

IN THE SUPREME COURT OF THE STATE OF NEVADA

TEVA PHARMACEUTICALS USA, INC.,
MCKESSON CORPORATION,
AMERISOURCEBERGEN DRUG
CORPORATION, CARDINAL HEALTH, INC.,
CARDINAL HEALTH 6 INC., CARDINAL
HEALTH TECHNOLOGIES LLC, CARDINAL
HEALTH 108 LLC d/b/a METRO MEDICAL
SUPPLY, CEPHALON, INC., ENDO HEALTH
SOLUTIONS INC., ENDO PHARMACEUTICALS
INC., ALLERGAN USA, INC., ALLERGAN
FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a
WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC., ACTAVIS
PHARMA, INC. f/k/a WATSON PHARMA, INC.,
ACTAVIS LLC, and MALLINCKRODT, LLC,

Petitioners,

v.

SECOND JUDICIAL DISTRICT COURT OF THE
STATE OF NEVADA, in and for the County of
Washoe, and the HONORABLE BARRY L.
BRESLOW, DISTRICT JUDGE,

Respondents,

and

CITY OF RENO,

Real Party in Interest.

Supreme Court Case No.

— Electronically Filed
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District Court Case No. Brown
CV18-01895 of Supreme Court

**PETITIONERS' APPENDIX
VOLUME XV**

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CHRONOLOGICAL INDEX TO PETITIONERS' APPENDIX

DATE	DOCUMENT	VOLUME	PAGE	RANGE
12/7/2017	Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00001	PA00050
5/15/2018	First Amended Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00051	PA00109
9/18/2018	Complaint (Case No. CV18-01895)	II	PA00110	PA00167
12/03/2018	First Amended Complaint (Case No. CV18-01895)	II	PA00168	PA00226
3/4/2019	Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint	III	PA00227	PA00264
3/5/2019	Distributors' Joint Motion to Dismiss First Amended Complaint	III	PA00265	PA00386
4/26/2019	City of Reno's Opposition to Manufacturer Defendants' Joint Motion to Dismiss and All Joinders Thereto	IV-V	PA00387	PA00709
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5/28/2019	Reply in Support of Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint	VIII-IX	PA00959	PA01214
5/28/2019	Distributors' Joint Reply in Support of Motion to Dismiss First Amended Complaint	X	PA01215	PA01285

DATE	DOCUMENT	VOLUME	PAGE	RANGE
6/17/2019	Complaint (Case No. A-19-796755-B)	XI-XII	PA01286	PA01535
6/27/2019	First Amended Complaint (Case No. A-19-796755-B)	XIII-XV	PA01536	PA02049
7/3/2019	Order Directing Answer (Case No. 79002)	XVI	PA02050	PA02052
8/22/2019	Complaint (Case No. A-19-800695-B)	XVI	PA02053	PA02144
8/22/2019	Complaint (Case No. A-19-800697-B)	XVI	PA02145	PA02235
8/22/2019	Complaint (Case No. A-19-800699-B)	XVII	PA02236	PA02326
9/12/2019	Third Amended Complaint and Demand for Jury Trial (Case No. A-17-76828-C)	XVII	PA02327	PA02423
9/13/2019	City of Reno's Supplemental Briefing in Support of Oppositions to Defendants' Motions to Dismiss	XVIII	PA02424	PA02560
10/4/2019	Distributors' Response to Plaintiff's Supplemental Briefing re Motions to Dismiss	XVIII	PA02561	PA02566
10/4/2019	Manufacturer Defendants' Response to Plaintiff's Supplemental Briefing re Motions to Dismiss	XVIII	PA02567	PA02587
10/21/2019	Order Dismissing Petition (Case No. 79002)	XVIII	PA02588	PA02591

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1/4/2020	City of Reno's Supplemental Briefing in Support of Oppositions to Distributors' Joint Motion to Dismiss	XVIII	PA02592	PA02602
1/7/2020	Transcript of Proceedings	XIX-XX	PA02603	PA02871
1/8/2020	Transcript of Proceedings	XXI	PA02872	PA03034
2/14/2020	Omnibus Order Granting In Part and Denying in Part Defendants' Motions to Dismiss; and Granting Leave to Amend	XXI	PA03035	PA03052

ALPHABETICAL INDEX TO PETITIONERS' APPENDIX

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12/7/2017	Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00001	PA00050
3/5/2019	Distributors' Joint Motion to Dismiss First Amended Complaint	III	PA00265	PA00386
5/28/2019	Distributors' Joint Reply in Support of Motion to Dismiss First Amended Complaint	X	PA01215	PA01285
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1/7/2020	Transcript of Proceedings	XIX-XX	PA02603	PA02871
1/8/2020	Transcript of Proceedings	XXI	PA02872	PA03034

AFFIRMATION

Pursuant to NRS 239B.030, the undersigned does hereby affirm that Petitioners' Appendix Volume XV does not contain the social security number of any person.

Dated this 1st day of May, 2020.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of McDonald Carano LLP, and that on this 1st day of May, 2020, a copy of the foregoing Petitioners' Appendix Volume XV was electronically filed with the Clerk of the Court for the Nevada Supreme Court by using the Nevada Supreme Court's E-Filing system (Eflex) and served via U.S. Mail, postage prepaid, on the following individuals:

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In addition, in compliance with NRAP 21(a)(1) and Administrative Order 2020-05, a copy of this Petitioners' Appendix Volume XV was served upon the Honorable Barry Breslow, District Judge via electronic service and email to Christine.Kuhl@washoecourts.us.

By: /s/ Pat Lundvall
An Employee of McDonald Carano LLP

OxyContin PI Figure, Linear y-axis

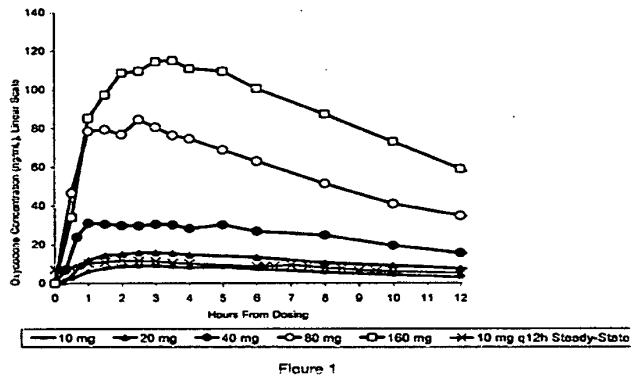


Figure 1

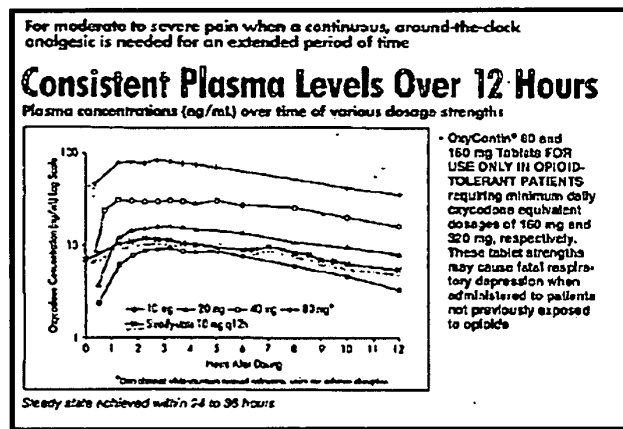
294. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief. As a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

295. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon known as “end of dose” failure. (The FDA found in 2008 that a “substantial number” of chronic pain patients will experience end-of-dose failure with OxyContin.)

296. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called

OxyContin's 12-hour dosing "the perfect recipe for addiction."⁷⁶ Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

297. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart, mirroring the chart on the previous page. However, this version of the chart deceptively minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



298. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin

⁷⁶ Harriet Ryan, et al., "'You Want a Description of Hell?' OxyContin's 12-Hour Problem," Los Angeles Times, May 5, 2016, <http://www.latimes.com/projects/oxycotin-part1/> (hereinafter, "You Want a Description of Hell").

1 launch team stated that “OxyContin’s positioning statement is ‘all of the analgesic efficacy of
2 immediate- release oxycodone, with convenient q12h dosing,’” and further that “[t]he
3 convenience of q12h dosing was emphasized as the most important benefit.”⁷⁷

4 299. In keeping with this positioning statement, a Purdue regional manager
5 emphasized in a 1996 sales strategy memo that representatives should “convinc[e] the
6 physician that there is no need” for prescribing OxyContin in shorter intervals than the
7 recommended 12-hour interval, and instead the solution is prescribing higher doses.”⁷⁸ One
8 sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped
9 in the bud NOW!!”⁷⁹

10 300. Purdue executives therefore maintained the messaging of twelve-hour dosing
11 even when many reports surfaced that OxyContin did not last twelve hours. Instead of
12 acknowledging a need for more frequent dosing, Purdue instructed its representatives to push
13 higher-strength pills, even though higher dosing carries its own risks, as noted above. It also
14 means that patients will experience higher highs and lower lows, increasing the craving for their
15 next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of
16 patients taking OxyContin longer than three months are on doses greater than 60 milligrams
17 per day— which converts to the 90 MME that the CDC Guideline urges prescribers to “avoid”
18 or “carefully justify.”⁸⁰

19 301. The information that OxyContin did not provide pain relief for a full twelve
20 hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers.
21 Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per
22 day instead of two was set out in Purdue’s internal documents as early as 1999 and is apparent
23 from MedWatch Adverse Event reports for OxyContin.

24 302. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that
25

26 ⁷⁷ Memorandum from Lydia Johnson, Marketing Executive at Purdue, to members of Oxycontin Launch Team (Apr.
27 4, 1995), <http://documents.latimes.com/oxycontin-launch-1995/> (last updated May 5, 2016).

28 ⁷⁸ Letter from Fisher, *supra*.

⁷⁹ *You Want a Description of Hell*, *supra*.

⁸⁰ CDC Guideline, *supra*, at 16.

prescribers were misinformed about the advantages of OxyContin in a manner that preserved Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

- i. Falsehood #9: The false or misleading claims that new formulations of certain opioids successfully deter abuse.

303. Rather than take the widespread opioid abuse as reason to cease their untruthful marketing efforts, Manufacturer Defendant Purdue, among others, seized the epidemic as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales while falsely reassuring prescribers, thereby prolonging the opioid epidemic. Other Manufacturer Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

304. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or deaths."

- i. *Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER*

305. Reformulated ADF OxyContin was approved in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference

1 to
2 the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone)
3 launched in 2014, the product included similar abuse-deterrent properties and limitations. But
4 in
5 the beginning, the FDA made clear the limited claims that could be made about ADF, noting
6 that
7 no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of
8 abuse.

9 306. It is unlikely a coincidence that reformulated OxyContin was introduced shortly
10 before generic versions of OxyContin were to become available, threatening to erode Purdue's
11 market share and the price it could charge. Purdue nonetheless touted its introduction of ADF
12 opioids as evidence of its good corporate citizenship and commitment to address the opioid
13 crisis.

14 307. Despite its self-proclaimed good intention, Purdue merely incorporated its
15 generally deceptive tactics with respect to ADF. Purdue sales representatives regularly
16 overstated and misstated the evidence for and impact of the abuse-deterrent features of these
17 opioids. Specifically, Purdue sales representatives:

- 18 • claimed that Purdue's ADF opioids prevent tampering and that its ADFs could
19 not be crushed or snorted;
- 20
- 21 • claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- 22
- 23 • asserted or suggested that its ADF opioids are non-addictive or less addictive,
- 24
- 25 • asserted or suggested that Purdue's ADF opioids are safer than other opioids,
26 could not be abused or tampered with, and were not sought out for diversion;
27 and
28

- failed to disclose that Purdue’s ADF opioids do not impact oral abuse or misuse.

308. If pressed, Purdue acknowledged that perhaps some “extreme” patients might still abuse the drug, but claimed the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue’s own information and publicly available data.

309. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with and abused.

310. Purdue’s own funded research shows that half of OxyContin abusers continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

311. In 2009, the FDA noted in permitting ADF labeling that “the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)”. In the 2012 medical office review of Purdue’s application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption, and that only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

312. The FDA’s Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin “actually made a reduction in abuse,” between continued oral abuse, shifts to injection of other drugs (including heroin), and defeat of the ADF mechanism. Even Purdue’s own funded research shows that half of OxyContin abusers continued to abuse OxyContin orally after the reformulation rather than shift to other drugs.

313. A 2013 article presented by Purdue employees based on review of data from poison control centers concluded that ADF OxyContin can reduce abuse, but it ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively

emphasized the advantages and ignored the disadvantages of ADF OxyContin.

314. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

315. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

316. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff

was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated OxyContin product has had a meaningful impact on abuse."⁸¹ Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

317. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continues to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the

⁸¹ Jill Hartzler Warner, Assoc. Comm'r for Special Med. Programs, *Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting*, 80(103) Fed. Reg. 30686, 30686 (May 29, 2015).

1 efficacy of its actions.

2 *ii. Other Manufacturer Defendants' misrepresentations regarding abuse*
3 *deterrence*

4
5 318. A guide for prescribers under Actavis's copyright deceptively represents that
6 Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that
7 "unique pharmaceutical formulation of KADIAN may offer some protection from extraction
8 of morphine sulfate for intravenous use by illicit users," and "KADIAN may be less likely to
9 be abused by health care providers and illicit users" because of its "[s]low onset of action."
10 Kadian, however, was not approved by the FDA as abuse deterrent, and, upon information and
11 belief, Actavis had no studies to suggest it was.

12 319. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and
13 Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For
14 example, Mallinckrodt's promotional materials stated that "the physical properties of
15 EXALGO may make it difficult to extract the active ingredient using common forms of physical
16 and chemical tampering, including chewing, crushing and dissolving."⁸² One member of the
17 FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a
18 high abuse potential comparable to oxycodone" and further stated that "we predict that
19 Exalgo will have high levels of abuse and diversion."⁸³

20 320. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that
21 "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the
22 active ingredient from the large quantity of inactive and deterrent ingredients."⁸⁴ In anticipation
23 of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it,
24

25 ⁸² Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-*
26 *Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012),
<http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159>.

27 ⁸³ 2010 Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee, at 157-
28 58, FDA, excerpt available at <https://www.markey.senate.gov/imo/media/doc/2016-02-19-Markey-ADF-Opioid-timeline.pdf>.

⁸⁴ Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

1 and CEO Mark Trudeau said the drug could generate “hundreds of millions in revenue.”⁸⁵

2 321. While Manufacturer Defendants promote patented technology as the solution to
3 opioid abuse and addiction, none of their “technology” addresses the most common form of
4 abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the
5 misleading impression that these reformulated opioids can be prescribed safely.

6 322. In sum, each of the nine categories of misrepresentations discussed above
7 regarding the use of opioids to treat chronic pain was deceptive and unconscionable. The
8 misrepresentations were material, false, and misleading, as well as unsupported by or contrary
9 to the scientific evidence. In addition, the misrepresentations and omissions set forth above and
10 elsewhere in this Complaint are misleading and contrary to the Manufacturing Defendants’
11 product labels.

12 **2. The Manufacturer Defendants Disseminated Their Misleading Messages About**
13 **Opioids Through Multiple Channels**

14
15 323. The Manufacturer Defendants’ false marketing campaign not only targeted the
16 medical community who had to treat chronic pain, but also patients who experience chronic
17 pain.

18 324. The Manufacturer Defendants utilized various channels to carry out their
19 marketing scheme of targeting the medical community and patients with deceptive information
20 about opioids: (1) “Front Groups” with the appearance of independence from the
21 Manufacturer Defendants; (2) Key Opinion Leaders or “KOLs”, that is, doctors who were paid
22 by the Manufacturer Defendants to promote their pro-opioid message; (3) CME programs
23 controlled and/or funded by the Manufacturer Defendants; (4) branded advertising; (5)
24 unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers
25 by sales representatives or “detailers”; and (8) speakers bureaus and programs.

26
27 ⁸⁵ Samantha Liss, *Mallinckrodt Banks on New Painkillers for Sales*, St. Louis Bus. J. 1 (Dec. 30, 2013),
28 <http://argenticapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

a. The Manufacturer Defendants Directed Front Groups to Deceptively Promote Opioid Use.

325. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Manufacturer Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These “Front Groups” put out patient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks.⁸⁶ Manufacturer Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

326. “Patient advocacy organizations and professional societies like the Front Groups ‘play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.’”⁸⁷ “Even small organizations— with ‘their large numbers and credibility with policymakers and the public’— have ‘extensive influence in specific disease areas.’ Larger organizations with extensive funding and outreach capabilities ‘likely have a substantial effect on policies relevant to their industry sponsors.’”⁸⁸ Indeed, the U.S. Senate’s report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Insys, and other opioid manufacturers, “provides the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the

⁸⁶ U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members’ Office, (February 12, 2018), <https://www.hsdl.org/?view&did=808171> at 3 (“*Fueling an Epidemic*”), at 3.

⁸⁷ *Id.* at 2.

⁸⁸ *Id.*

1 area of opioids policy,”⁸⁹ and found that the Manufacturer Defendants gave millions of dollars
2 in contributions to various Front Groups.⁹⁰

3 327. The Manufacturer Defendants also “made substantial payments to individual
4 group executives, staff members, board members, and advisory board members” affiliated with
5 the Front Groups subject to the Senate Committee’s study.⁹¹

6 328. As the Senate *Fueling an Epidemic* Report found, the Front Groups “amplified
7 or issued messages that reinforce industry efforts to promote opioid prescription and use,
8 including guidelines and policies minimizing the risk of addiction and promoting opioids
9 for chronic pain.”⁹² They also “lobbied to change laws directed at curbing opioid use, strongly
10 criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold
11 physicians and industry executives responsible for over prescription and misbranding.”⁹³

12 329. The Manufacturer Defendants took an active role in guiding, reviewing, and
13 approving many of the false and misleading statements issued by the Front Groups, ensuring
14 that Manufacturer Defendants were consistently in control of their content. By funding,
15 directing, editing, approving, and distributing these materials, Manufacturer Defendants
16 exercised control over and adopted their false and deceptive messages and acted in concert with
17 the Front Groups and through the Front groups, with each other to deceptively promote the use
18 of opioids for the treatment of chronic pain.

19 *i. American Pain Foundation*

20
21 330. The most prominent of the Front Groups was the American Pain Foundation
22 (“APF”). While APF held itself out as an independent patient advocacy organization, in reality
23 it received 90% of its funding in 2010 from the drug and medical-device industry, including
24 from defendants Purdue, Endo, and other manufacturers. APF received more than \$10 million
25

26 ⁸⁹ *Id.* at 1.

27 ⁹⁰ *Id.* at 1, 3.

28 ⁹¹ *Id.* at 10.

⁹² *Id.* at 12.

⁹³ *Id.*

1 in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011,
2 APF was entirely dependent on incoming grants from Defendants Purdue, Endo, and others to
3 avoid using its line of credit. Endo was APF's largest donor and provided more than half of its
4 \$10 million in funding from 2007 to 2012.

5 331. For example, APF published a guide sponsored by Purdue and another
6 opioid manufacturer titled *Treatment Options: A Guide for People Living with Pain* and
7 distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report.
8 This guide, which is still available online within the state of Nevada, contains multiple
9 misrepresentations regarding opioid use which are discussed below.

10 332. APF also developed the National Initiative on Pain Control ("NIPC"), which ran
11 a facially unaffiliated website, www.painknowledge.com. NIPC promoted itself as an education
12 initiative led by its expert leadership team, including purported experts in the pain management
13 field. NIPC published unaccredited prescriber education programs (accredited programs are
14 reviewed by a third party and must meet certain requirements of independence from
15 pharmaceutical companies), including a series of "dinner dialogues."

16 333. APF was often called upon to provide "patient representatives" for the
17 Manufacturer Defendants' promotional activities, including for Purdue's "Partners Against
18 Pain" and Janssen's "Let's Talk Pain." Although APF presented itself as a patient advocacy
19 organization, it functioned largely as an advocate for the interests of the Manufacturer
20 Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization
21 was Purdue's desire to strategically align its investments in nonprofit organizations that share
22 its business interests.

23 334. In practice, APF operated in close collaboration with Manufacturer Defendants,
24 submitting grant proposals seeking to fund activities and publications suggested by
25 Manufacturer Defendants and assisting in marketing projects for Manufacturer Defendants.

26 335. This alignment of interests was expressed most forcefully in the fact that Purdue
27 hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered
28

1 into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave
2 Purdue substantial rights to control APF’s work related to a specific promotional project.
3 Moreover, based on the assignment of particular Purdue “contacts” for each project and APF’s
4 periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the
5 misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in
6 connection with that project. The agreement gave Purdue—but not APF—the right to end the
7 project (and, thus, APF’s funding) for any reason. Even for projects not produced during the
8 terms of this Agreement, the Agreement demonstrates APF’s lack of independence and APF’s
9 willingness to harness itself to Purdue’s control and commercial interests, which would have
10 carried across all of APF’s work.

11 336. APF’s Board of Directors was largely comprised of doctors who were on the
12 Manufacturer Defendants’ payrolls, either as consultants or speakers at medical events. The
13 close relationship between APF and the Manufacturer Defendants demonstrates APF’s clear
14 lack of independence in its finances, management, and mission, and its willingness to allow
15 Manufacturer Defendants to control its activities and messages. This close relationship also
16 supports a reasonable inference that each Manufacturer Defendant that worked with it was able
17 to exercise editorial control over its publications—even when Manufacturer Defendants’
18 messages contradicted APF’s internal conclusions. For example, a roundtable convened by
19 APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid
20 therapy. APF’s formal summary of the meeting notes concluded that: “[An] important barrier[]
21 to appropriate opioid management [is] the lack of confirmatory data about the long-term safety
22 and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence.”

23 337. In May 2012, the U.S. Senate Finance Committee began looking into APF to
24 determine the links, financial and otherwise, between the organization and the manufacturers
25 of opioid painkillers. Within days of being targeted by the Senate investigation, APF’s board
26 voted to dissolve the organization “due to irreparable economic circumstances.” APF then
27 “cease[d] to exist, effective immediately.” Without support from Manufacturer Defendants, to
28 whom APF could no longer be helpful, APF was no longer financially viable.

1 ii. *American Academy of Pain Medicine and the American Pain Society*

2 338. The American Academy of Pain Medicine (“AAPM”) and the American Pain
3 Society (“APS”) are professional medical societies, each of which received substantial funding
4 from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that
5 endorsed opioids to treat chronic pain and claimed that the risk that patients would become
6 addicted to opioids was low.⁹⁴ The Chair of the committee that issued the statement, Dr. J.
7 David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee
8 was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement,
9 which also formed the foundation of the 1998 Model Guidelines for Use of Controlled
10 Substances for the Treatment of Pain issued by the Federation of State Medical Boards (see
11 below), was published on the AAPM’s website.

