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. Cardinal Health admits that wholesale distributors are part of the distribution chain for prescription medications, but denies the remaining allegations contained in Paragraph 290 of the Complaint as alleged against Cardinal Health.

291. Cardinal Health admits that footnotes 114 and 115 of the Complaint reference the deposition testimony of Nicholas B. Rausch and Mark Hartman, respectively, but denies any attempt by Plaintiff to characterize the testimony or selectively quote from the testimony. Cardinal Health denies the remaining allegations contained in Paragraph 291 of the Complaint.

292. Cardinal Health admits that it is a member of the Healthcare Distribution Alliance. The remaining allegations in Paragraph 292 of the Complaint do not indicate the source of the information alleged therein, and Cardinal Health accordingly denies the allegations.

293. Cardinal Health admits that footnote 116 of the Complaint references documents from Cardinal Health's MDL production, but denies Plaintiff's attempt to characterize or selectively quote from those documents, and respectfully refers the Court to the cited documents for the true and correct contents. Cardinal Health denies the remaining allegations contained in Paragraph 293 of the Complaint.

294. Cardinal Health admits that footnote 117 of the Complaint references documents from Cardinal Health's MDL production, but denies Plaintiff's attempt to characterize or selectively quote from those documents, and respectfully refers the Court to the cited documents for the true and correct contents. Cardinal Health denies the remaining allegations contained in Paragraph 294 of the Complaint.

295. The allegations contained in Paragraph 295 of the Complaint do not indicate the source of the information alleged therein, and accordingly Cardinal Health denies the allegations.

296. The allegations contained in Paragraph 296 of the Complaint do not indicate the source of the information alleged therein, and accordingly Cardinal Health denies the allegations.

297. The allegations contained in Paragraph 297 of the Complaint do not indicate the source of the information alleged therein, and accordingly Cardinal Health denies the allegations.

298. The allegations contained in Paragraph 298 of the Complaint do not indicate the source of the information alleged therein, and accordingly Cardinal Health denies the allegations as alleged against Cardinal Health.

299. The allegations of Paragraph 299 of the Complaint are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

300. The allegations of Paragraph 300 of the Complaint are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

301. Cardinal Health denies the allegations contained in Paragraph 301 of the Complaint as alleged against Cardinal Health.

302. Cardinal Health admits that the material cited in footnotes 119-122 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health admits that IQVIA and Symphony Health make limited data available, which Cardinal Health has, at times, accessed. Cardinal Health denies the remaining allegations in Paragraph 302 of the Complaint as alleged against Cardinal Health.

303. The material cited in footnote 123 of the Complaint does not appear at the link cited therein and as such Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 303 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

304. The allegations of Paragraph 304 of the Complaint are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

305. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 305 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

306. The allegations of Paragraph 306 of the Complaint are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

307. The allegations of Paragraph 307 of the Complaint are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

308. Cardinal Health denies the allegations contained in Paragraph 308 of the Complaint.

309. Cardinal Health denies the allegations contained in Paragraph 309 of the Complaint as alleged against Cardinal Health.

310. The allegations contained in Paragraph 310 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

311. The allegations contained in Paragraph 311 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations alleged against Cardinal Health.

312. The allegations contained in Paragraph 312 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

313. The allegations contained in Paragraph 313 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

314. Cardinal Health admits that wholesale distributors are part of the distribution chain for prescription medications and, as such, have certain legal obligations pursuant to state and federal law. The nature of those obligations is a legal question that does not require any response. The remaining allegations contained in Paragraph 314 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

315. The allegations contained in Paragraph 315 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

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

316. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 316 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

317. The materials cited in footnotes 129-131 of the Complaint do not appear at the web address listed therein, and as such, Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 317 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

318. Cardinal Health admits that the materials cited in footnotes 132 and 133 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations

contained in Paragraph 318 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

319. Cardinal Health admits that the materials cited in footnotes 134-136 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 319 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

320. Cardinal Health admits that the materials cited in footnotes 137 and 138 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 320 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

321. The materials cited in footnote 139 of the Complaint do not appear at the web address listed therein. Cardinal Health admits that the materials cited in footnote 140 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 321 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

322. Cardinal Health admits that the materials cited in footnotes 141 and 142 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 322 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

323. Cardinal Health admits that the materials cited in footnote 143 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 323 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

324. Cardinal Health admits that the materials cited in footnote 144 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 324 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

325. Cardinal Health admits that the materials cited in footnotes 145 and 146 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 325 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

326. Cardinal Health admits that the materials cited in footnote 147 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 326 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

327. Cardinal Health admits that the materials cited in footnote 148 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in

Paragraph 327 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

328. Cardinal Health admits that the materials cited in footnote 149 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 328 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

329. Cardinal Health admits that the materials cited in footnote 150 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 329 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

330. Cardinal Health admits that the materials cited in footnotes 151 and 152 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 330 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

331. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 331 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

332. Cardinal Health admits that the materials cited in footnote 153 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in

Paragraph 332 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

333. The materials cited in footnote 154 of the Complaint do not appear at the web address listed therein and Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 333 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

334. Cardinal Health admits that the materials cited in footnote 155 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 334 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

335. Cardinal Health admits that the materials cited in footnotes 156 and 157 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 335 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

336. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 336 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

337. The materials cited in footnote 158 of the Complaint do not appear at the web address listed therein and Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 337 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

V. Defendants Fraudulently Concealed Their Unlawful Conduct.

338. The allegations contained in Paragraph 338 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

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

339. Cardinal Health admits that the materials cited in footnote 159 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health admits that it and its subsidiaries reached a settlement agreement in 2006 under which Cardinal Health paid $11 million but denies Plaintiff's characterizations of those events and the settlement agreement. The settlement agreement speaks for itself, and Cardinal Health denies any attempt by Plaintiff to characterize the settlement. Cardinal Health denies the remaining allegations in Paragraph 339 of the Complaint.

340. Cardinal Health admits that it entered into a Settlement and Release Agreement and Administrative Memorandum of Understanding in 2008 pursuant to which Cardinal Health agreed to pay $34 million, but denies Plaintiff's characterizations those documents and cited materials in footnote 160, which speak for themselves. Cardinal Health denies the remaining allegations in Paragraph 340 of the Complaint.

341. Cardinal Health admits that the materials cited in footnote 161 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health denies the remaining allegations in Paragraph 341 of the Complaint.

342. Cardinal Health admits that the DEA issued an Order to Show Cause and Immediate Suspension Order to Cardinal Health with respect to its Lakeland, Florida Distribution Center on February 2, 2012, but denies Plaintiff's characterization of those documents, which speak for

themselves. Cardinal Health denies the remaining allegations contained in Paragraph 342 of the Complaint.

343. Cardinal Health admits that the materials cited in footnote 164 of the Complaint appear at the web address cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health denies the remaining allegations in Paragraph 343 of the Complaint.

