the Constitution of the United State or by the Constitution of the State of Vermont or that of any other state whose laws may apply.

16. Plaintiff's claims are barred to the extent that they violate the Due Process or Ex Post Facto clauses of the United States and Vermont Constitutions.

17. Defendant's rights under the Due Process Clause of the United States Constitution and applicable state Constitution or statute are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by Plaintiff's use of a contingency fee contract with private counsel.

18. Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Dormant Commerce Clause of the United States Constitution.

19. Defendant denies all types of causation including without limitation cause in fact, proximate cause, and producing cause, with respect to the claims asserted against Defendant.

20. The Complaint and each alleged claim contained therein, is barred, in whole or in part, because Defendant did not proximately cause the damages complained of, and because the acts of other persons (including individuals engaged in the illegal distribution or use of opioids without a proper prescription) intervened between Defendant's acts and Plaintiff's alleged harms. Defendant had no legal duty to protect Plaintiff from the intentional criminal acts of third persons, which are superseding causes that extinguish any liability.

21. The injuries and damages claimed by Plaintiff resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Defendant was not the proximate and/or competent producing cause of such alleged injuries and damages.

22. Plaintiff's injuries and damages, if any, were due to illicit use or abuse of the medications at issue on the part of the medication users, for which Defendant is not liable.

23. Any injuries and/or damages sustained by Plaintiff may have been caused or contributed to by the negligence or actual conduct of Plaintiff and/or other persons, firms, corporations, or entities over whom Defendant had no control or right to control and for whom it is not responsible.

24. Any injuries or damages alleged in the Complaint may have been caused by unforeseeable and uncontrollable circumstances and/or other forces over which Defendant had no control and for which Defendant is not responsible, including pre-existing medical conditions.

25. Any and all damages alleged by Plaintiff were caused by misuse of the products involved, failure to use the products properly, and/or alteration of, or criminal misuse or abuse of the product by third parties over whom Defendant had no control and for whom Defendant is not responsible.

26. Plaintiff's claims are barred to the extent they are based on alleged criminal acts of third parties, which Defendant has no duty to control or prevent and which operate as superseding causes which extinguish any liability.

27. Plaintiff suffered no injuries or damage as a result of any action by Defendant.

28. The derivative injury rule and the remoteness doctrine bar Plaintiff from recovering payments that Plaintiff allegedly made on behalf of residents to reimburse any expenses for health care, pharmaceutical care, and other public services.

29. Plaintiff's claims are barred to the extent that Defendant has valid defenses that bar recovery by those persons on whose behalf Plaintiff purportedly seeks recovery.

30. Plaintiff has failed to comply with the requirement that it must identify each patient in whose claim(s) it has a subrogation interest and on whose behalf it has incurred costs.

31. Plaintiff has failed to plead that it reimbursed any prescriptions for any opioid distributed by Defendant that harmed patients and should not have been written, or that Defendant's allegedly improper conduct caused any health care provider to write any ineffective or harmful opioid prescriptions. Plaintiff's alleged damages are speculative, uncertain, and hypothetical.

32. Any recovery by Plaintiff may be barred or reduced, in whole or in part, by the principles of comparative or contributory fault and proportionate responsibility.

33. Any recovery against Defendant is barred or limited under the principles of assumption of the risk and informed consent.

34. Plaintiff's damages, if any, were caused by the active, direct, and proximate negligence or actual conduct of entities or persons other than Defendant, and in the event that Defendant is found to be liable to Plaintiff, Defendant will be entitled to indemnification, contribution, and/or apportionment.

35. Defendant is entitled to a proportionate reduction of any damages found against it, based on the product, negligence, or other conduct of any settling tortfeasor and/or responsible third party and/or Plaintiff.

36. A specific percentage of the tortious conduct that proximately caused the injury or loss to person or property is attributable to (i) Plaintiff, (ii) other parties from whom Plaintiff seeks recovery, and (iii) persons from whom Plaintiff does not seek recovery in this action, including, but not limited to, prescribing practitioners, non-party pharmacies and pharmacists, individuals and entities involved in diversion and distribution of prescription opioids,

individuals and entities involved in distribution and sale of illegal opioids, individuals involved in procuring diverted prescription opioids and/or illegal drugs, delivery services, federal, state, and local government entities, and health insurers.

37. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or with reasonable certainty will indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source or any other applicable law.

38. Any damages that Plaintiff may recover against Defendant must be reduced to the extent that Plaintiff is seeking to recover damages for alleged injuries or expenses related to the same user(s) of the subject prescription medications, or damages recovered or recoverable by other actual or potential plaintiffs. Any damages that Plaintiff may recover against Defendant must be reduced to the extent they unjustly enrich Plaintiff.

39. Plaintiff's claims fail to the extent they are based on a theory of market share liability, which is not a recognized means for recovering damages under Vermont law.

40. Defendant further pleads, if such be necessary, and pleading in the alternative, that Plaintiff's claims are barred or limited by the economic loss rule.

41. Plaintiff is barred, in whole or in part, from recovering costs incurred in providing public services by the free public services and/or municipal cost recovery doctrine.

42. Plaintiff may have failed or refused to exercise reasonable care and diligence to avoid loss and minimize damages and, therefore, may not recover for losses that could have been prevented by reasonable efforts on its part, or by expenditures which might reasonably have been made. Recovery, if any, should therefore be reduced by Plaintiff's failure to mitigate damages, if any.

43. To the extent Plaintiff attempts to seek equitable relief, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

44. The claims asserted in the Complaint are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the Complaint.

45. Plaintiff's claims are preempted by federal law, including (without limitation) the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act ("FDCA").

46. The conduct of Defendant conformed with the FDCA and the requirements of the FDA, and the activities of Defendant alleged in the Complaint conformed with all state and federal statutes, regulations, and industry standards based on the state of knowledge at the relevant time(s) alleged in the Complaint.

47. Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

48. Plaintiff's claims are preempted insofar as they conflict with Congress's purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

49. To the extent Plaintiff claims that Defendant misled or defrauded FDA or any other federal agency with respect to the Manufacturer Defendants' disclosure of information related to the safety of their medications at issue, such claims are preempted by federal law. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Defendant further pleads, if such be necessary, and pleading in the alternative, that to the extent Plaintiff claims that Defendant

misled or defrauded DEA or any federal agency by failing to report suspicious pharmacy orders or other information, such claims are preempted by federal law. *See Buckman v. Plaintiffs' Legal Comm'n,* 531 U.S. 341 (2001).

50. Plaintiff's claims are barred, in whole or in part, by the deference that common law accords discretionary actions by the FDA under the FDCA and discretionary actions by the DEA under the Controlled Substances Act.

51. If the Plaintiff incurred the damages alleged, which is expressly denied, Defendant is not liable for damages because the methods, standards, or techniques of designing, manufacturing, labeling, and distributing of the prescription medications at issue complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDCA, and the generally recognized state of the art in the industry at the time the product was designed, manufactured, labeled, and distributed.

52. Defendant is not liable with respect to any allegations involving failure to provide adequate warnings or information because all warnings or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

53. Defendant further pleads, if such be necessary, and pleading in the alternative, that Plaintiff's claims and alleged damages are barred under the learned intermediary doctrine.

54. Defendant did not owe or breach any statutory or common law duty to Plaintiff.

55. Defendant appropriately, completely, and fully performed and discharged any and all obligations and legal duties arising out of the matters alleged in the Complaint.

56. Plaintiff's claims are barred, in whole or in part, because Defendant complied at all relevant times with all applicable laws, including all legal and regulatory duties.

57. To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish Defendant's regulatory duties, such informal guidance cannot enlarge Defendant's regulatory duties in the absence of compliance by DEA with the requirements of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

58. Plaintiff's claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on Defendant.

59. The claims asserted in the Complaint are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

60. To the extent that Plaintiff is alleging fraud, fraudulent concealment, or similar conduct, Plaintiff has failed to plead fraud with sufficient particularity.

