ineffective anti-diversion program, violating its legal duties and resulting in increasing and undetected diversion of opioids.

1. Cardinal understaffed its anti-diversion department.

99. Wholesale distributors of controlled substances have a duty under Vermont common law, statutes, and regulations to "employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs." 20-4 Vt. Code R. § 1400:17.5. Cardinal breached that duty by failing to staff enough well-trained individuals on its anti-diversion team.

100. Despite having 25,000 to 30,000 distinct pharmacy customers that order controlled substances nationwide—approximately 20,000 of which order opioid drugs—Cardinal employed only **two people** devoted to anti-diversion prior to 2007. Following the DEA's 2007 enforcement action against Cardinal, it increased the anti-diversion group, initially hiring 24 compliance officers. These compliance officers, however, were not responsible for analyzing threshold events or investigating pharmacies, but instead were tasked with "various compliance measures" that applied specifically to distribution centers, including spending significant time submitting licensing renewal applications and hosting regulatory inspections. By 2014, there were only around 14 employees responsible for these compliance functions.

101. Cardinal's failure to staff a sufficient number of properly trained investigators prevented it from conducting necessary investigations of its pharmacy customers. [redacted] Although Cardinal conducts approximately 20,000 surveillance visits per year nationwide, [redacted]

[redacted]

102. [redacted]

103. These staffing failures have had real-world consequences in Vermont. Cardinal's internal documents confirm that, [redacted] Vermont retail pharmacy customers that had placed orders for controlled substances. [redacted] in Chittenden County, Vermont and [redacted] in Franklin County, Vermont [redacted] Vermont [redacted]

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

104. Cardinal has admitted that it did not report all suspicious orders of controlled substances to the DEA. For example, from approximately December 2007 through 2012, Cardinal only reported orders that were so egregious that they led Cardinal to terminate a pharmacy's ability to order controlled substances altogether. Under this system, Cardinal's Massachusetts distribution center, which services Vermont, reported **zero** suspicious orders of opioid drugs in the more than two-year period from October 1, 2008 to December 8, 2010.

During that two-year period, Cardinal filled more than 58,000 opioid orders in Vermont, amounting to over 16.3 million dosage units. In fiscal year 2011, Cardinal reported just 47 total suspicious orders to the DEA from its 24 distribution centers **nationwide**. That same year, Vermont's opioid-related overdose death rate reached 9.1 deaths per 100,000 persons, nearly triple the rate it had been in 2000; that rate has since doubled again, rising to 18.4 deaths per 100,000 persons in 2016, the most recent year for which data are available.[41]

105. On several occasions, Cardinal shipped suspicious opioid orders to Vermont pharmacies without conducting any investigation and without reporting the suspicious orders to the DEA in direct violation of its duty under Vermont law. For example, [redacted] Lamoille County, Vermont, [redacted] In violation of Cardinal's duty, this notation provides no indication of whether Cardinal visited or otherwise contacted the pharmacy to inquire about these orders; whether the pharmacy provided any response that would justify the threshold events; or whether Cardinal engaged in any form of investigation whatsoever to ensure the legitimacy of these orders.

106. [redacted] Franklin County, Vermont [redacted]

[41] NIDA, Vermont Opioid Summary (Revised March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary (Filesite # 2471068)

[redacted][42][redacted][43][redacted] The cursory notations contained in these files similarly provide no indication that Cardinal ever conducted any form of investigation to determine the legitimacy of the orders, as required under Vermont law.

107. In some cases, Cardinal responded to an order that exceeded a threshold by improperly and [redacted] Cardinal increased these threshold levels with little or no documentation indicating that any investigation had been conducted to justify the threshold increases or to ensure the legitimacy of the orders.

108. For example, in [redacted], Cardinal's monitoring system [redacted] Chittenden County, Vermont [redacted]

[42] CAH_MULTISTATE_0008706.
[43] CAH_MDL2804_00539890

[redacted]

[redacted][44] These notations are conclusory; they provide no indication of whether Cardinal contacted the pharmacy, received a response, or engaged in any other manner of investigation to ensure the legitimacy of the order or the need for a threshold increase, in violation of Cardinal's duty under the law.

109. In other instances, when an order would have exceeded a threshold, [redacted] Although these pharmacies raised red flags by placing orders exceeding their thresholds, Cardinal did not document any investigation into the legitimacy of these orders and did not report these orders to the DEA.

110. For example, [redacted] Rutland County, Vermont [redacted]

[44] CAH_MULTISTATE_0008706.

