers.

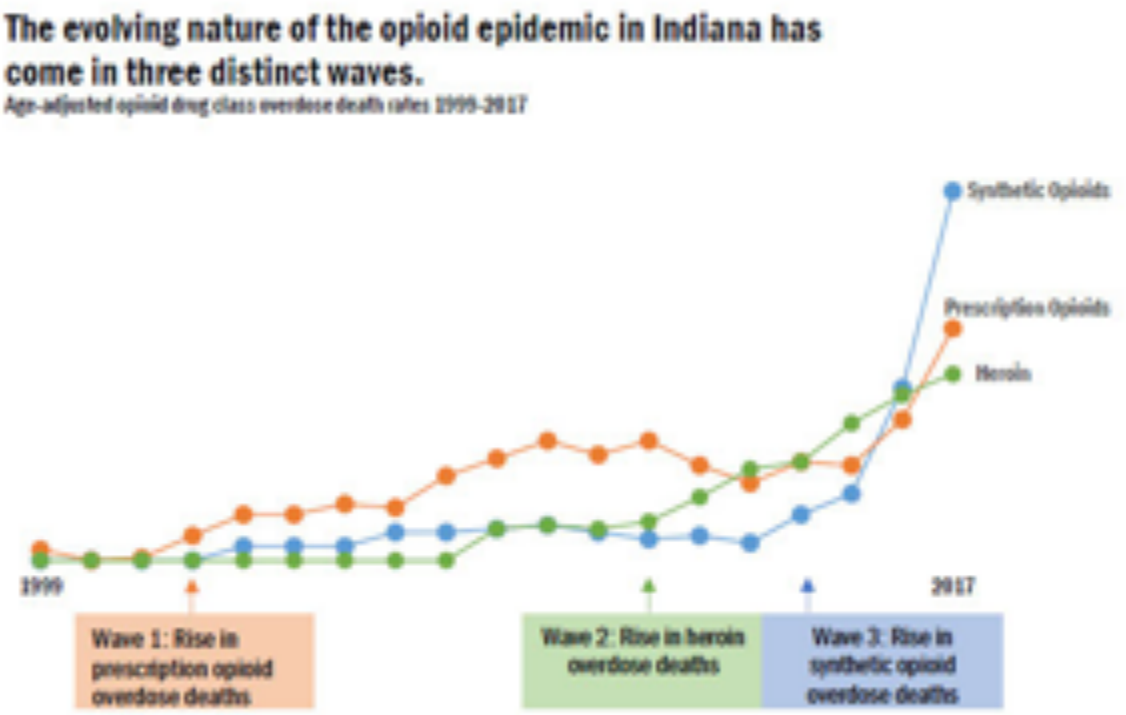


Source: NextLevel Recovery Indiana, https://www.in.gov/recovery/1054.htm

These overdose deaths have a broad impact—in the tight-knit communities across Indiana, there are no anonymous deaths.

578. Opioid prescribing and opioid-related overdoses have risen in tandem since 1999. Both have quadrupled. According to the CDC, patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC has concluded that efforts to rein in the prescribing of opioids for chronic pain are critical to "reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

579. Prescription opioids have been a major driver of overdose deaths in Indiana. And in addition to the steady climb in prescription opioid-related overdose deaths, Indiana has recently seen a steep increase of overdose deaths involving heroin and fentanyl (a highly potent synthetic opioid):



Excerpted from *The Drug Overdose Epidemic in Indiana: Behind the Numbers*, Indiana State Department of Health[27]

580. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or by taking a pill from a prescription bottle belonging to a family member or friend. But, as the Indiana Department of Health has explained, individuals may escalate to using the cheaper alternatives of heroin and—more recently—fentanyl, once they are no longer able to obtain legal prescription opioids. Prescription opioid users are statistically far likelier to use illegal opioids like heroin and fentanyl. U.S. Centers for Disease Control and Prevention ("CDC") statistics show that people addicted to prescription opioids are **40 times more likely** also to be addicted to heroin, and **nearly half** (45%) of people who use heroin also are addicted to prescription opioid

[27] *The Drug Overdose Epidemic in Indiana: Behind the Numbers*, Indiana State Department of Health, at 3, *available at* https://www.in.gov/isdh/files/85_Drug%20Overdose%20Data%20Brief_2019.pdf.

painkillers. Studies report that as many as 80% of heroin users took prescription opioids before turning to heroin.

581. Heroin overdose deaths in Indiana have risen dramatically, by more than 300%, from 54 in 2010 to 239 in 2015. And the rates of heroin dependence reported by people seeking treatment in Indiana have risen from 1.8% in 2001 to 7.9% in 2012.

582. Fentanyl—a synthetic opioid that is driving the third "wave" of overdose deaths (shown above)—is even more dangerous than heroin because it is more potent. This drug's prevalence has increased in Indiana in recent years. Indiana forensics labs recorded 600 cases of seized fentanyl in 2016, compared to 27 in 2013.

583. Areas of Indiana with the highest opioid prescribing rates have also been some of the hardest hit by this epidemic of overdose deaths. In Scott County, for example, prescribing rates were well over 200 opioid prescriptions per 100 residents, for each year from 2006 through 2013. As recently as 2017, Scott County's prescribing rate was 124.4 prescriptions per 100 residents—well above the statewide average of 74.2 prescriptions per 100 residents. And Scott County has one of the highest rates of drug overdose mortality in the state—46.2 deaths per 100,000 residents, between 2013 and 2017. Similar patterns can be observed in Fayette County (58.8 deaths per 100,000 residents), Vanderburgh County (25.5 deaths per 100,000 residents, and Howard County (30.5 deaths per 100,000 residents).

584. Opioid overdose deaths are only the tip of the iceberg, according to national data analyzed by the Centers for Disease Control and Prevention. For every overdose death in 2010, for example, there were 15 abuse treatment admissions, 26 emergency department visits for opioid abuse or misuse, 115 people with abuse or addiction problems, and 733 non-medical users of opioids.

585. The number of people in Indiana seeking treatment for opioid addiction also has risen. In 2000, of all Indiana admissions for substance abuse and addiction treatment, 5.5% reported prescription opioid misuse or abuse; by 2012, this number rose to 22%. According to public health experts' estimates, as many as 89,000 people in Indiana are currently struggling with opioid use, misuse, and addiction.

