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

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

125. As first referenced in Section II, McKesson failed to design an anti-diversion program to fulfill its obligations under Vermont law to detect, prevent, and report diversion. McKesson's anti-diversion program did not require adequate due diligence of new pharmacy customers; set artificially high thresholds based on poor data and metrics; proactively informed pharmacy customers of their thresholds to avoid investigations; and permitted threshold manipulation to support increased opioid sales.

126. In addition to its poor design, McKesson failed to even fully implement the inadequate components of its program, as discussed in Section D below. Consequently, McKesson's anti-diversion program, like Cardinal's, was both poorly designed and unenforced in practice.

1. Overview of McKesson's Controlled Substance Monitoring Program

127. 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 available to pharmacy customers; (3) and a three-tiered investigatory and reporting process to identify and report suspicious orders of prescription opioids that exceeded these thresholds.

128. The CSMP's three-tiered investigatory procedures were supposed to be triggered by an 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 deeming the order suspicious and reporting it to the DEA. **It was only after a Level 3 review that the order was deemed "suspicious" and was supposed to be reported to the DEA**.

129. To administer and oversee the CSMP in 2008, McKesson appointed one Director of Regulatory Affairs ("DRAs") for each of McKesson's four national regions to service a system of approximately 25,000 pharmacy customers. The DRAs' duties included approving new pharmacy customers, approving threshold increase requests, and overseeing and conducting investigations of existing pharmacy customers.

130. Sales personnel and Distribution Center Managers were also charged with core anti-diversion responsibilities, including gathering information, conducting diligence investigations, and reporting suspicious activity, despite the fact that their duties also included increasing and facilitating the sale of drugs to pharmacies.

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

131. Under the first component of the CSMP, McKesson was supposed to investigate new pharmacy customers before supplying them with prescription opioids. However, the design

of McKesson's customer onboarding procedures under the CSMP were inadequate to determine whether a pharmacy presented a risk of diversion.

132. First, McKesson's sales representatives, who had a financial incentive to bring on new customers, were responsible for conducting a site visit, collecting information on the pharmacy, and filling out a questionnaire. However, the questionnaire used by these sales representatives contains no section for listing the names and DEA information of the pharmacy's top controlled substance prescribers, despite this information being required by the CSMP from approximately 2008 to June 2015. In addition, McKesson improperly relied on certain pharmacy customers to inform McKesson of its previous ordering histories and suppliers, which precluded McKesson from conducting an independent review of ordering patterns and histories to detect diversion.

133. McKesson also routinely failed to adhere to these procedures. For example, a December 2016 document titled "Updated Questionnaire Listing" identifies more than [redacted] pharmacies served by McKesson's Methuen, Massachusetts, distribution center, which services Vermont. The date is blank for more than half of the listed pharmacies, indicating that updated questionnaires were not on file.

134. McKesson's onboarding policies were even more lax for its largest chain pharmacy customers. In fact, the CSMP only requires an "abbreviated customer questionnaire form" that is completed by the chain's corporate office, no site visit is required, and there is no requirement to identify the top controlled substance prescribers for a specific chain pharmacy location.

3. Unreasonably high threshold levels shielded McKesson from identifying and reporting suspicious orders.

135. The intended purpose of McKesson's threshold system, the second component of the CSMP, was to provide an "automatic block" to prevent pharmacy customers 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, "breach," or "incursion" by McKesson. Under the CSMP, a pharmacy customer's order could be unblocked after it exceeded a threshold only if: (1) the threshold limit was increased by McKesson after investigation of the excessive order; (2) the pharmacy returned some of the opioid drugs purchased to fall below the threshold; or (3) the pharmacy's threshold limit was refreshed at the beginning of a new month, thereby allowing the pharmacy to once again start from zero and purchase up to the threshold limit.

136. Although thresholds were the cornerstone of the CSMP, from 2008 through 2013 McKesson routinely used improper metrics and set thresholds at artificially high levels. To assign thresholds in 2008, McKesson first calculated the average monthly order or highest monthly order from the previous 12-month period spanning 2007 and 2008 for existing pharmacy customers. Yet as discussed above, 2007 and 2008 were years that set records for opioid overprescribing. 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, McKesson did not investigate these inflated historic order amounts before relying on them. On top of these inflated amounts, McKesson's threshold-setting procedures also added an additional buffer of between 10% and 25%, and then sometimes rounded this amount up to the nearest 500, to arrive at the assigned threshold levels.

Further, McKesson retained discretion to set the threshold higher than the default calculations mandated by the CSMP if they saw fit.

137. In addition, from at least 2008 through 2013, McKesson's thresholds did not take into account critical factors necessary to set thresholds that would be effective in identifying suspicious orders, such as the volume of prescription opioids supplied by other distributors to the same pharmacy or to other pharmacies in the same region, variations in geographic ordering patterns, variations in McKesson's pharmacy customer population, or differences in the relevant segment of the industry.

138. These artificially high thresholds thwarted the CSMP's ability to monitor and identify suspicious orders in Vermont. For example, in 2012, McKesson's oxycodone thresholds were two, three, or even five times higher than the pharmacy customer's average monthly ordering volume over the previous year. From 2008 through 2012, oxycodone thresholds were routinely set at levels 50% to 90% higher than pharmacies' average aggregate monthly ordering volume over that four-year period. By consistently setting thresholds well above a pharmacy's typical monthly ordering quantity, pharmacies did not exceed their thresholds unless they ordered many multiples of prescription opioids over their monthly averages, and McKesson's pharmacy customers were able to place unusually large and suspicious orders without triggering any investigation or review.

139. Only after significant pressure from the DEA and DOJ in 2014 did McKesson begin implementing revisions of its threshold calculation metrics to bring them more in line with realistic ordering patterns. These changes led to drastic reductions in thresholds for some pharmacies, demonstrating how inflated those pharmacies' previous thresholds had been. For example, in 2014, one pharmacy's opioid threshold of 122,000 units per month was lowered to

18,000, while another's was reduced from 62,000 to 8,500. In Vermont, one pharmacy's hydrocodone threshold was drastically reduced by 90% from 20,000 to 2,000 units, while another Vermont pharmacy's threshold was slashed from 12,500 units to 2,000.

140. Even after 2014, McKesson suggested that it continue using certain previous threshold metrics for its largest chain pharmacy customers. For example, in 2017, one Senior Director of Regulatory Affairs stated in an email to other McKesson employees that, despite changes to some thresholds, "it is business as usual from a threshold perspective" for its large chain pharmacy customers.[48]

4. McKesson's CSMP permitted advance warnings and inappropriate disclosures to pharmacy customers that they were approaching their monthly thresholds.

141. Although McKesson's CSMP mandated that a pharmacy's threshold was not to be disclosed to the pharmacy, it also included a loophole to permit McKesson to alert pharmacies when they approached their monthly thresholds to prevent a threshold event. As one employee explained in designing this loophole, "we are in the business to sell product" and providing threshold warnings was necessary so that "work could begin on justifying an increase in threshold prior to any lost sales."[49]

142. Similarly, McKesson wanted 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 "convincing" a large chain pharmacy customer that "our thresholds will not limit their business in any way which is their biggest concern. That may mean constant monitoring, warnings set at 80%, numerous TCRs [threshold change requests], …? They need to

[48] MCK-AGMS-032-0003426.
[49] MCK-AGMS-035-0001696.

be able to move on a moment's notice and they need to be able to know they can count on us to be there for them, in every case."[50]

143. Unsurprisingly, this loophole was written directly into the CSMP manual, which noted that "customers that approach a predetermined percentage of threshold maximum or exceed maximums will receive messaging." The CSMP manual also stated that "Sales or DC [distribution center] management may contact the customer to discuss threshold levels at their discretion." This manifested in the provision of routine "threshold warning reports" printed directly on customer invoices to alert them that their orders were approaching their thresholds.[51]

144. 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 Vermont law.

145. McKesson even went so far as to implement automated technology to monitor pharmacy customer purchases and affirmatively "alert customers when they were nearing their thresholds."[52] Such alerts were sometimes provided by customer service personnel at McKesson call centers who were instructed to monitor daily reports on thresholds and "proactively contact" pharmacies who were nearing their thresholds. If customers were not responsive, McKesson contacted them multiple times.[53]

146. In 2014, under pressure from renewed DEA and DOJ investigations, McKesson eliminated this loophole in the CSMP and banned threshold warning reports to pharmacy customers. To this day, however, McKesson provides threshold warning reports to the corporate

[50] MCK-AGMS-041-0066750.
[51] MCK-AGMS-001-0000195.
[52] MCK-AGMS-032-0004671.
[53] MCK-AGMS-032-0004685.

offices of its large chain customers, despite having made representations to the DEA that it would no longer provide threshold warning reports to any pharmacy customers.

5. McKesson manipulated thresholds to support increased opioid sales.

147. When the CSMP was created, requests for threshold changes by pharmacy customers were supposed to be made and granted only "on occasion," only when a pharmacy had a legitimate business need, and only when the regulatory team would be able to sufficiently analyze the requests in depth. However, in the face of ever-increasing prescription opioid sales, and as the opioid crisis ballooned, McKesson actively assisted pharmacies in obtaining threshold increases and evading thresholds, which further restricted the effectiveness of the already flawed CSMP.

148. In order 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, and was to be analyzed and approved by a DRA to ensure that the threshold increase was justified and would not result in drug diversion.

149. However, the DRA responsible for Vermont and the Northeast region has admitted under oath that although he relied on the frontline sales personnel for anti-diversion monitoring and due diligence, he did not have a good relationship with them because they had "conflicting goals" with his anti-diversion duties.[54] Another McKesson anti-diversion employee testified that even McKesson anti-diversion employees were supposed to support sales. As he

[54] Deposition of Michael Oriente, July 19, 2018, MCK-AGMS-032-0003732, at 520-522.

stated, "sales was pretty much at this point considered ourselves. We [anti-diversion] were the customer relations, if you will, of McKesson…."[55]

150. The conflict of interest between sales and regulatory duties comes as no surprise, because sales employees had a financial interest in the outcome of anti-diversion investigations in which they were involved until at least April 2012. McKesson sales employees were incentivized to keep pushing ever increasing supplies of opioids to pharmacy customers because their compensation was tied directly to the volume of opioids sold. As McKesson's 2011 Sales Compensation Plan put it in no uncertain terms: "[w]e continue to emphasize new accounts and have raised the commission factor to enrich the payouts." Similarly, "[t]he more customers you have enrolled in the programs and maintained participation within your territory, the more commission dollars you earn."[56] If McKesson blocked suspicious orders or stopped doing business with a pharmacy, sales employees would "lose money" and put the DEA "on notice," which could further disrupt sales if the pharmacy was closed down by the DEA.[57] McKesson thus designed a compliance system in which sales employees' financial interests were in direct conflict with their anti-diversion duties.