61. Plaintiff fails to plead any actionable misrepresentation or omission made by or attributable to Defendant.

62. No conduct of Defendant was misleading, unfair, or deceptive.

63. Plaintiff's claims may be barred, in whole or in part, because neither the users nor the prescribers of the medications allegedly distributed by Defendant, nor Plaintiff itself, relied to their detriment upon any statement by Defendant in determining to use the medications at issue.

64. Defendant is not liable for any statements in the Manufacturer Defendants' branded or unbranded materials.

65. Plaintiff's nuisance claims are barred to the extent that Plaintiff lacks the statutory authority to bring a nuisance claim under Vermont law.

66. Plaintiff's nuisance claims are barred because no action of Defendant involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of Defendant is too remote from the alleged injury as a matter of law and due process.

67. Plaintiff's claim for unjust enrichment is barred or limited because Defendant did not receive and retain any alleged benefit from Plaintiff.

68. Any and all damages claimed by Plaintiffs, whether actual, compensatory, punitive, attorneys' fees, or otherwise are barred, reduced, and/or limited pursuant to the applicable Vermont statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

69. If Defendant is found liable to Plaintiff in any amount, Defendant is entitled to a credit or set-off for any and all sums Plaintiff has received in the way of any and all settlements.

70. Plaintiff's Complaint is barred, in whole or in part, by the doctrines of acquiescence, settlement, or release.

71. Defendant's liability, if any, will not result from its conduct but is solely the result of an obligation imposed by law, and thus Defendant is entitled to complete indemnity, express or implied, by other parties.

72. Plaintiff's claims for punitive or exemplary damages or other civil penalties are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of this State or that of any other state whose laws may apply. Any law, statute, or other authority purporting to permit the recovery of punitive damages or civil penalties in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages or civil penalties and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages or civil penalties; (3) unconstitutionally may permit recovery of punitive damages or civil penalties based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) unconstitutionally may permit recovery of punitive damages or civil penalties in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any award of punitive damages or civil penalties; (7) lacks constitutionally sufficient standards for appellate review of any award of punitive damages or civil penalties; (8) would unconstitutionally impose a penalty, criminal in nature, without according to Defendant the same procedural protections that are accorded to criminal defendants under the constitutions of

the United States, this State, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

73. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

74. Plaintiff's claim for punitive or exemplary damages is barred for one or more of the following reasons: (a) Plaintiff cannot prove by clear and convincing evidence that Defendant actions or failure to act was outrageously reprehensible or malicious and (b) Defendant has neither acted nor failed to act in any manner which entitles Plaintiff to recover punitive or exemplary damages

75. Plaintiff cannot obtain relief on its claims based on actions undertaken by Defendant of which Defendant provided notice of all material facts.

76. Defendant is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of Vermont or any other state whose substantive law might control the action.

77. Plaintiff's claims are barred by the doctrine of *in pari delicto*.

78. Defendant reserves the right to assert all applicable defenses that it becomes aware of as investigation and discovery proceeds.

79. To the extent they are not otherwise incorporated herein, Defendant incorporates as a defense the defenses and arguments raised in any Motion to Dismiss filed on behalf of any defendants in this case.

80. There is no justiciable issue. Plaintiff has failed to assert claims over which the Court has the power to exercise its authority.

81. The Complaint fails in whole or in part because there is no genuine issue of material fact and Defendant is entitled to judgment as a matter of law.

82. Any alleged injuries were not legally foreseeable.

83. There is no cause of action in the Vermont Controlled Substances Act or its legislative rules against Defendant.

84. Plaintiff lacks the authority to file suit to collect penalties or fines based on alleged violations of the Vermont Controlled Substances Act.

85. Plaintiff's alleged damages were caused by the intentional and criminal activities of unidentified persons, including numerous unknown persons who abused, misused, wrongfully obtained, illegally trafficked, and/or sold prescription opioids in violation of criminal law. The criminal acts of these unknown persons caused the alleged loss or injury that is the subject of this lawsuit.

86. Any damages claimed by Plaintiff must be reduced by the amount of funding received for healthcare and other services from the Federal government.