586. Opioids harm not only those who take them. Infants exposed to opioids in utero are at increased risk for neonatal abstinence syndrome ("NAS")—with 60–80% experiencing withdrawal symptoms upon birth including tremors, difficulty eating, vomiting, seizures, and respiratory distress. When untreated, NAS can be life-threatening. Research shows these children may suffer serious neurologic and cognitive impacts.

587. Infants with NAS face more difficult and more expensive hospital stays. In 2014, the average length of a hospital stay in Indiana for infants without NAS was 2.24 days at an average cost of $4,167, compared to 17.88 days at an average cost of $97,555 for an infant with NAS. The total hospital cost for 657 infants with NAS in Indiana in 2014 was $64 million.

588. Opioid abuse has impacted hospital emergency departments. An Indiana University report identified 641,940 visits to Indiana emergency departments due to non-fatal poisonings in 2010 alone, 90% of which were due to drug abuse. Non-fatal emergency room visits due to opioid overdoses increased 60% from 2011 to 2015, per the State Department of Health. These visits represent not simply a health care cost, but a diversion of resources that affects the ability of emergency departments to deliver timely care.

589. More than 51,000 naloxone kits were distributed in 2016 - 2018 by treatment facilities, local health departments, schools, pharmacies, prisons, and jails through a State initiative to broaden the availability of this overdose-reversal drug. Since 2016, the State has also

implemented programs that provide training and naloxone kits to first responders, including local and state police officers, throughout the State.

590. Indiana's health care costs attributable to opioids totaled $650 million in 2007 according to a Matrix Global Advisors report. This figure is 12th highest among all U.S. states and places Indiana even higher—8th—among all 50 states on a per capita basis with a cost of $99 per citizen. This figure is certain to have risen as the opioid crisis has worsened.

591. In addition to the impact on Indiana's health care system, the proliferation of diverted prescription opioids has led to other substantial costs for the State, in the form of social welfare spending, law enforcement costs, and lost productivity.

592. More than 60% of children removed from homes by Indiana's Department of Child Services in 2017 came from families with parental drug use. Roughly one in four teenagers has abused prescription drugs, according to 2012 data. In 2015, 16.8% of Indiana teens had abused prescription drugs, including prescription opioids.

593. The proliferation of opioids has increased drug-related crime, requiring additional law enforcement resources. From 2013 through May 2016, Indiana led the nation in pharmacy robberies, with 367 reported. By contrast, California—with a population six times as large—had 57 fewer robberies during the same time period.

594. The increased use of injectable illicit opioids—heroin and fentanyl—has also resulted in negative public health impacts. A litany of adverse health outcomes is associated with heroin use, including spontaneous abortions, chronic infections, liver disease, pulmonary complication, and death. When heroin is administered by injection, needle-sharing puts users at

increased risk for HIV and Hepatitis B and C.[28] Ten Indiana counties have been recognized by CDC as among the U.S. counties most vulnerable to HIV outbreaks due to injection drug use.

595. The severity of the epidemic is also reflected in the State's prison population. More than 50% of the state's prison population have reported substance use disorders. Of those incarcerated two or more times, 75% have substance abuse disorders.

596. Finally, the impact of opioid over-prescribing and misuse has seeped into Indiana businesses. As many as 80% of Indiana's employers have observed prescription drug misuse by their employees, according to a survey by the National Safety Council and the Indiana Attorney General. Almost two-thirds of Indiana employers surveyed perceived that prescription drugs present bigger problems in the workplace than illegal substances.

597. Not surprisingly, drug overdoses are harming Indiana in terms of work loss. Data from the CDC show that the estimated lifetime medical and work loss costs in Indiana of drug overdose fatalities occurring in 2014 were $1.4 billion, while costs incurred for non-fatal drug overdose emergency room visits were $31.9 million. Over a four-year period from 2007 to 2010, hospitalizations for all non-fatal poisonings led to lifetime medical and work loss costs totaling $350 million.

598. Indiana has taken numerous steps to stop over-prescribing in the State and reduce the harms caused by opioids:

- Setting restrictions on opioid coverage under the Medicaid program;
- Setting a new, seven-day supply limit on initial opioid prescriptions;

[28] Increased risk of HIV and Hepatitis is not limited to heroin users. In fact, one of the worst recent outbreaks of these diseases is attributable to prescription opioid abuse *via* needle injections. In Austin, Indiana, there were only five reported cases of HIV between 2004 and 2014. In late 2014, three individuals were diagnosed with HIV. By April 2016, there were 191 cases, half of which were located within a half-square-mile area. Ninety percent of those infected with HIV were also infected with Hepatitis C.

- Improving INSPECT, the State's prescription drug monitoring program, to help providers determine what other opioids a patient has been prescribed;
- Requiring State health care professional licensing boards to review and revise their prescribing guidelines;
- Funding OB/GYN training on medication-assisted treatment (MAT) for opioid addiction to improve maternal health and reduce the incidence of NAS; and
- Passing legislation that provides funding and authority for first responders and laypersons to obtain and administer overdose-reversal drugs.

But despite these efforts, the consequences of the opioid epidemic have been significant for the State and its citizens, and they are likely to continue for years to come.

V. Defendants Fraudulently Concealed Their Unlawful Conduct.

599. Defendants misrepresented their conduct with respect to promoting opioids and their compliance with their legal obligations to monitor and prevent diversion. These actions misled Indiana and the public—preventing the State, through the exercise of reasonable diligence, from discovering the facts essential to its claims.

A. Defendants concealed their failure to comply with their duties to prevent diversion.

600. Defendants spoke publicly about their commitment to preventing diversion, their embrace of the vital role they play in the controlled substances distribution system, and their investment in state-of-the-art diversion prevention systems. At the same time, however, as detailed in Section II, Defendants understaffed their diversion prevention functions, provided such inadequate internal training that key personnel could not define and explain basic concepts like "diversion," relied on primitive systems with significant limitations, and failed even to implement those systems as designed. Further compounding these failures, Defendants also

failed to accurately and fulsomely report all suspicious orders to the State, as required by Indiana law.

601. Moreover, as detailed in Section III, Defendants actively promoted prescription opioids through their marketing programs. Through this deceptive, unfair, and/or abusive conduct, they reinforced and built upon the opioid manufacturers' decades of deceptive advertising, which shifted the medical consensus and drove overprescribing and overuse of these dangerous drugs. Yet Defendants have not been transparent with regulators about their role in these marketing efforts, and in recent years, Defendants have affirmatively told regulators that they did not market prescription drugs at all.