12 339. Since 1998, the Federation of State Medical Boards has been developing
13 treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model
14 Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.”

15 340. AAPM’s corporate council includes Purdue, Depomed, Teva and other
16 pharmaceutical companies. AAPM’s past presidents include Haddox (1998), Dr. Scott
17 Fishman (2005), Dr. Perry G. Fine (2011), and Dr. Lynn R. Webster (2013), all of whose
18 connections to the opioid manufacturers are well-documented as set forth elsewhere in this
19 Complaint.
20

21 341. Fishman, who also served as a KOL for Manufacturer Defendants, stated that
22 he would place the organization “at the forefront” of teaching that “the risks of addiction are . . .
23 small and can be managed.”⁹⁵
24

25 ⁹⁴ The Use of Opioids for the Treatment of Chronic Pain, *APS & AAPM (1997)*,
26 <http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf>
27 (as viewed August 18, 2017).

28 ⁹⁵ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine,
Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at
<http://www.medscape.org/viewarticle/500829>.

1 342. AAPM received over \$2.2 million in funding since 2009 from opioid
2 manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000
3 per year (on top of other funding) to participate. The benefits included allowing members to
4 present educational programs at off-site dinner symposia in connection with AAPM’s marquee
5 event – its annual meeting held in Palm Springs, California, or other resort locations.

6 343. AAPM describes the annual event as an “exclusive venue” for offering CMEs
7 to doctors. Membership in the corporate relations council also allows drug company executives
8 and marketing staff to meet with AAPM executive committee members in small settings.
9 Manufacturer Defendant Purdue, Endo, and Cephalon were members of the council and
10 presented deceptive programs to doctors who attended this annual event. The conferences
11 sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at
12 one conference alone.

13 344. AAPM’s staff understood that they and their industry funders were engaged in
14 a common task. Defendants were able to influence AAPM through both their significant and
15 regular funding and the leadership of pro-opioid KOLs within the organization.

16 345. With the assistance, prompting, involvement, and funding of Manufacturer
17 Defendants, AAPM and APS issued their own treatment guidelines in 2009 (“2009
18 Guidelines”), and continued to recommend the use of opioids to treat chronic pain. Fourteen of
19 the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received
20 support from Endo and Defendant Purdue. Of these individuals, six received support from
21 Purdue, eight from Teva, and nine from Endo.

22 346. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan
23 State University and founder of the Michigan Headache & Neurological Institute, resigned
24 from the panel because of his concerns that the 2009 Guidelines were influenced by
25 contributions that drug companies, including Purdue, Endo, and Teva, made to the sponsoring
26 organizations and committee members.

347. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

348. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Manufacturer Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these types of guidelines. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."⁹⁶

349. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain, and upon information and belief, the 2009 Guidelines were created just for that purpose.

350. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the 2009 Guidelines, or their financial backing of the authors of the 2009 Guidelines.

iii. *The Federation of State Medical Boards*

351. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints,

⁹⁶ 2016 CDC Guideline at 2.

1 and discipline physicians.

2 352. The FSMB finances opioid- and pain-specific programs through grants from
3 Manufacturer Defendants.

4 353. Since 1998, the FSMB has been developing treatment guidelines for the use of
5 opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled
6 Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with
7 pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped
8 author taught not that opioids could be appropriate in only limited cases after other treatments
9 had failed, but that opioids were "essential" for treatment of chronic pain, including as a first
10 prescription option.

11 354. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid*
12 *Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted
13 online and were available to and intended to reach physicians nationwide, including in Nevada.

14 355. *Responsible Opioid Prescribing* was backed largely by drug manufacturers,
15 including Purdue and Endo. The publication also received support from the American Pain
16 Foundation and the American Academy of Pain Medicine. The publication was written by Dr.
17 Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible*
18 *Opioid Prescribing* were distributed to state medical boards (and through the boards, to
19 practicing doctors). The FSMB website describes the book as "the leading continuing medical
20 education (CME) activity for prescribers of opioid medications." Nevada doctors could read
21 the book to obtain CME credit. This publication asserted that opioid therapy to relieve pain and
22 improve function is a legitimate medical practice for acute and chronic pain of both cancer and
23 non-cancer origins; that pain is under-treated, and that patients should not be denied opioid
24 medications except in light of clear evidence that such medications are harmful to the patient.⁹⁷

25 356. The Manufacturer Defendants relied on the 1998 Guidelines to convey the
26 alarming message that "under-treatment of pain" would result in official discipline, but no
27

28 ⁹⁷ Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

1 discipline would result if opioids were prescribed as part of an ongoing patient relationship and
2 prescription decisions were documented. FSMB turned doctors' fear of discipline on its head:
3 doctors, who used to believe that they would be disciplined if their patients became addicted
4 to opioids, were taught instead that they would be punished if they failed to prescribe opioids
5 to their patients with chronic pain.

6 *iv. The Alliance for Patient Access*

7
8 357. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described
9 patient advocacy and health professional organization that styles itself as "a national network
10 of physicians dedicated to ensuring patient access to approved therapies and appropriate
11 clinical care."⁹⁸ It is run by Woodberry Associates LLC, a lobbying firm that was also
12 established in 2006.⁹⁹ As of June 2017, the APA listed 30 "Associate Members and Financial
13 Supporters." The list includes Endo, Mallinckrodt, and Purdue.

14 358. APA's board members have also directly received substantial funding from
15 pharmaceutical companies.¹⁰⁰ For instance, board vice president Dr. Srinivas Nalamachu, who
16 practices in Kansas, received more than \$800,000 from 2013 through 2015 from
17 pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat
18 opioids' side effects, including Purdue among others. Nalamachu's clinic was raided by FBI
19 agents in connection with an investigation of Insys and its payment of kickbacks to physicians
20 who prescribed Subsys.¹⁰¹ Other board members include Dr. Robert A. Yapundich from North
21 Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies,
22

23 ⁹⁸ *About AfPA*, The Alliance for Patient Access, <http://allianceforpatientaccess.org/about-afpa> (last visited Apr. 25,
24 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the
Institute for Patient Access.

25 ⁹⁹ Mary Chris Jaklevic, *Alliance for Patient Access Uses Journalists and Politicians to Push Big Pharma's Agenda*,
Health News Review (Oct. 2, 2017), [https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-
26 access-uses-journalists-politicians-push-big-pharmas-agenda/](https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/) (hereinafter "Jaklevic, *Non-Profit Alliance for
Patient Access*").

27 ¹⁰⁰ All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's
Dollars for Docs database, <https://projects.propublica.org/docdollars/>.

28 ¹⁰¹ Andy Marso, *FBI Seizes Records of Overland Park Pain Doctor Tied to Insys*, Kansas City Star (July 20, 2017),
<http://www.kansascity.com/news/business/health-care/article162569383.html>.

including payments by Defendant Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including Defendant Mallinckrodt; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Purdue and Mallinckrodt; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

359. Among its activities, APA issued a “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.”¹⁰² Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

* * *

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.¹⁰³

¹⁰² Pain Therapy Access Physicians Working Group, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Dec. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.
¹⁰³ *Id.* at 4-5.

360. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.¹⁰⁴

361. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non- pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.¹⁰⁵

362. In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”¹⁰⁶

363. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare and are thus touted by their recipients as demonstrating a commitment to

¹⁰⁴ *Id.* at 5-6.

¹⁰⁵ *Id.* at 6.

¹⁰⁶ *Id.* at 7.

1 protecting the rights of senior citizens and the middle class, they appear to be given to provide
2 cover to and reward members of Congress who have supported the APA's agenda.¹⁰⁷

3 364. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter
4 supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing
5 the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control
6 Act of 1970, 21 USC §801 *et seq.* ("CSA" or "Controlled Substances Act"). The AAPM is also
7 a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the
8 proposed bill "could actually result in increased diversion, abuse, and public health and safety
9 consequences"¹⁰⁸ and, according to DEA chief administrative law judge John J. Mulrooney
10 ("Mulrooney"), the law would make it "all but logically impossible" to prosecute
11 manufacturers and distributors, like the defendants here, in the federal courts.¹⁰⁹ The bill passed
12 both houses of Congress and was signed into law in 2016.

13 v. *The U.S. Pain Foundation*

14
15 365. The U.S. Pain Foundation ("USPF") was another Front Group with systematic
16 connections and interpersonal relationships with the Manufacturer Defendants. The USPF was
17 one of the largest recipients of contributions from the Manufacturer Defendants, collecting
18 more than \$3 million in payments between 2012 and 2017 from Insys, Purdue, and others.¹¹⁰
19 The USPF was also a critical component of the Manufacturer Defendants' lobbying efforts to
20 reduce the limits on over-prescription. The USPF advertises its ties to the Manufacturer
21 Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil
22

23 ¹⁰⁷ Jaklevic, *Non-profit Alliance for Patient Access*, *supra*.

24 ¹⁰⁸ Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS
25 News (Oct. 17, 2017), [https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-](https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-bydrug-industry-and-congress/)
26 [bydrug-industry-and-congress/](https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-bydrug-industry-and-congress/).

27 ¹⁰⁹ John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion*
28 *Law*:

Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev., 333, 346
(2017).

¹¹⁰ Fueling an Epidemic, *supra*.

(i.e. Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members.¹¹¹ Industry Front Groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

vi. *American Geriatrics Society*

366. The American Geriatrics Society (“AGS”) was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The AGS was a large recipient of contributions from the Manufacturer Defendants, including Purdue. AGS contracted with Purdue to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter “2002 AGS Guidelines”) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*,¹¹² hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009.¹¹³ AGS’s complicity in the common purpose with the Manufacturer Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive upfront funding from drug companies, which would suggest drug company influence, but would instead, accept commercial support to disseminate pro-opioid publications.

367. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse.¹¹⁴ These

¹¹¹ *Id.* at 12; Transparency, U.S. Pain Foundation, <https://uspainfoundation.org/transparency/> (last visited on March 9, 2018).

¹¹² *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc’y 1331, 1339, 1342 (2009), available at <https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf> (last visited Apr. 25, 2018).

¹¹³ John Fauber & Ellen Gabler, “Narcotic Painkiller Use Booming Among Elderly,” *Milwaukee J. Sentinel*, May 30, 2012, <https://medpagetoday.com/geriatrics/painmanagement/32967>.

¹¹⁴ 2009 AGS Guidelines at 1342.

Guidelines further stated that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations and statements are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited as many as 1,833 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

368. Representatives of the Manufacturer Defendants, often during informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

369. Members of the AGS Board of Directors were doctors on the Manufacturer Defendants’ payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

b. The Manufacturer Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use.

370. To falsely promote their opioids, the Manufacturer Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Manufacturer Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Manufacturer Defendants’ well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception that science and respected medical professionals favored the broader use of opioids. These doctors include Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman, as set forth below.

371. Although these KOLs were funded by the Manufacturer Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

1 372. As the Manufacturer Defendants' false marketing scheme picked up steam,
2 these pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles,
3 and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on
4 committees that developed treatment guidelines that strongly encouraged the use of opioids to
5 treat chronic pain and they were placed on boards of pro-opioid advocacy groups and
6 professional societies that develop, select, and present CMEs.

7 373. Through use of their KOLs and strategic placement of these KOLs throughout
8 every critical distribution channel of information within the medical community, the
9 Manufacturer Defendants were able to exert control of each of these modalities through which
10 doctors receive their information.

11 374. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs
12 received money, prestige, recognition, research funding, and avenues to publish. For example,
13 Dr. Webster and Dr. Fine have received funding from Purdue, among others.

14 375. The Manufacturer Defendants carefully vetted their KOLs to ensure that they
15 were likely to remain on-message and supportive of the Manufacturer Defendants' agenda. The
16 Manufacturer Defendants also kept close tabs on the content of the materials published by these
17 KOLs. And, of course, the Manufacturer Defendants kept these KOLs well-funded to enable
18 them to push the Manufacturer Defendants' deceptive message out to the medical community.

19 376. Once the Manufacturer Defendants identified and funded KOLs and those
20 KOLs began to publish "scientific" papers supporting the Manufacturer Defendants' false
21 position that opioids were safe and effective for treatment of chronic pain, the Manufacturer
22 Defendants poured significant funds and resources into a marketing machine that widely cited
23 and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids
24 for chronic pain. The Manufacturer Defendants cited to, distributed, and marketed these studies
25 and articles by their KOLs as if they were independent medical literature so that it would be
26 well-received by the medical community. These studies and articles were available to and were
27 intended to reach doctors in Nevada. By contrast, the Manufacturer Defendants did not support,
28

1 acknowledge, or disseminate the truly independent publications of doctors critical of the use of
2 chronic opioid therapy.¹¹⁵

3 377. In their promotion of the use of opioids to treat chronic pain, the Manufacturer
4 Defendants' KOLs knew that their statements were false and misleading, or they recklessly
5 disregarded the truth in doing so, but they continued to publish their misstatements to benefit
6 themselves and the Manufacturer Defendants.

7 i. Dr. Russell Portenoy

8
9 378. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department
10 of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the
11 same time serving as a top spokesperson for drug companies, published an article reporting
12 that "[f]ew substantial gains in employment or social function could be attributed to the
13 institution of opioid therapy."¹¹⁶

14 379. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the
15 dangers of long-term use of opioids:

16 *The traditional approach to chronic non-malignant pain does*
17 *not accept the long-term administration of opioid drugs. This*
18 *perspective has been justified by the perceived likelihood of*
19 *tolerance, which would attenuate any beneficial effects over*
20 *time, and the potential for side effects, worsening disability, and*
21 *addiction. According to conventional thinking, the initial*
22 *response to an opioid drug may appear favorable, with partial*
23 *analgesia and salutary mood changes, but adverse effects*
24 *inevitably occur thereafter. It is assumed that the motivation to*
25 *improve function will cease as mental clouding occurs and the*
belief takes hold that the drug can, by itself, return the patient to
a normal life. Serious management problems are anticipated,
including difficulty in discontinuing a problematic therapy and
the development of drug seeking behavior induced by the desire
to maintain analgesic effects, avoid withdrawal, and perpetuate

26 ¹¹⁵ See, e.g., Volkow & McLellan, *supra*; see also Matthew Miller, et al., *Prescription Opioid Duration of Action*
27 *and the Risk of Unintentional Overdose Among Patients Receiving Opioid Therapy*, JAMA Intern Med 2015;
175(4): 608-615.

28 ¹¹⁶ R. Portenoy & K. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2)
Pain 171 (1986).

reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.¹¹⁷

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”¹¹⁸

380. Despite having taken this position on long-term opioid treatment, Dr. Portenoy soon became a spokesperson for Purdue and other Manufacturer Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, co-founder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”¹¹⁹

381. As one organizer of CME seminars who worked with Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”¹²⁰ Dr. Portenoy’s publications and other materials were available to and were intended to reach doctors in Nevada.

382. Dr. Portenoy was also a critical component of the Manufacturer Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

383. In recent years, some of the Manufacturer Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the

¹¹⁷ Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

¹¹⁸ *Id.*

¹¹⁹ Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* 314 (Bloomsbury Press 2015).

¹²⁰ *Id.* at 136.

scientific literature.¹²¹ Dr. Portenoy has now admitted that he minimized the risks of opioids, and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.”¹²² He mused, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did”¹²³

384. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn’t before. *In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*¹²⁴

385. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to always have to live with that one.”¹²⁵

ii. Dr. Lynn Webster

386. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster

¹²¹ See, e.g., John Fauber, *Painkiller Boom Fueled by Networking*, Journal Sentinel (Feb. 18, 2012), <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (reporting that a key Endo KOL acknowledged that opioid marketing went too far).

¹²² Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>. (Last updated Dec. 17, 2012 11:36 AM).

¹²³ *Id.*

¹²⁴ ¹⁴³ Harrison Jacobs, *This 1-Paragraph Letter May Have Launched the Opioid Epidemic*, AOL (May 26, 2016), <https://www.aol.com/article/2016/05/26/letter-may-have-launched-opioid-epidemic/21384408/>; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), <https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be>.

¹²⁵ Meier, *supra*, at 277.

was President of AAPM in 2013 and remains a current board member. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon alone).

387. Dr. Webster created and promoted the *Opioid Risk Tool*, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's *Opioid Risk Tool* ("ORT") appear on, or are linked to, websites run by Endo and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Nevada.¹²⁶

388. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Manufacturer Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids, and he prescribed staggering quantities of pills.

389. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain

¹²⁶ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

1 experience episodes of breakthrough pain, yet no currently available pharmacologic agent is
2 ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new
3 form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim
4 results of this study suggest that [fentanyl effervescent buccal tablets are] safe and well-
5 tolerated in patients with chronic pain and [breakthrough pain].”

6 *iii. Dr. Perry Fine*

7 390. Dr. Perry Fine’s ties to the Manufacturer Defendants have been well-documented.
8 He has authored articles and testified in court cases and before state and federal committees,
9 and he, too, has argued against legislation restricting high-dose opioid prescription for non-
10 cancer patients. He has served on Purdue’s advisory board, participated in CME activities for
11 Endo, along with serving in these capacities for several other drug companies. He co-chaired the
12 APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and
13 as president of that group from 2011 to 2013, and was also on the board of directors of APF.¹²⁷

14 391. Multiple videos feature Fine delivering educational talks about prescription
15 opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna
16 Nicole Smith for pain did not make her an addict before her death.

17 392. He has also acknowledged having failed to disclose numerous conflicts of
18 interest.

19
20 For example, Dr. Fine failed to fully disclose payments received as required by his employer,
21 the University of Utah.—

22 393. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in
23 which they downplayed the risks of opioid treatment, such as respiratory depression and
24 addiction:

25 At clinically appropriate doses, . . . respiratory rate typically does
26 not decline. Tolerance to the respiratory effects usually develops

27 ¹²⁷ Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*,
28 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>. (hereinafter, “Fishman”).

quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.¹²⁸

394. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain.¹²⁹ He states that the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.” The program assumes that opioids are appropriate treatment over a “protracted period of time,” even over a patient’s entire “lifetime.” Fine even suggests that opioids can be used to treat sleep apnea. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”¹³⁰ Dr. Fine’s articles and educational talks were available to and were intended to reach doctors in Nevada.

iv. Dr. Scott Fishman

395. Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants. He has also worked to oppose legislation requiring

¹²⁸ Perry G. Fine, MD & Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), at 20, 34. <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

¹²⁹ Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

¹³⁰ *Id.*

doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”¹³¹

396. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled *Responsible Opioid Prescribing* in 2007, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

397. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.¹³²

398. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.”¹³³ Nevada doctors could read the guide to obtain CME credit.

399. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.”¹³⁴ The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.” These physician’s guides were available to and were intended to reach doctors in Nevada.

¹³¹ Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

¹³² Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2d ed. 2012).

¹³³ *Id.*

¹³⁴ Scott M. Fishman, *Listening to Pain: A Clinician’s Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

c. The Manufacturer Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs.

400. Now that the Manufacturer Defendants had both a group of physician promoters and had built a false body of “literature,” Manufacturer Defendants needed to make sure their false marketing message was widely distributed.

401. One way the Manufacturer Defendants aggressively distributed their false message was through thousands of Continuing Medical Education courses (“CMEs”).

402. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

403. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for the Manufacturer Defendants’ opioid reeducation effort. As one target, Manufacturer Defendants aimed to reach general practitioners, whose broad area of practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Manufacturer Defendants’ deceptions.

404. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and

1 adverse effects. In order to conduct such CMEs in the State of Nevada, the Manufacturer
2 Defendants had to make the same misrepresentations regarding their opioid products to the
3 State agencies. Because of these misrepresentations and deceptive marketing, these CMEs
4 were available to and were intended to reach doctors in Nevada.

5 405. *Responsible Opioid Prescribing* was sponsored by Purdue and Teva, among
6 others. The FSMB website described it as the “leading continuing medical education (CME)
7 activity for prescribers of opioid medications.”

8 406. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were
9 distributed nationally.

10 407. The American Medical Association (“AMA”) recognized the impropriety that
11 pharmaceutical company-funded CMEs creates; stating that support from drug companies with
12 a financial interest in the content being promoted “creates conditions in which external interests
13 could influence the availability and/or content” of the programs and urges that “[w]hen
14 possible, CME[s] should be provided without such support or the participation of individuals
15 who have financial interests in the education subject matter.”¹³⁵

16 408. Physicians, including those who practice or practiced in Nevada, attended or
17 reviewed CMEs sponsored by the Manufacturer Defendants during the relevant time period
18 and were misled by them.

19 409. By sponsoring CME programs put on by Front Groups like APF, AAPM, and
20 others, the Manufacturer Defendants could expect instructors to deliver messages favorable to
21 them, as these organizations were dependent on the Manufacturer Defendants for other
22 projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to
23 give talks that supported chronic opioid therapy. Manufacturer Defendant-driven content in
24 these CMEs had a direct and immediate effect on Nevada prescribers’ views on opioids.
25 Producers of CMEs and the Manufacturer Defendants both measure the effects of CMEs on
26 prescribers’ views on opioids and their absorption of specific messages, confirming the
27

28 ¹³⁵ Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass’n (Nov. 2011), at 1.

1 strategic marketing purpose in supporting them.

2 d. The Manufacturer Defendants Used “Branded” Advertising to Promote Their
3 Products to Doctors and Consumers.
4

5 410. The Manufacturer Defendants engaged in widespread advertising campaigns
6 touting the benefits of their branded drugs, including within the state of Nevada. The
7 Manufacturer Defendants published print advertisements in a broad array of medical journals,
8 ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of*
9 *Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical*
10 *Association*. The Manufacturer Defendants collectively spent more than \$14 million on the
11 medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011
12 total includes \$8.3 million by Purdue.

13 411. The Manufacturer Defendants also targeted Nevada consumers in their
14 advertising. They knew that physicians are more likely to prescribe a drug if a patient
15 specifically requests it.¹³⁶ They also knew that this willingness to acquiesce to such patient
16 requests holds true even for opioids and for conditions for which they are not approved.¹³⁷ The
17 Manufacturer Defendants increasingly took their opioid sales campaigns directly to consumers,
18 including through patient-focused “education and support” materials in the form of pamphlets,
19 videos, or other publications that patients could view in their physician’s office.

