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.