602. Defendants also worked hard behind the scenes to lobby for decreased regulation and decreased law enforcement in their industry—actively seeking to weaken the safeguards and protections of laws governing the distribution of controlled substances.

603. Through these actions and inactions, Defendants avoided detection of and fraudulently concealed their misconduct from regulators and law enforcement. They concealed the facts that would have been sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of the Defendants' misconduct and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

1. Cardinal

604. In December 2006, Cardinal agreed to pay $11 million to settle an investigation by the New York Office of the Attorney General over Cardinal's secondary market trading of prescription drugs. As part of the settlement, Cardinal vowed to undertake a series of reforms to its distribution business, including maintaining "a comprehensive compliance manual addressing means to prevent and detect diversion and assure the safety and integrity of prescription pharmaceuticals." Cardinal also agreed to:

> gather, monitor, and analyze sales data to detect instances of possible diversion of prescription pharmaceuticals . . . including sales volume, volume changes over time or other significant changes in purchasing patterns, purchases of frequently diverted products, consistency with the customers' business … and any other available relevant information.

605. Less than two years later, in September 2008, Cardinal agreed to pay $34 million to settle an investigation by seven U.S. Attorney's Offices and the DEA over Cardinal's failure to comply with its diversion prevention duties. As part of the settlement, Cardinal vowed to "maintain a compliance program designed to detect and prevent diversion of controlled substances," including procedures to review orders by trained employees to determine whether the order is suspicious and should be canceled and reported to the DEA, and "review distributions of oxycodone, [and] hydrocodone…to retail pharmacy customers and physicians" and identify and investigate any customer that had exceeded Cardinal's distribution thresholds in the previous 18 months.

606. Cardinal proffered that, over the previous year, it had "invested more than $20 million to significantly enhance its controls across its network to prevent the diversion of controlled substances …. Specifically, the company has expanded its training, implemented new processes, introduced an electronic system that identifies and blocks potentially suspicious orders pending further investigation, and enhanced the expertise and overall staffing of its pharmaceutical distribution compliance team."

607. In 2012, Cardinal entered into a settlement with the DEA to resolve an investigation into its distribution center in Florida. As part of the settlement, Cardinal vowed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Cardinal also vowed to "commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled

substances … that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted."

608. That same year, Cardinal issued a press release touting its anti-diversion system, claiming that the company has "robust controls and performs careful due diligence." Specifically, Cardinal described its system as follows:

> The company's controls feature a system of advanced analytics and teams of anti-diversion specialists and investigators to identify red flags that could signal diversion. When the company's program raises a red flag, its teams immediately investigate. Cardinal Health's anti-diversion specialists use their professional judgment and expertise to determine the appropriate action.

609. Cardinal wrote that it "spent millions of dollars" to build its monitoring system, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

610. In a 2017 document published to shareholders, Cardinal acknowledged its role in "maintaining a rigorous program to prevent opioid pain medications from being diverted for improper uses." During an earnings call that same year, George Barrett, Cardinal's Chairman and then-CEO, claimed Cardinal "operate[s] a very strong, robust, suspicious order monitoring system and process that not only meets [] regulatory requirements," but also "exceeds what is required of distributors."

611. In a subsequent 2017 earnings call, Cardinal stated: "[W]e have spent nearly a decade continuously enhancing our best in class suspicious-order monitoring tools and analytics to keep pace with the ever-changing shape of this crisis …. We … take very seriously our

responsibilities to serve our health-care system. Our anti-diversion systems and controls are substantial, they are well-funded, and they are best in class."

612. To this day, Cardinal continues to publicly portray itself as "committed to fighting opioid addiction and misuse." Cardinal's website holds the company out as an "industry leader[]" that uses "state-of-the-art, constantly adaptive, rigorous systems supported by program specialists who monitor and investigate suspicious orders using advanced analytics and other tools."

613. Cardinal was aware that all of these public promises about what it purported to be doing with its compliance program and its efforts to address the opioid crisis did not align with its actions. Through its repeated statements, Cardinal fraudulently concealed its misconduct—violations of its obligations to monitor and prevent diversion.

2. McKesson

614. Similarly, McKesson has publicized the quality of its anti-diversion efforts since 2005, claiming that it "focuses intensely on … systems and processes that enable full compliance with the laws and regulations that govern [its] operations …. [because it is] especially aware of [its] responsibility to maintain the integrity of the pharmaceutical supply chain and consumer and patient safety."

615. In May 2008, McKesson entered into a settlement to resolve a DEA investigation over its failure to maintain effective controls at distribution centers in six states. As part of the settlement, McKesson vowed to "maintain a compliance program designed to detect and prevent diversion of controlled substances" and review orders that "exceed established thresholds and criteria" to determine whether the orders were suspicious and "should not be filled and reported to DEA." McKesson also vowed to "follow the procedures established by its CSMP [Controlled Substance Monitoring Program]."

616. McKesson subsequently reassured the public in 2016 that it "put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain." And McKesson claimed it is "deeply passionate about curbing the opioid epidemic in our country."

617. McKesson continued to hold itself out as committed to preventing diversion, assuring the public in 2017 that it is "doing everything [it] can to help address [the opioid] crisis in close partnership with doctors, pharmacists, government and other organizations across the supply chain." McKesson also claimed it "invested millions of dollars to build a first class Controlled Substance Monitoring Program [], allowing the company to monitor suspicious ordering patterns, block the shipment of controlled substances to pharmacies when certain thresholds are reached, report suspicious orders to the DEA, and educate customers on identifying opioid abuse."

618. Also in 2017, as part of an agreement with the Department of Justice and DEA to resolve an investigation into some of McKesson's distribution centers, McKesson vowed to "maintain a compliance program intended to detect and prevent diversion of controlled substances." Specifically, McKesson vowed to make specific staffing and organizational improvements to ensure rigorous compliance and eliminate conflicts of interest, maintain customer due diligence files, refrain from shipping suspicious orders, increase customer thresholds only through an established regulatory review process, and conduct periodic auditing.

619. To this day, McKesson continues to tout its commitment to preventing diversion, claiming that it "uses sophisticated algorithms designed to monitor for suspicious orders." McKesson also claims to have "developed a controlled substances threshold management program, using complex and dynamic data analytics."

620. Through these public promises about what McKesson purported to be doing with its compliance program and its efforts to address the opioid crisis, all of which were knowingly in contradiction to the actual facts, McKesson fraudulently concealed its misconduct—violations of its obligations to monitor and prevent diversion.