344. Cardinal Health admits that the materials cited in footnotes 165 and 166 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health denies the remaining allegations in Paragraph 344 of the Complaint

345. The materials cited in footnotes 167 and 168 of the Complaint speak for themselves and Cardinal Health denies any attempt by Plaintiff to characterize them. Cardinal Health denies the remaining allegations contained in Paragraph 345 of the Complaint as alleged against Cardinal Health.

346. The materials cited in footnote 169 of the Complaint speak for themselves and Cardinal Health denies any attempt by Plaintiff to characterize them. Cardinal Health denies the remaining allegations contained in Paragraph 346 of the Complaint as alleged against Cardinal Health.

347. Cardinal Health admits that the materials cited in footnotes 170 and 171 of the Complaint appear at the web addresses cited therein, but denies Plaintiff's characterization of those materials. Cardinal Health denies the remaining allegations in Paragraph 347 of the Complaint.

348. The allegations contained in Paragraph 348 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations.

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

349. The allegations of Paragraph 349 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

350. The allegations of Paragraph 350 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

351. The allegations of Paragraph 351 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

352. The allegations of Paragraph 352 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

353. The allegations of Paragraph 353 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

354. The allegations of Paragraph 354 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

355. The allegations of Paragraph 355 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

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

356. The materials cited in footnote 181 of the Complaint speak for themselves and Cardinal Health denies any attempt by Plaintiff to characterize them. Cardinal Health denies the remaining allegations contained in Paragraph 356 of the Complaint as alleged against Cardinal Health.

357. Cardinal Health denies the allegations contained in Paragraph 357 of the Complaint.

358. The allegations of Paragraph 358 are not directed at Cardinal Health, and therefore no response is required by Cardinal Health.

359. Cardinal Health admits that it is a member of the Healthcare Distribution Alliance. Cardinal Health also admits that the materials cited in footnote 184 of the Complaint appear at the web address listed therein, but denies Plaintiff's characterization of those materials. Cardinal Health denies the remaining allegations contained in Paragraph 359 of the Complaint, as alleged against Cardinal Health.

360. The allegations contained in Paragraph 360 of the Complaint state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

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

361. Cardinal Health denies the allegations contained in Paragraph 361 of the Complaint as alleged against Cardinal Health.

362. Cardinal Health admits that the materials cited in footnote 185 of the Complaint appear at the web address listed therein, but denies Plaintiff's characterization of those materials. Cardinal Health denies the remaining allegations contained in Paragraph 362 of the Complaint, as alleged against Cardinal Health.

363. Cardinal Health admits that it is a member of the Healthcare Distribution Alliance and other trade associations. Cardinal Health denies the remaining allegations contained in Paragraph 363 of the Complaint, as alleged against Cardinal Health.

364. Cardinal Health admits that it is a member of the Healthcare Distribution Alliance but denies the remaining allegations contained in Paragraph 364 of the Complaint, as alleged against Cardinal Health.

365. Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 365 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations.

366. Cardinal Health admits that it is a member of the Healthcare Distribution Alliance. Cardinal Health admits Jon Giacomin was employed as CEO of Cardinal Health's Pharmaceutical Segment from November 2014 to February 2018, and as CEO of Cardinal Health's Medical Segment from February 2018 to August 2019. Cardinal Health admits that Jon Giacomin served as Vice Chairman of the HDA Board of Directors from November 2014 to September 2016, and as Chairman of the HDA Board of Directors from September 2016 to September 2018. Cardinal Health admits that Craig Cowman is employed as the Executive Vice President, Global Sourcing, and currently serves on the HDA Research Foundation's Board of Directors. Cardinal Health admits that Mike Kaufmann is currently the CEO of Cardinal Health, and a former member of the executive committee of HDA.

367. Cardinal Health admits that it is a member of the Healthcare Distribution Alliance. Cardinal Health admits that, in 2017, it agreed to be assessed $1,161,667 to fund HDA's Education and Communications Campaign.

368. The materials cited in footnote 186 of the Complaint speak for themselves and Cardinal Health denies any attempt by Plaintiff to characterize them or selectively quote from them. Cardinal Health otherwise denies the allegations in Paragraph 368 of the Complaint.

369. The allegations in Paragraph 369 are not directed at Cardinal Health, and therefore no response is required. If a response is required, Cardinal Health is without adequate knowledge to admit or deny the allegations, and therefore denies the allegations.

370. The materials cited in footnote 187 of the Complaint speak for themselves and Cardinal Health denies any attempt by Plaintiff to characterize them.

371. The materials cited in footnote 188 of the Complaint speak for themselves and Cardinal Health denies any attempt by Plaintiff to characterize them.

372. The allegations in Paragraph 372 are not directed at Cardinal Health, and therefore no response is required. If a response is required, Cardinal Health is without adequate knowledge to admit or deny the allegations contained in Paragraph 372 of the Complaint as alleged against Cardinal Health, and therefore denies the allegations

373. The allegations in Paragraph 372 are not directed at Cardinal Health, and therefore no response is required.

374. Cardinal Health denies the allegations contained in Paragraph 374 of the Complaint as alleged against Cardinal Health.

CAUSES OF ACTION

COUNT I
Unfair Acts and Practices
Violations of the Vermont Consumer Protection Act

375. Cardinal Health incorporates by reference its responses to all other paragraph of this Complaint as if fully set forth herein.

376. The allegations contained in Paragraph 376 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 376 of the Complaint as alleged against Cardinal Health.

377. The allegations contained in Paragraph 377 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 377 of the Complaint as alleged against Cardinal Health.

378. The allegations contained in Paragraph 378 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 378 of the Complaint as alleged against Cardinal Health.

379. The allegations contained in Paragraph 379 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 379 of the Complaint as alleged against Cardinal Health

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

380. Cardinal Health incorporates by reference its responses to all other paragraphs of this Complaint as if fully set forth herein.

381. The allegations contained in Paragraph 381 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 381 of the Complaint as alleged against Cardinal Health.

382. The allegations contained in Paragraph 382 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 382 of the Complaint as alleged against Cardinal Health.

383. The allegations contained in Paragraph 383 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 383 of the Complaint as alleged against Cardinal Health.

COUNT III
Negligence

384. Cardinal Health incorporates by reference its responses to all other paragraphs of this Complaint as if fully set forth herein.

385. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 385 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

386. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 386 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

387. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 387 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

388. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 388 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

389. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 389 pertain to Plaintiff's dismissed negligence claim, no response is

required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

390. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 390 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

391. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 391 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

392. The Court has dismissed Plaintiff's negligence claim. *See State of Vermont v. Cardinal Health Inc., & McKesson Corp.*, Dkt. 279-3-19 Cncv (May 12, 2020). Because the allegations in Paragraph 392 pertain to Plaintiff's dismissed negligence claim, no response is required. To the extent a response is required, Cardinal Health denies the allegations as alleged against Cardinal Health.