20 e. The Manufacturer Defendants Used “Unbranded” Advertising to Promote
21 Opioid Use for Chronic Pain Without FDA Review.
22

23 412. The Manufacturer Defendants also aggressively promoted opioids in Nevada
24 through “unbranded advertising” to generally tout the benefits of opioids without specifically
25

26 ¹³⁶ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it,
27 compared with 1% of those making no specific request. J.B. McKinlay et al., *Effects of Patient Medication*
28 *Requests on Physician Prescribing Behavior, Results of a Factorial Experiment* 52(2) Med. Care 294-99 (April 2014).

¹³⁷ *Id.*

1 naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed
2 as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health
3 condition without promoting a specific product and, therefore, without providing balanced
4 disclosures about the product’s limits and risks. In contrast, a pharmaceutical company’s
5 “branded” advertisement that identifies a specific medication and its indication (i.e., the
6 condition which the drug is approved to treat) must also include possible side effects and
7 contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair
8 balance.” Branded advertising is also subject to FDA review for consistency with the drug’s
9 FDA-approved label. Through unbranded materials, the Marketing Defendants expanded the
10 overall acceptance of and demand for chronic opioid therapy without the restrictions imposed
11 by regulations on branded advertising.

12 413. By funding, directing, reviewing, editing, and distributing this unbranded
13 advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by
14 these third parties and acted in concert with them to falsely and misleadingly promote opioids
15 for the treatment of chronic pain. Much as Defendants controlled the distribution of their “core
16 messages” via their own “detailers” (an industry term for sales representatives) and speaker
17 programs, the Manufacturer Defendants similarly controlled the distribution of these messages
18 in scientific publications, treatment guidelines, CME programs, and medical conferences and
19 seminars. To this end, the Manufacturer Defendants used third-party public relations firms to
20 help control those messages when they originated from third-parties.

21 414. The Manufacturer Defendants marketed opioids in Nevada through third-party,
22 unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to,
23 and typically is not reviewed by, the FDA. The Manufacturer Defendants also used third-party,
24 unbranded advertising to give the false appearance that the deceptive messages came from an
25 independent and objective source. Like the tobacco companies, the Manufacturer Defendants
26 used third parties that they funded, directed, and controlled to carry out and conceal their
27 scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for
28

1 chronic pain.

2 415. Many of the Manufacturer Defendants utilized unbranded websites to promote
3 opioid use without promoting a specific branded drug, such as Purdue’s pain-management
4 website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen
5 “advocates,” including health care providers, urging more pain treatment. The website
6 presented the advocates as neutral and unbiased, but an investigation by the New York Attorney
7 General later revealed that Purdue paid the advocates hundreds of thousands of dollars and
8 never publicly disclosed those payments.

9 f. The Manufacturer Defendants Funded, Edited, and Distributed Publications
10 that Supported Their Misrepresentations.
11

12 416. The Manufacturer Defendants created a body of false, misleading, and
13 unsupported medical and popular literature about opioids that (a) understated the risks and
14 overstated the benefits of long-term use; (b) appeared to be the result of independent,
15 objective research; and
16 (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served
17 marketing goals rather than treatment goals and was intended to persuade doctors and
18 consumers that the benefits of long-term opioid use outweighed the risks.

19 417. To accomplish their goal, the Manufacturer Defendants—sometimes through
20 third- party consultants and/or Front Groups—commissioned, edited, and arranged for the
21 placement of favorable articles in academic journals, including journals distributed in Nevada.

22 418. The Manufacturer Defendants’ plans for these materials did not originate in the
23 departments with the organizations that were responsible for research, development, or any
24 other area that would have specialized knowledge about the drugs and their effects on patients;
25 rather, they originated in the Manufacturer Defendants’ marketing departments.

26 419. The Manufacturer Defendants made sure that favorable articles were
27 disseminated and cited widely in the medical literature, even when the Manufacturer
28

1 Defendants knew that the articles distorted the significance or meaning of the underlying study,
2 as with the Porter & Jick letter. The Manufacturer Defendants also frequently relied on
3 unpublished data or posters, neither of which are subject to peer review, but were presented as
4 valid scientific evidence. Posters are preliminary, unpublished, non-peer reviewed reports that
5 are intended to be turned into peer- reviewed academic papers, but sometimes do not.

6 420. The Manufacturer Defendants published or commissioned deceptive review
7 articles, letters to the editor, commentaries, case-study reports, and newsletters aimed
8 at discrediting or suppressing negative information that contradicted their claims or raised
9 concerns about chronic opioid therapy. These publications were available to and were intended
10 to reach doctors in Nevada.

11 g. The Manufacturer Defendants Used Detailing to Directly Disseminate Their
12 Misrepresentations to Prescribers.

13
14 421. The Manufacturer Defendants' sales representatives executed carefully crafted
15 marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted
16 doctors in Nevada with centrally orchestrated messages. The Manufacturer Defendants' sales
17 representatives also distributed third-party marketing material to their target audience that was
18 deceptive.

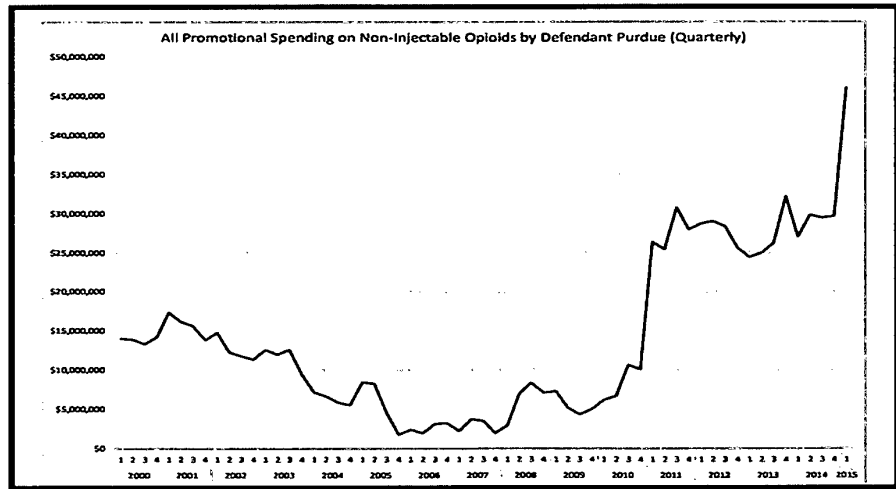
19 422. Each Manufacturer Defendant promoted opioids through sales representatives
20 (also called "detailers") and, upon information and belief, small group speaker programs to
21 reach out to individual prescribers. By establishing close relationships with doctors, the
22 Manufacturer Defendants were able to disseminate their misrepresentations in targeted, one-on-
23 one settings that allowed them to promote their opioids and to allay individual prescribers'
24 concerns about prescribing opioids for chronic pain.

25 423. In accordance with common industry practice, the Manufacturer Defendants
26 purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a
27 healthcare data collection, management and analytics corporation started by Arthur Sackler.
28

This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors, including doctors in Nevada, and disseminated the misinformation and materials described above.

424. Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$13 million by Teva, and \$10 million by Endo.

425. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation, but then spiked to above \$25 million in 2011 (for a total of \$110 million that year), and continues to rise, as shown below:



h. Manufacturer Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages.

426. In addition to making sales calls, Manufacturer Defendants' detailers also

identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; they qualify and/or vet doctors to be selected for a forum in which the Manufacturer Defendants can further market directly to the speaker himself or herself; and they provide an opportunity for Manufacturer Defendants to market to the speaker's peers. The Manufacturer Defendants grade their speakers, and make the offer of future opportunities contingent upon, speaking performance, post-program sales, and product usage. Purdue, Mallinckrodt, and others, each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

427. As detailed below, Insys paid prescribers for *fake* speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes included countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speakers' programs at which the only attendees at the events were the speaker and an Insys sales representative, amounting to no more than a pay-to-prescribe program. Insys used speakers' programs as a front to pay for prescriptions and paid to push opioids onto patients who did not need them.

3. The Manufacturer Defendants Targeted Vulnerable Populations.

428. The Manufacturer Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

429. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which occur more frequently in elderly patients.

430. The Manufacturer Defendants promoted the notion—without adequate

1 scientific foundation—that the elderly are particularly unlikely to become addicted to opioids.
2 The AAPM’s and APS 2009 Guidelines, for example, which Purdue and Endo publicized,
3 described the risk of addiction as “*exceedingly low* in older patients with no current or
4 past history of substance abuse.” (emphasis added). A 2010 study examining overdoses among
5 long-term opioid users found that patients 65 or older were among those with the largest
6 number of serious overdoses.¹³⁸

7 431. According to a study published in the 2013 *Journal of American Medicine*,
8 veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher
9 incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental
10 injuries. A 2008 survey showed that prescription drug misuse among military personnel
11 doubled from 2002 to 2005, and then nearly tripled again over the next three years.¹³⁹ Veterans
12 are twice as likely as non-veterans to die from an opioid overdose.¹⁴⁰

13 432. Yet the Manufacturer Defendants deliberately targeted veterans with deceptive
14 marketing. For example, a 2009 publication sponsored by Purdue and Endo was written as a
15 personal narrative of one veteran but was in fact another vehicle for opioid promotion. Called
16 *Exit Wounds*, the publication describes opioids as “underused” and the “gold standard of pain
17 medications” while failing to disclose significant risks of opioid use, including the risks of fatal
18 interactions with benzodiazepines. *Exit Wounds* was distributed within Nevada. According to
19 a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs
20 were also prescribed benzodiazepines, despite the increased danger of respiratory depression
21 from the two drugs together.

22 433. Opioid prescriptions have dramatically increased for veterans and the elderly.
23
24

25 ¹³⁸ Kate M. Dunn, PhD et al., *Opioid Prescriptions for Chronic Pain and Overdose*, *Ann Intern Med.* 2010 Jan. 19;
26 152(2):85-92, <https://www.ncbi.nlm.nih.gov/pubmed/20083827>.

27 ¹³⁹ National Institute on Drug Abuse, *Substance Abuse in the Military*, Revised March 2013,
<https://www.drugabuse.gov/publications/drugfacts/substance-abuse-in-military>.

28 ¹⁴⁰ Barbara Goldberg, “Opioid abuse crisis takes heavy toll on U.S. veterans,” *Reuters*, November 10, 2017,
<https://www.reuters.com/article/us-usa-veterans-opioids/opioid-abuse-crisis-takes-heavy-toll-on-u-s-veterans-idUSKBN1DA1B2>.

1 Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults
2 between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions
3 for narcotic pain pills—four times as many as they did in 2001.

4 **4. Insys Employed Deceptive, Illegal, and Misleading Marketing Schemes to**
5 **Promote Subsys.**

6
7 434. Insys deceptively marketed its opioid Subsys for chronic and mild pain even
8 though the FDA has expressly limited its use to the treatment of severe cancer pain in opioid
9 tolerant individuals. Subsys is an extremely powerful fentanyl-based sublingual opioid. It is
10 not approved for, and has not been shown to be safe or effective for, chronic or mild pain.
11 Indeed, the FDA expressly prohibited Insys from marketing Subsys for anything but
12 breakthrough cancer pain in opioid tolerant patients.

13 435. In 2012, Subsys was approved only for the “management of breakthrough pain
14 in adult cancer patients who are already receiving and who are tolerant to around-the-clock
15 opioid therapy for their underlying persistent cancer pain.” Under FDA rules, Insys was only
16 allowed to market Subsys for this use. Subsys consists of the highly addictive narcotic,
17 fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset
18 pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl
19 (“TIRF”).

20 436. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk
21 Evaluation and Mitigation Strategy (“REMS”) for Subsys and other TIRF products, such as
22 Cephalon’s Actiq and Fentora. The purpose of REMS was to educate “prescribers, pharmacists,
23 and patients on the potential for misuse, abuse, addiction, and overdose” for this type of drug
24 and to “ensure safe use and access to these drugs for patients who need them.”¹⁴¹ Prescribers
25 must
26

27
28 ¹⁴¹ Press Release, U.S. Food & Drug Admin., *FDA Approves Shared System REMS for TIRF Products* (Dec. 29, 2011).

enroll in the TIRF REMS before writing a prescription for Subsys.

437. Since its launch, Subsys has been an extremely expensive medication and its price continues to rise each year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

438. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes the following:

[C]onfirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied.¹⁴²

439. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center ("IRC"), to obtain approval for Subsys reimbursements. This unit employed a number of deceptive and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.

440. Subsys has proved to be extremely profitable for Insys. Insys made approximately

¹⁴² *Fueling an Epidemic, supra.*

1 \$330 million in net revenue from Subsys in 2015. Between 2013 and 2016, the value of Insys
2 stock rose 296%.

3 441. Since its launch in 2012, Insys aggressively worked to grow its profits through
4 deceptive, illegal, and misleading tactics, including its reimbursement-related fraud. Through
5 its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe
6 and appropriate for uses such as neck and back pain, without disclosing the lack of approval or
7 evidence for such uses and misrepresented the appropriateness of Subsys for treatment of those
8 conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers'
9 programs in exchange for prescribing Subsys. All of these deceptive and misleading schemes
10 had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

11 442. Insys incentivized its sales force to engage in illegal and fraudulent conduct.
12 Many of the Insys sales representatives were new to the pharmaceutical industry and their base
13 salaries were low compared to industry standard. The compensation structure was heavily
14 weighted toward commissions and rewarded reps more for selling higher (and more expensive)
15 doses of Subsys, a "highly unusual" practice because most companies consider dosing a
16 patient-specific decision that should be made by a doctor.¹⁴³

17 443. The Insys "speakers program" was perhaps its most widespread and damaging
18 scheme. A former Insys salesman, Ray Furchak, alleged in a qui tam action that the sole
19 purpose of the speakers program was "in the words of his then supervisor Alec Burlakoff, 'to
20 get money in the doctor's pocket.'" Furchak went on to explain that "[t]he catch . . . was that
21 doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or
22 800 micrograms instead of 200 micrograms), would receive the invitations to the program—
23 and the checks."¹⁴⁴ It was a pay-to-prescribe program.

24 444. Insys's sham speaker program and other deceptive and illegal tactics have been
25 outlined in great detail in indictments and guilty pleas of Insys executives, employees, and
26

27 ¹⁴³ *Id.*

28 ¹⁴⁴ Roddy Boyd, *Insys Therapeutics and the New 'Killing It'*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015, <http://sirf-online.org/2015/04/24/the-new-killing-it/>.

1 prescribers across the country, as well as in a number of lawsuits against the company itself.

2 445. In May of 2015, two Alabama pain specialists were arrested and charged with
3 illegal prescription drug distribution, among other charges. The doctors were the top
4 prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors
5 received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed
6 Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager
7 pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme
8 in order to induce one of these doctors to prescribe Subsys. The plea agreement states that
9 nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer
10 patients. In May of 2017 one of the doctors was sentenced to 20 years in prison.

11 446. In June of 2015, a nurse practitioner in Connecticut described as the state's
12 highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from
13 Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain.
14 Insys paid the nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per
15 event; however, she did not give any presentations. In her guilty plea, the nurse admitted
16 receiving the speaker fees in exchange for writing prescriptions for Subsys.

17 447. In August of 2015, Insys settled a complaint brought by the Oregon Attorney
18 General. In its complaint, the Oregon Department of Justice cited Insys for, among other things,
19 misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain,
20 and other uses for which Subsys is neither safe nor effective, and using speaking fees as
21 kickbacks to incentivize doctors to prescribe Subsys.

22 448. In August of 2016, the State of Illinois sued Insys for similar deceptive and
23 illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers
24 of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer
25 pain for which the drug is indicated. The Illinois Complaint also details how Insys used its
26 speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took
27 place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium"
28

1 ranging from \$700 to \$5,100, and they were allowed to order as much food and alcohol as they
 2 wanted. At most of the events, the “speaker” being paid by Insys did not speak, and, on many
 3 occasions, the only attendees at the events were the speaker and an Insys sales representative.

4 449. Clark County, Nevada, doctor, Dr. Steven Holper, pleaded guilty on December
 5 10, 2018, to charges related to his practice of issuing excessive and unnecessary Subsys
 6 prescriptions to his patients, including to Henderson, Nevada, Municipal Court Judge, Diana
 7 Hampton, who tragically died of an overdose of the Subsys prescribed by Dr. Holper.

8 450. In 2016 and 2017, a total of six Insys executives and managers - John Kapoor,
 9 Michael Babich, Richard M. Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry - were
 10 indicted, arrested, and charged with multiple felonies in connection with an alleged conspiracy
 11 to bribe practitioners to prescribe Subsys and defraud insurance companies. A U.S. Department
 12 of Justice press release explained that, among other things: “Insys executives improperly
 13 influenced health care providers to prescribe a powerful opioid for patients who did not need
 14 it, and without complying with FDA requirements, thus putting patients at risk and contributing
 15 to the current opioid crisis.”¹⁴⁵ A Drug Enforcement Administration (“DEA”) Special Agent in
 16 Charge further explained that: “Pharmaceutical companies whose products include controlled
 17 medications that can lead to addiction and overdose have a special obligation to operate in a
 18 trustworthy, transparent manner, because their customers’ health and safety and, indeed, very
 19 lives depend on it.”¹⁴⁶ Defendant Michael Babich pleaded guilty to the charges against him,
 20 while the remaining five (5) individual Insys Defendants were convicted of racketeering
 21 charges after a multi-week trial.

22 **5. The Manufacturer Defendants’ Scheme Succeeded, Creating a Public Health**
 23 **Epidemic.**

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 25
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 27 ¹⁴⁵ Press Release, U.S. Dep’t of Just., U.S. Attorney’s Office, Dist. of Mass., Founder and Owner of Pharmaceutical
 28 Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017), <https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrestedand-charged-racketeering>.

¹⁴⁶ *Id.*

a. Manufacturer Defendants Dramatically Expanded Opioid Prescribing and Use.

451. The Manufacturer Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

452. Upon information and belief, each of the Manufacturer Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors' prescribing before and after detailing visits, at various levels of detailing intensity, and before and after speaker programs. Manufacturer Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances and more generally, Manufacturer Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them to continue prescribing opioids or to switch to supposedly "safer" abuse-deterrent ("ADF") opioids.

453. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.¹⁴⁷ The effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic

¹⁴⁷ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.¹⁴⁸ The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

454. Manufacturer Defendants spent millions of dollars to market their drugs to prescribers and patients nationwide, including in Nevada, and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.¹⁴⁹ These results are directly due to the Manufacturer Defendants' fraudulent marketing campaign and repeated misrepresentations.

455. Thus, both independent studies and Manufacturer Defendants' own tracking confirm that Manufacturer Defendants' deceptive marketing scheme dramatically increased their sales, including sales within Nevada.

b. Manufacturer Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic.

456. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between

¹⁴⁸ Larkin et al, *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317(17) J. of Am. Med. Assoc. 1785-1795 (May 2, 2017), <https://jamanetwork.com/journals/jama/fullarticle/2623607>, 305(13).

¹⁴⁹ Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse.”¹⁵⁰ It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians’ prescriptions.¹⁵¹

457. 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. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”¹⁵²

458. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.”¹⁵³ Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses.¹⁵⁴ For these reasons, the CDC concluded that efforts to reign in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”¹⁵⁵

459. The Manufacturer Defendants’ scheme was and continues to be resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain— has become a commonplace, and often first-line, treatment. The Manufacturer Defendants’ deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent (“MME”) per person, tripled from 1999 to 2015. The prescribing rate in Nevada rose during this time, from 87.7 prescriptions per 100 residents in 2006 to 100.3 in 2010.¹⁵⁶ Nevada’s death rate from drug overdose grew

¹⁵⁰ Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16.8 *Pharmacopidemiology and Drug Safety*, 827-40 (2007).

¹⁵¹ Anna Lembke, M.D., *Why Doctors Prescribe Opioids to Known Opioid Abusers*, *New Eng. J. Med.* 2012; 367:1580-1581 (Oct. 25, 2012), <https://www.nejm.org/doi/full/10.1056/NEJMp1208498>.

¹⁵² Robert M. Califf, M.D., et al., *A Proactive Response to Prescription Opioid Abuse*, *New Eng. J. Med.*, <http://www.nejm.org/doi/full/10.1056/NEJMs1601307>.

¹⁵³ Rose A. Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000- 2014*, January 1, 2016, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

¹⁵⁴ Olfson, et al., *Service Use Preceding Opioid-Related Fatality*, *Am J. Psychiatry* 2018 Jun 1; 175(6):538-544.

¹⁵⁵ Rudd et al., *supra*.

¹⁵⁶ CDC, U.S. State Prescribing Rates, 2006 and 2011 maps for Nevada,

1 dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs.¹⁵⁷
2 In 2015, more than 650,000 opioid prescriptions were dispensed in the U.S. every day on
3 average. While previously a small minority of opioid sales, today between 80% and 90% of
4 opioids dispensed (measured by weight) are for chronic pain. Approximately 20% of the
5 population between the ages of 30 and 44, and nearly 30% of the population over 45, have used
6 opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now
7 include the prescription of an opioid.

8 **E. Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to**
9 **Maintain Effective Controls to Prevent Diversion and to Identify, Report, and Take**
10 **Steps to Halt Suspicious Orders.**

11
12 460. Through their systematic and deceptive marketing schemes, the Manufacturer
13 Defendants created a vastly and dangerously larger market for opioids both in Nevada and
14 nationwide. All of the Defendants, including the Distributor Defendants, compounded this
15 harm by facilitating the supply of far more opioids than could have been justified to serve that
16 market. The failure of the Defendants to maintain effective controls and to investigate, report,
17 and take steps to halt orders that they knew or should have known were suspicious breached
18 both their State statutory and common law duties.

19 461. For over a decade, as the Manufacturer Defendants increased the demand for
20 opioids, all the Defendants, including the Distributor Defendants, aggressively sought to
21 bolster their revenue, increase profit, and grow their share of the prescription painkiller market
22 by unlawfully and surreptitiously increasing the volume of opioids they sold. However,
23 Defendants are not permitted to engage in a limitless expansion of their sales through the
24 unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to
25 various duties to report the quantity of Schedule II controlled substances in order to monitor
26

27 <https://www.cdc.gov/drugoverdose/maps/rxstate2015.html>.

28 ¹⁵⁷ Haeyoun Park & Matthew Bloch, *How the Epidemic of Drug Overdose Deaths Ripples Across America*, N.Y. Times, Jan. 18, 2016, <https://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html>.

1 such substances and prevent oversupply and diversion into the illicit market.