3. AmerisourceBergen

621. Like Cardinal and McKesson, AmerisourceBergen highlights its long history of complying with its diversion control duties. AmerisourceBergen claims that its "diversion control program traces its roots to the 1980s, when [AmerisourceBergen]'s predecessor companies developed programs to identify and report suspicious orders."

622. In April 2007, the DEA issued an [redacted] AmerisourceBergen entered into a settlement with the DEA to resolve those allegations in June 2007. As part of the terms of the settlement, AmerisourceBergen agreed to [redacted]

623. In 2014, AmerisourceBergen promised the public that the "safety and security of the product [AmerisourceBergen] distribute[s] is an absolute top priority."

624. In 2016, AmerisourceBergen touted its "sophisticated and highly engineered order-monitoring systems" in their corporate citizenship report. AmerisourceBergen again promised in its 2017 corporate citizenship report its "diversion control program takes full advantage of the latest advanced data analysis tools to prevent opioid diversion, including mathematical algorithm and data analytics, peer group comparisons, interquartile range analysis, and real-time dashboards with comprehensive ordering and customer information."

AmerisourceBergen also asserted that its "dedicated diversion control team of internal and external experts consists of former law enforcement professionals, diversion investigators, and pharmacists or pharmacy technicians."

625. In January 2017, AmerisourceBergen entered a $16 million settlement with West Virginia's Attorney General for failing to respond to suspicious orders. As part of the settlement, AmerisourceBergen promised it would promptly alert state authorities to suspicious orders from pharmacies.

626. In the wake of the settlement, AmerisourceBergen hurried to reassure the public that it had strong controls against diversion by "employ[ing] teams of experts to interview and learn about our customers, and [] invest[ing] heavily to ensure that [AmerisourceBergen's] facilities have the best possible protocols and technology to eliminate the diversion or theft of these controlled and highly regulated products from the minute they enter [AmerisourceBergen's] facilities to the time they are delivered to our pharmacy customers." AmerisourceBergen also claimed it "use[s] complex algorithms to identify and stop orders that are deemed to be suspicious."

627. In August 2017, AmerisourceBergen's Vice President of Communications wrote an article addressing the opioid crisis wherein he promised that AmerisourceBergen's "substantial diversion-control program vets our thousands of customers to ensure we, like our peers, only sell medicines to pharmacies that are licensed and registered with the appropriate federal and state authorities (DEA, Board of Pharmacy, Department of Health, etc.)."

628. In [redacted] In response, AmerisourceBergen

claimed to [redacted] However, AmerisourceBergen [redacted]

629. AmerisourceBergen also touted its own efforts to combat the opioid crisis to the public, claiming that "[a]s a supply chain partner, we are committed to finding comprehensive solutions to mitigate the opioid epidemic impacting our communities, and we understand the important role we play in helping to combat medication diversion and abuse." In a December 2017 press release, AmerisourceBergen described their "[o]ngoing utilization of, and enhancements to, a sophisticated set of algorithms and data analytics tools that analyze the orders of individual customers … to identify and stop shipment on orders that are deemed to be suspicious."

630. AmerisourceBergen also publicly pledged "continued commitment to the Company's existing practices of taking no action to market or create demand for opioid-based medicines."

631. To this day, AmerisourceBergen continues to assert on its website that "[r]igorous compliance with all applicable regulatory mandates, laws, procedures and protocols is a foundational underpinning of AmerisourceBergen's longstanding success as a pharmaceutical distributor. Our track record indicates that **we have always complied with regulation and enforcement efforts to the absolute best of our understanding and ability**" (emphasis added).

632. AmerisourceBergen wove a public narrative of its effective compliance program and efforts to address the opioid crisis in clear and knowing disregard of the facts. Through its

repeated public promises, AmerisourceBergen fraudulently concealed its misconduct in violating its obligations to monitor and prevent diversion.

B. Defendants concealed their marketing and promotion of prescription drugs.

633. As recently as 2018, at a hearing on "Combatting the Opioid Epidemic: Examining Concerns About Distribution and Diversion," Cardinal's Chairman testified before Congress that Cardinal does not market any medications to patients, a statement now known to be deceptive. As detailed in Section III.A.1 *supra*, Cardinal has run marketing programs for drug manufacturers—including promoting opioids—for many years. Cardinal's Chairman also testified that opioid prescriptions are written by healthcare providers and filled by pharmacies, suggesting distributors have no role in this decision-making process. He claimed that, "[a]s an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids." However, as detailed in Section III.A.1 above, Cardinal has worked for years to drive increased demand for opioids through its marketing programs.

634. These misstatements are emphasized on the Cardinal website, where the company styles itself a transporter of prescription medications, responsible for secure delivery, and claims that it does not promote prescription medications to members of the public.

635. At the same Congressional hearing, McKesson's Chairman likewise testified that McKesson does not market prescription drugs to doctors or patients, nor "any particular category of drugs, such as opioids, to pharmacies." The State now knows this to be false. As discussed *supra* (Section III.B), McKesson markets prescription drugs to pharmacies through multiple programs and to consumers through the Pharmacy Information Program. McKesson's Chairman also testified that the company does not ship prescription drugs absent a pharmacy order.

However, McKesson has, in the past, auto-shipped opioids to pharmacies, through one of its marketing programs, as detailed in Section III.B.1.

636. Similarly, AmerisourceBergen's Chairman testified before Congress that AmerisourceBergen "does not promote the prescribing or use of medications, including opioids." As discussed above in Section III.C, in reality AmerisourceBergen utilizes multiple programs to market prescription drugs, including opioids, to pharmacies. AmerisourceBergen's Chairman also testified that AmerisourceBergen has "no ability, and no desire, to encourage the prescribing or dispensing of pain medications" and that AmerisourceBergen does not provide "sale representatives special compensation or incentives of any kind that target opioid orders in particular." This testimony glosses over the fact that, until as late as 2017, AmerisourceBergen sales representatives were offered incentives based on sales quotas that included opioid sales, as discussed in Section II.F.1.

637. Defendants' trade lobbying association, HDA, has also falsely denied that Defendants marketed opioids. In publicly denying distributors' role in the opioid epidemic, HDA stated: "Distributors have no ability to influence what prescriptions are written. The fact is that distributors don't make medicines, **market medicines**, prescribe medicines or dispense them to consumers."