COUNT IV
Public Nuisance

393. Cardinal Health incorporates by reference its responses to all other paragraphs of this Complaint as if fully set forth herein.

394. The allegations contained in Paragraph 394 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 394 of the Complaint as alleged against Cardinal Health.

395. The allegations contained in Paragraph 395 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 395 of the Complaint as alleged against Cardinal Health.

396. The allegations contained in Paragraph 396 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 396 of the Complaint as alleged against Cardinal Health.

397. The allegations contained in Paragraph 397 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 397 of the Complaint as alleged against Cardinal Health.

398. The allegations contained in Paragraph 398 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 398 of the Complaint as alleged against Cardinal Health.

399. The allegations contained in Paragraph 399 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 399 of the Complaint as alleged against Cardinal Health.

400. The allegations contained in Paragraph 400 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 400 of the Complaint as alleged against Cardinal Health.

401. The allegations contained in Paragraph 401 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 401 of the Complaint as alleged against Cardinal Health.

402. The allegations contained in Paragraph 402 state legal conclusions as to which no response is required. To the extent a response is required, Cardinal Health denies the allegations contained in Paragraph 402 of the Complaint as alleged against Cardinal Health.

AFFIRMATIVE DEFENESES

Defendant, Cardinal Health, asserts the following defenses to Plaintiff's Original Complaint.

Defendant does not admit or acknowledge that it bears the burden of proof and/or burden of persuasion with respect to any such defense. All of the following defenses are pled in the alternative, and none constitutes an admission that Defendant is liable to Plaintiff, that Plaintiff has or will be injured or damaged in any way, or that Plaintiff is entitled to any relief whatsoever. Defendant reserves the right to (i) rely upon any other applicable defenses set forth in any Answer of any other defendant in this Action, (ii) rely upon any other defenses that may become apparent during fact or expert discovery in this matter, and (iii) to amend this Answer to assert any such defenses.

1. The Complaint, and each cause of action or count alleged therein, fails to state facts sufficient to constitute a claim upon which an award of actual damages, compensatory damages, restitutionary damages, punitive damages, or other relief may be granted.

2. The Complaint and each alleged claim therein, is barred, in whole or in part, by the applicable statute of limitations.

3. The Complaint and each alleged claim therein, is barred, in whole or in part, by the applicable statute of repose.

4. Plaintiff's claims for relief are barred by the doctrines of laches.

5. Plaintiff's claims are barred or limited for lack of standing.

6. Plaintiff lacks capacity to bring its claims, including claims indirectly maintained on behalf of its citizens and claims brought as *parens patriae*.

7. Plaintiff's claims are barred because Plaintiff is not the real party in interest.

8. Plaintiff's claims are not ripe and/or have been mooted.

9. Defendant further pleads, if such be necessary, and pleading in the alternative, that Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrine.

10. Plaintiff may be barred by the doctrine of unclean hands from all forms of relief sought in the Complaint.

11. Plaintiff's claims may be barred as a result of the Plaintiff's failure to exhaust administrative remedies.

12. Plaintiff's claims may be barred by the doctrines of estoppel, quasi-estoppel, equitable estoppel, and/or waiver from all forms of relief sought in the Complaint.

13. Plaintiff's claims are barred or limited by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of res judicata and collateral estoppel, failure to fulfil conditions precedent, failure to provide requisite notice, payment, accord and satisfaction, and compromise and settlement.

14. Plaintiff has failed to join all necessary parties, including without limitation health care providers, prescribers, patients, and other third parties whom Plaintiff alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products.

15. Plaintiff's claims are barred to the extent that they relate to Defendant's alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

82. Any alleged injuries were not legally foreseeable.

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

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

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

JURY TRIAL DEMANDED

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

DEMAND FOR BIFURCATED TRIAL

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

Dated: June 11, 2020

Respectfully submitted,

CARDINAL HEALTH, INC.

By its attorneys

Devine Millimet & Branch, P.A.

By: _____

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CERTIFICATE OF SERVICE

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

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Office of the Attorney General
109 State Street
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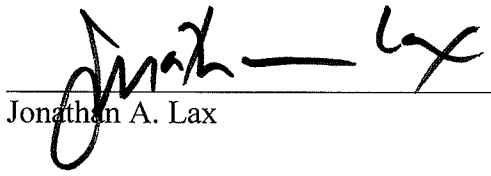
Date: June 11, 2020



Jonathan A. Lax

STATE OF VERMONT

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

STATE OF VERMONT,

Plaintiff,

vs.

CARDINAL HEALTH, INC. and
MCKESSON CORPORATION,

Defendants.

COMPLAINT

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

PRELIMINARY STATEMENT

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

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

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

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

5. Just the presence of prescription opioids in the State represents a risk that must be managed. Prescription opioids—including fentanyl, oxycodone, hydrocodone, and combination drugs—are controlled substances. They have a high potential for abuse and misuse; can cause serious injury, including severe psychological or physical dependence; and, therefore, are highly regulated. Equally significant, prescription opioids are subject to diversion away from legitimate

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

medical, research, and scientific channels to unauthorized use and illegal sales. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[4] Prescription opioids are diverted away from legitimate medical channels in a variety of ways, but the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that, for most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

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

7. By law, distributors—who are the gatekeepers in the prescription opioid supply chain—have strict obligations to monitor and control the sales of prescription opioids to prevent diversion.[5] The federal Drug Enforcement Administration ("DEA") recognized: "[D]istributors handle such large volumes of controlled substances and are the **first major line of defense** in the movement of legal pharmaceutical controlled substances … from legitimate channels into the

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

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

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

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

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

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

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

11. Cardinal and McKesson relied on sales-volume-based "thresholds" to detect suspicious orders *(*i.e., orders of unusual size, deviating substantially from a normal pattern, or of unusual frequency). These thresholds were caps set for each pharmacy's monthly opioid orders based on certain factors. If a pharmacy's order exceeded its threshold, that was an indication of potential diversion, and the Defendants were supposed to flag, stop, and investigate the order. These thresholds should have served as an important tool in detecting and preventing illegal orders. However, those thresholds were flawed in their design and implementation: not only did Defendants set them at improperly high levels, but they were also inadequately enforced.

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

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

14. As a result of Cardinal's and McKesson's flawed systems, Defendants systematically failed to notify regulators about the increasing indications of widespread diversion that should have been apparent from their own distribution and sales data, as well as additional data they acquired from third-party databanks. Rather than utilizing the wealth of data they possessed to prevent and curtail the diversion of opioids, Defendants used the data to target potential customers and strategize ways to increase their market share, allowing them to profit from the rising tide of opioid misuse and abuse.