151. Given this conflict of interest, thresholds were routinely and improperly increased by McKesson to keep pharmacy customers happy, ensure renewal of accounts, and maintain a high volume of drug sales. For example, McKesson's DRAs were directed by McKesson executives to respond to TCR requests within 24 hours, further eroding the already lax investigatory procedures mandated by the CSMP. In some instances, if a pharmacy called in to request a threshold increase after receiving a threshold warning report, a McKesson employee

[55] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 29.
[56] McKesson Sales Compensation Plan for FY 2011, MCK-AGMS-032-004738.
[57] Deposition of Michael Oriente, July 19, 2018, MCK-AGMS-032-0003732, at 158-160.

could fill out the one-page form over the phone, and the threshold increase would be approved in as little as five minutes after it was requested by the pharmacy.

152. Information to justify threshold change requests was often merely collected over the phone. Threshold change requests became so routine that McKesson customer service representatives were instructed to tell pharmacies that they would receive a call only if the threshold request was denied, but otherwise to consider it approved because such approvals were "commonplace."

153. McKesson also increased thresholds without appropriate justification and without adequate investigation. These problems were systemic. For example, from June 2010 through November 2010, McKesson justified multiple threshold increases for a pharmacy serviced by McKesson's Aurora distribution center, which was licensed to conduct business in Vermont, based upon an alleged "influx of customers" due to the closure of a neighboring pharmacy. Several of the threshold changes granted to this this pharmacy were based on representations that a neighboring pharmacy had stopped selling controlled substances. However, the neighboring pharmacy had closed **seven years earlier** in 2003. Nevertheless, McKesson continued providing threshold increases to this pharmacy on this improper basis for another four months.

154. Although a particular pharmacy's "business growth" was not in and of itself a sufficient justification to increase thresholds in most cases, in one region business growth alone was used 106 times in a two-year period to justify threshold increases. At one of the pharmacies for which "business growth" was used to justify a threshold increase, state regulators watched from a parking lot as drivers dropped off multiple patients to pick up prescriptions, which they

reported as "diversion so obvious that the pharmacies readily admitted to misconduct when confronted."[58]

155. Mirroring these systemic and nationwide problems, diligence records for pharmacies in Vermont reflect that increases in thresholds were approved based on nothing more than a reported increase in prescription volume, with no further investigation, such as review of the pharmacy's prescription records or the prescribing physicians. For example, in April 2009, a pharmacy in Rutland County, Vermont requested a permanent 20% oxycodone threshold increase "due to increased business." The request was granted on this basis alone.[59] Similarly, in May 2010 a pharmacy in Orleans County, Vermont requested a 15% increase in oxycodone, due to an "increase of scripts – business for this product at this location." The request was approved as one of four other threshold changes submitted and approved the same day without any documentation of further investigation.[60]

156. 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, 200 pharmacies, in bulk, received a 30% threshold increase in November 2008 without any documentation or justification. A month later, in December, a McKesson DRA improperly signed and backdated a single TCR form to justify the bulk increase.

157. In another example, in an email dated December 27, 2012, the Operations Manager at McKesson's Aurora distribution center emailed another McKesson employee:

[58] DEA Correspondence to McKesson (Nov. 4, 2014), MCK-AGMS-019-0005802.
[59] MCK-AGMS-066-0000177.
[60] MCK-AGMS-066-0000226.

"REDACTED is not on here for Hydrocodone… also we have REDACTED. Do you think we should do *pre-emptive TCR* [threshold change request] for these two?"[61]

158. Notably, preemptive threshold increases were often granted in response to either the threshold warning reports created by McKesson or threshold events, the very information that McKesson was supposed to rely on to trigger an investigation of pharmacy activity, not use as a tool to increase sales.

159. In yet another example, a May 2008 bulk threshold increase was granted to every pharmacy in a region that was approaching 75–80% of its threshold. In justifying this broad increase, one McKesson employee suggested that McKesson needed a reason to increase the thresholds, but no documentation or justification was ever provided. Four months later, in September 2008, another McKesson employee discovered that no documentation had ever been filed justifying the increase. In response, McKesson employees improperly backdated the documentation to justify the threshold increase to make it appear as though it was created contemporaneously in May 2008, as required by the CSMP.

160. McKesson personnel also improperly coached pharmacy customers on how to write threshold change requests to justify an increase [redacted]

161. The result of McKesson's poorly designed threshold change system was evident in Vermont. A sample of pharmacies investigated by the State shows 33 threshold change requests were recorded between June 2010 and November 2013 from 19 pharmacies. Of those 33, only one was denied, further demonstrating that denial of threshold change requests was rare. In addition, thresholds for various opioid drugs were often increased, and the drugs shipped to the requesting pharmacies, on the same day threshold increase requests were made.

[61] MCK-AGMS-032-0003383 at 12.

162. These practices should have stopped in 2014, when McKesson made changes to its CSMP, under pressure from the DEA and DOJ, and altered the program to require that threshold changes be initiated by the pharmacy and accompanied by supporting documentation and appropriate investigation. Yet even in 2014, a DRA attempted to request a bulk threshold increase without initiation by the pharmacy customer. Similarly, in 2014, McKesson employees were still trying to figure out ways to avoid lowering thresholds for certain pharmacy customers and avoid the necessity of investigations.

163. The threshold system, touted as the cornerstone of McKesson's 2008 CSMP, thus, never served its purpose. McKesson did not "set" and then "maintain" thresholds. The thresholds did not meaningfully restrict McKesson's customers from obtaining opioid drugs, but instead were used to accommodate whatever pharmacy customers wanted to purchase, or they were set so high that they never triggered any review.

164. The result was a consistent pattern of excessive opioid sales in Vermont. For example, in 2011, McKesson shipped approximately 284,180 opioid pills to a pharmacy in Franklin County, Vermont, in a town with a population of approximately 2,779—the equivalent of 102 pills for every resident in that year alone. Similarly, McKesson shipped 550,173 opioid pills to another pharmacy in Franklin County, Vermont, which was located in a town of approximately 6,427—the equivalent of 85 pills for every resident. In 2011 McKesson shipped approximately 1,656,982 opioid pills to Franklin County, Vermont, which had a total population of approximately 47,746—the equivalent of 35 pills per county resident in that year.

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

165. 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 Vermont 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.

166. DRAs were the only full-time field employees responsible for administering the CSMP program and preventing and detecting diversion from 2008 through 2013. In one region, a DRA was responsible for 15 states, 8 distribution centers, and 13,000 pharmacy customers. Given that volume, the DRA testified that he was only able to complete five sites visits per month, spread across the 13,000 pharmacies for which he was responsible. This means the DRA was visiting less than 0.0004% of his or her assigned pharmacies per month. At this rate, it would take [redacted] years to complete a single visit to each of the pharmacies for which the DRA was responsible. This understaffing occurred despite the fact that McKesson knew or should have known that the DEA's diversion department was severely under-resourced, and that the opioid distribution chain was vulnerable to exploitation and abuse.

167. 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 disclaimed that he was responsible for preventing and monitoring diversion despite acknowledging his regulatory and anti-diversion duties. Similarly, a former McKesson employee stated that even after 18 years of working in the Regulatory Affairs Department he did not have "precise knowledge" or a working definition of the basic concept of

"pill diversion,"[62] did not recall receiving training regarding the components of the CSMP, did not understand the components of the CSMP, and stated "the training I received personally was not adequate for me to fulfill the role of regulatory affairs manager."[63]

168. While McKesson incentivized sales personnel to increase sales, little or no effort was focused on training sales personnel to enforce the CSMP. The CSMP itself did not articulate detailed standard operating procedures for investigation and analysis of potentially suspicious orders. Instead, the CSMP was nothing more than a how-to guide for filling out CSMP paperwork and collecting information, rather than a tool by which McKesson employees would evaluate potentially suspicious orders.

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

169. As discussed in Section II.C.1., 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. In practice, however, McKesson conducted some investigations into orders that exceeded threshold limits, termed Level 1 reviews, in name only and failed to follow even the low bar required by the CSMP. Instead, McKesson often used threshold events as an opportunity to raise pharmacy thresholds. Consequently, threshold events became yet another tool to increase sales, rather than a way to monitor orders and detect and prevent diversion.

170. Critically, Level 1 Reviews did not require any approval or involvement by the full-time DRA; they were perfunctory, and sometimes never completed at all. In the North East region, which included Vermont, "customer service people" at the relevant distribution center would merely call a pharmacy customer to conduct a Level 1 review over the phone. In other

[62] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 18-20.
[63] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 21; 62; 109.

instances, sales personnel or Distribution Center Managers would undertake the Level 1 review. For example, when a threshold event triggered a Level 1 review for a pharmacy in 2012, a McKesson sales employee merely discussed calling the pharmacy to ask if it "need[ed] an adjustment" instead of gathering information and conducting a Level 1 review as required under the CSMP.[64]

171. McKesson's employees were also left to develop their own *ad hoc* investigative techniques under the vague directives of the CSMP, which failed to provide specific standard operating procedures for investigations. The investigative procedures sometimes included generally conducting an interview, observing operations and customer flow, and internet research on public websites. McKesson also failed to standardize the interview questions for pharmacy site visits and interviews. One DRA noted that he created his own questionnaire, and answers were only recorded if something "stood out." Despite directing employees to consider various red flags, McKesson had no standard policy or practice for evaluating red flags. And deciding whether to stop supplying a pharmacy with opioid drugs, or to escalate a review to Level 2 or 3, was largely left to the discretion of the McKesson Distribution Center Managers without involvement of full-time regulatory staff.

172. An internal McKesson audit from March 2011 confirmed a pattern of deficiencies in its investigatory practices following threshold events, including Distribution Center Management's failure to sign Level 1 review forms as required by policy. The audit also found that the required Level 1 review documentation was not completed for 20 of the 56 Level 1 reviews that were triggered by threshold events in July 2010, and McKesson failed to complete documentation for reviews of 54 threshold events that occurred in November 2010 alone. In

[64] MCK-AGMS-032-0004751.

many cases, the salespeople were not filling out the Level 1 reports correctly, or at all, despite repeated threshold events.