638. Defendants' deceptive and misleading public statements, including to the U.S. House of Representatives Oversight Committee, were intended to and did conceal their conduct, preventing the State of Indiana from discovering facts essential to its claims.

C. Defendants fought to safeguard the market for opioids, further ensuring that their misconduct remained concealed.

639. Defendants spent millions of dollars to protect the market for opioids and ensure their misconduct remained concealed.

640. From 2008 through 2018, Defendants' lobbying expenditures increased, corresponding with the increase in opioid use and abuse. To further their interests, including decreased enforcement, Cardinal spent over $19 million, McKesson spent over $17 million, and AmerisourceBergen spent over $16 million on lobbying during these deadly years. Meanwhile, law enforcement actions related to opioids declined—civil case filings by the DEA against distributors, manufacturers, pharmacies, and doctors dropped from 131 in fiscal year 2011 to just 40 in fiscal year 2014. During that same period, [redacted]

641. AmerisourceBergen's [redacted] —detailed AmerisourceBergen's successes. On the federal level, AmerisourceBergen successfully worked with HDA, National Association of Chain Drug Stores, National Community Pharmacists Association, and other organizations to pass the Ensuring Patient Access and Effective Drug Enforcement Act, a bill which significantly weakened the DEA's ability to regulate the distribution industry. The controversial bill, rather than protecting patients, curbed the DEA's power to go after distributors and halt suspicious orders. The [redacted] outlined how AmerisourceBergen targeted [redacted]; and engaged in [redacted] In December 2016, AmerisourceBergen [redacted]

[redacted]

642. AmerisourceBergen's [redacted] also [redacted] AmerisourceBergen coordinated those efforts with Cardinal and McKesson. AmerisourceBergen also completed intelligence gathering on the [redacted] AmerisourceBergen's near-future action items included [redacted]

643. Cardinal, McKesson, and AmerisourceBergen also worked with trade associations and other organizations. Chief among them is their powerful lobbying association: HDA.

644. Defendants are members of HDA, and Defendants' executives have long maintained leadership positions in HDA's management. These privileged and powerful positions have enabled Defendants to influence the agendas pushed by the trade association.

645. Paul Julian, who was an Executive Vice President and Group President at McKesson, was chairman of HDA from 2008 to 2010, on the HDA Board of Directors from 2000 to 2013, and on its Executive Committee from 2005 to 2013. For his service in furthering distributors' agendas, Julian received HDA's Nexus Award for Lifetime Achievement in 2015. While President of McKesson, Mark Walchirk served on HDA's Board of Directors and Executive Committee for multiple years, beginning in 2014. [redacted] Layne Martin currently serves on the HDA Research

Foundation's Board of Directors in addition to his duties as Vice President and General Manager of Specialty Distribution at McKesson. McKesson's President of Pharmaceutical Solutions & Services, Kirk Kaminsky, is currently on HDA's Executive Committee and its Board of Directors.

646. Cardinal senior executives also have served as HDA leaders. [redacted] While employed as CEO of Cardinal's Pharmaceutical Segment, Jon Giacomin concurrently served as the Vice Chairman of the HDA Board of Directors from 2014 to 2016, and as its Chairman from 2016 to 2017. Cardinal's Executive Vice President of Global Sourcing, Craig Cowman, currently serves on the HDA Research Foundation's Board of Directors. And Cardinal's current CEO, Mike Kaufman, is a former member of HDA's Board of Directors as well as its Executive Committee. Cardinal's Chief Executive Officer of its Pharmaceutical Segment, Victor Crawford, currently serves on HDA's Executive Committee and its Board of Directors.

647. AmerisourceBergen executives have similarly occupied high ranking roles within HDA. Robert Mauch, AmerisourceBergen's Executive Vice President and Group President, currently serves as Vice Chairman on the Board of Directors and as a member of the Executive Committee. While President of AmerisourceBergen, David Neu also served on the Executive Committee for four years and was elected Board Chairman of HDA in 2012 and 2013. AmerisourceBergen's former CEO, R. David Yost, sat on HDA's [redacted] AmerisourceBergen's Chairman, CEO, and President, Steve Collis, also held a position [redacted]

648. McKesson, Cardinal, and AmerisourceBergen utilized their unique influence to [redacted] Members of McKesson, Cardinal, and AmerisourceBergen [redacted] Defendants successfully leveraged HDA to improve public perceptions of the opioid crisis. McKesson's [redacted] McKesson's Director of Public Relations again acknowledged the combined power of HDA, McKesson, Cardinal, and AmerisourceBergen, [redacted]

649. Defendants also played key roles [redacted]

650. In addition to maintaining leadership positions in HDA, Defendants made significant financial contributions to the association. In 2017 alone, McKesson paid abou [redacted] to HDA for dues and other expenses. McKesson [redacted]

651. Defendants' contributions to HDA [redacted]

[redacted]

652. Part of HDA's stated mission was to prevent [redacted]—legislation that could have brought Defendants' misconduct to light much sooner. [redacted]

653. Not surprisingly then, by 2014, HDA had a state government affairs budget of almost [redacted]

654. [redacted]

655. Defendants also used HDA as a vehicle for influence over federal legislation. [redacted]

656. [redacted] In 2016, [redacted] the passage of the Act, which implemented a standard for monitoring distribution of controlled substances that was advantageous to Defendants to the detriment of law enforcement agencies.

657. [redacted]

658. [redacted]

659. Defendants' efforts succeeded—the Act has not been repealed. The head of the DEA office that regulates the pharmaceutical industry testified before the Senate Judiciary Committee that the Act has made enforcement more difficult in urgent circumstances and should be revised. HDA, however, argued in support of the Act that it does not handcuff DEA's ability to enforce the law because DEA can focus on bad doctors and pharmacists or limit quotas for opioid production—an attempt to shift DEA focus away from distributors.

660. In 2016, HDA submitted an amicus brief to the United States Court of Appeals in *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). In the brief, the HDA represented that Cardinal, McKesson, and AmerisourceBergen "take seriously their duty to

report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.” [redacted]

661. Significantly, while acknowledging distributors’ duties regarding suspicious orders, HDA also requested the Court of Appeals to limit those duties. HDA asked the court to renounce “any attempt to impose additional obligations on [Defendants] to investigate and halt suspicious orders.” The court rejected HDA’s arguments.