87. Defendant further pleads, if such be necessary, and pleading in the alternative, that to the extent any agents, employees, or contractors of Defendant caused any of the damages alleged by Plaintiff, such agents, employees, or contractors were acting outside the scope of agency employment, or contract with Defendant, and any recovery against Defendant must be

reduced by the proportionate fault of such agents, employees, or contractors. Defendant further pleads, if such be necessary, and pleading in the alternative, that any injuries and/or damages sustained by Plaintiff were caused, in whole or in part, by its own failure to effectively enforce the law and prosecute violations thereof and any recovery by Plaintiff is barred or, alternatively, should be diminished according to its own fault.

88. Defendant further pleads, if such be necessary, and pleading in the alternative, that Plaintiff's claims for relief in the Complaint are barred, in whole or in part, based on the principles of equity. Numerous facts would render the imposition of injunctive relief, civil penalties, or other remedies inequitable here, including but not limited to Defendant's good faith reliance on state and federal guidance and the absence of any intentionally unlawful conduct.

89. Defendant adopts by reference any additional applicable defense pled by any other defendants not otherwise pled herein and reserve the right to amend this answer to assert any such defenses.

90. Defendant hereby gives notice that it may rely upon any other applicable affirmative defense(s) of which it may become aware during discovery in this Action and reserves the right to amend this answer to assert any such defenses.

PRAYER FOR RELIEF

Cardinal Health admits that Plaintiff purports to seek the relief identified in this unnumbered WHEREFORE Paragraph of the Complaint, but denies that Plaintiff is entitled to any relief whatsoever. To the extent any further response is required, Cardinal Health denies the allegations.

JURY TRIAL DEMANDED

Cardinal Health demands a jury trial on all issues so triable, including all claims and third-party claims, and objects to proceeding with a depleted panel.

DEMAND FOR BIFURCATED TRIAL

If Plaintiff is permitted to proceed to trial upon any claims for punitive or exemplary damages, such claims, if any, must be bifurcated from the remaining issues.

Dated: June 11, 2020

Respectfully submitted,

CARDINAL HEALTH, INC.

By its attorneys

Devine Millimet & Branch, P.A.

By: _____

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CERTIFICATE OF SERVICE

I, Jonathan A. Lax, hereby certify that on this 11th day of June, 2020, I served the above Answer, Affirmative Defenses and Jury Demand via United States first-class mail, postage pre-paid and email to:

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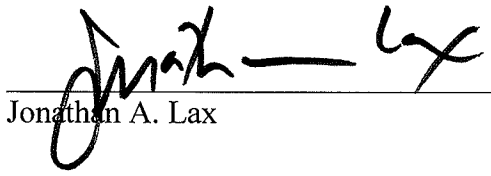
Date: June 11, 2020



Jonathan A. Lax

STATE OF VERMONT

SUPERIOR COURT — CIVIL DIVISION
CHITTENDEN UNIT — DOCKET NO. 279-3-19 Cncv

STATE OF VERMONT,

Plaintiff,

vs.

CARDINAL HEALTH, INC. and
MCKESSON CORPORATION,

Defendants.

COMPLAINT

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The Vermont Attorney General brings this suit against Cardinal Health, Inc. and McKesson Corporation for violations of the Vermont Consumer Protection Act, negligence, and creating a public nuisance. The Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

PRELIMINARY STATEMENT

1. Over the past two decades, a public health crisis caused by prescription opioids has spread across Vermont and the entire country.

2. In Vermont, drug-related fatalities involving opioids nearly tripled between 2010 and 2018.[1]

3. Vermont ranks as the 8th-highest state in the nation for drug dependence,[2] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[3]

4. Serious consequences radiate from every case of overdose and addiction, including harm to individuals and families and strain on the State's healthcare and social services systems. In a small state like Vermont, no case of addiction or overdose is anonymous.

5. 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

[1] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.
[2] amfAR Opioid & Health Indicators Database, Percent of people 12+ Reporting Drug Dependence, http://opioid.amfar.org/indicator/drugdep.
[3] *See* State Health Assessment Plan - Healthy Vermonters 2020 (December 2012), http://www.healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

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."[4] 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 drugs in the community, beyond what is needed for legitimate medical purposes.