173. These were not isolated incidents, but rather part of a systemic and nationwide problem. McKesson's Senior Vice President of Distribution Operations stated that "I am sure that if we picked four different [distribution centers] we would find the same issues so we should assume this is a network wide concern."[65]

174. In a communication to sales personnel, one DRA was aware of the pattern of poor review practices, and even confirmed that some Level 1 reviews were fabricated. As he noted, "[p]lease do not assume the reason, then fill out a [Level 1] form as if a call had taken place. If we ever find ourselves in a court of law regarding diversion and then we have to admit that we didn't really call the customer but rather just filled the form out like we had called, it will not be pretty. Word of advice."[66]

175. A pharmacy in rural Franklin County, Vermont, provides yet another example of McKesson's failure to conduct investigations in response to orders that exceeded thresholds. McKesson documents indicate that this pharmacy had a remarkable history of exceeding its threshold over a number of years, single-handedly accounting for 219 threshold events, or 44% of the state's threshold events and blocked orders from May 2008 through July 2013. While this deluge of threshold events in and of itself should have triggered a careful investigation of the pharmacy's business practices, there is no evidence of a single site visit or any Level 1 review conducted or completed pursuant to the McKesson's CSMP, let alone a Level 2 or Level 3 investigation. In fact, there are no indications that McKesson conducted a Level 2 or 3 review

[65] MCK-AGMS-076-0000319.
[66] MCK-AGMS-035-0001600 at 2.

between 2008 and 2013 at all, based on records produced for a sample group of Vermont pharmacies investigated by the State.

176. In some instances, the Franklin County pharmacy declined to request a threshold increase after exceeding a threshold with an order. In response, McKesson personnel merely noted that the pharmacy did not need the order, and the pharmacy simply ran out the clock and waited until the threshold was reset at the end of the month before resubmitting its order. For these instances, McKesson's sample regulatory files contain no indication that McKesson did anything further to carry out its duty to investigate and determine whether the order, even if withdrawn, was suspicious.

177. As a result of its systematic failure to conduct diligent investigations of threshold events, and in violation of its duty, McKesson failed to submit any suspicious orders to the DEA for this pharmacy at any point from 2008 to August 1, 2013. From 2010 to 2013, the county in which this pharmacy is located recorded 14 prescription opioid-related overdose deaths. Despite all this, McKesson continued doing business with the pharmacy [redacted]

3. McKesson failed to report flagged orders and shipped orders without conducting a diligent investigation.

178. 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.

179. McKesson also failed to report and block orders in Vermont. During a similar time period, from May 16, 2008 to August 1, 2013, McKesson failed to report **any** suspicious orders from Vermont pharmacies, despite profiting from and shipping approximately 54 million prescription opioid pills into Vermont during that period. For example, in September 2012,

McKesson blocked an order for oxycodone placed by a pharmacy in Franklin County, Vermont because the order exceeded the pharmacy's threshold for oxycodone. While it was supposed to conduct a Level 1 review of the threshold event, there is no documentation indicating any review, and McKesson instead initiated a threshold change, approved the threshold change, and resumed oxycodone shipments the very same day.

180. Three months later, in December 2012, McKesson again blocked an order for oxycodone from the same Vermont pharmacy because the order exceeded its monthly threshold. Again, on the same day that the order was blocked, McKesson initiated a threshold change request and again commenced shipments of oxycodone the next business day without documentation of a Level 1 review. Even after this repeated pattern of suspicious orders, McKesson's diligence records provide no indication of whether McKesson regulatory personnel visited this Vermont pharmacy, and there is no documentation of any investigations.

181. Such practices were not limited to Vermont—they were a symptom of McKesson's systemic anti-diversion failures. Often McKesson failed to report any suspicious orders until the DEA initiated an investigation. For example, McKesson failed to report any suspicious orders to the DEA nationwide from May 2008 to July 2011. Only after the DEA commenced an investigation in 2011 did McKesson begin a flurry of remedial reporting activity and cease doing business with certain customers in an overdue attempt to comply with its duty. In January 2012, for example, McKesson discontinued doing business with two pharmacies and submitted suspicious order reports for these two pharmacies to the DEA—just one week before McKesson was scheduled to meet with the DEA.

182. In November 2011, McKesson ceased shipping controlled substances to a pharmacy—less than one month after the DEA requested the pharmacy's diligence files from

McKesson for its own investigation. In that case, one doctor accounted for 80% of the pharmacy's oxycodone business, and the doctor was more than 25 miles from the pharmacy—two clear red flags for the presence of diversion. Although it had never previously reported a suspicious order from the [redacted] pharmacy, and had supplied it for years, McKesson claimed that it was in the process of ceasing business with the pharmacy and that it was only a coincidence that the DEA investigation commenced at that time. Even when McKesson stopped doing business with the [redacted] pharmacy, it failed to report any suspicious order reports to the DEA, instead claiming that there were no individual suspicious orders.

183. Further demonstrating its systemic problems, McKesson also failed to report suspicious orders by [redacted] that were owned by the same person and whose opioid thresholds were approved for permanent increase by McKesson from 4,000 to 16,000 per month in August 2010, and increased again to 20,000 in 2011. In addition to the exponential threshold increases granted to these pharmacies, 70% of the controlled substances that they were ordering from McKesson were hydrocodone products—"obvious indicia of diversion" that McKesson ignored. The owner of this pharmacy and dozens of other participants were later convicted on charges related to a drug trafficking conspiracy.

184. McKesson failed to block or report orders that represented significant multiples of the average monthly orders at its distribution centers. Over a four-year period at one distribution center, there were 122,288 instances in which pharmacies ordered and received two times the monthly average of a pharmacy their size; 71,000 instances where pharmacies received three times the monthly average of a pharmacy their size; 10,609 instances where pharmacies received ten times the monthly average of a pharmacy of their size.

185. Overall, between 2008 and 2013, McKesson failed to report **any** suspicious orders from its Methuen distribution center, which was the primary distribution point for shipment of drugs into Vermont, and which also serviced other states. Because of McKesson's poor implementation of its already inadequately-designed CSMP, McKesson failed to identify, report, and prevent shipment of suspicious orders, as required under Vermont law.

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

186. McKesson wholly abdicated its responsibility to investigate threshold events triggered by orders from its large chain pharmacy customers, in violation of its duties under Vermont law. McKesson's pharmacy customers were typically divided into ISM (independent/small/medium size) and larger chains identified as "RNAs" (Retail National Accounts). When an ISM pharmacy exceeded a threshold, the pharmacy was contacted and was supposed to be investigated directly by McKesson. However, if a Retail National Account pharmacy did the same, McKesson did not initiate any investigation, but rather contacted the chain's corporate office, because "they perform their own due diligence internal regulatory review."

187. McKesson relied on the corporate offices of the Retail National Accounts to conduct their own due diligence, despite a pattern that the pharmacy chains were violating their duties under federal law. For example, McKesson engaged in this conduct for one Retail National Account that was one of the largest chains serviced by McKesson in Vermont and had a significant history of settlements related to alleged violations of the Controlled Substance Act (CSA) settlements. In 2009, this chain agreed to pay $5 million in civil penalties to settle allegations of violations of the CSA, violations alleged to have occurred in several states from New York to California. This chain entered into another settlement in 2017, agreeing to pay

$834,200 to resolve allegations arising from an investigation in Los Angeles, California. And in late 2018, the chain entered into yet another settlement, agreeing to pay a $300,000 penalty for filling prescriptions at Rhode Island pharmacies over the maximum allowed under state law.

188. This chain has a significant foothold in the Vermont retail pharmacy marketplace: at least 51 individual DEA registration numbers associated with its pharmacies in Vermont with more than 145,000 transactions with these pharmacies from 2014-2018 alone. 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 Vermont without interruption.

189. McKesson's uniform policy of special treatment for chain pharmacies was also evident in a September 2008 agreement with another Retail National Account, pursuant to which McKesson temporarily stopped monitoring thresholds for that chain altogether. By November 2008, McKesson was back to monitoring thresholds but instructed its regulatory personnel to automatically increase this chain's thresholds without any investigation at all, even if the threshold was exceeded. As McKesson explained, any location within this chain "that encroaches upon these new thresholds will be increased by the Regulatory Affairs team without [ ] explanations so long as they don't fall into a category we are identifying as 'unusual' thus requiring further explanation from [the company]."[67] McKesson also approved permanent bulk threshold change requests to chains without appropriate reasons or documentation. A permanent threshold increase was provided to all of this chain's pharmacies in a region due to "the thanksgiving increases."[68] In yet another example, McKesson provided a bulk increase to this chain's pharmacies without any justification or documentation at all.

[67] MCK-AGMS-041-0066748.
[68] MCK-AGMS-032-0004722.

III. Cardinal and McKesson Unfairly and Deceptively Promoted Opioids by Spreading Opioid Manufacturers' Misleading Marketing to Pharmacies and Consumers.

190. Cardinal's and McKesson's 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 marketed 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.

191. Cardinal's and McKesson's promotion and marketing of prescription opioids constitutes an unfair business practice, 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 "reminder" advertisements—awareness-building messages about the availability of certain drugs—to affirmative promotion of opioids, disseminated through marketing channels over which they had unique control, as well as promotion and/or administration of prescription savings card programs designed to encourage initiation and long-term use of branded prescription opioids. Through these marketing activities, Cardinal and McKesson built upon and reinforced the opioid manufacturers' deceptive, misleading, and highly successful marketing campaign to promote prescription opioid use.

192. Cardinal's and McKesson's 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.

193. Cardinal and McKesson 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.

194. 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.[69]

195. 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.[70]

196. Cardinal expressly acknowledged pharmacists as important conduits for educating and influencing patients and for providing drug recommendations to prescribers. One Cardinal marketing proposal emphasized to an opioid manufacturer client that [redacted]

[69] https://www.pharmacytimes.com/publications/issue/2015/october2015/the-pharmacists-expanded-role
[70] https://www.pharmacytimes.com/publications/issue/2012/january2012/strong-pharmacy-entrepreneurs-make-for-a-strong-profession

[redacted] Cardinal's proposal advised the drug company that "[redacted]"[71]

197. 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 2013 marketing plan that promotion to pharmacists was necessary for "educating on benefits of OxyContin (to avoid negative pharmacist recommendations)."[72] In 2015, when Purdue launched its extended-release hydrocodone product, Hysingla, it cited the aforementioned NCPA survey to conclude that "[t]he ability to partner with … pharmacists will be key to ensure that when a patient presents a prescription for Hysingla ER, they won't recommend a switch to generic IR hydrocodone."[73] Purdue also noted that "educated" pharmacists "may be willing to speak to HCPs [healthcare providers] about Hysingla ER where appropriate."[74]

198. Purdue and other manufacturers worked hand-in-glove with Defendants to promote their products—through the distributors—to pharmacies and pharmacists. For example, Purdue partnered closely with Cardinal to support its Hysingla launch through an email campaign, managed by Cardinal, to market the opioid to pharmacists.