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

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

17. Defendants' promotion and marketing of prescription opioids—particularly when viewed in the context of their obligations (and failures) to prevent and control diversion—constituted an unfair business practice. Through these marketing activities, Defendants echoed and reinforced the unfair and deceptive prescription opioid marketing that the drug manufacturers were disseminating through many different channels nationwide, and in Vermont. Further, some of Cardinal's and McKesson's marketing materials misrepresented the benefits of opioids or omitted the serious risks posed by opioid use. These marketing activities, together with the overwhelmingly deceptive branded and unbranded marketing that drug manufacturers disseminated through other channels, encouraged and normalized over-prescribing of

prescription opioids and effectively shifted the medical consensus regarding opioid prescribing and dispensing, nationally and in Vermont, in ways that will take years to undo.

18. Cardinal and McKesson also promoted and—in the case of McKesson, administered—the opioid manufacturers' prescription savings card programs to increase opioid sales by eliminating cost barriers otherwise associated with the initiation of brand-name opioid use. These discount programs subsidized or eliminated the out-of-pocket cost of these drugs, making them more accessible to Vermont consumers and effectively providing free or inexpensive samples of highly addictive substances. These programs also encouraged long-term use of prescription opioids—indeed, many of the savings cards had **no limit** to the number of times they could be used by the same patient—despite the fact that no good evidence existed to support long-term use of opioids.[7]

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

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

quality, purpose, and key components of their programs; and that Defendants unfairly and deceptively marketed prescription opioids.

20. Defendants have continuously and routinely violated Vermont law, taking advantage of the dramatic rise in opioid prescribing and profiting heavily from the sale of prescription opioids that they knew, or should have known, were being diverted from the legitimate and necessary uses. The consequences have devastated the lives of many Vermonters and will reverberate in Vermont for years to come.

21. The effects of the opioid epidemic in Vermont have been profound: increased health care costs; premature death and disability; lost productivity during prime work years; increases in drug-related crime and incarceration; and the consequential devastation of households and extended families. These predictable outcomes have created a full-blown public health crisis.

22. The State now asks the Court to hold Cardinal and McKesson accountable for their conduct for the damage they have caused, the costs they have imposed on the State, and the burdens they have placed on Vermont's citizens.

PARTIES

23. Plaintiff the State of Vermont brings this action, by and through its Attorney General, Thomas J. Donovan Jr., who is authorized to represent the State in all civil matters at common law and as allowed by statute. 3 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the Consumer Protection Act and all regulations promulgated thereunder. 9 V.S.A. § 2458.

24. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have substantially affected a significant segment of the population of Vermont.

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

26. Cardinal, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. Cardinal operates 18 wholesale drug outlets that are currently licensed to conduct business in Vermont. Cardinal distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, Cardinal marketed and promoted opioids—including, on information and belief, in Vermont.

27. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in San Francisco, California.

28. McKesson, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. McKesson operates 30 wholesale drug outlets that are currently licensed to conduct business in Vermont. McKesson distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, McKesson marketed and promoted opioids—including, on information and belief, in Vermont.

JURISDICTION AND VENUE

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

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

31. McKesson is registered to do business in Vermont, with Corporation Service Company as its registered agent, located at 100 North Main Street, Suite 2, Barre, VT 05641. Several Cardinal affiliates and/or subsidiaries also are registered to do business in Vermont, with either Corporation Service Company, located at 100 North Main Street, Suite 2, Barre, VT 05641, or CT Corporation System, located at 17 G W Tatro Dr., Jeffersonville, VT 05464, as their registered agent.

32. Venue is proper in this Court, pursuant to 9 V.S.A. § 2458(a), because Defendants do business in Chittenden County, including distributing opioids within the county.

FACTUAL ALLEGATIONS

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

33. Cardinal and McKesson are licensed to distribute prescription drugs in Vermont, including prescription opioids, which are designated as controlled substances due to their high potential for abuse. A license to distribute controlled substances is valuable—it allows Defendants to participate in a tightly controlled, national market valued at more than $7 billion annually for opioids alone.

34. Distribution of controlled substances comes with a substantial duty. Distributors are obligated to take steps to provide effective controls and procedures to guard against theft and diversion of controlled substances, as a critical part of a regulatory system designed to combat drug abuse. These obligations are a crucial component of the State's efforts to protect the public health, welfare, and safety by regulating access to potentially dangerous controlled substances.

35. Vermont's common law imposes a general duty to exercise the degree of care that a reasonably prudent person / entity would exercise under similar circumstances. The scope of this duty of care is determined by the foreseeability of the consequences of the acts or omissions. It is foreseeable that distributing vast amounts of highly addictive prescription opioids into the State, while simultaneously promoting higher sales of these drugs and failing to take reasonable steps to minimize their illegitimate use, could result in widespread misuse, abuse, diversion, and serious injury.

36. Defendants acknowledge that their status as wholesale distributors of controlled substances subjects them to common law duties of care. For example, Defendants' professional lobbying association, the Healthcare Distribution Alliance ("HDA") acknowledges that distributors' responsibilities to detect and prevent diversion of controlled substances arise from the obligations that attach to "responsible members of society."[8]

37. The duty of care imposed under Vermont common law is reasonably informed by Vermont's statutes and regulations, which impose a variety of legal obligations on wholesale distributors that are designed "to promote, preserve, and protect the public health, safety, and welfare."[9]

[8] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), ECF No. 1607110, 2016 WL 1321983 at *3.
[9] 26 V.S.A. § 2021.

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

- "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;
- equip their facilities with security systems suitable to protect against diversion, 20-4 Vt. Code R. § 1400:17.8; and
- adopt, maintain, and adhere to written security policies, 20-4 Vt. Code R. § 1400:17.20.

39. Vermont law also imposes duties of care on controlled substance distributors that are co-extensive with those imposed under the federal Controlled Substances Act (21 U.S.C. § 801 *et seq.*) and its implementing regulations, but that are independently enforceable under state law. Vermont law requires: (1) that distributors maintain operations "in compliance with all federal requirements applicable to wholesale drug distribution;" 26 V.S.A. § 2068(9); (2) that distributors comply with all "applicable federal, state, and local laws and rules," 20-4 Vt. Code R. § 1400:17.23; and (3) that distributors dealing in controlled substances "register with the [DEA], and …. comply with all applicable state, local, and DEA requirements," 20-4 Vt. Code R. § 1400:17.25.

40. Congress designed the federal Controlled Substances Act ("CSA") "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States."[10] The CSA carries out this goal by creating a "closed system" of distribution in which every entity that

[10] 1 H.R. Rep. No. 91–1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

handles controlled substances—including manufacturers, distributors, and dispensers—does so pursuant to a registration with the DEA.[11]

41. The distributors' role is central to the efficacy of the CSA's regulatory system. As the DEA has explained, "[b]ecause distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances … from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses."[12]

42. Under the CSA, a registered distributor must "provide effective controls and procedures to guard against theft and diversion of controlled substances."[13] Diversion occurs when controlled substances move out of legitimate medical, scientific, and industrial channels.[14] In Vermont, "legitimate medical channel" is narrowly defined as the possession and use by a patient of a narcotic (opioid) prescription drug in accordance with the directions of the patient's licensed health care provider, whose prescription has been dispensed by a licensed pharmacist. Any other type of dispensing,[15] possession, or use is prohibited by Vermont law[16] and thus outside a legitimate medical channel.