662. In addition to its own matters, HDA supported the activities of other front groups. It was a member of the Pain Care Forum, a lobbying consortium whose members spent more than $880 million from 2006 through 2015 on campaign contributions and lobbying expenses at the state and federal level on an array of issues, including opioid-related measures. From 2006 to 2015, the number of registered lobbyists in Indiana employed by members of the Pain Care Forum ranged from 13 to 25.

663. The Pain Care Forum lobbied both state and federal governments to prevent restrictions on opioid prescribing. For example, the group agreed to pay a public relations consultant to implement a multi-pronged approach to encourage a state medical board to adopt more lax guidelines on opioid dosage. According to reporting by the Associated Press and the Center for Public Integrity, as early as 2008, the Pain Care Forum was developing a strategy to “inform the process” at FDA, generating 2,000 comments opposing new barriers to opioids. According to the article, the Pain Care Forum has, for over a decade, met with some of the highest-ranking health officials in the federal government, while quietly working to influence proposed regulations on opioids and promote legislation and reports on the problem of untreated pain. The group is coordinated by the chief lobbyist for Purdue Pharma, the maker of OxyContin.

From 2006 through 2015, participants in the Pain Care Forum spent over $740 million on lobbying.

664. Through these efforts, Cardinal, McKesson, and AmerisourceBergen not only concealed their own misconduct in marketing and promoting opioids and failing to comply with their duties to prevent diversion, but actively lobbied against increased regulation of the opioids market and enforcement of existing laws and regulations, for the purpose of protecting their lucrative market and ensuring that their wrongdoing did not come to light.

CAUSES OF ACTION

COUNT ONE: Violations of the DCSA

665. The State realleges and incorporates by reference each of the allegations contained in this Complaint as though fully alleged herein.

666. The Deceptive Consumer Sales Act makes it unlawful for a supplier to engage in an "unfair, abusive, or deceptive act, omission, or practice" in connection with a consumer transaction. Ind. Code § 24-5-0.5-3(a).

667. Defendants are "suppliers" as defined by Ind. Code § 24-5-0.5-2(a)(3).

668. The purchase and sale of opioid products are "consumer transactions" as defined by Ind. Code § 24-5-0.5-2(a)(1).

669. As suppliers, Defendants are required to comply with the provisions of the DCSA in their marketing, promotion, sale, and distribution of prescription drugs.

670. Defendants committed unfair, abusive, and/or deceptive acts, omissions, and practices in connection with consumer transactions, in violation of Ind. Code § 24-5-0.5-3, by:

- Transporting and selling opioids in the State of Indiana while failing to comply with their duties under federal and state law to detect, prevent, and report diversion of opioids to other than legitimate channels, including by:

- Designing suspicious order monitoring programs that failed to monitor, identify, report, and prevent fulfillment of suspicious orders by, *inter alia*, utilizing inflated order thresholds that failed to account for known characteristics of suspicious orders, allowing for manipulation of order thresholds by and for the benefit of pharmacy customers, and failing to require adequate investigations or pharmacies; and

- Failing to adhere to the terms of their suspicious order monitoring programs by, *inter alia*, assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and exempting chain pharmacies from important aspects of the anti-diversion programs;

- Advertising and promoting opioids in the State of Indiana, for the purpose of increasing sales, while failing to design and maintain effective systems to detect, prevent, and report diversion of opioids to other than legitimate channels, as required by federal and state law;

- Making and disseminating false or misleading statements about the benefits, risks, and diversion potential of opioids;

- Making statements to promote the use of opioids that omitted and concealed material facts, including the risks of diversion and misuse, dependence, addiction, overdose, and death associated with these drugs;

- Disseminating advertising and promotional messages in the State of Indiana that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information;

- Promoting the initiation and long-term continuation of opioid use by providing savings cards or savings club memberships to reduce patients' out-of-pocket expense for these drugs;

- Providing the means and instrumentalities for the diversion of opioids to other than legitimate channels, and for the deceptive advertising, marketing, and sale of opioids by opioids manufacturers.

671. Defendants' material omissions rendered even seemingly truthful or neutral statements about opioids false and misleading, because they were materially incomplete.

672. These acts, omissions, and practices are unfair, abusive, and/or deceptive in that they offend public policy reflected in (a) established legal standards that require the truthful and balanced marketing of prescription drugs; and (b) Indiana and federal law, which require

licensed wholesale distributors of controlled substances to take steps to combat drug abuse, to regulate legitimate and illegitimate traffic in controlled substances, and to detect, prevent, and report diversion of controlled substances to other than legitimate channels. *See* Ind. Code 25-26-14-17(6); the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and its implementing regulations.

673. These acts, omissions, and practices are unfair, abusive, and deceptive in that they represented a dereliction of the Defendants' duties to monitor, prevent, and report diversion of the dangerous and addictive opioids that they sold in the State. Defendants understood that they had a critical role in the federal- and state-mandated system to prevent diversion, and that they were responsible for not sending more opioids into Indiana communities than were reasonably necessary to meet legitimate demand for medical use. However, Defendants' financial interests were best served by (a) increasing sales of these expensive and profitable drugs, and (b) avoiding damage to customer relationships (and potential loss of market share) that could result from holding or investigating suspiciously high orders. Defendants chose to prioritize their financial interests ahead of consumer health and safety, designing and implementing ineffective diversion control systems, and marketing and promoting opioids on behalf of their manufacturer clients. This conduct is accurately described as unfair, abusive, and deceptive.

674. By reason of Defendants' conduct, Indiana consumers have suffered substantial injury by reason of the health risks associated with opioid abuse and misuse, including the pain and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

675. The State requests an order under Ind. Code § 24-5-0.5-4 permanently enjoining Defendants from engaging in these unfair and abusive acts and practices; directing disgorgement

of any ill-gotten gains; directing the payment of civil penalties for each violation of the DCSA; awarding attorneys' fees and costs to the State, and any other just and proper relief.

COUNT TWO: Knowing Violations of the DCSA

676. The State realleges and incorporates by reference each of the allegations contained in this Complaint as though fully alleged herein.

677. The deceptive acts asserted in Count One were committed by Defendants with knowledge of their deceptive acts.

COUNT THREE: Incurable Deceptive Acts

678. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

679. The deceptive acts asserted in Count One are incurable deceptive acts and were committed by Defendants as part of a scheme, artifice, or device with intent to defraud or mislead.

COUNT FOUR: Public Nuisance

680. The State realleges and incorporates by reference each of the allegations contained in this Complaint as though fully alleged herein.