199. The targeting of pharmacists by Cardinal and McKesson in their marketing activities was particularly problematic because of Cardinal's and McKesson's existing and often long-term business relationships with pharmacies—with whom Defendants shared a legal responsibility to prevent diversion. Opioid distributors, like Defendants, were in a unique and trusted position in the controlled substances supply chain from which they could have spoken

[71] CAH_MDL2804_02879120.
[72] PWG00062629.
[73] PWG000362181.
[74] PWG000362181.

truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have remained silent about the benefits and risks of opioids, and simply filled orders and shipped drugs. Instead, Cardinal and McKesson abused their unique position for profit, by contributing to the chorus of deception surrounding opioids.

200. 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. Both Cardinal and McKesson 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 unfair and deceptive conduct, Defendants put Vermont 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 Vermont, and increased misuse and addiction that has created an epidemic of health problems, overdose, and death in Vermont.

A. Cardinal unfairly and deceptively marketed opioids.

201. Cardinal has actively sought to increase the sale of opioids in Vermont 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.

202. Increased drug sales benefit Cardinal. [redacted]

203. Through Cardinal's marketing programs, it disseminated the drug manufacturers' promotional messages about opioids nationally and, upon information and belief, into Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

204. Cardinal offers a range of marketing services to its drug manufacturer clients. These marketing services are a key feature in the overall portfolio of amenities that Cardinal provides. For many manufacturers, the cost of Cardinal's marketing services is [redacted]

[redacted]"[75] [redacted]

[75] CAH_MDL2804_002893641.

[redacted]

205. [redacted]

206. [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. Undeterred, Cardinal continued working with Purdue to promote its opioid products. [redacted]

207. As another example, [redacted]

[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. Cardinal personnel were aware of, and circulated internally, news reports regarding the widespread off-label use of SUBSYS by October 2014. [redacted] Cardinal "eConnections" blast email to pharmacists promoting SUBSYS.

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

209. Cardinal did not simply disseminate manufacturer-created marketing content, it also [redacted]

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

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

211. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally

and, on information and belief, in Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

212. ***Direct-to-Consumer Marketing.*** Cardinal markets drugs directly to consumers through its placement of flat-screen televisions running "health and wellness" content, including advertisements for prescription drugs, in the patient waiting area of pharmacies. Cardinal describes this program, Pharmacy Health Network ("PHN"), as a "consumer-facing" network that provides manufacturers with marketing opportunities right at the "point of influence."[76]

213. 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.[77]

214. 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

[76] CAH_MULTISTATE_0013372.
[77] *Nielson Study Confirms Ads on Cardinal Health's Retail Pharmacy Digital Advertising Network Motivate Consumers to Discuss, Purchase Products* (March 17, 2014), https://digitalsignagefederation.wildapricot.org/widget/memberpress/1520048.

positive response from advertisers and consumers alike, we look forward to expanding the number of stores and advertisers that participate in the program.[78]

215. In fact, additional studies show that, as of November 2015, Cardinal's PHN was proven to increase sales of advertised products.[79]

216. Although it is currently unknown to the State whether opioid advertisements were run through PHN, it is clear that Cardinal offered and recommended PHN as a channel for opioid advertising. [redacted][80] [redacted][81]

217. ***Direct Mail Marketing.*** Cardinal utilizes direct mail campaigns to promote opioids, despite internal company guidelines that prohibit direct mail advertising for controlled substances. The company promoted Cephalon's Actiq and Fentora (both fentanyl products) through direct mail marketing in January 2012.

218. Cardinal charges [redacted]

219. ***Email Marketing.*** Cardinal also disseminates opioid marketing content to pharmacists and other healthcare providers through mass emails, referred to as its eConnections program.

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[78] *Id.* (emphasis added).
[79] Respario, *Case Study: Cardinal Health Engages Retail Pharmacy Customers Through Digital Signage Network* (November 2015), http://respario.com/wp-content/uploads/2015/11/respario-case-study-cardinalhealth.pdf.
[80] CAH_MDL2804_01296417.
[81] CAH_MDL2804_00134274.

220. Through a listserv called RxInsider—part of the eConnections program—Cardinal sends colorful, full-page advertisements with graphics and pictures for products, including opioids, to prescribers and pharmacists nationwide.

221. Cardinal claims that through eConnections, marketing messages can reach [redacted] Cardinal specifically promotes its ability to effectively target marketing—including these eConnections messages—to prescribers. 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."

222. From 2010 through at least 2015, Cardinal used eConnections to target prescribers—including pediatricians, nurse practitioners and physician assistants—for promotion of opioids.[82]

223. From at least 2012 through 2017, Cardinal frequently used eConnections to market opioids—including oxycodone, hydrocodone, fentanyl, and morphine—to pharmacists.[83]

[82] [redacted]

[83] Cardinal used eConnections to market to pharmacists Actavis's Kadian (a Schedule II morphine drug) in September and October 2012 (CAH_MDL2804_02959967); Endo's Opana (a Schedule II oxycodone drug) in April 2013 (CAH_MDL2804_02956220), April 2014 (CAH_MDL2804_02957406-02957407), and January 2015 (CAH_MDL2804_02957401-02957404); Teva's Vantrela ER (a Schedule III hydrocodone drug) in October 2015 (CAH_MDL284_00132780); INSYS's SUBSYS (a Schedule II fentanyl spray) in December 2015 (CAH_MULTISTATE_0001483); The Medicines Company's Ionsys (a Schedule II fentanyl patch) in January 2016 (CAH_MDL2804_02957456-02957457); Mallinckrodt's Fentanyl (also a Schedule II fentanyl patch) in January 2016 (CAH_MDL2804_02957398-02957399); Pernix's Zohydro (a Schedule II hydrocodone drug) in February

224. ***Marketing in Customer Newsletters.*** Cardinal also offers opioid marketing through its "Service Flash" newsletter, distributed to pharmacists nationwide, including in Vermont.

225. The "Service Flash" newsletter is a weekly publication distributed to all of Cardinal's [redacted] both in hard copy, to accompany product shipments to all Cardinal customers, and via email. Cardinal has distributed its Service Flash newsletter—and the marketing content contained therein—to pharmacies nationwide, including in Vermont. Service Flash carries the Cardinal logo and promotes various drugs, in addition to containing basic product ordering and recall information.

226. Drug manufacturers can purchase [redacted]

227. Cardinal used Service Flash to market opioids—including oxycodone, levorphanol, Vicodin, and fentanyl—to pharmacists, including pharmacists in Vermont, from at least 2009 through 2017.[84]

228. ***Telemarketing.*** Cardinal offers its manufacturer clients the option of purchasing custom telemarketing campaigns to target both pharmacists and physicians with marketing messages about their drugs. Cardinal offered this service as recently as November 2017.

2016 (CAH_MULTISTATE_0001487); and Depomed's Nucynta ER (a Schedule II tapentadol drug) in June 2017. (CAH_MDL2804_02959244).

[84] [redacted] Cardinal's Service Flash featured advertisements for Abbott's Vicodin in December 2012 (CAH_MDL2804_00134473; Confidential), Sentynl Therapeutics drug Levorphanol (opioid similar to morphine, but 8x more powerful) in June 2015 (CAH_MDL2804_02955757; Confidential), Depomed's Lazanda (a Schedule II fentanyl drug) in July 2016, (CAH_MDL2804_00132701; Confidential) and Depomed's Nucynta ER in June 2017. (CAH_MDL2804_02959244; Confidential).

229. One telemarketing script from August 2011 for Hawthorn Pharmaceuticals's Rezira and Zutripro (both Schedule III[85] hydrocodone drugs) offered [redacted] to pharmacists ordering the drugs from the caller. The script described the indications for these drugs but did not include any warnings about the risks of opioid use, including the danger of abuse or addiction.[86]

230. ***Advertisements on Ordering Platform.*** Cardinal also runs drug advertisements on "Order Express," the web-based ordering platform that pharmacists at Cardinal's pharmacy customers use to place orders. [redacted]

231. Cardinal offers drug manufacturers the options of home-page advertisements and across-screen banner advertisements on Order Express. Banner advertisements are triggered by keywords that pharmacists use to search for products on the site, [redacted]

[85] 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.

[86] [redacted]

[redacted]

232. As of 2015, advertisements on the Order Express platform reached [redacted][87] Cardinal marketed opioids—including oxymorphone, hydrocodone combination drugs, and oxycodone combination drugs—through home-page and banner-page content on Order Express until at least 2017.[88]

233. ***Pharmacy Rebates.*** Cardinal further encourages purchases of opioids through its RxDeals program, which offers discounts and rebates to pharmacies for the purchase of drugs, including opioids. Cardinal typically includes promotional language about the featured drug in the notice of the discount.

234. As of 2015, promotion through the RxDeals program reached approximately [redacted], including, on information and belief, in Vermont. Cardinal used RxDeals to promote opioids—including oxymorphone, hydrocodone combination drugs, and oxycodone combination drugs—from 2008 until at least 2015.[89]

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[87] CAH_MDL2804_00134788.

[88] Cardinal ran advertisements for Covidien's Exalgo (a Schedule II, hydromorphone drug) in April and May 2013 (CAH_MDL2804_02959126-02959129; Highly Confidential), Global Pharmaceutical's generic Opana ER (a Schedule II oxymorphone drug) in March (CAH_MDL2804_00133481; Confidential) and June 2013 (CAH_MDL2804_02956402; Highly Confidential), Abbvie's Vicodin in March 2014 (CAH_MDL2804_02955369-02955370; Confidential), Egalet's Oxaydo (a Schedule II oxycodone drug) in March 2017 (CAH_MDL2804_00132543-00132544; Confidential), Global/Impax Laboratories Inc.'s generic oxymorphone drug in August 2017 (CAH_MDL2804_02959282; Highly Confidential), and Purdue's Hysingla ER (a Schedule II hydrocodone drug) in June 2017. (CAH_MDL2804_02959381-02959385; Highly Confidential). Cardinal's advertisement for Hysingla linked to an interactive game that quizzes the player on information about the drug. (CAH_MDL2804_02959382; Highly Confidential).

[89] Cardinal used RxDeals to promote Opana in 2008 (encouraging pharmacists to "Order Today!") (CAH_MDL2804_02956242; Highly Confidential), Stagesic in 2010 (emphasizing that the discount was a "limited time offer" and including deceptive statements related to the risk of diversion) (CAH_MDL2804_02957392;

235. ***Auto-Shipments.*** Through its "First Script" program, Cardinal contracted with drug manufacturers to auto-ship their drugs to pharmacies (without first receiving an order), for the purpose of ensuring that the pharmacies were stocked with the drug "before the first script arrives." This service was sometimes packaged with other marketing programs as part of a new product launch.