43. In particular, distributors must "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and must report to the DEA the discovery

[11] 21 U.S.C. §§ 821-823.
[12] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.
[13] 21 C.F.R. § 1301.71.
[14] 21 U.S.C. § 823(b).
[15] "Dispense" is defined to include "leave with" and "give away." 18 V.S.A. § 4201(7).
[16] Any possession, administering, or dispensing not specifically authorized under Chapter 84 (the Vermont controlled substances act) is prohibited by 18 V.S.A. § 4205. *See also* 18 V.S.A. § 4216.

of any suspicious orders.[17] The duty to monitor, identify, and report suspicious orders is referred to as the "Reporting Requirement."

44. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.[18] This list is not exhaustive,[19] and the DEA has provided extensive guidance on the identification and reporting of suspicious orders.

45. The DEA has advised distributors that:

- they must "consider the totality of the circumstances when evaluating an order for controlled substances";[20]
- monitoring only the volume of controlled substance orders is insufficient to guard against diversion because if an order "deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious";[21] and
- signs that might be indicative that a pharmacy is engaged in diverting controlled substances, include "[o]rdering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs," and ordering controlled drugs "in quantities disproportionate to the quantity of non-controlled medications ordered."[22]

46. Defendants were aware of DEA's guidance.

47. In addition to requiring a distributor to monitor, identify, and report suspicious orders, Vermont law also requires a distributor to prevent the shipment of suspicious orders to customer pharmacies, a duty referred as the "Shipping Requirement."[23]

48. The DEA has explained the scope of the Shipping Requirement to distributors on multiple occasions.[24] Before shipping an order that has raised a suspicion, a distributor must

[17] 21 C.F.R. § 1301.74(b).
[18] 21 C.F.R. § 1301.74(b).
[19] *Masters Pharm., Inc. v. Drug Enf't Admin*., 861 F.3d 206, 221 (D.C. Cir. 2017).
[20] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[21] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).
[22] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[23] *Masters*, 861 F.3d at 222.

"conduct an independent analysis … to determine whether the controlled substances are likely to be diverted from legitimate channels."[25] That independent analysis must be thorough and must include certain steps, including: (1) requesting information from the pharmacy that placed the order; (2) documenting the pharmacy's explanation for the order; and (3) engaging in any additional follow-up necessary to determine the legitimacy of the order.[26] The independent investigation must be sufficient to dispel all of the red flags that gave rise to the suspicion.[27]

49. Even the HDA, Defendants' lobbying organization, expressly acknowledged the Shipping Requirement in 2008, where it advised distributors that they "should not ship to the customer any units" of a potentially suspicious order without conducting a "fully documented" investigation to determine whether the order is legitimate.[28]

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

50. Despite their duty to prevent the diversion of opioid drugs, neither Cardinal nor McKesson attempted to create formal anti-diversion programs to fulfill their duty until 2007. And even then, the programs they designed failed to meet their legal obligations to detect, prevent, and report diversion. Defendants also failed to fully implement these anti-diversion programs, rendering them both deficient on their face and unenforced in practice.

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[24] *See, e.g., Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01, 36,500 (DEA July 3, 2007) (holding that a distributor violated its duty by shipping suspicious orders without first conducting a due diligence investigation); Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51) (providing that a distributor must "exercise due care in confirming the legitimacy of all orders prior to filling").

[25] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).

[26] *Masters Pharm., Inc.*, 861 F.3d at 212-13.

[27] *Masters Pharm., Inc*., 861 F.3d at 212-13.

[28] *HDA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, available as Attachment 1 to "Prescription Drug Diversion: Combatting the Scourge," Hearing before the Subcommittee on Commerce, Manufacturing & Trade of the U.S. House of Representatives Committee on Energy and Commerce (112th Cong., 2d Session) (March 1, 2012) at 216, 227, 230 (hereinafter "HDMA Industry Compliance Guidelines"), available at https://archive.org/details/gov.gpo.fdsys.CHRG-112hhrg80861.

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

52. Both Defendants' anti-diversion programs relied on monthly, volume-based order "thresholds" for each pharmacy customer as the purported trigger for identifying potentially suspicious orders. Their systems failed to identify all orders of unusual size, frequency, and pattern, in violation of Defendants' duties to identify, report, and prevent shipment of all suspicious orders.

53. Cardinal and McKesson each designed and implemented their anti-diversion programs in a way that manipulated and reduced the likelihood of "threshold events," which in turn allowed them to avoid conducting appropriate investigations of their pharmacy customers. Defendants were motivated to minimize threshold events because they wanted to avoid losing customers.

54. Cardinal and McKesson pumped unwarranted volumes of prescription opioids into Vermont, disregarding the obvious signs that diversion was occurring and that a serious health crisis was developing. Based on information currently available to the State, McKesson shipped 75,333,960 dosage units of opioids into Vermont from 2008 through 2014. That is equivalent to more than 120 prescription opioid pills for every man, woman, and child in the State. Based on the same data, Cardinal shipped 40,078,061 dosage units of opioids into Vermont during the same time frame, equivalent to about 64 opioid pills for every man, woman, and child in the State.

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

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

56. Following a series of investigations in 2006 and 2007 by state and federal law enforcement into Cardinal's anti-diversion monitoring practices, *see infra* at Part V.A, Cardinal created an anti-diversion program that purported to monitor, identify, report, and prevent the shipment of suspicious controlled substance orders. The main components of Cardinal's program purported to include:

- conducting a due diligence review before onboarding new pharmacy customers;
- setting thresholds, or order limits, to restrict the number / volume of opioids a pharmacy could order each month;
- utilizing an electronic system to hold orders that exceeded thresholds, termed "threshold events," pending further review by Cardinal's anti-diversion staff; and
- conducting regular site visits of existing customers to uncover evidence of suspicious activity.

57. In actuality, Cardinal's four-pronged system was designed to ensure that its pharmacy customers would receive a steady stream of opioids and that anti-diversion duties would never interfere with the Cardinal's bottom line.

1. Cardinal's due diligence policies for onboarding new pharmacy customers were facially inadequate.

58. Cardinal's anti-diversion policy required review of potential new pharmacy customers before onboarding them to ensure that customers purchasing opioids from Cardinal were not engaged in diversion. However, Cardinal's customer onboarding policies were

inadequate because they did not allow Cardinal to independently assess a pharmacy's risk of diversion.