2 462. Both the Manufacturer Defendants and the Distributor Defendants have several
3 responsibilities under Nevada law with respect to control of the supply chain of opioids. First,
4 they must set up a system to prevent diversion, including excessive volume and other
5 suspicious orders. That would include reviewing their own data, relying on their observations
6 of prescribers and pharmacies, and following up on reports or concerns of potential diversion.
7 All suspicious orders must be reported to relevant enforcement authorities and the Nevada
8 Board of Pharmacy. Further, they must also stop shipment of any order which is flagged as
9 suspicious and should only ship orders which were flagged as potentially suspicious if, after
10 conducting due diligence, they can determine that the order is not likely to be diverted into
11 illegal channels.

12 **1. All Defendants Have a Duty to Provide Effective Controls and Procedures to**
13 **Guard Against Theft and Diversion, and to Report Suspicious Orders and Not to**
14 **Ship Those Orders Unless Due Diligence Disproves Their Suspicions.**

15
16 463. Multiple sources, including Nevada statutes and regulations, impose duties on
17 the Manufacturer Defendants and the Distributor Defendants to provide effective controls and
18 procedures to guard against theft and diversion of opioid drugs. Multiple sources also impose
19 duties on all the Defendants to report suspicious orders and to not ship such orders unless due
20 diligence disproves those suspicions.

21 464. Under the common law, all Defendants had a duty to exercise reasonable care
22 in delivering dangerous narcotic substances. By flooding the State with more opioids than could
23 be used for legitimate medical purposes, by failing to provide effective controls and procedures
24 against theft and diversion, and by filling and failing to report orders that they knew or should
25 have known were likely being diverted for illicit uses, Defendants breached that duty and both
26 created and failed to prevent a foreseeable risk of harm.

27 465. Each of the Defendants assumed a duty, when speaking publicly about opioids
28

and their efforts to combat diversion, to speak accurately and truthfully.

466. The Manufacturer Defendants and Distributor Defendants also had multiple duties under Nevada statutes and regulations. Opioids are Schedule II controlled substances. NAC § 453.520. As such, opioids are defined as substances that pose a high potential for abuse that may lead to severe psychological or physical dependence. NRS § 453.176.

467. Under Nevada law, each of the Defendants was required to be registered through the Nevada Board of Pharmacy. NAC § 453.110; NRS § 639.070.

468. The Nevada Board of Pharmacy governs the licensing of wholesale drug distributors in this state. NRS § 639.070. *See also* NRS §§ 639.009; 639.0085; 639.012; 639.0155; 639.016; 639.233 (including manufacturers, repackagers, chain drug warehouses, wholesale drug warehouses, and retail pharmacies within the scope of the Nevada wholesale distributing regulations). Wholesalers and wholesale distributors are subject to additional licensing requirements. NRS §§ 639.500 – 639.515.

469. As registrants, each of the Defendants was required to maintain effective controls and procedures to guard against theft and diversion (*see* NAC §§ 453.400, 435.410; NRS §§ 639.500 – 639.515, 639.585) and to operate in compliance with all applicable federal, state and local laws and regulations. *See* NRS §§ 639.510. Defendants violated their obligations and breached their duties under Nevada law.

470. Specifically, under Nevada law, it is “[u]nlawful to manufacture, engage in wholesale distribution, compound, sell or dispense or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical,” without first complying with the regulations adopted by the Nevada Board of Pharmacy. NRS § 639.100.

471. Under Nevada law, each of the Defendants was required to provide effective controls and procedures to guard against the theft and diversion of opioid drugs. *See* NAC § 453.400 (“[a]ll applicants and registrants shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances”).

472. In addition, the Nevada Board of Pharmacy has the power to regulate the

“means of recordkeeping and storage, handling, sanitation and security of drugs” including those drugs “stored for the purpose of wholesale distribution.” NRS § 639.070.

473. The Nevada Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations. *See, e.g.*, NAC §§ 453.100; 453.120; 453.220; 453.410. In fact, wholesalers are defined by 21 CFR § 205.3(g) as an entity that “supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law.” NRS § 639.016. Additionally, it is grounds for suspension or revocation of a license or registration to violate “any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs.” NRS § 639.210(11).

474. Under Nevada law, it is unlawful for a person who is licensed to engage in wholesale distribution to fail to “deliver to another person a complete and accurate statement of prior sales for a prescription drug, if such a statement is required, before selling or otherwise transferring the drug to that person.” NRS § 639.550(1). Additionally, it is unlawful for a wholesaler to fail to “acquire a complete and accurate statement of prior sales for a prescription drug, if such a statement is required, before obtaining the drug from another person.” NRS § 639.550(2). Furthermore, Nevada law requires wholesalers, manufacturers, and their employees to adopt and abide by a marketing code of conduct, enforce policies regarding investigation into compliance and corrective actions, and submit and report certain information to the Board. NRS § 639.570.

475. Both Manufacturer Defendants and Distributor Defendants have violated their duties under the Nevada Controlled Substances Act and the Nevada Administrative Code. *See, e.g.*, NRS §§ 639.100, 639.210, 639.550, 639.570; NAC §§ 453.110, 453.400, 435.410.

476. Defendants violated their duties as licensed wholesale distributors by selling huge quantities of opioids that were diverted from their lawful, medical purpose, thus causing an opioid and heroin addiction and overdose epidemic in this State.

477. A reasonable manufacturer or distributor of a Schedule II substance would be on notice of suspicious orders such as orders of an unusual size, orders deviating substantially

1 from a normal pattern, and orders of unusual frequency. These criteria are disjunctive and are
2 not all-inclusive. For example, if an order deviates substantially from a normal pattern, the size
3 of the order does not matter, and the order should be reported as suspicious. Likewise, a
4 wholesale distributor need not wait for a normal pattern to develop over time before
5 determining whether a particular order is suspicious. The size of an order alone, whether or not
6 it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility
7 to report the order as suspicious. The determination of whether an order is suspicious depends
8 not only on the ordering patterns of the particular customer but also on the patterns of the
9 wholesale distributor's customer base and the patterns throughout the relevant segment of the
10 wholesale distributor industry.

11 478. To be clear, the Manufacturer Defendants were required to comply with the
12 same licensing and permitting requirements as the Distributor Defendants. *See* NRS § 639.233
13 (requiring manufacturers and distributors to register with the Nevada Board of Pharmacy);
14 NRS § 639.570 (requiring manufacturers and distributors to adopt a marketing code of conduct
15 and requiring annual audits to monitor compliance); NRS § 639.288 (requiring manufacturers
16 and distributors to comply with state laws in handling, selling, possessing, or dealing such
17 drugs).

18 479. The same legal duties to prevent diversion and to monitor, report, and prevent
19 suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants
20 were also legally required of the Manufacturer Defendants under Nevada law. *See, e.g.,* NAC
21 § 453.400; NRS §§ 639.233, 639.570. Like the Distributor Defendants, the Manufacturer
22 Defendants also breached these duties.

23 480. The Manufacturer Defendants had access to and possession of the information
24 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
25 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid
26 distributors. A chargeback is a payment made by a manufacturer to a distributor after the
27 distributor sells the manufacturer's product at a price below a specified rate. After a distributor
28 sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback

1 from the manufacturer and, in exchange for the payment, the distributor identifies to the
2 manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the
3 Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume,
4 frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants
5 built receipt of this information into the payment structure for the opioids provided to the opioid
6 distributors.

7 481. In sum, all Defendants have many responsibilities under Nevada law related to
8 controlling the supply chain of opioids. They must set up a system to prevent diversion,
9 including identifying excessive volume and other suspicious orders by reviewing their own
10 data, relying on their observations of prescribers and pharmacies, and following up on reports
11 or concerns of potential diversion. All suspicious orders or noncompliance with a marketing
12 code of conduct must be reported to relevant enforcement authorities.

13 482. State statutes and regulations reflect a standard of conduct and care below which
14 reasonably prudent manufacturers and distributors would not fall. Together, these laws and
15 industry guidelines make clear that Distributor and Manufacturer Defendants alike possess and
16 are expected to possess specialized and sophisticated knowledge, skill, information, and
17 understanding of both the market for scheduled prescription narcotics and of the risks and
18 dangers of the diversion of prescription narcotics when the supply chain is not properly
19 controlled.

20 483. Further, these laws and industry guidelines make clear that the Distributor
21 Defendants and Manufacturer Defendants alike have a duty and responsibility to exercise their
22 specialized and sophisticated knowledge, information, skill, and understanding to prevent the
23 oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

24 484. Since their inception, Distributor Defendants have continued to integrate
25 vertically by acquiring businesses that are related to the distribution of pharmaceutical products
26 and health care supplies. In addition to the actual distribution of pharmaceuticals, as
27 wholesalers, Distributor Defendants also offer their pharmacy, or dispensing, customers a broad
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1 range of added services. For example, Distributor Defendants offer their pharmacies
2 sophisticated ordering systems and access to an inventory management system and distribution
3 facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also
4 able to use the combined purchase volume of their customers to negotiate the cost of goods with
5 manufacturers and offer services that include software assistance and other database
6 management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41
7 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the
8 potential benefits to customers did not outweigh the potential anti-competitive effect of a
9 proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of
10 their acquisition of a diverse assortment of related businesses within the pharmaceutical
11 industry, as well as the assortment of additional services they offer, Distributor Defendants
12 have a unique insight into the ordering patterns and activities of their dispensing customers.

13 485. Manufacturer Defendants also have specialized and detailed knowledge of the
14 potential suspicious prescribing and dispensing of opioids through their regular visits to
15 doctors' offices and pharmacies, and from their purchase of data from commercial sources,
16 such as IMS Health (now IQVIA). Their extensive boots-on-the-ground sales forces allow
17 Manufacturer Defendants to observe the signs of suspicious prescribing and dispensing
18 discussed elsewhere in the Complaint—lines of seemingly healthy patients, out-of-state license
19 plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants
20 regularly mined data, including, upon information and belief, chargeback data, that allowed
21 them to monitor the volume and type of prescribing of doctors, including sudden increases in
22 prescribing and unusually high dose prescribing that would have alerted them, independent of
23 their sales representatives, to suspicious prescribing. These information points gave
24 Manufacturer Defendants all the insight into prescribing and dispensing conduct they would
25 have needed to prevent diversion and fulfill their obligations under Nevada and related laws.

26 486. Defendants have a duty to, and are expected to, be vigilant in deciding whether
27 a prospective customer can be trusted to deliver controlled substances only for lawful purposes.
28

1 487. Each of the Defendants sold prescription opioids, including hydrocodone and/or
2 oxycodone, to retailers in Nevada.

3 488. Thus, each Defendant owes a duty under Nevada law to monitor and detect
4 suspicious orders of prescription opioids.

5 489. Each Defendant owes a duty under Nevada law to investigate and refuse
6 suspicious orders of prescription opioids.

7 490. Each Defendant owes a duty under Nevada law to report suspicious orders of
8 prescription opioids, including suspicious orders originating outside Nevada that would likely
9 result in distribution of Defendants' opioids into Nevada .

10 491. Each Defendant owes a duty under Nevada law to prevent the diversion of
11 prescription opioids into illicit markets in Nevada.

12 492. The foreseeable harm resulting from a breach of these duties is the diversion of
13 prescription opioids for nonmedical purposes.

14 493. The foreseeable harm resulting from the diversion of prescription opioids for
15 nonmedical purposes is abuse, addiction, morbidity and mortality in Nevada and the damages
16 caused thereby.

17 494. Defendants breached these duties by failing to: (a) control the supply chain;
18
19 (b) maintain effective controls, procedures and security to prevent diversion; (c) report
20 suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have
21 known could not be justified and were indicative of serious overuse of opioids.

22 **2. Defendants Were Aware of and Have Acknowledged Their Obligations to**
23 **Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.**

24 495. The reason for the reporting rules is to create a "closed" system intended to
25 control the supply and reduce the diversion of these drugs out of legitimate channels into the
26 illicit market, while at the same time providing the legitimate drug industry with a unified
27 approach to narcotic and dangerous drug control. Both because distributors handle large
28

volumes of controlled substances, and because they are uniquely positioned based on their knowledge of their customers and orders, distributors are supposed to act as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market. Because of this role, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses as it did here.

496. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

497. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA." Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."¹⁵⁸

498. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have

¹⁵⁸ Administrative Memorandum of Agreement, available at <https://www.justice.gov/usao-edmi/press-release/file/986026/download>.

responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.” Guidelines established by the HDA also explain that distributors, “[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.” The guidelines set forth recommended steps in the “due diligence” process, and note in particular: If an order meets or exceeds a distributor’s threshold, as defined in the distributor’s monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.¹⁵⁹

499. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion

500. The DEA advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are “one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only

¹⁵⁹ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App’x B).

for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”¹⁶⁰ The DEA’s September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.”¹⁶¹ The same letter warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”¹⁶²

501. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.”¹⁶³ The DEA’s December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”¹⁶⁴

¹⁶⁰ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

¹⁶¹ *Id.* at 2.

¹⁶² *Id.*

¹⁶³ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

¹⁶⁴ *Id.*

1 **3. Defendants Worked Together to Inflate the Quotas of Opioids They Could**
2 **Distribute.**

3
4 502. Finding it impossible to legally achieve their ever-increasing sales ambitions,
5 Defendants engaged in the common purpose of increasing the supply of opioids through
6 deceptive means, thereby falsely increasing the quotas that governed the manufacture and
7 distribution of their prescription opioids.

8 503. Wholesale distributors such as the Distributor Defendants had close financial
9 relationships with both Manufacturer Defendants and customers, for whom they provide a
10 broad range of value-added services that render them uniquely positioned to obtain information
11 and control against diversion. These services often otherwise would not be provided by
12 manufacturers to their dispensing customers and would be difficult and costly for the dispenser
13 to reproduce. For example, “[w]holesalers have sophisticated ordering systems that allow
14 customers to electronically order and confirm their purchases, as well as to confirm the
15 availability and prices of wholesalers’ stock.” *Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12
16 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also
17 able “to combine the purchase volumes of customers and negotiate the cost of goods with
18 manufacturers.” Wholesalers typically also offer marketing programs, patient services, and
19 other software to assist their dispensing customers.

20 504. Distributor Defendants had financial incentives from the Manufacturer
21 Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill
22 suspicious orders or using any effective controls to prevent diversion. Wholesale drug
23 distributors acquire pharmaceuticals, including opioids, from manufacturers at an established
24 wholesale acquisition cost. Discounts and rebates from this cost may be offered by
25 manufacturers based on market share and volume. As a result, higher volumes may decrease
26 the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to
27 offer more competitive prices, or alternatively, pocket the difference as additional profit. Either
28 way, the increased sales volumes result in increased profits.

1 505. The Manufacturer Defendants engaged in the practice of paying rebates and/or
2 chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help
3 them boost sales and better target their marketing efforts. The *Washington Post* has described
4 the practice as industry-wide, and the HDA includes a “Contracts and Chargebacks Working
5 Group,” suggesting a standard practice. Further, in a recent settlement with the DEA,
6 Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects
7 transaction information, referred to as chargeback data, from their direct customers
8 (distributors).” The transaction information contains data relating to the direct customer sales
9 of controlled substances to ‘downstream’ registrants,” meaning pharmacies or other
10 dispensaries, such as hospitals. Manufacturer Defendants buy data from pharmacies as well.
11 This exchange of information, upon information and belief, would have opened channels
12 providing for the exchange of information revealing suspicious orders as well.

13 506. The contractual relationships among the Defendants also include vault security
14 programs. Defendants are required to maintain certain security protocols and storage facilities
15 for the manufacture and distribution of their opioids. The manufacturers negotiated agreements
16 whereby the Manufacturer Defendants installed security vaults for the Distributor Defendants
17 in exchange for agreements to maintain minimum sales performance thresholds. These
18 agreements were used by the Defendants as a tool to violate their reporting and diversion duties
19 in order to reach the required sales requirements.

20 507. In addition, Defendants worked together to achieve their common purpose
21 through trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

22 508. The PCF has been described as a coalition of drug makers, trade groups and
23 dozens of non-profit organizations supported by industry funding, including the Front Groups
24 described in this Complaint. The PCF recently became a national news story when it was
25 discovered that lobbyists for members of the PCF quietly shaped federal and state policies
26 regarding the use of prescription opioids for more than a decade.

27 509. The Center for Public Integrity and The Associated Press obtained “internal
28

documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.”¹⁶⁵ Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.¹⁶⁶

510. Rather than abide by these public safety statutes, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s license from “imminent harm” to “immediate harm” and provided the industry the right to “cure” any violations of law before a suspension order can be issued.¹⁶⁷

511. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included Purdue and Actavis.¹⁶⁸ Each of the Manufacturer Defendants worked together through the PCF. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.¹⁶⁹ The Distributor Defendants participated directly in the

¹⁶⁵ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity, <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echochamber-shaped-policy-amid-drug-epidemic>. (Last Updated Dec. 15, 2016, 9:09 AM) (emphasis added).

¹⁶⁶ *Id.*

¹⁶⁷ See Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; see also Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: “We Had No Leadership” in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->

¹⁶⁸ Mallinckrodt became an active member of the PCF sometime after 2012.

¹⁶⁹ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer,

PCF as well.

512. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants, including Actavis, Purdue, and Mallinckrodt, were members of the HDA. The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including “strengthen[ing] . . . alliances.”¹⁷⁰

513. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”¹⁷¹ Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Manufacturer Defendants and Distributor Defendants.

514. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other’s businesses.¹⁷² For example, the manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key

Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. *Executive Committee, Healthcare Distribution Alliance*, <https://www.healthcaredistribution.org/about/executive-committee> (last accessed Apr. 25, 2018).
¹⁷⁰ *Manufacturer Membership, Healthcare Distribution Alliance*, <https://healthcaredistribution.org/about/membership/manufacturer> (last accessed Apr. 25, 2018).

¹⁷¹ *Id.*
¹⁷² *Manufacturer Membership Application, Healthcare Distribution Alliance*, <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

1 contact and any additional contacts from within its company.

2 515. The HDA application also requests that the manufacturer identify its current
3 distribution information, including the facility name and contact information. Manufacturer
4 members were also asked to identify their “most recent year end net sales” through wholesale
5 distributors, including the Distributor Defendants AmerisourceBergen, Anda, Inc., Cardinal
6 Health, McKesson, and their subsidiaries.

7 516. The closed meetings of the HDA’s councils, committees, task forces and
8 working groups provided the Manufacturer Defendants and Distributor Defendants with the
9 opportunity to work closely together, confidentially, to develop and further the common
10 purpose and interests of the enterprise.

11 517. The HDA also offers a multitude of conferences, including annual business and
12 leadership conferences. The HDA and the Distributor Defendants advertise these conferences
13 to the Manufacturer Defendants as an opportunity to “bring together high-level executives,
14 thought leaders and influential managers . . . to hold strategic business discussions on the
15 most pressing industry issues.”¹⁷³ The conferences also gave the Manufacturer Defendants and
16 Distributor Defendants “unmatched opportunities to network with [their] peers and trading
17 partners at all levels of the healthcare distribution industry.”¹⁷⁴ The HDA and its conferences
18 were and continue to be significant opportunities for the Manufacturer Defendants and
19 Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer
20 Defendants have embraced this opportunity by attending and sponsoring these events.¹⁷⁵

21 518. After becoming members of HDA, Defendants were eligible to participate on
22 councils, committees, task forces and working groups, including:

- 23 1. Industry Relations Council: “This council, composed of distributor and
24 manufacturer members, provides leadership on pharmaceutical

25
26 ¹⁷³ *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution
Alliance, [https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-](https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers)
for-manufacturers.

27 ¹⁷⁴ *Id.*

28 ¹⁷⁵ *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance,
<https://www.healthcaredistribution.org/events/2015-distribution-management-conference>.

distribution and supply chain issues.”

2. Business Technology Committee: “This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee’s major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce.” Participation in this committee includes distributor and manufacturer members.
3. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributor and manufacturer members.
4. Manufacturer Government Affairs Advisory Committee: “This committee provides a forum for briefing HDA’s manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement.” Participation in this committee includes manufacturer members.
5. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

519. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.¹⁷⁶ For example, on April 27, 2011, the HDA offered a webinar to “accurately and effectively exchange business transactions between distributors and

¹⁷⁶ *Webinar Leveraging EDI: Order-to-Cash Transactions CD Box Set*, Healthcare Distribution Alliance, (Apr. 27, 2011), <https://www.healthcaredistribution.org/resources/webinar-leveraging-edi>.

manufacturers....” The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

520. Taken together, the interaction and length of the relationships between and among the Manufacturer Defendants and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly-knit industry. The Manufacturer Defendants and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids in the state of Nevada and nationwide.

521. The HDA and the PCF are but two examples of these overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperating with each other during the relevant time period.

522. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the “Industry Compliance Guidelines”) regarding diversion. As the HDA (then the HDMA) explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.¹⁷⁷

523. This statement by the HDA and the Industry Compliance Guidelines themselves support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under controlled substances laws. As John M. Gray, President/CEO of the HDA stated in April 2014, it is “difficult to find the right balance between proactive anti-

¹⁷⁷ See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. of Justice*, No. 12- 5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *5.

1 diversion efforts while not inadvertently limiting access to appropriately prescribed and
2 dispensed medications.” Here, it is apparent that all of the Defendants, working together, found
3 the same balance – an overwhelming pattern and practice of failing to identify, report or halt
4 suspicious orders and failure to prevent diversion, all the while obscuring naked profit motives
5 with opaque concerns about drug “access.”

6 524. The Defendants’ scheme involved a decision-making structure driven by the
7 Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer
8 Defendants worked together to control the state and federal government’s response to the
9 manufacture and distribution of prescription opioids by increasing production quotas through
10 a systematic refusal to maintain effective controls against diversion, and to identify, report or
11 halt suspicious orders or report them to any appropriate agencies.

12 525. The Defendants worked together to control the flow of information and
13 influence state and federal governments to pass legislation that supported the use of opioids
14 and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and
15 distribution. The Marketing and Distributor Defendants did this through their participation in
16 the PCF and HDA.

17 526. The Defendants also worked together to ensure that the Aggregate Production
18 Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially
19 high and ensured that suspicious orders were not reported to the DEA in order to ensure that
20 the DEA had no basis for refusing to increase or decrease the production quotas for prescription
21 opioids due to diversion of suspicious orders.

22 527. The Defendants also had reciprocal obligations to report suspicious orders of
23 other parties if they became aware of them. Defendants were thus collectively responsible for
24 each other’s compliance with their reporting obligations.