236. Cardinal auto-shipped Schedule III opioids, including [redacted] through the FirstScript program, although internal company guidelines restricted use of this program for Schedule II[90] controlled substances.

2. Cardinal deceptively marketed opioids.

237. In addition to being an unfair 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.

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

239. Cardinal disseminated certain opioid advertisements that contained deceptive statements regarding the risk of addiction, abuse, and diversion posed by these drugs. For example, a 2010 advertisement for Stagesic, a drug in the hydrocodone family, claimed that this opioid "has no street value! (IE. Drug seekers and dealers do not trust capsule forms)."[91] This

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Confidential), Nucynta ER in 2011 (including the Cardinal logo and asking the viewer to "Place your order with Cardinal Health today!") (CAH_MDL2804_02956566; Highly Confidential), Primlev in 2012 (CAH_MDL2804_00134299; Confidential) and Embeda in 2015 (CAH_MDL2804_02957340; Highly Confidential).

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

[91] CAH_MDL2804_02957392.

advertisement was sent to prescribers in one state and to pharmacists across the country. This 2010 advertisement built upon earlier deceptions regarding the diversion potential of Stagesic, which had made similar misrepresentations to pharmacists. Titled "Important Information Regarding Filling Hydrocodone Prescriptions," the advertisement asked pharmacists, "[d]o you ever worry when filling a hydrocodone prescription?" and went on to state "[t]he capsule formulation helps to assure pharmacists and physicians that the intended patient is the legal recipient of the hydrocodone versus when prescriptions are filled with tablet formulations."[92]

240. 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, a 2011 advertisement for Lortab Elixer, an opioid-based cough medicine, emphasized that this drug contained the lowest dose of acetaminophen among comparable drugs, "which may help reduce concerns of acetaminophen toxicity."[93] But nowhere on the advertisement does it disclose or explain the risk for addiction and dependence, respiratory distress, and death associated with opioids. Likewise, Cardinal disseminated advertisements promoting opioids without mentioning any of the drugs' risks—providing, at most, a link to additional information on the manufacturer's website. These advertisements failed to provide "fair balance" and had material omissions, which rendered them misleading to their intended recipients, in violation of the Consumer Protection Act.

241. 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.

[92] CAH_MDL2804_02955823.
[93] CAH_MDL2804_02955979.

242. 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. Cardinal 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, 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 unfairly and deceptively marketed opioids nationally and in Vermont.

243. McKesson actively sought to increase the sale of opioids by assisting manufacturers in marketing these dangerous, addictive, and misuse- and abuse-prone drugs.

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

244. McKesson's marketing programs disseminated drug manufacturers' promotional messages about opioids nationally and, upon information and belief, into Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

245. McKesson claims to have had a policy of not providing advertising for Schedule II drugs as early as 2014. Despite that policy, [redacted], McKesson's marketing team identified Xtampza ER, a Schedule II oxycodone drug, [redacted]

246. Prior to 2014, McKesson offered marketing services across the drug lifecycle (from product development to product launch and beyond), including creating new markets for

drugs. McKesson pitched the following to drug manufacturers: "We have proven solutions for the challenges you face when commercializing a new therapy. Prescriber access and education, adherence services, and reimbursement support are just a few of many ways we can help …. Our connected network of providers coupled with our array of expertise offers a unique access channel for understanding and successfully developing drugs."[94]

247. ***Auto-Shipments.*** Specifically, McKesson promoted prescription opioids through its RxFocus Autoship program. This marketing program identified pharmacies that were high dispensers of medications similar to the newly-released medications—and then **auto-shipped** those newly released medications to the identified pharmacies, without ever receiving an order for these drugs from the pharmacy.

248. McKesson described RxFocus Autoship as delivering "the latest blockbuster Branded Rx medications to retail pharmacies within 72 hours of release—helping to make sure that our customers can be **one of the first** to serve patients newly prescribed a medication" (emphasis in the original).[95]

249. The prescription opioids McKesson promoted and auto-shipped (including to Vermont pharmacies) through RxFocus Autoship include the following:

Opioid	Manufacturer	Approximate Date[96]
Butrans (buprenorphine)	Purdue Pharma	Jan. 2011
Suboxone (buprenorphine/naloxone)	Reckitt Benckiser	Dec. 2012
Zubsolv (buprenorphine/naloxone)	Orexo	Aug. 2013

250. McKesson charged manufacturers $[redacted] for its RxFocus Autoship program. McKesson eventually discontinued auto-shipping controlled substances in late 2013, recognizing that it does "not want to be auto-shipping, up-selling or providing sales incentives for any

[94] MCKAGMS-069-0000020.
[95] MCK-AGMS-019-0008109, -8171; MCK-AGMS-038-0000040.
[96] All dates in this table reflect implementation dates.

controlled substances (all schedules) to customers" and that "all orders must come from the customer."[97] In stopping auto-shipping, McKesson lamented that it would "be giving up marketing income" and would need to get their customers "to order before the manufacturer's deal period ends (more work without the autoship)."[98]

251. ***Email Marketing.*** McKesson also promoted opioids through the RxBulletin program, which sent e-mail campaigns to pharmacies. McKesson described RxBulletin as having the capability to deliver e-mail messages to approximately 7,000 independent pharmacies. McKesson promoted RxBulletin to drug manufacturers as offering "rapid delivery of time-sensitive messages and requir[ing] minimal development time."[99]

252. The prescription opioids that McKesson marketed through RxBulletin include the following:

Opioid	Manufacturer	Approximate Date[100]
Exalgo (hydromorphone)	Mallinckrodt	Nov. 2012
Actiq (fentanyl)	Cephalon	Jan. 2012
Fentora (fentanyl)	Cephalon	Jan. 2012
Suboxone (buprenorphine/naloxone)	Reckitt Benckiser	Jan. & Mar. 2013
Zubsolv (buprenorphine/naloxone)	Orexo	Sept. 2013

253. McKesson charged manufacturers between $[redacted]$[redacted] **for each** RxBulletin e-mail campaign.

254. ***Fax Marketing.*** McKesson promoted opioids through its Fax Blast program, which sent marketing campaigns via fax to pharmacies. McKesson described Fax Blast as having the ability to distribute a fax promoting a product to its network of 5,000 pharmacy customers.

255. The prescription opioids that McKesson promoted through Fax Blast include the following:

[97] MCK-AGMS-069-0002800.
[98] MCK-AGMS-069-0002796.
[99] MCK-AGMS-019-0008143; MCK-AGMS-019-0008201.
[100] The dates in this table reflect the implementation date or, if unavailable, the date the marketing agreement was executed.

Opioid	Manufacturer	Approximate Date[101]
Lortab and Lortab Elixir (hydrocodone combination)	ECR Pharmaceuticals	Oct. and Nov. 2013
TussiCaps (hydrocodone)	ECR Pharmaceuticals	Jan. 2013
Primlev (oxycodone combination)	Akrimax Pharmaceuticals	July 2012

256. McKesson charged manufacturers between $[redacted] $[redacted] per Fax Blast campaign.

257. ***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]

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

Opioid	Manufacturer	Approximate Date[102]
OxyContin (oxycodone)	Purdue Pharma	Aug. 2010
Butrans (buprenorphine)	Purdue Pharma	Oct. 2016
Zohydro ER (hydrocodone)	Zoginex	July 2014
Primlev (oxycodone combination)	Akrimax Pharmaceuticals	July 2012
Abstral (fentanyl)	ProStraken	Mar. 2011
Suboxone (buprenorphine/naloxone)	Reckitt Benckiser	Jan. and May 2013
Zubsolv (buprenorphine/naloxone)	Orexo	Sept. 2013
Fioricet with Codeine	Actavis	Aug. 2013

259. McKesson charged between $[redacted] $[redacted] per week for direct advertising on McKesson Connect.

260. ***Direct Mail Marketing.*** Lastly, McKesson used its RxMail program to promote opioids via direct mail campaigns. McKesson promoted RxMail as having the ability to send

[101] All dates in this table reflect implementation dates.
[102] The dates in this table reflect the implementation date or, if unavailable, the date the marketing agreement was executed.

printed material directly to approximately 6,000 recipients at independent pharmacies and as being ideal for announcements that require supporting information.

261. McKesson used the RxMail program to promote opioids. For example, in January 2012, McKesson promoted Cephalon's fentanyl drugs, Actiq and Fentora, through direct mail marketing campaigns to more than 400 of its independent pharmacy customers nationally. According to the agreement between McKesson and Cephalon, the estimated cost for Cephalon's RxMail campaign was [redacted]

262. ***Pharmacy Intervention Program.*** Calling it a "flagship" program, McKesson offered its Pharmacy Intervention Program to provide a way for pharmacists to "engage[] patients through a series of face-to-face coaching"[103] focused on promoting patient adherence (i.e., encouraging patients to stay on a drug). McKesson billed the program as providing "[m]anufacturers and pharmacies the opportunity to partner to support patients."[104]

263. Through the program, participating pharmacies received alerts and prompts for the pharmacist to conduct a "behavioral coaching session" for patients when patients came in to fill their prescriptions. Upon confirmation from the pharmacist of a completed coaching session, the pharmacy received a service fee from McKesson.

264. As part of the program, pharmacists pledged to review "branded consultation aid[s]" to ensure that they "communicate the appropriate messages."[105] McKesson also instructed pharmacists to ask "[o]pen-ended questions to uncover the patient's unique barrier(s) to adherence."[106]

[103] MCK-AGMS-069-0003449.
[104] MCK-AGMS-069-0000108.
[105] MCK-AGMS-028-0080256.
[106] MCK-AGMS-028-0083903.

265. McKesson touted the Pharmacy Intervention Program as a proven way to increase patient adherence, thereby increasing revenue to the pharmacy via increased refills of prescriptions and fees received from completed coaching sessions. McKesson stated that the program was "[p]roven effective across multiple therapeutic categories including … **pain management**" (emphasis added).[107]

266. In 2013, Purdue used McKesson's Pharmacy Intervention Program for its opioid drug Butrans, explaining: "One of our 2013 commercial goals for Butrans is to reduce the patient discontinuation rate and increase patient adherence. We believe that we can meet this goal by enlisting pharmacists to help educate patients …."[108]

2. McKesson deceptively marketed opioids.

267. In addition to being an unfair 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.

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

269. For example, McKesson distributed a Fax Blast advertisement to 5,000 pharmacy customers in October and November 2013 for Lortab Elixer, a cough medicine containing an opioid analgesic. The advertisement emphasized that the drug contains the lowest dose of acetaminophen among comparable drugs "which may help **reduce concerns of acetaminophen**

[107] MCK-AGMS-028-0073543.
[108] PVT0001185.

toxicity" (emphasis in original).[109] Yet nowhere does the advertisement mention the risk for addiction and dependence from the opioid ingredient in the drug.