681. The State and its citizens have a right, shared by the public at large, to be free from injury to the public health, safety, peace, comfort, and convenience.

682. Defendants, through their acts and omissions as alleged throughout this complaint, have unreasonably interfered with this right.

683. Defendants' acts and omissions have created an ongoing, significant, and unreasonable interference with the comfortable enjoyment of life and property.

684. Defendants have interfered with the above-enumerated right by creating a long-lasting and continuing public nuisance through distributing prescription opioids that they knew, or reasonably should have known, were being overprescribed, misused, abused, and diverted to illicit channels, while illegally failing to maintain appropriate controls over such distribution. By causing or substantially contributing to the opioid crisis in Indiana, Defendants have created an unreasonable public nuisance. Without Defendants' actions, opioid use, abuse, and diversion would not have become so widespread in Indiana, and the opioid epidemic which the State now faces would have been averted or would be much less severe.

685. As a direct and proximate result of Defendants' actions and omissions, the State and its citizens suffered harms including, *inter alia*, the following:

- Normalization of over-prescribing and over-dispensing of prescription opioids by prescribers and pharmacists in the State;
- Increased availability and sales of prescription opioids, accompanied by increased abuse and diversion of prescription opioids to illicit channels;
- Oversupplying certain pharmacies and enabling criminal diversion to occur without prompt detection, by filling suspicious orders, rather than stopping them and reporting them to the State and the DEA, as required by law;
- Dependence and addiction to prescription opioids leading to escalation to non-prescription opioids such as heroin and fentanyl;
- Higher rates of opioid misuse, abuse, injury, overdose, and death, and their impact on Indiana families and communities;
- Heightened rates of opioid use disorder in pregnant women and resulting neonatal abstinence syndrome in their children;
- Increased health care costs for individuals, families, employers, and the State; and
- Greater demands on law enforcement—in the context of both policing and adjudication—arising from illegal markets for prescription opioids and illicit opioids.

686. Efforts to address the opioid epidemic have necessitated the consumption of public resources, reducing the available resources that could be used to benefit the Indiana public at large.

687. At all relevant times, Defendants controlled the instrumentalities of the nuisance: distribution channels that moved prescription opioids from manufacturers to pharmacies in the State, and the systems for monitoring and identifying suspicious orders of prescription opioids and the protocols for halting, investigating, and reporting those orders.

688. At all times relevant, Defendants knew that prescription opioids are regulated controlled substances that have a high potential for abuse and may lead to severe psychological or physical dependence. Defendants were further aware—because they helped create it—that a national opioid epidemic had led to widespread addiction, overdoses, hospitalizations, and fatalities. Moreover, Defendants were aware that abuse and diversion of prescription opioids to illicit channels was a significant problem nationwide and that a significant volume of the prescription opioids they sold were being abused and diverted to illicit channels. The harms alleged herein were therefore foreseeable to Defendants as a direct and proximate result of their actions and omissions. It was unreasonable for them to move prescription opioids from manufacturers to pharmacies and other dispensaries without systems in place to detect, investigate, halt, and report suspicious orders. It was also unreasonable for Defendants to fail to design and operate a system that would disclose the existence of suspicious orders of prescription opioids and to fail to report, investigate, and halt those orders, as required under the law. And, it was unreasonable for them to engage in the promotion of controlled substances when they had been uniquely tasked with the responsibility of preventing misuse and abuse.

689. Defendants' actions and omissions were a material element and a substantial factor in allowing prescription opioids to become available throughout the State on an unnecessarily and dangerously large scale.

690. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

COUNT FIVE: Negligence

691. The State realleges and incorporates by reference each of the allegations contained in this Complaint as though fully alleged herein.

692. Defendants have a duty under the common law of Indiana to exercise the degree of care that a reasonable person would under like circumstances. This common law duty of care is owed to those who might reasonably be foreseen to be subject to injury by breach of the duty, and it expands according to the foreseeability of the consequences of a defendant's acts or omissions.

693. Defendants are distributors of prescription opioid narcotics. These drugs are known to be addictive and dangerous, and in fact are designated as controlled substances under state and federal law because of their dangerous and addictive qualities. It was foreseeable that Defendants' failure to design and operate effective systems and controls to monitor, identify, report, and prevent the shipment of suspicious orders of opioids would create a risk of abuse, misuse, and injury to the State and its citizens. Defendants therefore owe a common law duty to the State and its citizens to prevent the diversion of these controlled substances into illegitimate channels.

694. The common law duty of care owed by Defendants is fully supported and informed by state laws governing distributors of controlled substances, which impose a statutory duty on such distributors to provide effective controls and procedures to guard against diversion. The statutory duty includes the explicit requirements that a distributor must: (a) design and operate a system to identify suspicious orders of controlled substances; (b) report the identification of all suspicious orders of controlled substances; and (c) exercise sufficient diligence to prevent the fulfillment of any suspicious orders.

695. Defendants breached their duty to prevent the diversion of controlled substances by failing to maintain effective controls over prescription opioids. Defendants breached their duty through, *inter alia*, the following acts and omissions:

- Creating ineffective anti-diversion and suspicious order monitoring systems that utilized inflated order thresholds that failed to account for known characteristics of suspicious orders, allowed for manipulation of order thresholds by or for the benefit of pharmacy customers, and failed to require adequate investigations of pharmacies;
- Failing to effectively implement their anti-diversion programs, including by assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and applying different, even looser rules to their chain pharmacy customers;
- Failing to report to the proper authorities all suspicious orders identified by their own monitoring protocols; and
- Failing to prevent the shipment of suspicious orders by, among other things, failing to conduct proper diligence prior to filling suspicious or potentially suspicious orders.

696. Defendants' breach of their duties has fueled the widespread circulation of opioids into illegitimate channels in Indiana. The structure of Indiana's controlled substances regulations—and of the federal regulations incorporated by Indiana law—acknowledges that preventing the abuse, misuse, and diversion of controlled substances can only occur where every participant in the distribution chain maintains effective controls. Defendants' failure to satisfy

their duties to monitor, identify, report, and prevent the fulfillment of suspicious orders for prescription opioids has caused or substantially contributed to the abuse, misuse, and diversion of those opioids. These consequences were the foreseeable and proximate result of Defendants' failure to design and implement effective diversion controls in accordance with their legal duties. A reasonably prudent distributor of controlled substances would foresee that failing to maintain effective controls against the diversion of highly addictive narcotics would fuel over-prescription and would result in the attendant costs of addressing an opioid crisis. Had Defendants effectively carried out their duties, opioid abuse, misuse, diversion, and addiction would not have become so widespread in Indiana, and the costs borne by the State in addressing and abating the opioid epidemic would have been averted or been much less severe.