59. From approximately December 2007 through 2012, Cardinal's process for approving new pharmacy customers seeking to order opioids was limited to (1) receiving a customer survey with basic information about the pharmacy's business; (2) receiving an agreement signed by the pharmacy pledging compliance with DEA regulations; and (3) confirming that the pharmacy and its employees were registered with the DEA and relevant state regulatory entities.

60. As written, Cardinal's policies were insufficient to determine whether new pharmacy customers were involved in diversion. Those policies provided Cardinal's sales representatives—who had a financial incentive, due to their compensation structure, to bring on new customers—with responsibility for collecting relevant documents and completing the survey for the customer. Cardinal did not require an independent inquiry into whether other distributors were providing controlled substances to the pharmacy, nor did it require the pharmacy to provide [redacted] preventing Cardinal from investigating the doctors whose prescriptions the pharmacy was filling. Cardinal also did not require site visits at a new pharmacy customer before beginning to ship opioid drugs to it, further evidence of Cardinal's failure to fulfill its broader duty to guard against diversion.

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

[redacted] These inadequacies prevent Cardinal from ensuring the legitimacy of controlled substance purchases by new pharmacy customers.

2. Unreasonably high "thresholds" made it possible for Cardinal to avoid identifying and reporting suspicious orders.

62. Cardinal's suspicious order monitoring system relied on thresholds to identify opioid orders that required review. But Cardinal relied on unreasonably high thresholds, which minimized the number of flagged orders, and allowed Cardinal to avoid investigating or reporting its pharmacy customers when they placed ever-increasing or otherwise suspicious orders for opioids.

63. Cardinal designed its system so that, if an opioid order exceeded a pharmacy's pre-set monthly threshold limit, the order would be held pending review. Moreover, under Cardinal's system, subsequent orders of opioids in the same drug family (i.e., opioids sharing the same narcotic ingredient) also were supposed to be held pending review, interrupting the pharmacy's supply of all opioids in that drug family.[29]

64. However, Cardinal systematically set thresholds at inappropriately high levels to minimize the number of threshold events, to avoid order delays, and to prevent disruption of Cardinal's revenue stream and pharmacy customer satisfaction. Cardinal (1) used unreasonably high sales figures to set thresholds, (2) allowed chain pharmacies with their own anti-diversion programs to have even *higher* thresholds; and (3) set thresholds without accounting for critical factors that the DEA had explained it was required to consider and that would have allowed Cardinal to detect diversion.

65. Fearing that any "aggressive limits will cause … [c]ustomer backlash," Cardinal set its thresholds at unreasonably high levels from approximately December 2007 through 2012.

[29] For example, OxyContin and Percocet are in the same drug family with generic oxycodone, while hydrocodone is a different drug family.

66. Cardinal categorized pharmacy customers based on order volume (small, medium, and large) and business class (e.g., retail pharmacies, hospitals, and long-term care facilities). Cardinal then averaged the monthly quantity of each opioid drug family [redacted] for a given pharmacy size and type, and then **tripled** the monthly average to create the threshold amount. Cardinal's thresholds thus allowed its pharmacy customers to order **three times** the average volume of opioid drugs ordered by pharmacies of similar size and type before triggering any suspicious order review.

67. Moreover, the averages on which Cardinal relied were inflated even before Cardinal tripled them to set the final thresholds. As the baseline for its thresholds, [redacted]—a time period during which opioid sales, and diversion of opioids to non-medical use, were already at dangerously excessive levels. In 2007, for example, pharmacies dispensed 228.43 million opioid prescriptions nationwide—at the time, the highest number ever recorded—equivalent to 75.9 prescriptions per 100 persons and a 243% percent increase compared to opioid prescription levels in 1996, the year OxyContin ER, an extended release formulation of oxycodone, was launched with an aggressive marketing campaign. In 2008, opioid prescribing increased further, reaching 78.2 prescriptions per 100 persons.

68. From approximately December 2007 through 2012, Cardinal's system granted even higher thresholds to pharmacies that maintained their own anti-diversion or loss-prevention programs. Cardinal permitted these higher thresholds based on the flawed premise that "[its] role in the customer's anti-diversion decreases as the customer ability increases,"[30] which ignores and abdicates Cardinal's own independent duty to identify and report suspicious orders and guard against diversion.

[30] CAH_MDL2804_02953792 at 3–4.

69. Cardinal's records confirm that, as of April 2012, oxycodone thresholds for Cardinal's Vermont retail pharmacy customers were frequently four, five, or six times higher than the pharmacies' average monthly oxycodone purchases from the previous twelve months. Cardinal's oxycodone thresholds for its Vermont "institutional retail" pharmacies, such as those in proximity to a hospital, were even more disproportionate to the pharmacies' actual oxycodone purchases. Cardinal justified the disproportionate thresholds at these pharmacies on the theory that the hospitals or other institutions they serve are "less risky because of the vertical integration of the system, which includes the hospital's own risk management."[31] Yet Cardinal acknowledged that not all "institutional" pharmacies were connected to a hospital; some were over a mile away from a hospital; and many served non-hospital patients. Through these inflated thresholds, Cardinal ensured that Vermont pharmacies would not trigger a threshold event, even if they ordered significantly greater-than-usual volumes of opioids.

70. Only when confronted with enforcement actions by the DEA and DOJ in 2012, *see infra* at Part V.A, did Cardinal begin reforming its threshold formulas to more accurately reflect pharmacies' actual order volumes. These changes resulted in drastic reductions in pharmacy thresholds, making clear just how inflated Cardinal's threshold formulas had been previously. For example, [redacted] in Chittenden County, Vermont [redacted]

[31] CAH_MDL2804_01891921 at 4, 8.

[redacted]

71. Additionally, Cardinal's threshold calculations failed to incorporate critical factors necessary to make the thresholds a meaningful tool for monitoring suspicious orders. Despite the DEA's guidance that a suspicious order monitoring system should account for factors including the geographic location of its pharmacy customers, Cardinal's thresholds have never accounted for the size or demographics of the population served by a pharmacy, nor the total number of pharmacies within the same service area.

72. From approximately December 2007 through 2012, Cardinal's thresholds also did not account for the possibility that pharmacies were receiving opioids from multiple distributors. Cardinal also sometimes set its thresholds without considering pharmacies' actual prescription volumes. If a retail independent pharmacy did not provide Cardinal with its dispensing data, Cardinal automatically provided the pharmacy with generic "mid-level" threshold limits rather than demand the information or conduct an investigation. Cardinal did this to reduce the number of threshold events experienced by new pharmacy customers, which had been assigned "small" threshold limits under a former policy governing thresholds for new pharmacy customers.