[redacted]

111. Cardinal's failure to report or sufficiently investigate these orders is particularly egregious considering this pharmacy's pattern of placing suspicious orders for controlled substances. [redacted]

112. [redacted][45] [redacted]

[45] CAH_MDL2804_00551310.

[redacted]

113. In some instances, Cardinal's failure to report suspicious orders resulted from negligent management of its IT systems. For example, during the three-year period spanning 2012 to 2015, Cardinal's monitoring system suffered from what one executive described as "an IT glitch." That "glitch" resulted in Cardinal failing to report 14,128 separate suspicious orders that had been placed by pharmacies across the country, the vast majority of which involved orders for prescription opioids. These included orders placed at Cardinal distribution facilities registered to distribute controlled substances in Vermont, including Cardinal's Massachusetts distribution center. Cardinal did not inform the DEA of this "glitch" until 2018, at which point it claimed, without evidentiary support, that the orders were not filled.[46]

114. In all, an initial review of data derived from Cardinal's suspicious order monitoring system indicates that, from 2011 to 2017, in at least 40% of the instances in which a prescription opioid order from a Vermont pharmacy exceeded the pharmacy's threshold, Cardinal filled the order without reporting it to the DEA and/or without conducting a diligent investigation.

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

115. On several occasions, Cardinal violated its duty under Vermont law by cancelling (also referred to as "cutting") an order that exceeded a threshold and allowing the pharmacy to place a subsequent, often smaller order for the same drug family (that would not trigger a threshold event). [redacted]

[46] CAH_MDL2804_02101802.

[redacted]

116. [redacted]

117. Cardinal engaged in this practice in Vermont. For example, [redacted] in Rutland County, Vermont [redacted]

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

118. Cardinal did not independently investigate potentially suspicious orders by "chain pharmacies"—retail pharmacies owned by a common parent company and operating under the same name with multiple locations. Instead, when a chain pharmacy hit a threshold, Cardinal merely asked the chain pharmacy's corporate headquarters for an explanation. Cardinal relied

entirely on the corporate office's response, conducted no investigation of its own, and did not even make contact with the individual pharmacy in the chain that placed the potentially suspicious order.

119. Cardinal cannot abdicate its anti-diversion duties by delegating them to another player in the opioid distribution chain. To the contrary, Cardinal's duty to prevent diversion exists regardless of whether its customers are small, independent pharmacies or part of a large chain. As early as 2009, the DEA specifically admonished Cardinal for treating chain pharmacies differently from independent pharmacies. During a DEA review of Cardinal's Massachusetts distribution center, which ships prescription opioids into Vermont, Cardinal was unable to produce any diligence files for its chain pharmacy customers. When the DEA pressed Cardinal for the reason no diligence files existed for these pharmacies, Cardinal admitted that it was because the investigation of suspicious orders was delegated to the chain pharmacy's corporate headquarters and that Cardinal did not undertake any independent investigation of the conduct. The DEA told them at the time that "due diligence investigations must be performed on all customers, chain pharmacies included," and that those due diligence responsibilities included site visits.[47]

120. Since at least 2009 through approximately 2012, Cardinal continued to exempt its chain pharmacy customers from Cardinal's monitoring programs and instead relied on them to investigate and report their own suspicious activity. In doing so, Cardinal abdicated one of its core legal duties, and improperly relied on chain pharmacies to investigate and report their own suspicious activity—something that creates an obvious conflict and is improper on its face.

[47] Decl. of Joseph Rannazzisi, Deputy Administrator, DEA ¶ 59 (Feb. 10, 2012), filed in *Cardinal Health v. Holder*, 12-cv-00185-RBW (D.D.C.) (Dkt. No. 14-2).

121. In instances where a chain pharmacy placed an order that resulted in a threshold event, Cardinal's policy was **not** to conduct a site visit and **not** to contact the specific pharmacy that had placed the potentially-suspicious order. Instead, Cardinal's protocol was to contact only the corporate headquarters of the pharmacy chain and then permit the chain's headquarters to supply information about the held order without Cardinal taking steps to independently verify the information provided by the pharmacy's corporate headquarters.

122. Cardinal's internal policies even permitted **permanent threshold increases** for a specific pharmacy based solely on the explanation proffered provided by the pharmacy's corporate headquarters. Prior to May 14, 2012, Cardinal failed to conduct **any** site visits at any of its large chain pharmacy customers.

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

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

Cardinal was able to appease its largest customers and continue shipping excessive quantities of opioids into 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.