270. McKesson disseminated other advertisements promoting opioids without any mention of the risks, simply providing a link to additional information on the manufacturer's website.

271. Finally, in 2016, McKesson ran an advertisement for Purdue that directed pharmacies to Purdue's now-defunct website, TeamAgainstOpioidAbuse.com. The advertisement—at McKesson's suggestion—purported to be a "public service announcement," and it linked to a Purdue website that is known to have spread misleading information regarding the effectiveness of abuse-deterrent properties of certain opioid formulations.

272. 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. 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. Cardinal and McKesson helped to initiate and facilitate long-term opioid use by disseminating prescription savings cards for these drugs.

273. Cardinal and McKesson also engaged in an unfair business practice by promoting—and in McKesson's case, administering—prescription savings card programs, which encouraged and supported both initiation and long-term use of prescription opioids.

[109] MCK-AGMS-038-0000008; *see also* MCK-AMGS-038-0000006, -7.

274. 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.

275. Cardinal promoted and disseminated savings cards through its marketing programs, including eConnections, Service Flash, and Order Express, offering vouchers and co-payment discounts for opioids. These discounts were sent to all Cardinal's pharmacy customers—including in Vermont. Opioid savings cards and programs that Cardinal promoted included:

Opioid	Manufacturer	Savings Card Offer	Approx. Year
Primlev (oxycodone)	Akrimax	Free, reusable up to 12 times	2011–2012
Lazanda (fentanyl)	Depomed	First 10 bottles free, $5 per bottle thereafter	2013 & 2016
Nucynta (tapentadol)	Depomed	Free, reusable 6 times per year	2015
Nucynta ER (tapentadol)	Depomed	Free, reusable 19 times per year	2015
SUBSYS (fentanyl)	Insys	Free trial and $0 co-payment (redeemable an unlimited number of times until offer expired in Jan. 2015)	Jan. 2014 – Jan. 2015
Hysingla ER (hydrocodone)	Purdue	$0 co-pay trial offer; $100 off	Expired Mar. 2016

276. McKesson administers two programs, LoyaltyScript and TrialScript, that include the use of trial offers, savings cards, or e-coupons. McKesson runs both programs pursuant to contractual agreements with manufacturers, through which discounts are offered on selected opioid drugs. 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.

277. An affiliate of McKesson, RelayHealth Pharmacy Solutions, also administers a similar program, eVoucherRx, which automatically applies at the point of sale the drug manufacturers' discounts for certain opioid drugs without the use of savings cards or e-coupons. Discounts are automatically applied at the point of sale, eliminating the need for patients and pharmacists to submit claims to or through McKesson for reimbursement.

278. In promoting its eVoucherRx program to Allergan (an opioids manufacturer), McKesson explained why savings cards are worth the investment: acquisition (i.e., encouraging patients to start on a drug) and adherence (i.e., encouraging patients to stay on the drug). McKesson also touted the ability to "Target Naïve patients (NEW TO THERAPY)" as they are "most at risk to abandon" therapy and "most vocal to prescriber."[110]

279. The opioids that McKesson promoted through savings-card programs include the following:

Opioid	Manufacturer	Savings Card Offer	Approx. Year
Duragesic (fentanyl)	Janssen	5 free patches (25mcg/hr)	2004
Nucynta & Nucynta ER (tapentadol)	Janssen	$25 copay for 14 prescriptions per year for Nucynta ER and for 3 prescriptions per year of Nucynta, or three vouchers for 10 free pills of Nucynta ER or one voucher for 10 free pills of Nucynta	2011–2012
Butrans (buprenorphine)	Purdue	$0 copay for the first 28 days, or $40 in savings on each prescription.	2011–2013
Hysingla (hydrocodone)	Purdue	$0 co-pay for first prescription, or $100 in savings on each prescription.	2015-2016
OxyContin (oxycodone)	Purdue	$70 in savings on each prescription	2016

280. The savings cards that Defendants promoted and disseminated were intended to—and did—encourage patients to initiate and stay on long-term opioid therapy by making it easier

[110] MCK-AGMS-069-0000091 to -107.

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 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 Vermont Communities.

281. Vermont—like many other states—saw an explosion in opioid prescribing between 1996 and 2008 that has fueled an escalating public health crisis of opioid overuse, misuse, and abuse over the last decade. The effects of this crisis are reverberating through Vermont 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.[111]

282. Despite increased public awareness surrounding the dangers of opioid use and Vermont's own extensive and nationally recognized efforts to reduce overprescribing and to prevent and treat opioid abuse and addiction, opioid sales only began to meaningfully decline in the State very recently, after nearly two decades of unacceptably and unnecessarily high prescribing levels. In 2010, for example, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.[112] In 2015, the number of opioid

[111] Chen, Qiushi, *et al., Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, JAMA Network Open, Feb. 1, 2019.
[112] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

prescriptions increased to 498,973[113]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

283. These high levels of prescription opioid sales reflect more than legitimate medical use. Increased sales and availability of these drugs in Vermont communities have been accompanied by increased abuse and diversion, leading many Vermonters 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.

284. Increased rates of prescription opioid diversion—and the 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 Vermont.

285. 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, 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.

286. 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

[113] *Id.*

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 and McKesson. 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 from minor procedures, like removal of wisdom teeth. The supply of opioids available in communities across Vermont and the United States ballooned.

287. By 2002 to 2003, more than 5% of Vermonters had **misused** prescription pain relievers in the preceding twelve months. Opioid misuse was particularly prevalent among young people: in 2005 to 2006, for example, an estimated 7% of teens (ages 12-17) and 15% of young adults (ages 18-25) had misused prescription pain relievers in the preceding year.

288. These numbers remained consistently high for nearly a decade. In 2010 and 2011, it was still the case that more than 5% of all Vermonters—roughly 30,000 people—had misused prescription opioids within the prior twelve months.

289. Since then, through increased awareness, regulatory efforts, and addiction treatment, the rate of prescription opioid misuse in Vermont has begun to decrease—but not by enough. Many Vermonters 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 inappropriately high levels of opioid sales would lead to increased diversion and harm to public health.

290. Because of their place in the closed system of prescription drug distribution and their significant market share, Cardinal and McKesson were in a unique position to see that an epidemic of prescription opioid overprescribing and diversion was unfolding.

291. Defendants tracked news coverage of the opioid epidemic as early as 2007. Asked at deposition if he understood that "there was an opioid crisis in America in September of 2007," Nick Rausch, who previously served as Cardinal's Director of Regulatory Management and is now a Vice President responsible for manufacturer relationships, responded, "I understood that there were – abuse of opioids was occurring, yes."[114] Similarly, Mark Hartman, formerly in charge of Cardinal's anti-diversion efforts, said of the opioid crisis in America, "I started to become much more informed in understanding this problem in December of 2007."[115]

292. In 2010, Michael Moné, Cardinal's Vice President, Supply Chain Integrity & Senior Regulatory Counsel, Quality & Regulatory Affairs, forwarded an email to a group of Cardinal staff members from the listserv RxNews, discussing an FDA proposal intended to reduce the misuse and abuse of long-acting painkillers like OxyContin. In follow-up emails, Cardinal staff discussed whether distributors should be responsible for ensuring that their pharmacy customers were trained in dispensing drugs known to cause overdose and death. Moné wrote that responsibility should rest with regulators and should not be placed on distributors, and in response, Cardinal's Vice President of Government Relations instructed him to contact Cardinal's trade and lobbying association, HDA, to encourage the organization to respond to the FDA proposal.

[114] Deposition of Nicholas B. Rausch, Nov. 16, 2018, CAH_MULTISTATE_0017218, at 28:10-15.
[115] Deposition of Mark Hartman, Nov. 15, 2018, CAH_MULTISTATE_0016766, at 320:21-322:8.

293. Cardinal personnel continued tracking the development of the opioid epidemic. In 2011, Gilberto Quintero, Cardinal's Senior Vice President, Quality & Regulatory Affairs, saved an article entitled, "As Abuse Mounted, DEA Boosted Painkiller Supply," which reported that a half-billion doses of oxycodone were distributed in 2009 alone, and noted that "the scope of damage wrought by Oxycodone's oversupply in Florida is felt nationwide. The article mentioned the lawsuit West Virginia brought against Purdue Pharma in the early 2000s, highlighting the allegations that Purdue engaged in coercive and deceptive marketing techniques. The article quoted West Virginia's Chief Deputy Attorney General, who said, "We have a black market only because the supply exceeds legitimate demand …."[116]

294. Throughout his tenure as Cardinal's CEO, from 2009 to 2017, and into 2018, George Barrett received emails tracking articles about opioid overdoses and addiction as well as the pharmaceutical industry's role in what one article described as the "trail of addiction and destruction unparalleled in the field of pharmaceutical medicine."[117]

295. Cardinal also knew about the devastating effects that the opioid crisis was having in Vermont in particular. In 2012, Michael Moné received an email from the RxNews listserv reporting on the prescription opioid problem in Vermont and a State Senate committee hearing that was held in response to the crisis.

296. Cardinal was aware that there was a link between increased opioid sales and increased addiction and overdose deaths. In 2013, Robert Giacalone, Cardinal's Chief Regulatory Counsel, received a DEA presentation on prescription drug abuse that showed parallel trends of increasing opioid sales, treatment admissions, and overdose deaths from 1999

[116] CAH_MDL2804_01103324
[117] CAH_MDL2804_03171557-03171563 ("Cardinal Health Morning Wrap Up 06.11.12"); CAH_MDL2804_03179982 (article stating: "Targeting Cardinal Health for the inappropriate sale and use of oxycodone is like blaming the pizza delivery man for obesity," from USA Today, Letter to the Editor, Lee H. Perlman, president, GNYHA Ventures Inc., March 5, 2012).

to 2010. The presentation emphasized the scope of the opioid problem, explaining that for every opioid-related death in 2009, there were 41 emergency department visits for abuse, 148 people abusing the drugs, and 419 non-medical users. In addition, the presentation highlighted the ties between opioid manufacturers and non-profit, patient-advocacy organizations like the American Pain Foundation.