25 528. Defendants thus knew that their own conduct could be reported by other
26 distributors or manufacturers and that their failure to report suspicious orders they filled could
27 be brought to the DEA’s attention. As a result, Defendants had an incentive to communicate
28

with each other about the reporting of suspicious orders to ensure the continued appearance of consistency in their dealings with DEA.

529. The desired appearance of consistency was achieved. As described below, none of the Defendants reported suspicious orders as required by law, and the flow of opioids continued unimpeded.

4. Defendants Kept Careful Track of Prescribing Data and Knew About Diversion and Suspicious Orders and Prescribers.

530. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

531. Publicly available information confirms that the Manufacturer Defendants and Distributor Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use and ignored other red flags of suspicious orders. This information, along with the information known only to the Manufacturer Defendants and Distributor Defendants, would have alerted them to likely signs of diversion and potentially suspicious orders of opioids.

532. This information includes the following facts:

1. Distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
2. Manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
3. Manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described elsewhere in this Complaint;

4. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
5. Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

533. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids – even the artificially wider market for chronic pain.

534. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber-and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

535. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.¹⁷⁸ The “know your customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other

¹⁷⁸ *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Admin. Div., https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC (Oct. 2010), https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

536. Defendants purchased nationwide, regional, state, and local prescriber- and patient- level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.¹⁷⁹

537. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.¹⁸⁰

538. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.¹⁸¹

539. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.¹⁸²

540. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities because Defendants have made

¹⁷⁹ A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 661712, *9-10 (Feb. 22, 2011).

¹⁸⁰ Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-Rich Molehills*, (accessed on February 15, 2018), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf>, Figure 2 at p.3.

¹⁸¹ Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011).

¹⁸² In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vendor, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.*; see also Joint Appendix in *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

1 it part of their collective business to know where those orders went and to whom.

2 541. Defendants refused to maintain effective controls to prevent diversion, and
3 refused to identify, investigate and report suspicious orders to the DEA or the Nevada Board
4 of Pharmacy when they became aware of the same, despite their actual knowledge of drug
5 diversion rings. For instance, as described in detail below, Defendants refused to identify
6 suspicious orders and diverted drugs despite the DEA issuing final decisions against the
7 Distributor Defendants in 178 registrant actions between 2008 and 2012¹⁸³ and 117
8 recommended decisions in registrant actions from The Office of Administrative Law Judges.
9 These numbers include seventy-six (76) actions involving orders to show cause and forty-one
10 (41) actions involving immediate suspension orders, all for failure to report suspicious
11 orders.¹⁸⁴

12 542. In fact, Manufacturer and Distributor Defendants internalized illegal diversion
13 as an expected and foreseeable result of their business and incorporated those expectations into
14 their business planning.

15 543. Sales representatives were also aware that the prescription opioids they were
16 promoting were being diverted, often with lethal consequences. As a sales representative wrote
17 on a public forum:

18 Actions have consequences – so some patient gets Rx'd the
19 80mg OxyContin when they probably could have done okay on
20 the 20mg (but their doctor got “sold” on the 80mg) and their teen
21 son/daughter/child’s teen friend finds the pill bottle and takes out
22 a few 80’s... next they’re at a pill party with other teens and some
23 kid picks out a green pill from the bowl... they go to sleep and
24 don’t wake up (because they don’t understand respiratory
25 depression) Stupid decision for a teen to make...yes... but do they
26 really deserve to die?

24 544. Moreover, Defendants’ sales incentives rewarded sales representatives who
25 happened to have pill mills within their territories, enticing those representatives to look the
26

27 ¹⁸³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement*
28 *Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁸⁴ *Id.*

1 other way even when their in-person visits to such clinics should have raised numerous red
2 flags. In one example, Dr. Rand, operated a pill mill in Reno, Nevada, an activity for which he
3 has been indicted, charged, and sentenced. Additionally, as discussed, *supra*, Dr. Steven
4 Holper in Clark County, Nevada, has been indicted on charges related to the excessive Subsys
5 prescriptions he has written to patients.

6 545. In another example, a Purdue sales manager informed her supervisors in 2009
7 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic
8 with her sales representative, “it was packed with a line out the door, with people who looked
9 like gang members,” and that she felt “very certain that this is an organized drug ring[.]”¹⁸⁵ She
10 wrote, “This is clearly diversion. Shouldn’t the DEA be contacted about this?” But her
11 supervisor at Purdue responded that while they were “considering all angles,” it was “really up
12 to [the wholesaler] to make the report.”¹⁸⁶ This pill mill was the source of 1.1 million pills
13 trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after
14 the clinic was shut down in 2010 to inform the authorities. This was a pattern and practice in
15 the medical community of which Purdue was familiar and about which it did nothing.

16 546. As to Actavis, a Kadian prescriber guide discusses abuse potential of Kadian. It
17 is full of disclaimers that Actavis has not done any studies on the topic and that the guide is
18 “only intended to assist you in forming your own conclusion.” However, the guide includes the
19 following statements: 1) “unique pharmaceutical formulation of KADIAN may offer some
20 protection from extraction of morphine sulfate for intravenous use by illicit users,” and 2)
21 “KADIAN may be less likely to be abused by health care providers and illicit users” because
22 of “Slow onset of action,” “Lower peak plasma morphine levels than equivalent doses of other
23 formulations of morphine,” “Long duration of action,” and “Minimal fluctuations in peak to
24 trough plasma levels of morphine at steady state.” The guide is copyrighted by Actavis in 2007,
25 before Actavis officially purchased Kadian from Alpharma.

26
27 ¹⁸⁵ Harriet Ryan et al., *More Than 1 million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What*
the Drugmaker Knew, LOS ANGELES TIMES (July 10, 2016), [http://www.latimes.com/projects/la-me-oxycontin-](http://www.latimes.com/projects/la-me-oxycontin-part2//)
28 [part2//](http://www.latimes.com/projects/la-me-oxycontin-part2//).

¹⁸⁶ *Id.*

547. Defendants' obligations to maintain effective controls against diversion and to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

548. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

549. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow / Grow = New Patient Starts and Conversions." In an example of how new patients plus a high-volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."

550. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

551. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturer Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their

marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”¹⁸⁷

552. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were “fooled.” In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.¹⁸⁸

553. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Manufacturer Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

5. Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion.

554. As discussed above, Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into communities in Nevada and across America. Despite the notice described above, and in disregard of their duties, Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report, and take steps to halt suspicious orders.

555. Governmental agencies and regulators have confirmed (and in some cases, Defendants have admitted) that Defendants did not meet their obligations and engaged in

¹⁸⁷ Meier, *supra*, at 179.

¹⁸⁸ Harriet Ryan et al., *More Than 1 million OxyContin Pills Ended Up in the Hands of Criminals and Addicts*, *supra*.

1 especially blatant wrongdoing.

2 556. For example, on January 5, 2017, McKesson entered into an Administrative
3 Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty
4 for, inter alia, failure to identify and report suspicious orders at its facilities in Aurora, CO;
5 Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia,
6 MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento,
7 CA. McKesson admitted that, at various times during the period from January 1, 2009 through
8 the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the]
9 DEA certain orders placed by certain pharmacies which should have been detected by
10 McKesson as suspicious based on the guidance contained in the DEA Letters.”

11 557. McKesson further admitted that, during this time period, it “failed to maintain
12 effective controls against diversion of particular controlled substances into other than legitimate
13 medical, scientific and industrial channels by sales to certain of its customers in violation of
14 the
15 CSA and the CSA’s implementing regulations, 21 CFR Part 1300 et seq., at the McKesson
16 Distribution Centers.” Due to these violations, McKesson agreed to a partial suspension of its
17 authority to distribute controlled substances from certain of its facilities some of which,
18 investigators found “were supplying pharmacies that sold to criminal drug rings.”

19 558. Additionally, Defendant CVS Pharmacy, Inc. owned and/or operated, more than
20 9,800 pharmacies in the United States. Collectively CVS pharmacies made Defendant CVS
21 Pharmacy, Inc. one of the largest customers of McKesson.

22 559. Using the economic leverage resulting from being one of its largest customers,
23 Defendant CVS Pharmacy, Inc. negligently and/or purposefully limited the ability of
24 McKesson to fulfill its regulatory and statutory responsibilities to prevent diversion and
25 monitor suspicious orders of controlled substances placed by CVS pharmacies.

26 560. Beginning in 2008, with the implementation of the McKesson Controlled
27 Substance Monitoring Program (CSMP), CVS represented to McKesson as follows:

- That it had a controlled substance monitoring program;

- That it possessed a dedicated Regulatory Control/Compliance resource that was responsible for monitoring pharmacy purchases of controlled substances;
- That its pharmacy management regularly reviews pharmacy purchases of controlled substances;
- That it possessed the process and tools used to monitor controlled substance purchases made by individual pharmacies.

561. Specifically, CVS represented the existence of a more comprehensive “Viper” regulatory program that it claimed the “DEA is very well aware of.” The Viper program was further represented to be a monitoring program. Don Walker, Senior Vice President of Distribution at McKesson, felt comfortable allowing opioid threshold increases by McKesson, without CVS explanation, because of McKesson’s understanding that “CVS is also co-managing on their side with Viper and their regulatory team.”

562. As a result of the misrepresentations made by CVS with respect to the existence of a controlled substance monitoring program, McKesson gave its “proxy” to CVS headquarters to perform due diligence investigations of potentially suspicious orders and individual CVS pharmacies that were ordering excessive amounts of prescription opioids. McKesson inquiries concerning suspicious orders and activities of individual CVS pharmacies were made to Defendant CVS Pharmacy, Inc. and not to individual CVS pharmacies. McKesson negligently relied upon the due diligence efforts and findings of CVS in its decisions to ship opioids to CVS pharmacies. Additionally, prescription opioid thresholds for CVS pharmacies were increased by McKesson without input or explanation from CVS, again relying upon CVS representations of internal regulatory controls. McKesson stated in 2012 that “the assumption is made that they have done their due diligence.”

563. Contrary to the representations of CVS, Viper was not a monitoring program. CVS’s 30(b)(6) witness Mark Vernazza admitted at deposition that Viper “was not deemed an SOM report.” Viper was no more than a theft report that provided no ability to evaluate specific orders of controlled substances placed by CVS pharmacies to McKesson. In reality, CVS had

1 no policies, procedures or programs to monitor prescription opioid orders placed by its
2 pharmacies to McKesson or any other outside vendor until 2014.

3 564. When McKesson sought to fulfill its responsibilities, efforts to monitor CVS
4 pharmacies were resisted by CVS as early as 2008. In 2008 and 2010 CVS refused to provide
5 McKesson sales or dispensing information for individual stores in order to establish accurate
6 opioid thresholds. In March of 2012, Don Walker, the Senior Vice President of Distribution at
7 McKesson and Tom McDonald, Director of Regulatory Affairs, met with CVS. At that
8 meeting, CVS was requested to provide information with regard to "cash sales ratio per store."
9 Don Walker of McKesson acknowledged that this was "important information" to have to
10 identify diversion. CVS refused to provide this information. Mr. Walker described this as a
11 "business decision" on the part of CVS.

12 565. At the same meeting described above, McKesson requested that CVS provide it
13 with "mechanisms for the review of prescribing doctors". Mr. Walker testified that this
14 information was requested in an attempt to "improve our abilities to monitor all of our retail
15 national account pharmacies". McKesson did not have such information relating to CVS at
16 this point in time. According to Mr. Walker, the DEA, as early as 2006, had identified
17 prescribing doctors as a focus of monitoring. CVS again refused to provide this information.

18 566. At the March 2012 meeting described above, McKesson additionally requested
19 that CVS provide them with "the ratio of prescriptions per doctor." Prior to 2012, McKesson
20 had not been provided such information. CVS again refused to provide such information.

21 567. At the March 2012 meeting described above, McKesson requested that CVS
22 provide them with a "rate of growth of each store, year over year." McKesson had no such
23 information prior to this meeting and CVS refused to provide it at that time. Again, CVS
24 indicated that such information was "proprietary."

25 568. As a result of its misrepresentations, affirmative acceptance, and refusals outlined
26 above, although CVS knew the importance of the data and responsibility for the monitoring of
27 prescription opioid orders distributed from McKesson to CVS Pharmacies throughout the
28

United States including Nevada and Plaintiff's communities specifically, CVS failed to make reasonable efforts to maintain effective controls against diversion of controlled substances and to monitor suspicious orders of controlled substances placed by CVS pharmacies to McKesson.

569. Similarly, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

570. On December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 CFR §1301.74(b)";
- b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 CFR §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 USC §842(a)(5)"; and
- c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 USC §828 and 21 CFR Part 1305."

571. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal

1 Health, as well as several smaller wholesalers, for numerous causes of action, including
2 violations of the CSA, consumer credit and protection, and antitrust laws as well as for the
3 creation of a public nuisance. Unsealed court records from that case demonstrate that
4 AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million
5 pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3
6 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These
7 quantities alone are sufficient to show that the Defendants failed to control the supply chain or
8 to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle
9 the West Virginia lawsuit for \$16 million to the state; Cardinal Health settled for \$20 million.

10 572. Upon information and belief, AmeriSourceBergen, Cardinal Health, and
11 McKesson, are three (3) of the largest distributors in the State of Nevada, resulting in excessive
12 shipments of opioids into Nevada's communities.

13 573. Thus, it is the various governmental agencies who have alleged or found—and
14 the Defendants themselves who have admitted—that the Defendants, acting in disregard of
15 their duties, pumped massive quantities of opioids into communities around the country despite
16 their obligations to control the supply, prevent diversions, and report and take steps to halt
17 suspicious orders.

18 574. The sheer volume of prescription opioids distributed to pharmacies in the State
19 of Nevada is excessive for the medical need of the community and facially suspicious.¹⁸⁹ Some
20 red flags are so obvious that no one who engages in the legitimate distribution of controlled
21 substances can reasonably claim ignorance of them.¹⁹⁰

22 575. The State is of the information and belief that the Defendants failed to report
23 “suspicious orders” originating from Nevada to the DEA, the Nevada Department of Public
24 Safety, and/or the Nevada Board of Pharmacy as they were required to do under Nevada law.

26
27 ¹⁸⁹ *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-02 (Sept. 15, 2015) (1.47 million dosage units of oxycodone
to Nevada customers in 2009, 2.8 million dosage units of oxycodone. To Nevada customers in 2010, and 192,000
doses to Nevada customers in 2011.

28 ¹⁹⁰ *Id.* (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,316, 62,322 (2012)).

1 576. The Defendants unlawfully filled suspicious orders of unusual size, orders
2 deviating substantially from a normal pattern and/or orders of unusual frequency in Nevada.

3 577. The Defendants illegally promoted the sale of dangerous and harmful drugs, in
4 violation of the Nevada Controlled Substances Act, §§ 453.005 to 453.730, by supplying
5 suspicious orders for opiates to retail pharmacies, hospitals, and other health care facilities
6 throughout the State of Nevada that the Defendants knew were suspicious, including orders of
7 unusual size, orders deviating substantially from a normal pattern, and orders of unusual
8 frequency.

9 578. The laws at issue here, and cited above, are public safety laws.

10 579. The Defendants breached their duty to maintain effective controls against
11 diversion of prescription opiates into other than legitimate medical, scientific, and industrial
12 channels.

13 580. The Distributor Defendants' violations of public safety statutes constitute prima
14 facie evidence of negligence under Nevada law.

15 581. The Distributor Defendants breached their duty to exercise due diligence to
16 avoid filling suspicious orders that might be diverted into channels other than legitimate
17 medical, scientific and industrial channels.¹⁹¹

18 582. The Defendants breached their duty to monitor, detect, investigate, refuse and
19 report suspicious orders of prescription opiates originating from Nevada.

20 583. The Defendants' failures to monitor, report, and halt suspicious orders of
21 opioids were intentional and unlawful. They refuse to abide by the duties imposed by law which
22 are required to maintain a Nevada license to distribute prescription opiates.

23 584. The Defendants have misrepresented their compliance with Nevada law, both to
24 the public and to Nevada state regulators.

25 585. The Defendants enabled the supply of prescription opioids to obviously
26 suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal
27

28 ¹⁹¹ See *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

activity, and disseminated massive quantities of prescription opioids into the black market.

586. The Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Nevada and into areas surrounding Nevada from which opioids were illicitly diverted into Nevada.

6. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement.

587. To protect their registered distributor status with *inter alia* the Nevada Board of Pharmacy, Defendants undertook efforts to fraudulently assure the public that they were complying with their obligations under licensing regulations. Through such statements, Defendants attempted to assure the public they were working to curb the opioid epidemic.

588. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting and without maintaining effective controls against diversion by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all. Indeed, this notice to law enforcement is the very essence of what the suspicious order reporting requirements are all about.

589. After being caught for failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even

1 though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations
2 regarding controlling diversion and reporting suspicious orders, and even though McKesson
3 had specifically agreed in 2008 that it would no longer violate those obligations, McKesson
4 continued to violate the laws in contrast to its written promises not to do so.

5 590. More generally, the Distributor Defendants publicly portrayed themselves as
6 committed to working with law enforcement, opioid manufacturers, and others to prevent
7 diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We
8 challenge ourselves to best utilize our assets, expertise and influence to make our communities
9 stronger and our world more sustainable, while governing our activities as a good corporate
10 citizen in compliance with all regulatory requirements and with a belief that doing ‘the right
11 thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-
12 diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along
13 the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block
14 and report to regulators those orders of prescription-controlled medications that do not meet [its]
15 strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,”
16 which funds grants related to prescription drug misuse. A Cardinal executive recently claimed
17 that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public
18 it was being “as effective and efficient as possible in constantly monitoring, identifying, and
19 eliminating any outside criminal activity.”

20 591. Along the same lines, Defendant McKesson publicly claims that its “customized
21 analytics solutions track pharmaceutical product storage, handling and dispensing in real time
22 at every step of the supply chain process,” creating the impression that McKesson uses this
23 tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a
24 “best-in-class controlled substance monitoring program to help identify suspicious orders,” and
25 claimed it is “deeply passionate about curbing the opioid epidemic in our country.”

26 592. Defendant AmerisourceBergen, too, has taken the public position that it is
27 “work[ing] diligently to combat diversion and [is] working closely with regulatory agencies
28

and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances.” A company spokeswoman also provided assurance that: “At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients.”

593. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, the HDMA (now HDA) and the National Association of Chain Drugstores (“NACDS”), filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements.¹⁹²

1. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
2. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.”

594. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed, falsely, that their conduct was in compliance with those obligations.

595. Defendant Mallinckrodt similarly claims to be “committed . . . to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances”

596. Other Manufacturer Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its

¹⁹² Brief for HDMA and NACDS, *Masters Pharms., Inc. v. U.S. Drug Enf’t Admin.*, Case No 15- 1335, 2016 WL 1321983, (D.C. Cir. April 4, 2016) at *3-4, *25.

1 “constructive role in the fight against opioid abuse,” including its commitment to ADF opioids
2 and its “strong record of coordination with law enforcement.”¹⁹³

3 597. At the heart of Purdue’s public outreach is the claim that it works hand-in-glove
4 with law enforcement and government agencies to combat opioid abuse and diversion. Purdue
5 has consistently trumpeted this partnership since at least 2008, and the message of close
6 cooperation is in virtually all of Purdue’s recent pronouncements in response to the opioid
7 abuse.

8 598. Touting the benefits of ADF opioids, Purdue’s website asserts: “[W]e are
9 acutely aware of the public health risks these powerful medications create That’s why we
10 work with health experts, law enforcement, and government agencies on efforts to reduce the
11 risks of opioid abuse and misuse”¹⁹⁴ Purdue’s statement on “Opioids Corporate
12 Responsibility” likewise states that “[f]or many years, Purdue has committed substantial
13 resources to combat opioid abuse by partnering with . . . communities, law enforcement, and
14 government.”¹⁹⁵ And, responding to criticism of Purdue’s failure to report suspicious
15 prescribing to government regulatory and enforcement authorities, the website similarly
16 proclaims that Purdue “ha[s] a long record of close coordination with the DEA and other law
17 enforcement stakeholders to detect and reduce drug diversion.”¹⁹⁶

18 599. These public pronouncements create the misimpression that Purdue is
19 proactively working with law enforcement and government authorities nationwide to root out
20 drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance
21

22 ¹⁹³ Purdue, *Setting The Record Straight On OxyContin’s FDA-Approved Label*, May 5, 2016,
23 <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on- oxycontin-fda-approved-label/>;
24 *Setting The Record Straight On Our Anti-Diversion Programs*, Purdue Pharma (July 11, 2016),
<http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/>.

25 ¹⁹⁴ *Opioids With Abuse-Deterrent Properties*, Purdue Pharma, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/>.

26 ¹⁹⁵ *Opioids & Corporate Responsibility*, Purdue Pharma, <http://www.purduepharma.com/news-media/opioids-corporate-responsibility/>.

27 ¹⁹⁶ Purdue, *Setting The Record Straight On Our Anti-Diversion Programs* (July 11, 2016),
28 <http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-antidiversion-programs/>. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

1 Purdue from its past conduct in deceptively marketing opioids and make its current marketing
2 seem more trustworthy and truthful.

3 600. Public statements by the Defendants and their associates created the false and
4 misleading impression to regulators, prescribers, and the public that the Defendants rigorously
5 carried out their legal duties, including their duty to report suspicious orders and exercise due
6 diligence to prevent diversion of these dangerous drugs, and further created the false impression
7 that these Defendants also worked voluntarily to prevent diversion as a matter of corporate
8 responsibility to the communities their business practices would necessarily impact.

9 601. By misleading the public and the State of Nevada about the effectiveness of their
10 controlled substance monitoring programs, the Defendants successfully concealed the facts
11 sufficient to arouse suspicion of the claims that the State now asserts. The State did not know
12 of the existence or scope of Defendants' industry-wide conduct and could not have acquired
13 such knowledge earlier through the exercise of reasonable diligence.

14 **7. The National Retail Pharmacies Were on Notice of and Contributed to Illegal**
15 **Diversion of Prescription Opioids.**

16
17 602. National retail pharmacy chains earned enormous profits by flooding the
18 country with prescription opioids. They were keenly aware of the oversupply of prescription
19 opioids through the extensive data and information they developed and maintained as both
20 distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of
21 opioids into communities, they continued to participate in the oversupply of opioids and earned
22 a substantial profit as a result.

23 603. Each of the National Retail Pharmacies does substantial business throughout the
24 United States and in Nevada. This business includes the distribution and dispensing of
25 prescription opioids.