73. Cardinal's thresholds for chain pharmacies—retail pharmacies owned by a common parent company and operating under the same name with multiple locations—were based on a standard threshold for the entire chain. Thus, a pharmacy serving a small community in Vermont, or that had a minimal opioid portfolio, could nevertheless be permitted to order unnecessarily large quantities of opioids merely because that pharmacy was part of a retail pharmacy chain. In one instance, [redacted]

[redacted] Windham County, Vermont [redacted]

[redacted]

74. Throughout the entire period from approximately December 2007 to the present, Cardinal's thresholds have failed to account for the quantity of opioids distributed and dispensed in a given geographic region. Despite easily accessible state and regional (1) distribution data, (2) prescribing data, (3) market share data, and (4) population data, some of which is also available at the county- and census tract-level, and all of which [redacted] [redacted] see *infra* Section IV.B, Cardinal's thresholds did not account for opioid distribution, opioid prescribing, its own market share, or the population of a given geographic area. Cardinal failed to take this critically important geolocation data into account even after [redacted]

[redacted]

[redacted]

75. Because of these fundamental design flaws and Cardinal's exclusive reliance on volume-based thresholds to trigger investigation of orders, Cardinal's threshold-based system has been ineffective at identifying suspicious orders. From approximately December 2007 to the present, Cardinal's system has relied exclusively on these thresholds to trigger investigation of pharmacy orders. Cardinal's monitoring system was originally "primarily focused on volume," and even after Cardinal began considering additional factors in 2011—pharmacy ordering patterns and frequency—Cardinal only reviewed those factors when an investigation of an order was "triggered" by exceedance of the volume-based threshold. By design, this system is too simplistic for Cardinal to reliably identify orders that are potentially suspicious for other reasons, such as unusual frequency or pattern.

76. Because of the flaws in Cardinal's design of—and exclusive reliance on—these improperly high volume-based thresholds, Cardinal's suspicious order monitoring system was and is insufficient to identify, review, and report suspicious orders as Cardinal is required to do under applicable law.

3. Cardinal manipulated its policies to help pharmacies prevent threshold events.

77. Cardinal has been aware of attempts by pharmacy customers to "game the system" since the beginning of its suspicious order monitoring program. From approximately December 2007 through 2012, Cardinal's official policy was to not disclose specific threshold levels to pharmacies. However, Cardinal also wanted to prevent threshold events from occurring.

78. Thus, without disclosing a specific threshold to a pharmacy, Cardinal would: (1) alert pharmacies when they were approaching their thresholds, thereby allowing the pharmacies to request a preemptive threshold increase; (2) coach pharmacies on how to avoid triggering review of their orders; and (3) raise thresholds without conducting any investigation into the pharmacy's operations.

79. While in the earliest stages of designing its suspicious order monitoring program, the senior leadership of Cardinal's anti-diversion department emphasized the need to be "proactive in determining if we need to raise the threshold prior to [the pharmacy customer] hitting it" to avoid customer backlash. To meet this need, from approximately December 2008 through 2012, Cardinal tracked pharmacies' proximity to their thresholds—their "threshold accrual"—and used an "early dialogue" process, in which sales representatives were required to "immediately contact" a pharmacy when the pharmacy's controlled substance orders reached a certain percentage of its threshold. Intended "to prevent SOM [Suspicious Order Monitoring]

events" from happening,[32] this process directly subverted the very purpose of the thresholds—alerting Cardinal to potentially suspicious orders. Instead, Cardinal warned pharmacies when they were approaching a potential threshold event so that the pharmacy could request—and Cardinal could grant—a preemptive increase. Cardinal was extremely successful in shielding itself and its pharmacy customers from threshold events: from 2010 to 2011—the first year of the early dialogue intervention program—threshold events dropped by 37%.

80. After 2012, Cardinal became even more aggressive about helping pharmacies to avoid threshold events and evade review. From approximately [redacted] to [redacted] [33] Sales representatives had multiple tools available to review a pharmacy customer's thresholds and accruals, [redacted] [34]

81. Further undermining the threshold system, Cardinal's [redacted]

[32] CAH_MDL2804_02246162 at -197.
[33] CAH_MDL2804_02011099.
[34] Deposition of Todd Cameron, Sept. 26, 2018, CAH_MDL2804_02953369, at 295:5–22.

[redacted][35] Pharmacies selected [redacted] However, instead of investigating these pharmacies during visits, Cardinal's anti-diversion investigator instead provided pharmacy personnel with key information about Cardinal's system for detecting suspicious orders—the metrics that Cardinal uses to track pharmacy order patterns—which they could use to alter the pharmacy's purchasing patterns to avoid further scrutiny.

82. Moreover, Cardinal had no written policy defining the criteria or process for raising a pharmacy customer's threshold until approximately January 15, 2013. Before then, its anti-diversion employees had broad discretion to grant threshold increases whenever they saw fit. In one year from October 2009 to October 2010, Cardinal increased Vermont pharmacy opioid thresholds 19 times. In one instance, Cardinal raised five different opioid thresholds for one pharmacy in a single day, resulting in a combined 200,800 dosage unit increase in the volume of opioids the pharmacy could purchase every month—including a more than 100,000 dosage unit increase for oxycodone. Cardinal's records contain no documentation showing that it conducted any comprehensive investigation to determine the legitimacy of the threshold increases. The only justification for the increases contained in Cardinal's records was the cursory notation that the "data supports quantity ordered."

83. Even after Cardinal finally did implement a threshold increase policy in 2013, it continued to permit threshold increases without conducting legitimate investigations into the propriety of those increases. For example, the policy [redacted]

[35] CAH_MDL2804_00035120 at 1.

[redacted] Cardinal's policy also allows [redacted]

[redacted]

4. Cardinal avoided adequately investigating, blocking, and reporting orders triggered by threshold events.

84. Cardinal designed its suspicious order monitoring system so that when a pharmacy did place an order exceeding a threshold—indicating that the order was potentially suspicious and required further review—Cardinal could resume normal shipments to that pharmacy as quickly as possible. To that end, Cardinal (1) gave pharmacies [redacted] [redacted] (2) required minimal due diligence before fulfilling held orders; (3) allowed pharmacies that exceeded a threshold for one opioid drug family to continue ordering opioids from other drug families; and (4) used a monthly accrual period, which allowed pharmacies whose orders were identified as suspicious and reported to the DEA to resume ordering once the period re-set. Finally, even when Cardinal determined that an order was "unreasonable" and should not be shipped, Cardinal (5) failed to report all such orders to the DEA, as required by law.

85. From approximately 2013 to the present, [redacted] Under this policy, and in violation of its duty, Cardinal failed to investigate, failed to report to the DEA, and shipped orders that exceeded a pharmacy customer's threshold [redacted]

[redacted]

86. When Cardinal did hold a pharmacy's order pending review, Cardinal failed to conduct adequate due diligence to determine whether to cancel the order and report it as suspicious or to release and ship the order. From approximately December 2007 through 2012, Cardinal's diligence review was limited to an online survey completed by the pharmacy responsible for the potentially suspicious order; a "customer profile" that included only basic information about the pharmacy and its opioid drug purchases; and the held order itself. Cardinal did not require a site investigation before releasing an order that exceeded a threshold, and it did not even have a written policy specifying when a site visit was required until 2012.