6. Because of the risks inherent in the distribution of prescription opioids, each of the participants in their supply chain has important legal responsibilities intended to protect against misuse and diversion of these dangerous drugs. The legal distribution of prescription opioids involves three key participants: (1) manufacturers that make the opioids; (2) distributors that supply the opioids to pharmacies; and (3) pharmacies that dispense the opioids to consumers.

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.[5] 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

[4] Dart, Richard C., *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[5] 21 U.S.C. § 823(b) (Controlled Substances Act, discussing diversion).

illicit market ….” Therefore, “it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances.”[6]

8. The State brings this lawsuit against two major distributors for failing to fulfill their most fundamental legal duties in violation of Vermont statutory and common law. Cardinal Health, Inc. (“Cardinal”) and McKesson Corporation (“McKesson”) (collectively, Defendants) have a commanding share of the Vermont market: together they are responsible for about 69% of the prescription opioids distributed in the State.

9. Cardinal and McKesson violated their duties to prevent diversion by selling ever-increasing quantities of prescription opioids in Vermont and ignoring the mounting evidence that opioid sales—nationally, and within the State—were far out-pacing legitimate need. Indeed, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered, Defendants normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout Vermont communities. This over-supply of opioids flowed into Vermont through two primary channels. First, prescription opioids flowed unchecked into the State from Cardinal’s and McKesson’s excessive sales to Vermont pharmacies—far beyond what was needed for legitimate medical needs. Second, over-supply came to Vermont through illegal channels from other states, including those where “pill mills” stocked with opioids supplied by Cardinal and McKesson poured millions of prescription opioids into the black market.

10. Ultimately, Cardinal’s and McKesson’s inadequate systems to monitor, detect, and prevent diversion enabled the excessive sales of opioids to Vermont pharmacies. The

[6] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.

systems that Cardinal and McKesson designed were not only flawed; Defendants failed to adhere to their own flawed systems.

11. Cardinal and McKesson 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 monthly opioid orders based on certain factors. If a pharmacy's order exceeded its threshold, that was an indication of potential diversion, and the 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, those thresholds were flawed in their design and implementation: not only did Defendants set them at improperly high levels, but they were also inadequately enforced.

12. Specifically, Cardinal and McKesson set the 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 Cardinal and McKesson routinely **increased** the thresholds or found other ways to ship the orders without conducting an appropriate investigation, canceling the order, or reporting the pharmacy to the DEA, as required by law.

13. Additionally, Cardinal and McKesson designed and implemented anti-diversion systems that were wholly inadequate and failed to satisfy their core legal duties as distributors of controlled substances. Defendants not only understaffed their anti-diversion compliance programs, but they provided inadequate training to those they employed. Moreover, Defendants 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 Cardinal's and McKesson's 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. Cardinal's and McKesson's systematic failures to report suspicious volumes and patterns of prescription opioid sales—as they were required to do under Vermont and federal law—allowed the opioid epidemic to grow, unchecked, for years.

16. Compounding Defendants' failures to identify and prevent diversion, both companies actively engaged in marketing designed to increase the sale of opioids. Cardinal and McKesson promoted opioids to prescribers, pharmacies, and even 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 an unfair business practice. Through these marketing activities, Defendants echoed and reinforced the unfair and deceptive prescription opioid marketing that the drug manufacturers were disseminating through many different channels nationwide, and in Vermont. Further, some of Cardinal's and McKesson's 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 Vermont, in ways that will take years to undo.

18. Cardinal and McKesson also promoted and—in the case of McKesson, administered—the opioid manufacturers' prescription savings card programs to increase opioid sales by eliminating cost barriers otherwise associated with the initiation of brand-name opioid use. These discount programs subsidized or eliminated the out-of-pocket cost of these drugs, making them more accessible to Vermont 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** to 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.[7]

19. Cardinal and McKesson actively concealed their misconduct in 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 vowed to the State and 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 pharmaceuticals—including opioids—directly to consumers. 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

[7] *See* Centers for Disease Control and Prevention, Guideline for Prescribing Opioids for Chronic Pain (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").