26 604. The National Retail Pharmacies failed to take meaningful action to stop this
27 diversion despite their knowledge of it, and contributed substantially to the diversion problem.
28

605. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, the National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Nevada in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so.

a. The National Retail Pharmacies Have a Duty to Prevent Diversion

606. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

607. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under Nevada law. NRS § 639.070. *See also* NRS §§ 639.009; 639.0085; 639.012; 639.0155; 639.016; 639.233 (including manufacturers, repackagers, chain drug warehouses, wholesale drug warehouses, and *retail pharmacies* within the scope of the Nevada wholesale distributing regulations). Wholesalers and wholesale distributors are subject to additional licensing requirements. NRS §§ 639.500 – 639.515. Under Nevada law, pharmacy registrants are required to provide effective controls and procedures to guard against the theft and diversion of opioid drugs. *See* NAC § 453.400 (“[a]ll applicants and registrants shall establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances”). Because pharmacies themselves are registrants under Nevada Pharmacy laws, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

608. The DEA, among others, has provided extensive guidance to pharmacies

concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

609. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

610. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

611. Suspicious pharmacy orders are red flags for, if not direct evidence of diversion.

612. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

613. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted. As registrants, retail pharmacies are required to maintain effective controls and procedures to guard against theft and diversion (*see* NAC §§ 453.400, 435.410; NRS §§ 639.500 – 639.515, 639.585) and to operate

1 in compliance with all applicable federal, state and local laws and regulations. *See* NRS §§
2 639.510. This would include reporting evidence of prescription diversion to the DEA.
3 Furthermore, Nevada law requires retail pharmacies to adopt and abide by a marketing code of
4 conduct, enforce policies regarding investigation into compliance and corrective actions, and
5 submit and report certain information to the Board. NRS § 639.570

6 614. Despite their legal obligations as registrants under Nevada law, the National
7 Retail Pharmacies knowingly allowed widespread diversion to occur.

8 615. Performance metrics and prescription quotas adopted by the National Retail
9 Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for
10 example, pharmacists are directed to meet high goals that make it difficult, if not impossible,
11 to comply with applicable laws and regulations. There is no measurement for pharmacy
12 accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on
13 how many prescriptions that pharmacist fills within a year. The result is both deeply troubling
14 and entirely predictable: opioids flowed out of National Retail Pharmacies and into
15 communities throughout the country. The policies remained in place even as the epidemic
16 raged.

17 616. Upon information and belief, this problem was compounded by the Pharmacies'
18 failure to adequately train their pharmacists and pharmacy technicians on how to properly and
19 adequately handle prescriptions for opioid painkillers, including what constitutes a proper
20 inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition
21 for which the FDA has approved treatments with opioids, what measures and/or actions to take
22 when a prescription is identified as phony, false, forged, or otherwise illegal, or when
23 suspicious circumstances are present, including when prescriptions are procured and pills
24 supplied for the purpose of illegal diversion and drug trafficking.

25 617. Upon information and belief, the National Retail Pharmacies also failed to
26 adequately use data available to them to identify doctors who were writing suspicious numbers
27 of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use
28

data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

618. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

619. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

620. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

621. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas was so high that illegal diversion was the only logical explanation; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

b. Multiple Enforcement Actions against the National Retail Pharmacies
Confirm their Compliance Failures

622. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their irresponsible and illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the

product of, and confirm, national policies and practices of the National Retail Pharmacies.

i. CVS

623. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations, including in Nevada. Due to its size and market penetration, CVS could have been a force for good in connection with the opioid crisis. But like other Defendants, CVS valued profits over people.

624. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations.

625. As recently as July 2017, CVS entered into a \$5 million settlement regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.¹⁹⁷

626. This fine was preceded by numerous others throughout the country arising out of CVS's failure to report suspicious orders, failure to maintain proper records; filling prescriptions without a legitimate medical purpose; filling forged prescriptions; filling prescriptions written by doctors with expired registrations:

1. February 2016, CVS paid \$8 million in a settlement in Maryland;
2. October 2016, CVS paid \$600,000 in a settlement in Connecticut;
3. September 2016, CVS paid \$795,000 in a settlement with the Massachusetts Attorney General;
4. June 2016, CVS agreed to pay \$3.5 million arising out of allegations that it filled forged prescriptions;

¹⁹⁷ *CVS Pharmacy Inc. Pays \$5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), <https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc- pays-5m-settle-alleged-violations-controlled-substance-act>.

- 1 5. August 2015, CVS paid \$450,000 in a settlement with the U.S. Attorney's
- 2 Office for the District of Rhode Island;
- 3 6. May 2015, CVS agreed to pay a \$22 million penalty arising out of an
- 4 investigation in Sanford, Florida;
- 5 7. September 2014, CVS paid \$1.9 million in civil penalties;
- 6 8. August 2013, CVS was fined by \$350,000 by the Oklahoma Pharmacy
- 7 Board; and

8 627. Dating back to 2006, CVS retail pharmacies across the country intentionally
 9 violated its duties by filling prescriptions signed by prescribers with invalid DEA registration
 10 numbers.

11 628. Upon information and belief, CVS continued its wrongful, irresponsible,
 12 deceptive, and illegal activities throughout the country, including in the State of Nevada.

13 *ii. Walgreens*

14 629. Walgreens is the second-largest pharmacy store chain in the United States
 15 behind CVS, with annual revenue of more than \$118 billion. According to its website,
 16 Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a
 17 30-day adjusted basis in fiscal year 2017.

18 630. Walgreens also has been penalized for serious and flagrant violations of its
 19 duties to prevent diversion. Indeed, Walgreens agreed to pay \$80 million to resolve allegations
 20 that it committed an unprecedented number of recordkeeping and dispensing violations,
 21 including negligently allowing controlled substances such as oxycodone and other prescription
 22 painkillers to be diverted for abuse and illegal black-market sales.¹⁹⁸

23 631. The settlement resolved investigations into violations in Florida, New York,
 24 Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

25 632. Walgreens has also settled with a number of state attorneys general, including
 26

27 ¹⁹⁸ *Walgreens Agrees To Pay A Record Settlement Of \$80 Million For Civil Penalties Under The Controlled*
 28 *Substances Act*, U.S. Dep't of Just. (June 11, 2013), <https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled>.

West Virginia (\$575,000) and Massachusetts (\$200,000).¹⁹⁹

633. Upon information and belief, Walgreens continued its wrongful, irresponsible, deceptive, and illegal activities throughout the country, including in the State of Nevada.

634. Walgreens' conduct underscores its attitude that profit outweighs compliance with legal obligations and the health of the communities it serves.

F. The Opioids the Defendants Sold Migrated into Other Jurisdictions.

635. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state lines in a variety of ways. Upon information and belief, this practice is common and impacts Nevada as well.

636. First, prescriptions written in one state would, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another.

637. When authorities in states such as Ohio and Kentucky cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of Nevada and other states would simply fly or drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

638. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as \$100 a pill—ten times the pharmacy price.²⁰⁰ In

¹⁹⁹ *Walgreens to Pay \$200,000 Settlement for Lapses with Opioids*, APhA (Jan. 25, 2017), <https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids>.

²⁰⁰ Andrew Welsh-Huggins, *'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers*, NBC News (July 8, 2012), http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.

Columbus, Ohio, in 2011, 16 individuals were prosecuted for being involved in the “oxycodone pipeline between Ohio and Florida.”²⁰¹ When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. District Judge Michael Watson, contributing to a “pipeline of death.”²⁰²

639. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other states, including North Carolina, Kentucky, Tennessee, Ohio, South Carolina, and Florida. Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states, including Ohio and Alabama.

640. In yet another case, defendants who operated a pill mill in south Florida within Broward County were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward’s] customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts.”²⁰³ The court further noted that the pill mill “gained massive financial benefits

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²⁰¹ *16 Charged in Pill Mill Pipeline*, Columbus Dispatch (June 7, 2011), <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html>.

²⁰² *Leader of Ohio Pill Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015), http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html.

²⁰³ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

by taking advantage of the demand for oxycodone by Kentucky residents.”²⁰⁴

641. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.²⁰⁵ Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag.²⁰⁶ If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.²⁰⁷ Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the “Oxy Express.”²⁰⁸

642. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.²⁰⁹

643. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California.²¹⁰ Another similar pipeline developed in Michigan. According to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.²¹¹

²⁰⁴ *Id.* at 861.

²⁰⁵ John Temple, *American Pain* 171 (2016).

²⁰⁶ *Id.* at 172.

²⁰⁷ *Id.* at 171.

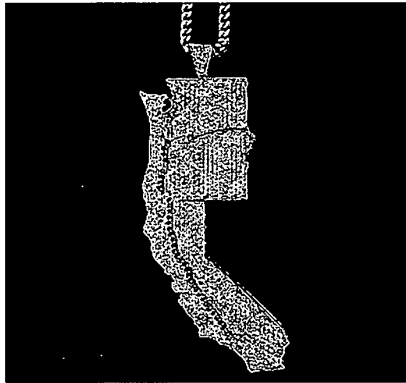
²⁰⁸ *Id.*; see also Welsh-Huggins, *supra*. Note that Interstate 75 was also called as the Oxy Express; for example, the Peabody Award-winning documentary named *The OxyContin Express* focuses on the transport of prescription opioids along I-75. <https://www.youtube.com/watch?v=wGZEvXNqzkM>.

²⁰⁹ *The OxyContin Express*. YouTube (Feb. 26, 2014), <http://www.youtube.com/watch?v=wGZEvXNqzkM>.

²¹⁰ Nok-Noi Ricker, *Slaying of Florida Firefighter in Maine Puts Focus on Interstate 95 Drug Running*, Bangor Daily News (March 9, 2012), <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>.

²¹¹ Julia Smillie, *Michigan's Opioid Epidemic Tackled From All Directions By Detroit FBI*, Workit Health (October 6, 2017), <https://www.workithealth.com/blog/fbi-michigan-opioid-crisis>.

644. Along the West Coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.²¹² Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.²¹³ The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.²¹⁴



G. Nevada's Opioid Epidemic

645. Nevada has been especially ravaged by the opioid crisis.

646. As reported by the National Institute on Drug Abuse, Nevada's drug overdose rate has been one of the highest in the nation for most of the last two decades. In fact, in 2017, the rate of overdose deaths involving opioids dropped below the national average for the first time since at least 1999. Unchanged is the fact that the highest number of deaths every year for drug overdoses involved prescription opioids.

²¹² Harriet Ryan et al., *How Black-Market Oxycontin Spurred a Town's Descent Into Crime, Addiction and Heartbreak*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-everett/>.

²¹³ *Id.*

²¹⁴ *Id.*

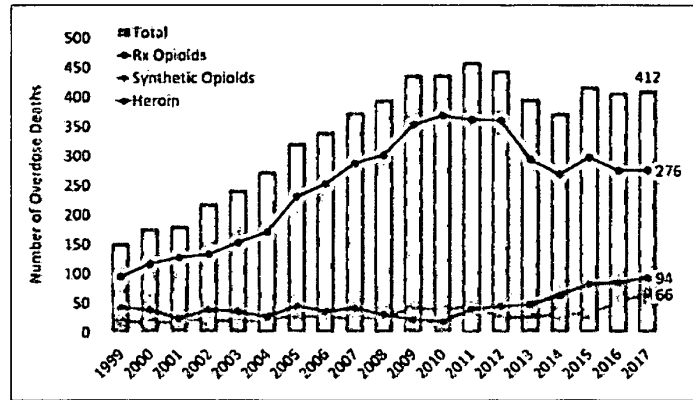


Figure 1. Number of overdose deaths involving opioids in Nevada, by opioid category. Drug categories presented are not mutually exclusive, and deaths might have involved more than one substance. Source: CDC WONDER.

Since 2010, the rate of opioid-related hospitalization for residents of Nevada has steadily increased for both the number of hospitalizations as well as the length of stay during those hospitalizations. In fact, the number of opioid-related emergency room encounters increased by around 250% from 2010 to 2017. In Office of Analytics, Department of Health and Human Services, Nevada Opioid Surveillance at 2.

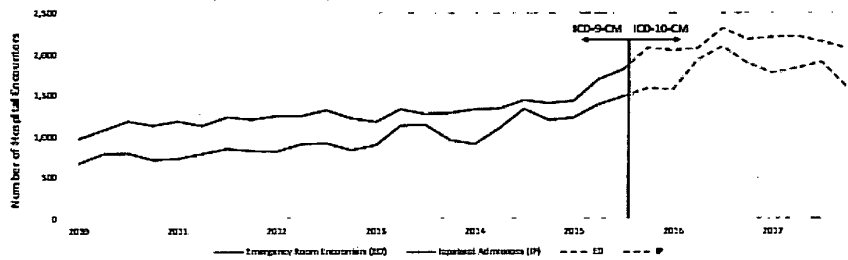
Opioid-Related Hospital Data, Nevada Residents, 2010-2017

In October 2015, ICD-10-CM codes were implemented. Previous to October 2015, ICD-9-CM codes were used for medical billing. Therefore, 2015 data consists of two distinct coding schemes, ICD-9-CM and ICD-10-CM respectively. Due to this change in coding schemes, hospital billing data from October 2015 forward may not be directly comparable to previous data.

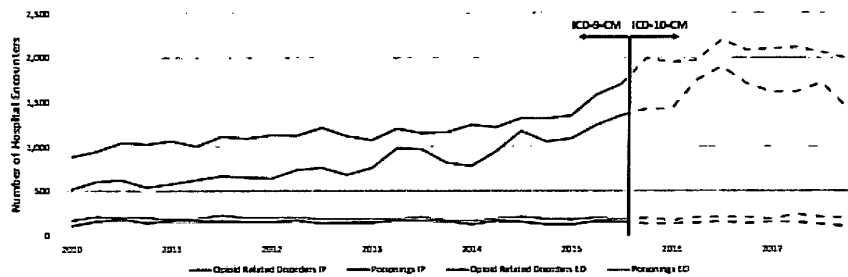
Year	Emergency Room Encounters (ED)	Emergency Room Crude Rates	Percent Change	Inpatient Admissions (IP)	Inpatient Crude Rates	Percent Change
2010	2,963	109.5		4,362	161.2	
2011	3,188	117.1	7%	4,755	174.7	8%
2012	3,473	126.3	8%	5,042	183.3	5%
2013	4,122	147.2	17%	5,067	180.5	-1%
2014	4,543	159.8	9%	5,317	194.0	7%
2015	5,695	196.5	23%	7,022	242.3	25%
2016	7,495	253.8	29%	8,621	291.9	20%
2017	7,125	238.7	-6%	8,661	290.1	-1%
Percent Change 2010-2017			118%			80%

Rates are per 100,000 Nevada Population.

Opioid-Related Hospitalizations by Quarter, Nevada Residents, 2010-2017



Opioid-Related Hospitalizations by Quarter, ICD Group and Year, Nevada Residents, 2010-2017



A person can be included in more than one drug group, and therefore the counts above are not mutually exclusive.

Opioid-Related Hospitalization (Inpatient) Visits by Length of Stay (Days), Nevada Residents, 2010-2017

Year	0-1	2-4	5-9	10-14	15-19	20-24	25+
2010	648	1,833	1,158	330	132	97	114
2011	691	1,977	1,339	403	132	74	139
2012	670	1,953	1,531	467	160	102	159
2013	754	1,952	1,483	411	192	113	164
2014	740	2,124	1,604	505	215	111	218
2015	880	2,771	2,196	592	245	117	221
2016	925	3,209	2,916	721	312	169	309
2017	1,104	3,357	2,725	705	322	182	266

647. In 2010, Nevada's opioid-related emergency room hospitalizations totaled 4,518 patients. In 2015, that number increased to 8,231 patients. Similarly, in 2010, the number of opioid-related inpatient admissions statewide totaled 3,095 hospitalizations. That

number increased to 7,035 in 2015.

648. Nevada's death rate from drug overdose grew dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs. The State went from an age-adjusted drug overdose death rate of 11.5 in 1999 to 21.7 in 2016.²¹⁵ Nevada has the fourth highest drug overdose mortality rate in the United States. Between 2010 and 2015, approximately 2,800 deaths in Nevada were attributed to opioid-related overdose. It is estimated that 55% of those deaths were caused by natural and semi-synthetic opioids.

649. Millions of claims have been submitted to, and paid by, Nevada's Medicaid program, for the following: opioid prescriptions for non-cancer and non-hospice patients; rehabilitation services for non-cancer and non-hospice patients; opioid treatment drugs for non-cancer and non-hospice patients; services for Neonatal Abstinence Syndrome for infants born with an opioid dependency; and other prescriptions and/or services arising out of Nevada residents' opioid use, abuse, and dependency, caused by Defendants' conduct.

650. The State of Nevada provides services to assist its residents in recovery from opioid dependency and addiction, which have been used in increasing numbers as a result of the opioid epidemic.

651. Defendants' conduct in Nevada is much the same as their conduct around the country and includes, but is not limited to: sending detailers to speak to Nevada's medical providers, leading classes and seminars in which Defendants and/or their representatives made misrepresentations regarding their opioid products, filling suspicious opioid orders, failing to report suspicious opioid orders, favoring those medical providers who were prescribing more opioids and stronger dosages of the drugs, and other conduct as discussed throughout this Complaint.

²¹⁵ CDC, Drug Overdose Death Data, 1999 tab, 2016 tab, available at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.html (last visited May 17, 2019).

H. Defendants' Unlawful Conduct And Breaches Of Legal Duties Caused Substantial Damages.

652. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products in Nevada, as have the sizes of the opioid shipments into the State of Nevada — and the rates of opioid-related substance abuse, hospitalization, and death among the people of Nevada. The increase in shipments of opioids to the State of Nevada was dramatic and, by 2016, Nevada was ranked as the sixth highest state for the number of milligrams of opioids distributed per adult according to a study by the DEA.

653. 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.”²¹⁶

654. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.²¹⁷

655. The epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²¹⁸

656. The increased use of prescription painkillers for nonmedical reasons (meaning without a prescription for the high they cause), along with growing sales, has contributed to a large number of overdoses and deaths.

657. As discussed above, Nevada has experienced a substantial increase in the rates of opiate-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opioids.

658. Given the well-established relationship between the use of prescription opioids

²¹⁶ See Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

²¹⁷ See Volkow & McLellan, *supra*.

²¹⁸ See Califf et al., *supra*.

and the use of heroin, the State is informed and believes, and based thereon alleges, that the increase in opioid usage in the State of Nevada is dramatically increasing the rate of heroin addiction among Nevada residents.

659. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Nevada.

660. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Nevada.

661. The State seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

662. The State seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

663. To eliminate the hazard to public health and safety, and abate the public nuisance, a “multifaceted, collaborative public health and law enforcement approach is urgently needed.”²¹⁹

664. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.²²⁰

665. These community-based problems require community-based solutions that have been limited by “budgetary constraints at the state and Federal levels.”²²¹ Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their

²¹⁹ See Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, *supra* at 1445.

²²⁰ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf

²²¹ See Office of Nat’l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

conduct has inflicted upon the State of Nevada.

I. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

1. Conspiracy Among Manufacturer Defendants.

666. The Manufacturer Defendants agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors, through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

667. This interconnected and interrelated network relied on the Manufacturer Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Manufacturer Defendants intended to mislead consumers and medical providers of the appropriate uses, risks, and safety of opioids.

668. The Manufacturer Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

1 669. The Manufacturer Defendants knew that none of these propositions is true and
2 that there was no evidence to support them.

3 670. Each Manufacturer Defendant worked individually and collectively to develop
4 and actively promulgate these nine false propositions in order to mislead physicians, patients,
5 health care providers, and healthcare payors regarding the appropriate uses, risks, and safety of
6 opioids.

7 671. What is particularly remarkable about the Manufacturer Defendants' effort is
8 the seamless method in which the Manufacturer Defendants joined forces to achieve their
9 collective goal: to persuade consumers and medical providers of the safety of opioids, and to
10 hide their actual risks and dangers. In doing so, the Manufacturer Defendants effectively
11 built a new – and extremely lucrative – opioid marketplace for their select group of industry
12 players.

13
14 672. The Manufacturer Defendants' unbranded promotion and marketing network
15 was a wildly successful marketing tool that achieved marketing goals that would have been
16 impossible to meet for a single or even a handful of the network's distinct corporate members.

17 673. For example, the network members pooled their vast marketing funds and
18 dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the
19 creation of Front Groups. These collaborative networking tactics allowed each Manufacturer
20 Defendant to diversify its marketing efforts, all the while sharing any risk and exposure,
21 financial and/or legal, with other Manufacturer Defendants.

22 674. The most unnerving tactic utilized by the Manufacturer Defendants' network,
23 was their unabashed mimicry of the scientific method of citing "references" in their materials.
24 In the scientific community, cited materials and references are rigorously vetted by objective
25 unbiased and disinterested experts in the field, and an unfounded theory or proposition would,
26 or should, never gain traction.

27 675. Manufacturer Defendants put their own twist on this method: they worked
28

1 together to fabricate an entire ecosystem of misinformation, paid experts and Front Groups to
2 legitimize, cite to, and create more of that misinformation, used legally-mandated medical
3 education to spread and reinforce that misinformation, and then collected massive quantities of
4 data to target for special attention those prescribers who were not playing along, all to
5 manufacture wide support for their unfounded theories and propositions involving opioids. Due
6 to their sheer numbers and resources, the Manufacturer Defendants were able to create the
7 illusion of consensus through their materials and references.

8 676. An illustrative example of the Manufacturer Defendants' utilization of this tactic
9 is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction
10 "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized
11 patients who were given opioids in a controlled setting to ease suffering from acute pain. These
12 patients were *not* given long-term opioid prescriptions or provided opioids to administer to
13 themselves at home, nor was it known how frequently or infrequently and in what doses the
14 patients were given their narcotics. Rather, it appears the patients were treated with opioids for
15 short periods of time under in-hospital doctor supervision.

16 677. Nonetheless, Manufacturer Defendants widely and repeatedly cited this letter as
17 proof of the low addiction risk in connection with taking opioids in connection with taking
18 opioids despite its obvious shortcomings. Manufacturer Defendants' egregious
19 misrepresentations based on this letter included claims that less than one percent of opioid users
20 became addicted.

21 678. Manufacturer Defendants' collective misuse of the Porter & Jick Letter helped
22 the opioid manufacturers convince patients and healthcare providers that opioids were not a
23 concern. The enormous impact of Manufacturer Defendants' misleading amplification of
24 this letter was well documented in another letter published in the NEJM on June 1, 2017,
25 describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some
26 cases, "grossly misrepresented." In particular, the authors of this letter explained:

27 [W]e found that a five-sentence letter published in the Journal in
28 1980 was heavily and uncritically cited as evidence that
addiction was rare with long-term opioid therapy. We believe that

this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy...

679. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Manufacturer Defendants committed overt acts in furtherance of their conspiracy.

2. Conspiracy Among All Defendants.

680. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids by fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

681. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly-knit industry. The Manufacturer Defendants and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

682. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in a number of ways, including, for example, membership in the HDA.

683. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from legal scrutiny for the entire industry as Defendants were, thanks to their own significant lobbying and policy efforts, collectively responsible for each other's compliance through their reporting obligations. Defendants were

1 aware, both individually and collectively, of the suspicious orders that flowed directly from
2 Defendants' facilities.

3 684. Defendants knew that their own conduct could be reported by other Defendants
4 and that their failure to report suspicious orders or maintain controls against diversion could be
5 brought to the DEA or the Nevada Board of Pharmacy's attention. As a result, Defendants had
6 an incentive to communicate with each other about the reporting or suspicious orders to ensure
7 consistency in their dealings with the DEA and Nevada state authorities.

8 685. The Defendants also worked together to ensure that opioid quotas remained
9 artificially high and ensured that suspicious orders were not reported to the DEA or Nevada
10 state authorities, in order to ensure that there was no basis for refusing to increase or decrease
11 production quotas due to diversion. The desired consistency and collective end goal were
12 achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating
13 the unimpeded flow of opioids to the market they created.

14 **J. Statutes of Limitations are Tolloed and Defendants Are Estopped From Asserting**
15 **Statutes of Limitations as Defenses.**

16
17 686. Generally speaking, the statute of limitations does not run against the State.
18 Independently, any allegedly applicable limitations period is tolled. The State of Nevada entered
19 into tolling agreements with a number of Manufacturer Defendants in 2017 which tolled the
20 running of any "Time-Related Defense" as to any claim arising out of the conduct alleged within
21 the instant Complaint until the State provided Notice of the Intent to Sue or until the agreements
22 expired, whichever came first.

23 **1. Continuing Conduct**

24
25 687. Plaintiff, State of Nevada, contends it continues to suffer harm from the
26 unlawful actions by the Defendants.

27 688. The continued tortious conduct by the Defendants causes a repeated or
28

continuous injury. The damages have not occurred all at once but have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Though the State has made efforts to abate the nuisance, the wrongdoing has not ceased and thus, the public nuisance remains, and the conduct causing the damages remains unabated.

2. Equitable Estoppel

689. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State of Nevada, that they were undertaking efforts to comply with their obligations under the Controlled Substances Act, §§ 453.005-453.730, all with the goals of protecting their registered manufacturer or distributor status in the State and of continuing to generate profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State of Nevada that they were working to curb the opioid epidemic.

690. For example, a Cardinal Health executive claimed that it uses “advanced analytics” to monitor its supply chain, and assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”²²²

691. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”²²³

692. Moreover, in furtherance of their effort to affirmatively conceal their conduct

²²² Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

²²³ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements.²²⁴

- “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.”
- “DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy’s placement of unusually frequent or large orders).”
- “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”
- “A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.”
- “Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.”

Through the above statements made on their behalf by their trade associations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

693. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. These Defendants invented “pseudoaddiction” and promoted it to an unsuspecting medical community using literature and materials created at the direction of, and paid for by, the Defendants. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased,

²²⁴ Brief for HDMA and NACDS, *supra*, 2016 WL 1321983, at *3-4, *25.

1 without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period
2 of years on a misinformation campaign aimed at highlighting opioids' alleged benefits,
3 disguising the risks, and promoting sales. The medical community, consumers, and the State
4 were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth
5 about the opioid drugs that they were aggressively pushing in the State of Nevada.

6 694. The State reasonably relied on Defendants' affirmative statements regarding
7 their purported compliance with their obligations under the law and consent orders.

8 3. Intentional Concealment

9 695. Alternatively, the State's claims are subject to equitable tolling, stemming from
10 Defendants' knowingly and intentionally concealing the facts alleged herein. Defendants knew
11 of the wrongful acts set forth above, had material information pertinent to their discovery, and
12 concealed them from the State. The State did not know, or could not have known through the
13 exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

14 696. The Defendants were deliberate in taking steps to conceal their misconduct in
15 the deceptive marketing and the oversupply of opioids through overprescribing and suspicious
16 sales, all of which fueled the opioid epidemic.

17 697. As set forth herein, the Manufacturer Defendants deliberately worked through
18 Front Groups purporting to be patient advocacy and professional organizations, through public
19 relations companies hired to work with the Front Groups and through paid KOLs to secretly
20 control messaging, influence prescribing practices and drive sales. The Manufacturer
21 Defendants concealed their role in shaping, editing, and approving the content of prescribing
22 guidelines, informational brochures, KOL presentations, and other false and misleading
23 materials addressing pain management and opioids that were widely disseminated to
24 regulators, prescribers and the public at large. They concealed the addictive nature and dangers
25 associated with opioid use and denied blame for the epidemic attributing it instead solely to
26 abuse and inappropriate prescribing. They manipulated scientific literature and promotional
27 materials to make it appear that misleading statements about the risks, safety and superiority of
28

opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Manufacturer Defendants' deceptions deprived the State of actual or implied knowledge of facts sufficient to put the State on notice of potential claims.

698. Defendants also concealed from the State the existence of the State's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including the State, and deprived the State of actual or implied knowledge of facts sufficient to put the State on notice of potential claims.

699. The State did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on jurisdiction, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

700. The Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in Nevada deceived the medical community, consumers, and the State.

701. Defendants intended that their actions and omissions would be relied upon, including by the State. The State did not know, and did not have the means to know, the truth, due to Defendants' actions and omissions.

702. The State reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

703. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the State filed suit promptly upon

1 discovering the facts essential to its claims, described herein, which Defendants knowingly
2 concealed.

3 704. In light of their statements to the media, in legal filings, and settlements, it is
4 clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in
5 that they consciously concealed the schemes set forth herein.

6 705. Defendants continually and secretly engaged in their scheme to avoid
7 compliance with their reporting obligations. Only Defendants and their agents knew or could
8 have known about Defendants' unlawful failure to report suspicious sales because Defendants
9 made deliberate efforts to conceal their conduct. As a result of the above, the State was unable
10 to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

11 **K. Facts Pertaining to Civil Penalties and Punitive Damages**

12
13 706. As set forth above, Defendants acted deliberately to increase sales of, and profits
14 from, opioid drugs. The Manufacturer Defendants knew there was no support for their claims
15 that addiction was rare, that addiction risk could be effectively managed, that signs of addiction
16 were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no
17 significant additional risks, that long-term use of opioids improves function, or that time-
18 release or abuse- deterrent formulations would prevent addiction or abuse. Nonetheless, they
19 knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

20 707. All of the Defendants, moreover, knew that large and suspicious quantities of
21 opioids were being poured into communities throughout the United States and in Nevada, yet,
22 despite this knowledge, took no steps to report suspicious orders, control the supply of opioids,
23 or otherwise prevent diversion. Indeed as described above, Defendants acted in concert
24 together to maintain high levels of quotas for their products and to ensure that suspicious orders
25 would not be reported to regulators.

26 708. Defendants' conduct was so willful, deceptive, and deliberate that it continued in
27 the face of numerous enforcement actions, fines, and other warnings from state and local
28

governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. Through their ongoing course of conduct, Defendants knowingly, deliberately and repeatedly threatened, harmed, and created a risk of harm to public health and safety, and caused large-scale economic loss to communities and government liabilities across the country.

709. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm.

710. So determined were the Manufacturer Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions.

711. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay \$600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay \$19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay \$8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay \$7.5 million in fines.

712. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued to deceptively market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly \$900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during

1 that period.

2 713. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described
3 Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they
4 wanna do, and not worry about what the law is. And if they don't follow the law in drug supply,
5 people die. That's just it. People die." He further explained that:

6 JOE RANNAZZISI: The three largest distributors are Cardinal
7 Health, McKesson, and AmerisourceBergen. They control
8 probably 85 or 90 percent of the drugs going downstream.

9 [INTERVIEWER]: You know the implication of what you're
10 saying, that these big companies knew that they were pumping
11 drugs into American communities that were killing people.

12 JOE RANNAZZISI: That's not an implication, that's a fact.
13 That's exactly what they did.

14 714. Another DEA veteran similarly stated that these companies failed to make even
15 a "good faith effort" to "do the right thing." He further explained that "I can tell you with
16 100 percent accuracy that we were in there on multiple occasions trying to get them to change
17 their behavior. And they just flat out ignored us."

18 715. Government actions against the Defendants with respect to their obligations to
19 control the supply chain and prevent diversion include, but are not limited to:

- 20 • On April 24, 2007, the DEA issued an Order to Show Cause and Immediate
21 Suspension Order against the AmerisourceBergen Orlando, Florida distribution
22 center ("Orlando Facility") alleging failure to maintain effective controls against
23 diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered
24 into a settlement that resulted in the suspension of its DEA registration;
- 25 • On November 28, 2007, the DEA issued an Order to Show Cause and Immediate
26 Suspension Order against the Cardinal Health Auburn, Washington Distribution
27 Center ("Auburn Facility") for failure to maintain effective controls against diversion
28 of hydrocodone;
- On December 5, 2007, the DEA issued an Order to Show Cause and Immediate
Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center
("Lakeland Facility") for failure to maintain effective controls against diversion of
hydrocodone;

- On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia (“McDonough Facility”), Valencia, California (“Valencia Facility”) and Denver, Colorado (“Denver Facility”);
- On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health’s Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and
- On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

716. McKesson’s conscious and deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.²²⁵ In the 2008 MOA, McKesson “recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA,” but had failed to do so.²²⁶

717. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the Controlled Substances Monitoring Program (“CSMP”)

²²⁵ See Administrative Memorandum of Agreement between the U.S. Dep’t of Justice, the Drug Enf’t Admin., and the McKesson Corp. at 4 (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

²²⁶ *Id.*

1 files maintained for many of its customers and bypassed suspicious order reporting procedures
2 set forth in the CSMP. It failed to take these actions despite its awareness of the great
3 probability that its failure to do so would cause substantial harm.

4 718. On January 5, 2017, McKesson Corporation entered into an Administrative
5 Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty
6 for violation of the 2008 MOA, as well as failure to identify and report suspicious orders at its
7 facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD;
8 La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse,
9 OH; and West Sacramento, CA. McKesson's 2017 agreement with the DEA documents
10 that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its
11 sales of controlled substances and/or report suspicious orders to DEA, in accordance with
12 McKesson's obligations."

13 719. McKesson admitted that, at various times during the period from January 1,
14 2009, through the effective date of the Agreement (January 17, 2017) it "did not identify or
15 report to [the] DEA certain orders placed by certain pharmacies which should have been
16 detected by McKesson as suspicious based on the guidance contained in the DEA Letters."²²⁷
17 Further, the 2017 Agreement specifically finds that McKesson "distributed controlled
18 substances to pharmacies even though those McKesson Distribution Centers should have
19 known that the pharmacists practicing within those pharmacies had failed to fulfill their
20 corresponding responsibility to ensure that controlled substances were dispensed pursuant to
21 prescriptions issued for legitimate medical purposes by practitioners acting in the usual course
22 of their professional practice, as required by 21 C.F.R § 1306.04(a)."²²⁸ McKesson admitted
23 that, during this time period, it "failed to maintain effective controls against diversion of
24 particular controlled substances into other than legitimate medical, scientific and industrial
25 channels."²²⁹ Due to these violations, McKesson agreed that its authority to distribute

26
27 ²²⁷ See Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and
the McKesson Corp. (Jan. 17, 2017), <https://www.justice.gov/opa/press-release/file/928476/download>.

28 ²²⁸ *Id.* at 4.

²²⁹ *Id.*

1 controlled substances from certain facilities would be partially suspended.²³⁰

2 720. As *The Washington Post* and *60 Minutes* recently reported, DEA staff
3 recommended a much larger penalty than the \$150 million ultimately agreed to for McKesson's
4 continued and renewed breach of its duties, as much as a billion dollars, and delicensing of
5 certain facilities. A DEA memo outlining the investigative findings in connection with the
6 administrative case against 12 McKesson distribution centers included in the 2017 Settlement
7 stated that McKesson "[s]upplied controlled substances in support of criminal diversion
8 activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily";
9 "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own
10 procedures designed to prevent diversion."

11 721. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant
12 Special Agent David Schiller, who described McKesson as a company that killed people for its
13 own financial gain and blatantly ignored the requirements to report suspicious orders:

14 DAVID SCHILLER: If they would [have] stayed in compliance
15 with their authority and held those that they're supplying the pills
16 to, the epidemic would be nowhere near where it is right now.
17 Nowhere near.

18 * * *

19 They had hundreds of thousands of suspicious orders they should
20 have reported, and they didn't report any. There's not a day that
21 goes by in the pharmaceutical world, in the McKesson world, in
22 the distribution world, where there's not something suspicious.
23 It happens every day.

24 [INTERVIEWER:] And they had none.

25 DAVID SCHILLER: They weren't reporting any. I mean, you
26 have to understand that, nothing was suspicious?²³¹

27 ²³⁰ *Id.* at 6.

28 ²³¹ Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), <https://www.cbsnews.com/news/whistleblowers-deaatorneys-went-easy-on-mckesson-the-country-largest-drug-distributor/>.

722. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

- a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";
- b. "[d]ocumentation evidencing new customer due diligence was incomplete";
- c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and
- d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

723. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

724. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in *The Washington Post*, "the company paid little or no attention to the unusually large and

1 frequent orders placed by pharmacies, some of them knowingly supplying the drug rings.”
 2 “Instead, the DEA officials said, the company raised its own self-imposed limits, known as
 3 thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the
 4 face of numerous red flags.”

5 725. Since at least 2002, Purdue has maintained a database of health care
 6 providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians
 7 could be added to this database based on observed indicators of illicit prescribing such as
 8 excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of
 9 the highest-strength pills (80 mg OxyContin pills or “80s,” as they were known on the
 10 street, were a prime target for diversion). Purdue claims that health care providers added to
 11 the database no longer were detailed, and that sales representatives received no compensation
 12 tied to these providers’ prescriptions.

13 726. Yet, Purdue failed to cut off these providers’ opioid supply at the pharmacy
 14 level— meaning Purdue continued to generate sales revenue from their prescriptions—and
 15 failed to report these providers to state medical boards or law enforcement. Purdue’s former
 16 senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five
 17 years of investigating suspicious pharmacies, the company never stopped the supply of its
 18 opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its
 19 drugs.

20 727. The same was true of prescribers. For example, as discussed above, despite
 21 Purdue’s knowledge of illicit prescribing from one Los Angeles clinic which its district
 22 manager called an “organized drug ring” in 2009, Purdue did not report its suspicions until
 23 long after law enforcement shut it down and not until the ring prescribed more than 1.1 million
 24 OxyContin tablets.

25 728. Indeed, the New York Attorney General found that Purdue placed 103 New
 26 York health care providers on its “No-Call” List between January 1, 2008 and March 7, 2015,
 27 and that Purdue’s sales representatives had continued to detail approximately two-thirds of these
 28 providers, some quite extensively, making more than a total of 1,800 sales calls to their offices

over a six- year period.

729. As all of the governmental actions against the Defendants show, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

730. Meanwhile, despite the State's efforts to limit the impact of the crisis, the opioid epidemic rages unabated in Nevada.

731. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. They pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

732. The Defendants have knowingly abandoned their duties imposed under Nevada law and federal law that is incorporated therein, taken advantage of a lack of DEA law enforcement in Nevada, and abused the privilege of distributing controlled substances in this community.

V. LEGAL CAUSES OF ACTION

FIRST CAUSE OF ACTION

NRS § 202 *et seq.* and common law (Against all Defendants)

733. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

734. The Attorney General may bring an action to abate a public nuisance in the name of the State under NRS § 202.480.

735. Defendants, individually and in concert with each other, have contributed to and/or assisted in creating and maintaining a condition that is harmful to the health of thousands of Nevada residents and which interferes with the enjoyment of life in violation of Nevada law.

1 736. Defendants have acted unlawfully and failed to perform their duties imposed by
2 state and federal statutes, as well as common law, which have annoyed, injured, and endangered
3 the safety, health, comfort, or repose of the residents of the State of Nevada.

4 737. Prescription opioid abuse, addiction, morbidity, and mortality are a public
5 nuisance in Nevada, which, despite the State's efforts, remains unabated. The unlawful conduct
6 by the Defendants as described herein has created these hazards to public health and safety.

7 738. The health and safety of the citizens of the State, including those who use, have
8 used or will use opioids, as well as those affected by users of opioids, is a matter of great public
9 interest and of legitimate concern to the State's citizens and residents.

10 739. The public nuisance created by Defendants' actions is substantial and
11 unreasonable - it has caused and continues to cause significant harm to the community, and the
12 harm inflicted outweighs any offsetting benefit.

13 740. Defendants knew, or should have known, that their promotion and irresponsible
14 distribution of opioids (in violation of their monitoring and reporting obligations) would create
15 a public nuisance.

16 741. Defendants' actions were, at the least, a substantial factor in opioids becoming
17 widely available and widely used.

18 742. Defendants' actions were, at the least, a substantial factor in doctors and patients
19 not accurately assessing and weighing the risks and benefits of opioids for chronic pain.

20 743. Without Defendants' actions, opioid use would not have become so widespread,
21 and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists
22 would have been averted.

23 744. Defendants, each of them, have contributed to, and/or assisted in creating and
24 maintaining a condition that is harmful to the health of Nevada citizens or interferes with the
25 comfortable enjoyment of life.

26 745. The public nuisance created by Defendants' actions is substantial and
27 unreasonable. It has caused and continues to cause significant harm to the community and the
28

harm inflicted outweighs any offsetting benefit. The staggering rates of opioid use resulting from Defendants' marketing efforts have caused harm to the community, and the health and safety of those individuals in Nevada, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern.

746. Defendants' conduct has affected and continues to affect a considerable number of people within the State and is likely to continue to cause significant harm to chronic pain patients who take opioids, their families, and the community at large.

747. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of injuries sustained by Plaintiff and that Plaintiff will continue to suffer if the nuisance is not abated.

748. That as a result of the aforesaid occurrence, Plaintiff has suffered extensive harm as a result of Defendants' conduct and will continue to suffer such harm if the nuisance is not abated.

749. The opioid crisis is an unreasonable interference with the right to public health and public safety – which are rights common to the public as a whole.

750. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the State's residents, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. The State has a clearly ascertainable right to abate conduct that perpetuates this nuisance

751. Defendants' actions created and expanded and/or assisted in the creation and expansion of the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Nevada, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids without reporting or refusing to fill

suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids. Such actions were inherently dangerous.

752. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Nevada.

753. Defendants acted recklessly, negligently and/or carelessly, in breach of their duties to maintain effective controls against diversion, thereby creating an unreasonable risk of harm.

754. Defendants acted with malice, actual or implied, because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

755. The damages available to the Plaintiff include, inter alia, abatement costs to stop the rise of damages from an ongoing and persistent public nuisance. Plaintiff seeks all damages flowing from Defendants' conduct as it relates to the increase in Medicaid payments arising out of the opioid epidemic and the thousands, if not millions, of incidents of deceptive trade practices by Defendants within the State. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

756. The State seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent interference with a right common to the public.

757. The public nuisance created by Defendants' actions is foreseeable, substantial, and unreasonable it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Distributor Defendants' abdication of their gate-keeping duties, and the

- 1 Manufacturer Defendants' deceptive marketing activities, have caused harm to the entire
- 2 community that includes, but is not limited to:
- 3 a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose,
- 4 injuries, and deaths.
- 5 b. Nor have children escaped the opioid epidemic unscathed. Easy access to
- 6 prescription opioids made opioids a recreational drug of choice among Nevada
- 7 teenagers. Even infants have been born addicted to opioids due to prenatal exposure,
- 8 causing severe withdrawal symptoms and lasting developmental impacts.
- 9 c. Even those State residents who have never taken opioids have suffered from the
- 10 public nuisance arising from Defendants' abdication of their gate-keeper duties and
- 11 deceptive promotions. Many residents have endured both the emotional and financial
- 12 costs of caring for loved ones addicted to or injured by opioids, and the loss of
- 13 companionship, wages, or other support from family members who have used,
- 14 abused, become addicted to, overdosed on, or been killed by opioids.
- 15 d. The opioid epidemic has increased health care costs.
- 16 e. Employers have lost the value of productive and healthy employees.
- 17 f. Defendants' conduct created an abundance of drugs available for criminal use and
- 18 fueled a new wave of addiction, abuse, and injury.
- 19 g. Defendants' dereliction of duties and/or fraudulent misinformation campaign
- 20 pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the
- 21 ensuing demand of addicts to buy them. More pills sold by Defendants led to more
- 22 addiction, with many addicts turning from prescription pills to heroin. People
- 23 addicted to opioids frequently require increasing levels of opioids, and many turned
- 24 to heroin as a foreseeable result.
- 25 h. The diversion of opioids into the secondary criminal market and the increased
- 26 number of individuals who abuse or are addicted to opioids increased the demands
- 27 on the State's Medicaid program.
- 28 i. The significant and unreasonable interference with the public rights caused by
- Defendants' conduct taxed the human, medical, public health, law enforcement, and
- financial resources of the State.
- j. Defendants' interference with the comfortable enjoyment of life in Nevada is
- unreasonable because there is no social utility to opioid diversion and abuse, and
- any potential value is outweighed by the gravity of the harm inflicted by

Defendants' actions.

758. The State has sustained specific and special injuries because its damages include *inter alia* the increase in demands on the State's Medicaid program, as described in this Complaint.

759. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement of the public nuisance, payment to the State of monies necessary to abate the public nuisance, all damages as allowed by law, attorney fees and costs, and pre- and post-judgment interest.

760. The continued tortious conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The State has taken efforts to abate the nuisance, but because the wrongdoing is ongoing, the public nuisance remains unabated.

761. Therefore, Plaintiff's claims are subject to equitable tolling, stemming from Defendants' wrongful concealment and from Plaintiff's inability to obtain vital information underlying its claims.

762. That Plaintiff has been required to prosecute this action and is entitled to attorneys' fees and costs as provided by Nevada statute.