87. From approximately 2013 to the present, [redacted] This practice has allowed pharmacies to continue receiving increasing quantities of opioid drugs [redacted]

88. Cardinal's suspicious order monitoring system also failed to ensure adequate investigation of orders flagged as potentially suspicious by Cardinal's distribution center employees. Cardinal labeled these potentially suspicious orders as "orders of interest." From approximately December 2007 through 2012, Cardinal allowed distribution center supervisors, "based upon [their] knowledge and experience," to release these orders of interest without any

further review, oversight, or documentation.[36] Only if the supervisor, in his or her sole discretion, decided to hold the order would the order be subject to review by Cardinal's anti-diversion department.

89. Cardinal also designed its thresholds so that "threshold events"—and any resulting hold and investigation of a pharmacy's order—would have as little impact as possible on the pharmacy's ability to continue ordering opioids. From approximately December 2007 to [redacted], Cardinal has set separate thresholds for each drug family, and following a threshold event, only holds orders for drugs in the specific drug family with the threshold exceedance. The logical result of this policy is that a threshold event in one drug family does not impact or interrupt a shipment of opioids belonging to another drug family, despite the indication that the pharmacy could be a source of opioid diversion. [redacted]

90. From approximately December 2007 to [redacted], Cardinal's monthly threshold levels reset with each new monthly accrual period—without accounting for suspicious ordering activity that occurred in the preceding accrual period. This means that pharmacies placing suspicious orders in one accrual period were allowed to continue ordering and receiving the same opioid as soon as their monthly accrual periods reset—with no further review or investigation by Cardinal to ensure that the pharmacies were not engaged in diversion.

91. From approximately December 2007 through 2012, Cardinal also failed to appropriately report suspicious orders to the DEA. Under Cardinal's policy, an employee reviewing a threshold event had the authority to decide whether the excessive order was

[36] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 15, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf

"reasonable" or "unreasonable." Cardinal's policy gave little guidance as to what orders were "reasonable," specifying only that a reviewer should use "applied reasoning" and offering several general factors for consideration, including "seasonal events, natural events, [and] regional prescribing habits." Even though an excessive and unreasonable order would certainly meet the definition of "suspicious" under the controlling regulations, Cardinal would still not report those orders to the DEA unless a Cardinal reviewer also designated those orders as suspicious at the reviewer's own discretion. By building this discretionary process into its anti-diversion system, Cardinal allowed its personnel to limit the number of "suspicious orders" they reported to the DEA, even when those orders were flagged by Cardinal's system because they bore all the hallmarks of a "suspicious order."

5. Cardinal's sales representatives conducted the majority of site visits, and Cardinal's investigators deferred to the pharmacies they were investigating.

92. Many indicators of diversion, including those listed in Cardinal's policies governing on-site investigations of its pharmacy customers, cannot be identified through electronic order monitoring alone. Thus, a critical component of Cardinal's duty was to conduct regular due diligence reviews of its pharmacy customers, including regular on-site visits, to monitor for and guard against diversion. Despite this, Cardinal relied on threshold events to trigger most site visits. Moreover, Cardinal (1) placed most of the responsibility for conducting site visits on its sales force; and (2) required that its investigators defer to the pharmacies supposedly under investigation.

93. Cardinal's anti-diversion program relies heavily on its sales force—rather than compliance personnel—to investigate the sales employees' own pharmacy customers. The

Cardinal sales force is treated as the company's "boots on the ground and the front line of defense" in its anti-diversion efforts.

94. Cardinal's sales employees look for the more extreme indicators of diversion including long lines, minimal front-end merchandise, and out-of-state license plates in the parking lot. But, from at least June 2009 to March 2013, sales employees only were required to report pharmacy customers that exhibited "two or more" of these indicators, thus allowing Cardinal to continue selling opioids to pharmacies that exhibited suspicious activity without further investigation.

95. From approximately December 2008 through May 2013, Cardinal's sales force monitored pharmacy customers using monthly "Highlight Reports" that identified pharmacies based on increases in their opioid drugs orders. Cardinal presented these Highlight Reports as a way to identify "which customers may be experiencing a change in business"—one of the justifications Cardinal used to raise customer thresholds[37]—rather than as a way to identify customers placing potentially suspicious orders. Where pharmacies had extreme increases in opioid sales—over 15 percent per month—sales employees visited the pharmacies to assess the pharmacy for visible signs of diversion. But where pharmacies had increases in their opioid sales of between 10 and 15 percent, sales employees merely were required to call the pharmacy "to understand the reason for the increased ordering."[38] Unless the pharmacy requested a threshold increase or the salesperson reported outward signs of diversion, no further action was taken. Cardinal's anti-diversion department did not use Highlight Reports to make decisions about whether to report suspicious orders or stop selling to certain pharmacy customers.

[37] *See* CAH_MDL2804_02954214 at 4; Deposition of Jennifer R. Norris, Aug. 7, 2018, CAH_MULTISTATE_0014000, at 269:8–22; CAH_MDL2804_02954268 at 3.
[38] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 13, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf.

96. Cardinal's sales employees' anti-diversion duties conflicted with their compensation incentives. Cardinal expected its sales employees to "build relationships with independent retail pharmacies that will increase account penetration, revenue growth and customer satisfaction" to meet Cardinal's business goals.[39] Reporting a pharmacy as a diversion risk could damage a sales representative's relationship with the pharmacy customer, potentially reducing the sales representative's ability to increase sales to that pharmacy. Cardinal also gave sales representatives performance-based bonuses for selling more drugs and retaining pharmacy customers. In contrast, sales representatives received no financial incentive to monitor pharmacies for signs of diversion, leaving little doubt as to where sales representatives were incentivized to direct their focus and time.

97. When Cardinal did conduct full site visits using anti-diversion investigators, those visits [redacted][40] [redacted] reducing the probability that Cardinal's investigator would find anything suspicious.

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

98. Not only did Cardinal design a seriously deficient anti-diversion program, it also failed to adhere to it. The company consistently has understaffed its anti-diversion department, raised pharmacy thresholds without enough scrutiny of factors relevant to potential diversion, and failed to report or otherwise diligently investigate all orders that exceeded a set threshold. Cardinal also allowed large chain pharmacies to operate independently, under their own set of rules—often by allowing chain pharmacies to carry out their own investigations of suspicious orders with no oversight from Cardinal. In each of these ways, Cardinal undermined its already-

[39] CAH_MDL2804_00618377 at 5, 9.
[40] CAH_MDL2804_02904365, at -380.

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,