297. Cardinal also tracked and circulated articles internally about the abuse and diversion of specific drugs. For example, in October 2014, personnel from Cardinal's compliance department circulated articles regarding the extensive off-label use of the oral fentanyl spray SUBSYS. While the drug was FDA-approved only for cancer patients, half the prescriptions were being written by general practitioners, dentists, podiatrists, and other non-cancer-treatment providers. Yet, as described in Section III.A *supra*, this did not stop Cardinal from marketing SUBSYS to pharmacists, and [redacted]

298. Both Defendants were aware of Vermont's efforts to restrict prescribing of certain high-risk drugs. For example, in 2014, Vermont put prescribing restrictions in place for Zohydro ER, a hydrocodone drug, only permitting physicians to prescribe Zohydro if they could document that other avenues for treatment had been ineffective for the patient. At the time, Cardinal's Director of Quality and Regulatory Affairs received and forwarded to its Regulatory Counsel an email from HDA noting this new restriction. McKesson—which was also a member of HDA, and would presumably have received the same information—continued to promote Zohydro ER through McKesson Connect, even after Vermont put these stringent restrictions in place.

299. As for McKesson, the company knew of the opioid epidemic as early as 2001. The company admitted in deposition testimony that it knew of the use and abuse of OxyContin during that time.

300. Later, in August 2013, McKesson trained its sales staff on the epidemic of prescription drug abuse, recognizing that "[n]on medical prescription drug use, particularly among young adults, is having a devastating effect on the United States."[118] McKesson also had specific knowledge of the commonly abused drugs, identifying the following: hydrocodone, oxycodone, methadone, morphine, hydromorphone, and oxymorphone.

301. Defendants also utilized sophisticated data visualization and analysis to track exactly how many opioids were being prescribed and sold in every geographic area they serviced, thereby making Defendants aware of the scope of the opioid epidemic and the flow of opioids into communities, including in Vermont. During this same time, the DEA repeatedly told Defendants that their internal controls were insufficient to detect, report, and prevent increasing opioid diversion. *See infra* Section V.A–B.

302. Specifically, Defendants had access to data from IQVIA (previously IMS Health Incorporated and Quintiles) and Symphony Health, which provide data analytics to the healthcare industry.[119] IQVIA has a databank of over "520 million non-identified patient records" and prescription drug data "to state, county, zip code or prescriber granularity."[120] In addition, IQVIA provides services that allow corporations such as Defendants to determine where individual products are sold,[121] "granular prescription performance," and "weekly

[118] MCK-AGMS-069-0001025.
[119] https://www.iqvia.com/about-us; https://symphonyhealth.prahs.com/about/
[120] https://www.iqvia.com/institute/research-support
[121] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information

prescription dispensing" through various proprietary databases, such as DDD, Xponent, and National Prescription Audit.[122]

303. 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."[123]

304. McKesson used IQVIA's data services to prioritize sales efforts. [redacted] In fact, [redacted]

305. In 2014, IQVIA marketed to both Defendants its "Controlled Substance Ratings" tool to help detect and prevent problems with controlled substances. The tool "[c]ombines the most complete, granular, and timely information assets available, "[a]pplies sophisticated statistical methodologies," "[t]racks and reports controlled substance products of interest," "[p]rovides geographic summaries and detailed outlet prescriber views," and "[i]dentifies potential misuse at the pharmacy and prescriber level."[124] The tool used a ratings system for "pharmacies, prescribers and patients based on controlled substance usage patterns across the ***total market***" (emphasis in original) to help identify which of Defendants' pharmacy customers they may want to look into further.[125]

[122] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information
[123] https://symphonyhealth.prahs.com/product/idv/
[124] MCK-AGMS-028-0128169; *see also* MCK-AGMS-028-0045067.
[125] MCK-AGMS-028-0128171, -177.

306. Symphony is cited as a [redacted] In addition, [redacted] Symphony Health provided [redacted]

307. In addition, [redacted]

308. Cardinal likewise [redacted]

309. 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.

310. 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.

311. 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 Vermont communities and to increased diversion. Cardinal and McKesson 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.

312. 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 that, on their face, should have restricted or prohibited such marketing of controlled substances. Cardinal's regulatory compliance personnel even understood—and told marketing personnel—that its marketing efforts were likely to result in increased orders that could trigger the thresholds in its own diversion-prevention system.

However, despite the risks associated with this marketing—which both Defendants appear to have known and understood—they continued to market opioids.

313. 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*.

314. 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 Cardinal and McKesson) to store them in a locked vault with walls, floors, and ceilings made of "at least 8 inches of reinforced concrete;"[126] to transport them with extensive security precautions;[127] and to sell them only to DEA-registered pharmacies whose orders distributors must carefully monitor and investigate (and report to DEA, if suspicious).[128] Defendants knew and accepted the rules when they entered the marketplace to sell these dangerous controlled substances.

315. The resulting harm—to both Vermont 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.

[126] 21 C.F.R. § 1301.72(a)(2)(3)(i).
[127] *See, e.g.*, 21 C.F.R. §§ 1301.74(e) & 1301.77.
[128] *See supra* Part I.

C. Vermont has suffered the devastating effects of widespread prescription opioid diversion.

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

317. This high volume of opioid use and diversion leads to increased incidence of dependence and addiction—a significant public health problem in Vermont. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[129] Vermont ranks as the 8th-highest state for drug dependence nationwide,[130] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states. [131]

318. Opioids have been killing Vermont citizens at skyrocketing rates, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly tripled between 2010 and 2018.[132] While the national average of opioid-related overdose deaths in 2016 was 13.3 per 100,000 persons, the rate in Vermont was 18.4, 38% higher than the national average.[133] And these overdose deaths have a broad impact—in a state like Vermont, there are no anonymous deaths.

319. 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

[129] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.
[130] *Id.*
[131] *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.
[132] 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.
[133] National Institute on Drug Abuse, *Vermont Opioid Summary* (March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

by taking a pill from a prescription bottle belonging to a family member or friend.[134] Prescription opioid users also are 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. The same CDC report shows that **nearly half** (45%) of people who used heroin also were addicted to prescription opioid painkillers.[135] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[136]

320. The heroin/fentanyl problem in Vermont is acute—in 2018, fentanyl was involved in three-fourths of all opiate-related fatalities, and heroin was involved in over half of all opiate-related fatalities.[137] The number of fatal overdoses involving fentanyl in particular has skyrocketed in recent years—a **twentyfold increase** from 4 fatalities in 2010 to 83 fatalities in 2018.[138]

321. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[139] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified **two**

[134] Nora Volkow and Francis Collins, National Institute on Drug Abuse, "*All Scientific Hands On Deck*" *to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").
[135] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.
[136] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief*, April 2017, http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.
[137] *Opioid-Related Fatalities Among Vermonters*, *supra* n.133, at 1.
[138] *Id.* at 2.
[139] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (June, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those **in the 95th percentile (top 5% nationwide) at greatest risk** for outbreaks of HIV and Hepatitis C.[140]

322. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[141] and that 25% percent had received an opioid prescription within 30 days prior to their death.[142]

323. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid prescription during the year prior to their death, the average opioid prescription supply was 261 days.[143]

324. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016, 2017, and 2018), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[144]

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[140] Michelle M. Van Handel *et al.*, *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

[141] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[142] *Id.*

[143] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www.healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[144] *Opioid-Related Fatalities Among Vermonters, supra* n.133, at 2.

325. Opioid use disorder in pregnant women has become prevalent in Vermont as opioid use has proliferated more broadly, with potentially devastating health consequences for women and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over **seven times** the national average, and the highest among the 30 states that have compiled this data.[145] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[146]

326. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was **five times higher** than the national average, and the Vermont statistics have continued to rise.[147]

327. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had **more than doubled** to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[148]

328. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress,

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[145] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1 htm?s_cid=mm6731a1_e, at 847.
[146] *Id.* at 845.
[147] *Opioids in Vermont: Prevalence, Risk, and Impact*, *supra* n.144, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").
[148] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[149]

329. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2 times longer and nearly 3 times more expensive, averaging 7.4 days and $15,456 (respectively).[150]

330. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[151] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012 to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[152]

331. Moreover, Vermont's efforts to prevent and treat opioid addiction, and to reduce the overall impact of the opioid epidemic on its citizens, have come at a significant cost to the State.

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[149] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome and Associated Health Care Expenditures,* Journal of the American Medical Association (2012), https://www ncbi nlm.nih.gov/pubmed/ 22546608.
[150] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont, supra* n.149, at 2.
[151] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www.healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3 n.1.
[152] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

332. The demand for opioid addiction treatment has risen dramatically. In 2006, 1,897 Vermonters were treated for opioid use in state-funded treatment facilities. By 2015, that number had **more than tripled**, to 6,084.[153]

333. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[154] From 2007 to 2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

334. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[155] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

335. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population.[156] For example, overall health care costs are approximately 3 times higher among patients receiving Medication Assisted Treatment for opioid addiction than is true for the general Medicaid population. The average national private payer cost per person with opioid use disorder was $63,356 (in 2015).[157]

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[153] Vermont Department of Health, *People Treated for Opiate Use in Vermont by Fiscal Year*, http://www.healthvermont.gov/sites/default/files/documents/2016/12/adap_TotalOpiatebyFY.pdf.
[154] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.
[155] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts – Health Reform Oversight Committee* (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 22.
[156] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.
[157] *Status of Opioid Treatment Efforts, supra* n.156.

336. The prevalence of opioids in Vermont also places a greater burden on law enforcement—increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

337. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with prescription drugs—chiefly robbery and burglary—have risen.[158] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day. In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

V. Defendants Fraudulently Concealed Their Unlawful Conduct.

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

A. Cardinal concealed its failure to comply with its duty to prevent diversion.

339. 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:

[158] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont*, at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

> 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.[159]

340. 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 "[m]aintain 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 cancelled and reported to the DEA, and "[r]eview distributions of [opioids] to retail pharmacy customers and physicians" and identify and investigate any customer that has exceeded Cardinal's distribution thresholds.[160]

341. 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."[161]

342. 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

[159] New York Office of the Attorney General Assurance of Discontinuance (Dec. 26, 2006) at 14, https://ag.ny.gov/sites/default/files/press-releases/archived/Assurance%20of%20Discontinuance.pdf.
[160] Settlement and Release Agreement and Administrative Memorandum of Agreement, Sept. 30, 2008, CAH_MDL2804_01444908 at 3–5.
[161] Press Release, Cardinal Health Resolves Controlled Substance License Suspension (Oct. 2, 2008), https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122576.

substances as required under the CSA and applicable DEA regulations."[162] 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."[163]

343. 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.[164]

344. Cardinal wrote that it "spent millions of dollars" to build its monitoring system,[165] and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[166]

345. In a 2017 document published to shareholders, Cardinal acknowledged its role in "maintaining a vigorous program to prevent opioid pain medications from being diverted to improper uses."[167] During an earnings call that same year, George Barrett, Cardinal's Chairman

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[162] Administrative Mem. of Agreement between DEA and Cardinal at 3, CAH_MDL2804_02465982.
[163] *Id.*
[164] Press Release, Cardinal Health Inc. Seeks Restraining Order to Avoid Disruption in Controlled Medicine Shipments from Florida (Feb. 3, 2012), https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122803.
[165] Press Release, Cardinal Health Statement in Response to Preliminary Injunction Hearing: February 29, 2012, https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122811.
[166] Bernstein, Lenny, *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: No One Was Doing Their Job*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story html?utm_term=.b5b04da86c80.
[167] Cardinal Health Proxy, Form 14A at 9 (filed Oct. 23, 2017).

and then-CEO, vowed to "operate a very strong, robust, suspicious order monitoring system and process that not only meets [] regulatory requirements," but also "exceeds what is required of distributors."[168]

346. 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 the 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."[169]

347. To this day, Cardinal continues to publicly portray itself as "committed to fighting opioid addiction and misuse."[170] Cardinal's website holds the company out as an "industry leader" that uses "constantly adaptive, rigorous systems supported by program specialists who monitor and investigate suspicious orders using advanced analytics and other tools."[171]

348. 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.