697. The State has expended millions of dollars in addressing and attempting to abate the wide-spread public health epidemic that has been fueled by the drugs that Defendants sent into Indiana.

698. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

COUNT SIX: Negligence Per Se

699. The State realleges and incorporates by reference each of the allegations contained in this Complaint as though fully alleged herein.

700. Defendants have a duty under the common law of Indiana to exercise the degree of care that a reasonable person would under like circumstances. This common law duty of care is owed to those who might reasonably be foreseen to be subject to injury by breach of the duty,

and it expands according to the foreseeability of the consequences of a defendant's acts or omissions.

701. The standard of care required of Defendants is supplied by Indiana statute. The Indiana Code includes a variety of legal obligations relating to pharmaceutical distribution, as described in Section II above. In addition, Indiana Code 25-26-14-17(6), imports into Indiana law "all federal legal requirements applicable to wholesale drug distribution." The violation of these state and federal laws and regulations supports a finding of negligence per se.

702. Legal duties applicable to wholesale drug distribution include explicit requirements that a distributor must: (a) design and operate a system to identify suspicious orders of controlled substances; (b) report the identification of all suspicious orders of controlled substances; and (c) exercise sufficient diligence to prevent the fulfillment of any suspicious orders. 21 C.F.R. § 1301.74(b).

703. The purpose of the state and federal laws governing Defendants' distribution of controlled substances is to protect the class of persons who are at risk of being harmed by the diversion and abuse of dangerous and addictive drugs such as opioids.

704. Defendants breached their statutory duties by failing to maintain effective controls over prescription opioids by, *inter alia*, the following acts and omissions:

- Creating ineffective anti-diversion and suspicious order monitoring systems that utilized inflated order thresholds that failed to account for known characteristics of suspicious orders, allowed for manipulation of order thresholds by or for the benefit of pharmacy customers, and failed to require adequate investigations of pharmacies;
- Failing to effectively implement their anti-diversion programs, including by assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and applying different, even looser rules to their chain pharmacy customers;
- Failing to report to the proper authorities all suspicious orders identified by their own monitoring protocols; and

- Failing to prevent the shipment of suspicious orders by, among other things, failing to conduct proper diligence prior to filling suspicious or potentially suspicious orders.

705. Defendants' breach of their duties has fueled the widespread circulation of opioids into illegitimate channels in Indiana. The structure of Indiana's controlled substances statutes—including the federal regulations incorporated by Indiana law—acknowledges that preventing the abuse, misuse, and diversion of controlled substances can only occur where every participant in the distribution chain maintains effective controls. Defendants' failure to satisfy their duties to monitor, identify, report, and prevent the fulfillment of suspicious orders for prescription opioids has caused or substantially contributed to the abuse, misuse, and diversion of those opioids. These consequences are the foreseeable and proximate result of Defendants' failure to design and implement effective diversion controls in accordance with their legal duties. A reasonably prudent distributor of controlled substances would foresee that failing to maintain effective controls against the diversion of highly addictive narcotics would fuel over-prescription, would lead to overpayment by payors, and would result in the attendant costs of addressing an opioid crisis. Had Defendants effectively carried out their duties, opioid abuse, misuse, diversion, and addiction would not have become so widespread in Indiana, and the costs borne by the State in addressing and abating the opioid epidemic would have been averted or been much less severe. These harms are precisely the harms that the statutes were designed to protect against.

706. The State has expended millions of dollars in addressing and attempting to abate the wide-spread public health epidemic that has been fueled by the drugs that Defendants delivered into Indiana.

707. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could

not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

COUNT SEVEN: Unjust Enrichment

708. The State realleges and incorporates by reference each of the allegations contained in this Complaint as though fully alleged herein.

709. Under Indiana common law, restitution for unjust enrichment is supported where the circumstances are such that under the law of natural and immutable justice there should be a recovery. This is established when a measurable benefit has been conferred on a defendant under such circumstances that the defendant's retention of the benefit without payment would be unjust.

710. Defendants engaged in wrongdoing by failing to design and maintain controls and procedures to guard against diversion of the drugs which they distribute.

711. The State has conferred measurable benefits on Defendants that it would not have conferred but for that wrongdoing by, *inter alia*, the following:

- Allowing Defendants to distribute opioids in Indiana, which generated millions of dollars in revenue for the Defendants, and
- Expending state resources to address all aspects of the opioid epidemic in Indiana. To do so, it has increased spending on healthcare, social welfare, law enforcement, and other services. Defendants have profited from the State's remedial expenditures. Had Defendants been bearing these costs, there would not have been a profitable market for the dangerous and addictive opioids that Defendants were distributing.

712. By engaging in the wrongdoing described throughout this Complaint, Defendants impliedly requested the benefits conferred on them by the State.

713. Defendants have enjoyed hundreds of millions of dollars of revenue from the benefits conferred on them by the State, enriching themselves at the State's expense.

714. It would be wrong and unjust for Defendants to retain the benefits conferred on them by the State. But for the wrongdoing set forth in this Complaint, the State would not have conferred those benefits on Defendants.

715. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

716. The State seeks restitution of the sum, to be determined at trial, by which Defendants have been unjustly enriched.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of Indiana respectfully requests the Court enter judgment against the Defendants:

(a) Awarding judgment in the State's favor and against Defendants on each cause of action asserted in the Complaint;

(b) Permanently enjoining Defendants from engaging in the deceptive, unfair, and abusive acts and practices described in the Complaint, including by directing Defendants to disgorge any ill-gotten gains acquired by virtue of the conduct described in the Complaint;

(c) Assessing maximum statutory civil penalties for each violation of the Deceptive Consumer Sales Act;

(d) Awarding all damages allowable under common law;

(e) Entering an order providing for abatement of the nuisance that Defendants created or were a substantial factor in creating, enjoining Defendants from further conduct contributing to the nuisance, and awarding compensation for funds the State has already used to abate the nuisance;

(f) Requiring Defendants to pay the costs of the suit, including attorneys' fees; and

(g) Awarding such other, further, and different relief as this Court may deem just.

Jury Trial Demanded

The State demands a trial by jury on all issues properly so tried.

Dated: October 22, 2019

Respectfully submitted,

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