B. McKesson concealed its failure to comply with its duty to prevent diversion.

349. 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

[168] Cardinal Health Quarterly Earnings Call Tr. at 22 (Aug. 2, 2017).
[169] Cardinal Health Quarterly Earnings Call Tr. at 4–5 (Nov. 6, 2017).
[170] Cardinal, Cardinal Health Opioid Action Program, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/opioid-action-program html (last visited Feb. 24, 2019).
[171] Cardinal, Addressing the Opioid Crisis, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance/board-engagement-and-governance.html (last visited Feb. 24, 2019).

[its] responsibility to maintain the integrity of the pharmaceutical supply chain and consumer and patient safety."[172]

350. 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."[173] McKesson also vowed to "follow the procedures established by its Controlled Substance Monitoring Program."[174]

351. 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."[175] And McKesson claimed it is "deeply passionate about curbing the opioid epidemic in our country."[176]

352. 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

[172] McKesson Corporate Citizenship Report 2005, https://www.slideshare net/finance2/mckesson-corporate-citizenship-report-74m-2005.
[173] Settlement and Release Agreement and Administrative Mem. of Agreement at 3–4 (May 2, 2008), https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf.
[174] Administrative Mem. of Agreement between McKesson and DEA at 3 (Jan. 17, 2017); https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202017_0.pdf.
[175] Higham, Scott, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story html?utm_term=.b40d6961d1df.
[176] Higham, Scott, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story html?utm_term=.b40d6961d1df.

supply chain."[177] 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."[178]

353. 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."[179] 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.

354. 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 cutting-edge controlled substances threshold management program, using complex and dynamic data analytics."[180]

355. 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.

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[177] Morgenson, Gretchen, *Hard Questions for a Company at the Center of the Opioid Crisis*, NY Times (July 21, 2017), https://www nytimes.com/2017/07/21/business/mckesson-opioid-packaging.html.
[178] *McKesson Announces Preliminary Voting Results From 2017 Annual Meeting of Stockholders* (July 26, 2017), https://www.businesswire.com/news/home/20170726005746/en/.
[179] Administrative Mem. of Agreement at 5 (Jan. 17, 2017), https://www.justice.gov/usao-nj/press-release/file/928636/download.
[180] McKesson's Controlled Substance Monitoring Program, https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/controlled-substance-monitoring-program (last visited Feb. 24, 2019).

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

356. 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."[181] However, as detailed in Section III.A.1 *supra*, Cardinal has worked for years to drive increased demand for opioids through its marketing programs.

357. 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.

358. 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."[182] The State now knows this to be deceptive. As discussed in Section III.B *supra*, 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

[181] Testimony of George S. Barrett, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, May 8, 2018.
[182] Testimony of John Hammergren, Chairman, President, and Chief Executive Officer McKesson Corporation, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, May 8, 2018.

order.[183] However, McKesson has, in the past, auto-shipped opioids to pharmacies, through one of its marketing programs, as detailed in Section III.B.1.

359. 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."[184]

360. 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 Vermont from discovering facts essential to its claims.

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

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

362. 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 $19.17 million and McKesson spent $17.27 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.[185]

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[183] *Id.*
[184] HDA Press Release, *HDA Statement On Attorneys General Opioid Investigations*, Sept. 19, 2017, https://www.prnewswire.com/news-releases/hda-statement-on-attorneys-general-opioid-investigations-300522358.html
[185] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowedenforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.e2d89d4ccd07.

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

364. 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.

365. 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. 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 Supply Chain Solutions at McKesson.

366. Cardinal senior executives also have served as HDA leaders. While employed as CEO of Cardinal's Medical 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.

367. In addition to maintaining leadership positions in HDA, Defendants made significant financial contributions to the association. In 2017 alone, McKesson paid about [redacted] to HDA for dues and other expenses. McKesson increased that contribution to [redacted] the following year due to additional advertising and public affairs expenses. Also in 2017,

Cardinal and McKesson each contributed $1,161,667 for HDA's Education and Communications Campaign.

368. Part of HDA's stated mission was to prevent "onerous legislation from being enacted"—legislation that could have brought Defendants' misconduct to light much sooner. McKesson's VP of Federal Government Affairs, Joseph Ganley, admitted that controlled substance lobbying was the top priority of HDA's Federal and State Affairs Committee. Mr. Ganley admitted: "State efforts to address, reduce, prevent Rx abuse and diversion" is the primary challenge for HDA.[186]

369. Not surprisingly then, by 2014, HDA had a state government affairs budget of almost $1 million, with an additional budget of $235,000 for contract lobbyists. HDA also had an employee assigned to every single state.

370. 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 and McKesson "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."[187]

371. 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."[188] The court rejected HDA's arguments. *Id.* at 222–223.

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[186] Deposition of Joseph Ganley, July 27, 2018, MCK-AGMS-032-0000550 at 118-119; MCK-AGMS-032-0000878 at 4.
[187] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), 2016 WL 1321983 at *25.
[188] *Id.* at *26.

372. 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 that spent more than $880 million from 2006 through 2015 on campaign contributions and lobbying expenses at the state and federal level in an effort to increase the flow of dangerous opioids to consumers. From 2007 to 2014, the number of registered lobbyists in Vermont employed by members of the Pain Care Forum ranged from 16 to 29.

373. The Pain Care Forum lobbied both state and federal governments to prevent restrictions on opioid prescribing. For example, the group paid a PR consultant to draft patient testimonials to encourage the state medical boards 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.

374. Through these efforts, Cardinal and McKesson 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 I
Unfair Acts and Practices
Violations of the Vermont Consumer Protection Act

375. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint, as though fully set forth herein.

376. Defendants engaged in unfair acts or practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by:

- Transporting and selling opioids in the State of Vermont 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/or for the benefit of pharmacy customers, and failing to require adequate investigations of 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 Vermont, 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;
- Disseminating advertising and promotional messages in the State of Vermont 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; and
- Promoting the initiation of opioid use and/or long-term continuation of opioid use by providing Savings Cards to reduce patients' out-of-pocket expense for these drugs.

377. These acts or practices may be deemed "unfair" in that they offend public policy reflected in (a) established legal standards that require the truthful and balanced marketing of

prescription drugs; and (b) Vermont 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* 20-4 Vt. Code R. § 1400, Part 17; the Controlled Substances Act, 21 U.S.C. § 801, *et seq*., and its implementing regulations.

378. These acts or practices were unfair because 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 Vermont communities than were reasonably necessary to meet legitimate demand for medical use. However, their financial interests were best served by (1) increasing sales of these expensive and profitable drugs, and (2) 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 immoral, unethical, oppressive, and unscrupulous.

379. By reason of Defendants' conduct, Vermont 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.

COUNT II
Deceptive Acts and Practices
Violations of the Vermont Consumer Protection Act

380. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint, as though fully set forth herein.

381. Defendants engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by making material misrepresentations and omissions regarding the risks and benefits of its opioid products, including by:

- Making and disseminating false or misleading statements about the benefits, risks, and diversion-potential of opioids; and
- Making statements to promote the use of opioids that omitted or concealed material facts, including the risks of diversion and misuse, dependence, addiction, overdose, and death associated with these drugs.

382. Defendants' material omissions rendered even seemingly truthful or neutral statements about opioids false and misleading, because they were materially incomplete. At the time Defendants made these statements and disseminated these promotional materials, Defendants failed to include material facts about the risks and benefits of opioid use and failed to provide "fair balance," as required by law.

383. These misrepresentations and omissions were likely to mislead the prescribers and pharmacists to whom they were directed, affecting their decisions regarding the prescribing, dispensing, and use of opioids. The meaning Plaintiff ascribes to Defendants' misrepresentations herein is reasonable, given the nature thereof.

COUNT III
Negligence

384. The State incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

385. Defendants have a duty under the common law of Vermont to exercise the degree of care that a reasonably prudent person would under the circumstances. The scope of this common law duty of ordinary care expands according to the foreseeability of the consequences of a defendant's acts or omissions.

386. Defendants distribute large quantities of addictive prescription opioid narcotics, which have been designated as controlled substances under state and federal law. It is foreseeable that Defendants' failure to design and operate effective controls to monitor, identify, report, and prevent the fulfillment of suspicious orders of prescription opioids would create a risk of abuse, misuse, and injury to the State and its citizens. The very purpose of state and federal laws regulating Defendants' activities is to prevent the abuse of controlled substances and to prevent the diversion of those substances. Thus, Defendants have a common law duty to prevent the diversion of controlled substances into illegitimate channels.

387. This common law duty of care is fully supported by and incorporates 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. 26 V.S.A. § 2068; 20-4 Vt. Code R. § 1400:17.25 (incorporating the security requirement set forth under federal law).

388. State laws regulating the distribution of controlled substances are "safety statutes" under Vermont law, the violation of which gives rise to a rebuttable presumption of negligence.

389. Defendants breached their common law and 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 and/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.

390. Defendants' breach of their duties fueled the widespread circulation of opioids into illegitimate channels in Vermont. The structure of Vermont's controlled substances regulations—and of the federal regulations incorporated by Vermont 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. Had Defendants effectively carried out their duties, opioid abuse, misuse, diversion, and addiction would not have become so widespread in Vermont, and the costs borne by the State in addressing and abating the opioid epidemic would have been averted or much less severe.

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

392. 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 IV
Public Nuisance

393. The State incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

394. Defendants, through their actions described throughout the Complaint, have created—or were a substantial factor in creating—a public nuisance by unreasonably interfering with a right that is common to the general public.

395. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Defendants' actions and omissions.

396. Defendants have interfered with the above enumerated right by creating a long-lasting and continuing public nuisance through distributing prescription opioids that they knew,