763. That Plaintiff's general, special and punitive damages are in amounts in excess of \$15,000.00.

**SECOND CAUSE OF ACTION
VIOLATION OF NEVADA DECEPTIVE TRADE PRACTICES
ACT (NRS §§ 598.0903 to 598.0999)**

764. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

765. At all times relevant herein, the Defendants violated the Nevada Deceptive

1 Trade Practices Act, §§ 598.0903 to 598.0999, by repeatedly and willfully committing
2 deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce,
3 both of which are violations of the Act.

4 766. The Attorney General is authorized to bring an action in the name of the State
5 to remedy violations of the Deceptive Trade Practices Act. NRS §§ 598.0999. This action is
6 proper in this Court because Defendants are using, have used, and are about to use practices that
7 are unlawful under the Act. NRS § 598.0915(5).

8 767. Because Defendants' knowingly made false representations as to the
9 characteristics, uses, and benefits of opioids, they violated the Nevada Deceptive Trade
10 Practices Act.

11 768. The Distributor Defendants willfully committed deceptive trade practices
12 because of false representations as well as omission of material facts. *See* NRS § 598.0915(5);
13 *see also* §§ 598.0915(2) (“[k]nowingly makes a false representation as to the source,
14 sponsorship, approval or certification of goods or services for sale...”), 598.0915(3)
15 (“[k]nowingly makes a false representation as to affiliation, connection, association with or
16 certification by another person”), and 598.0915(15) (“[k]nowingly makes any other false
17 representation in a transaction”).

18 769. The Distributor Defendants knowingly failed to disclose the material facts that
19 *inter alia* they were not in compliance with laws and regulations requiring that they maintain a
20 closed distribution system, protect against addiction and severe harm, and specifically monitor,
21 investigate, report, and refuse suspicious orders. The Distributor Defendants knowingly
22 misrepresented to regulators and the public that their distribution services and methods for
23 preventing diversion were safe and effective when they were not. But for these knowing and
24 material factual misrepresentations and omissions, the Distributor Defendants would not have
25 been able to receive and renew licenses to sell opioids.

26 770. As alleged herein, each Manufacturer Defendant, at all times relevant to this
27 Complaint, violated the Deceptive Trade Practices Act by committing deceptive trade practices
28

1 by representing that the opioid prescription pills “have ... characteristics, ... uses, [or] benefits
2 ...” that they do not have. NRS § 598.0915(5).

3 771. The Manufacturer Defendants committed further deceptive trade practices by
4 causing confusion or misunderstanding as to what their drugs were actually approved or
5 certified to be used for. NRS § 598.0915(2).

6 772. The Manufacturer Defendants and Distributor Defendants committed further
7 deceptive trade practices by making “false representation as to [their] affiliation, connection,
8 association with or certification” of opioids by the other Defendants. NRS § 598.0915(3)

9 773. The Manufacturer Defendants committed further deceptive trade practices by
10 creating and widely disseminating misleading research studies and marketing literature written
11 to resemble research studies without disclosing that the creators of those materials were
12 affiliated, connected with, or associated with the Manufacturer Defendants. NRS §
13 598.0915(3).

14 774. The Manufacturer Defendants committed further deceptive trade practices by
15 representing that the opioids were safe and effective when such representations were untrue,
16 false, and misleading. NRS § 598.0915(15)

17 775. The Manufacturer Defendants committed further deceptive trade practices by
18 disparaging competing products like NSAIDs by misleading consumers into believing that
19 opioids were a safer option. NRS § 598.0915(8).

20 776. The Manufacturer Defendants committed further deceptive trade practices by
21 using exaggeration and/or ambiguity as to material facts and omitting material facts, which had
22 a tendency to deceive and/or did in fact deceive. NRS § 598.0915(15).

23 777. The Manufacturer Defendants made deceptive representations about the use of
24 opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or
25 concealed material facts and failed to correct prior misrepresentations and omissions about the
26 risks and benefits of opioids. Each Defendant’s omissions rendered even their seemingly
27 truthful statements about opioids deceptive.
28

778. On or after May 8, 2007, Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Nevada consumers that contained deceptive statements;
- b. Upon information and belief, within Nevada, distributing materials that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements nationally that reached doctors and prescribers within Nevada concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers, including consumers in Nevada;
- d. Distributing brochures to doctors, patients, and law enforcement officials nationally, and upon information and belief, in Nevada, that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications nationally that were available and distributed to doctors within Nevada, that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications nationally that were distributed, upon information and belief, to doctors within Nevada, that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements, available to doctors and patients in Nevada, concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials available nationally, and upon information and belief, in Nevada, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines nationally and within Nevada, that

- 1 contained deceptive statements concerning the use of opioids to treat chronic non-
2 cancer pain and misrepresented the risks of opioid addiction;
- 3 j. Endorsing and assisting in the distribution of CMEs, attended by or made available
4 to doctors licensed in Nevada, containing deceptive statements concerning the use
5 of opioids to treat chronic non-cancer pain;
- 6 k. Developing and disseminating scientific studies nationally, and upon information
7 and belief, within Nevada that misleadingly concluded opioids are safe and effective
8 for the long-term treatment of chronic non-cancer pain and that opioids improve
9 quality of life, while concealing contrary data;
- 10 l. Assisting in the dissemination of literature nationally and within Nevada, written by
11 pro-opioid KOLs that contained deceptive statements concerning the use of opioids
12 to treat chronic non-cancer pain;
- 13 m. Creating, endorsing, and supporting the distribution of patient and prescriber
14 education materials nationally, and upon information and belief, within Nevada, that
15 misrepresented the data regarding the safety and efficacy of opioids for the long-
16 term treatment of chronic non-cancer pain, including known rates of abuse and
17 addiction and the lack of validation for long-term efficacy;
- 18 n. Targeting veterans nationally, and upon information and belief, in Nevada, by
19 sponsoring and disseminating patient education marketing materials that contained
20 deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- 21 o. Targeting the elderly nationally, and upon information and belief, in Nevada, by
22 assisting in the distribution of guidelines that contained deceptive statements
23 concerning the use of opioids to treat chronic non-cancer pain and misrepresented
24 the risks of opioid addiction in this population;
- 25 p. Exclusively disseminating misleading statements in education materials to Nevada
26 hospital doctors and staff while purportedly educating them on new pain standards;
- 27 q. Making deceptive statements concerning the use of opioids to treat chronic non-
28 cancer pain to Nevada prescribers through in-person detailing; and
- r. Withholding from Nevada law enforcement the names of prescribers Purdue
believed to be facilitating the diversion of its products, while simultaneously
marketing opioids to these doctors by disseminating patient and prescriber
education materials and advertisements and CMEs they knew would reach these
same prescribers.

779. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Nevada prescribers through in-person detailing;
- b. Creating and disseminating advertisements nationally and, upon information and belief, in Nevada, that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements nationally and, upon information and belief, in Nevada, that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies nationally that reached doctors and prescribers in Nevada, that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

780. Defendant Mallinckrodt made and/or disseminated deceptive statements, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials throughout the United States—including, upon information and belief, Nevada prescribers—that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients throughout the United States—including, upon information and belief, in Nevada;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids that, upon information and belief, reached Nevada doctors and prescribers, to treat chronic non-cancer pain and breakthrough chronic non-cancer pain; and
- d. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials that, upon information and belief, reached Nevada doctors and prescribers, concerning the use of opioids to treat chronic non-cancer pain.

781. Defendant Insys made and/or disseminated untrue, false and deceptive

statements, including, but not limited to, the following:

- a. Providing significant financial support to pro-opioid doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- b. Providing significant financial support to doctors who increased the dosage amount and number of prescriptions they made for Subsys;
- c. Directing its marketing of Subsys to a wide range of doctors who were not oncologists, and promoting the drug for off-label uses like back and neck pain;
- d. Making deceptive statements concerning the use of Subsys to treat chronic non-cancer pain to prescribers throughout the United States—including, upon information and belief, Nevada prescribers—through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and
- e. Making deceptive statements to insurers and pharmacy benefit managers, including misrepresenting that they were the patients' health care provider calling to get prior authorization from the payor for the prescription, and falsely and intentionally implying or stating that the patient had cancer when the patient did not.

782. Defendants' deceptive and unconscionable representations, concealments, and omissions were knowingly made in connection with the sale of opioids, were reasonably calculated to deceive the State, the Nevada Board of Pharmacy and Nevada consumers, were statements that may deceive or tend to deceive, were willfully used to deceive the State, Nevada Board of Pharmacy and Nevada consumers, and did in fact deceive the State, the Nevada Board of Pharmacy, and Nevada consumers, who paid for prescription opioids for chronic pain.

783. As described more specifically above, Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day. Unless enjoined from doing so, the Manufacturer and Distributor Defendants will continue to violate the Nevada Deceptive Trade Practices Act.

784. But for these deceptive representations and concealments of material fact and material omissions, Nevada consumers would not have incurred millions of dollars in damages, including without limitation the costs of harmful drugs.

785. Defendants' deceptive trade practices are willful and subject to a civil penalty and equitable relief. NRS § 598.0971.

786. Defendants' deceptive trade practices toward the elderly are willful and subject to additional civil penalties and equitable relief. NRS § 598.0973.

787. Each exposure of a Nevada resident to opioids resulting from the aforementioned conduct of each and all Defendants constitutes a separate violation of the Deceptive Trade Practices Act.

788. Each and every prescription filled by the Distributor Defendants that was part of a suspicious order or in violation of their duties under the Nevada Controlled Substances Act constitutes a separate violation of the Deceptive Trade Practices Act on the part of the Distributor Defendants.

789. Each exposure of a state employee or contractor, Nevada health care professional or Nevada patient to the Manufacturer Defendants' misleading and deceptive information regarding opioids, including *inter alia* through print information, websites, presentations, brochures, or packaging, constitutes a separate violation pursuant to the Deceptive Trade Practices Act.

790. Plaintiff, State of Nevada, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement, reimbursement of all monies paid for prescription opioids by the State of Nevada via its Medicaid program, damages as allowed by law, all recoverable penalties under all sections of the Deceptive Trade Practices Act including all civil penalties per each violation per each Defendant named in this Count, attorney fees and costs, and pre- and post-judgment interest

**THIRD CAUSE OF ACTION
VIOLATION OF THE NEVADA RACKETEERING ACT (NRS §§ 207.350 TO
207.520) (AGAINST DEFENDANTS PURDUE AND THE SACKLER
DEFENDANTS, MALLINCKRODT, ACTAVIS, MCKESSON, CARDINAL, AND
AMERISOURCEBERGEN)**

792. The State re-alleges all prior paragraphs of this Complaint as if set forth fully

1 herein.

2 793. The State, both as a “person” who has sustained injury *and* on behalf of Nevada
3 citizens who have been injured, brings this claim for civil remedies under the Racketeering Act,
4 NRS §§ 207.350 to 207.520, against the following Defendants, as defined above: Purdue and
5 the Sackler Defendants, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen
6 (collectively, for purposes of this Count, the “Racketeering Defendants”). The Attorney General
7 has the specific statutory authority to bring this action pursuant to NRS §§ 207.415 and
8 207.490.

9 794. The Racketeering Defendants conducted and continue to conduct their business
10 through legitimate and illegitimate means in the form of a criminal syndicate or enterprise as
11 defined by NRS §§ 207.370 and 207.380. At all relevant times, the Racketeering Defendants
12 were “persons” under NRS § 0.039 and are included in the definition stating that a person is
13 “any form of business or social organization...including, but not limited to, a corporation,
14 partnership, association, trust or unincorporated organization.”

15 795. Section 207.400 of the Racketeering Act makes it unlawful “for a
16 person....employed by or associated with any enterprise to conduct or participate, directly or
17 indirectly, in: (1) The affairs of the enterprise through racketeering activity; or (2) Racketeering
18 activity through the affairs of the enterprise.” NRS § 207.400(1)(c).

19 796. The term “enterprise” is defined as including a “sole proprietorship, partnership,
20 corporation, business trust or other legal entity” as well as a “union, association or other group
21 of persons associated in fact although not a legal entity.” The definition includes “illicit as well
22 as licit enterprises and governmental as well as other entities.” NRS § 207.380.

23 797. For over a decade, the Racketeering Defendants aggressively sought to bolster
24 their revenue, increase profit, and grow their share of the prescription painkiller market by
25 unlawfully and surreptitiously increasing the volume of opioids they sold. However, the
26 Racketeering Defendants are not permitted to engage in a limitless expansion of their market
27 through the unlawful sales of regulated painkillers. As “registrants,” the Racketeering
28

Defendants operated and continue to operate within the nationwide “closed-system” created under the Controlled Substances Act, 21 USC § 821, *et seq.* (the “CSA”) and the Nevada Controlled Substances Act, §§ 453.005 to 453.730. Together, the CSA and Nevada Controlled Substances Act restrict the Racketeering Defendants’ ability to manufacture or distribute Schedule II substances like opioids nationally and in Nevada by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA, the Nevada Pharmacy Board, and the FDA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

798. The nationwide closed-system, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from “legitimate channels of trade” to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances].”²³²

799. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their duty under Nevada law to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA, the Nevada Board of Pharmacy, and the FDA of suspicious orders.²³³ As discussed in detail below, through the Racketeering Defendants’ scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas throughout the United States for opioids allowed by the DEA.²⁸² In doing so, the Racketeering Defendants allowed hundreds of millions of pills to enter the illicit market

²³² 1970 U.S.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

²³³ 21 USC § 823(a)(1), (b)(1); 21 CFR § 1301.74(b)-(c).

1 which allowed them to generate obscene profits.

2 800. Defendants' illegal scheme was hatched by an association-in-fact enterprise
3 between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect
4 harmony by each of them. In particular, each of the Racketeering Defendants were associated
5 with, and conducted or participated in, the affairs of the racketeering enterprise (defined below
6 and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage
7 in the unlawful sales of opioids, and to deceive the public, and federal and state regulators into
8 believing that the Racketeering Defendants were faithfully fulfilling their statutory obligations.
9 The Racketeering Defendants' scheme allowed them to make billions in unlawful sales of
10 opioids and, in turn, increase and/or maintain high production quotas with the purpose of
11 ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the
12 Racketeering Defendants' fraudulent scheme, course of conduct, and pattern of racketeering
13 activity, they were able to extract billions of dollars of revenue from the addicted American
14 public, while entities like the State of Nevada experienced tens of millions of dollars of injury
15 caused by the reasonably foreseeable consequences of the prescription opioid addiction
16 epidemic. As explained in detail below, the Racketeering Defendants' misconduct violated §
17 207.400 of the Racketeering Act and the State is entitled to treble damages for its injuries under
18 NRS § 207.410.

19 801. Alternatively, the Racketeering Defendants were members of a legal entity
20 enterprise within the meaning of NRS § 207.380 through which the Racketeering
21 Defendants conducted their pattern of racketeering activity in Nevada and throughout the
22 United States. Specifically, the Healthcare Distribution Alliance (the "HDA")²³⁴ is a distinct
23 legal entity that satisfies the definition of a racketeering enterprise. The HDA is a non-profit
24 corporation formed under the laws of the District of Columbia and doing business in Virginia.
25 As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in §
26 207.380 because it is a corporation and a legal entity.

27
28 ²³⁴ Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017),
<https://www.healthcaredistribution.org/about/hda-history>.

1 802. On information and belief, each of the Racketeering Defendants is a member,
2 participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion
3 Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

4 803. Each of the Racketeering Defendants is a legal entity separate and distinct from
5 the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the
6 Racketeering Defendants. Therefore, the HDA exists separately from the Opioid Diversion
7 Enterprise, and each of the Racketeering Defendants exists separately from the HDA.
8 Therefore, the HDA may serve as a racketeering enterprise.

9 804. The legal and association-in-fact enterprises alleged in the previous and
10 subsequent paragraphs were each used by the Racketeering Defendants to conduct the Opioid
11 Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and
12 association- in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded
13 in the alternative and are collectively referred to as the “Opioid Diversion Enterprise.”

14 **A. THE OPIOID DIVERSION ENTERPRISE**

15
16 805. Throughout the United States—and within the State of Nevada—the
17 Racketeering Defendants have operated at all relevant times under a “closed distribution
18 system” of quotas that governs the production and distribution of prescription opioid drugs.
19 The Opioids Diversion Enterprise is an ongoing and continuing business organization that
20 created and maintained systemic links for a common purpose: To protect and maximize their
21 profitability under this quota system through the unlawful sale of opioids. The Racketeering
22 Defendants participated in the Opioids Diversion Enterprise through a pattern of racketeering
23 activity, which includes multiple violations of Nevada state criminal law.

24 806. Recognizing that there is a need for greater scrutiny over controlled substances
25 due to their potential for abuse and danger to public health and safety, the United States
26 Congress enacted the Controlled Substances Act in 1970.²³⁵ The CSA and its implementing
27

28 ²³⁵ Joseph T. Rannazzisi Decl. ¶4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*,

regulations created a closed-system of distribution for all controlled substances and listed chemicals.²³⁶ Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.²³⁷ As reflected in comments from United States Senators during deliberation on the CSA, the “[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.”²³⁸ Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.”²³⁹ Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.²⁴⁰ All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.²⁴¹ When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.²⁴² The result is the scourge of addiction that has occurred.

807. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade”

D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

²³⁶ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

²³⁷ *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 USC § 801(20); 21 USC §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

²³⁸ See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

²³⁹ See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

²⁴⁰ See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at <https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf>).

²⁴¹ *Id.*; 16.19.8.13(F) NMAC (requiring anyone licensed to distribute Schedule II controlled substances in Nevada to “report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and where applicable, to the DEA.”); 16.19.20.48(A) NMSA (“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”).

²⁴² Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, Case No. 12-cv-185 (Document 14-2 February 10, 2012).

by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.”²⁴³

When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the United States Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant’s production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.²⁴⁴

808. Under the CSA, as incorporated into Nevada law, it is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.²⁴⁵

809. At all relevant times, the Racketeering Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their duty under Nevada law to identify, investigate, halt or report suspicious orders of opioids

²⁴³ 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

²⁴⁴ *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

²⁴⁵ *Id.* (citing 21 USC 842(b)); NRS § 453.385 (regulations must ensure “compliance with, but may be more stringent than required by, applicable federal law governing controlled substances and the rules, regulations and orders of any federal agency administering such law.”); NRS § 453.146 (the Nevada Board of Pharmacy may consider findings of “the federal Food and Drug Administration or the Drug Enforcement Administration as prima facie evidence relating to one or more of the determinative factors.”).

and diversion of their drugs into the illicit market, *see generally* IV.E.1 *supra*, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Racketeering Defendants conducted their pattern of racketeering activity in Nevada and throughout the United States through this enterprise.

810. The Racketeering Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Racketeering Defendants were filling on a daily basis - leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

811. The Racketeering Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and illegal trafficking in and distribution of prescription opioids, in violation of Nevada law.

812. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding reports and representations about their systems for controlling against diversion, and refusal to report suspicious orders.

813. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, nationwide per capita purchases of methadone, hydrocodone, and oxycodone increased 13-fold, 4- fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.²⁴⁶ On information and belief, the Opioid Diversion Enterprise has been ongoing nationally and in Nevada for at least the last decade.²⁴⁷

814. The Opioid Diversion Enterprise was and is a shockingly successful endeavor.

²⁴⁶ Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. *Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States*. Am J Public Health. 2014;104(2):e52-9.

²⁴⁷ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy- amid-drug-epidemic>.

1 The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis.
2 But, it was not until recently that State and federal regulators finally began to unravel the extent
3 of the enterprise and the toll that it exacted on the American public and the State of Nevada and
4 its citizens.

5 815. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence
6 separate and distinct from each Racketeering Defendant; (b) was separate and distinct from the
7 pattern of racketeering in which the Racketeering Defendants engaged; (c) was an ongoing and
8 continuing organization consisting of legal entities, including each of the Racketeering
9 Defendants; (d) characterized by interpersonal relationships among the Racketeering
10 Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)
11 functioned as a continuing unit. Each member of the Opioid Diversion Enterprise participated
12 in the conduct of the enterprise, including patterns of racketeering activity, and shared in the
13 astounding growth of profits supplied by fraudulently inflating opioid sales generated as a
14 result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their
15 drugs into the illicit market and then requesting the DEA increase production quotas, all so that
16 the Racketeering Defendants would have a larger pool of prescription opioids from which to
17 profit.

18 816. The Opioid Diversion Enterprise functioned by selling prescription opioids.
19 While there may be some legitimate uses and/or needs for prescription opioids, the
20 Racketeering Defendants, through their illegal enterprise, engaged in a pattern of racketeering
21 activity that involves a fraudulent scheme to increase revenue by violating State and Federal
22 laws requiring the maintenance of effective controls against diversion of prescription opioids,
23 and the identification, investigation, and reporting of suspicious orders of prescription opioids
24 destined for the illicit drug market. The goal of Defendants' scheme was to increase profits
25 from opioid sales. But, Defendants' profits were limited by the production quotas set by the
26 DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their
27 prescription opioids being diverted into the illicit drug market. The end result of this strategy
28

1 was to increase and maintain artificially high production quotas of opioids so that there was a
2 larger pool of opioids for Defendants to manufacture and distribute for public consumption.

3 817. Within the Opioid Diversion Enterprise, there were interpersonal relationships
4 and common communication by which the Racketeering Defendants shared information on a
5 regular basis. These interpersonal relationships also formed the organization of the Opioid
6 Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships
7 and communication network for the purpose of conducting the enterprise through a pattern of
8 racketeering activity.

9 818. Each of the Racketeering Defendants had a systematic link to each other through
10 joint participation in lobbying groups, trade industry organizations, contractual relationships
11 and continuing coordination of activities. The Racketeering Defendants participated in the
12 operation and management of the Opioid Diversion Enterprise by directing its affairs, as
13 described herein. While the Racketeering Defendants participated in, and are members of, the
14 enterprise, they each have a separate existence from the enterprise, including distinct legal
15 statuses, different offices and roles, bank accounts, officers, directors, employees, individual
16 personhood, reporting requirements, and financial statements.

17 819. The Racketeering Defendants exerted substantial control over the Opioid
18 Diversion Enterprise by their membership in the Pain Care Forum (“PCF”), the HDA, and
19 through their contractual relationships.

20 820. PCF has been described as a coalition of drugmakers, trade groups and dozens
21 of non-profit organizations supported by industry funding. The PCF recently became a national
22 news story when it was discovered that lobbyists for members of the PCF quietly shaped federal
23 and state policies regarding the use of prescription opioids for more than a decade.

24 821. The Center for Public Integrity and The Associated Press obtained “internal
25 documents shed[ding] new light on how drugmakers and their allies shaped the national
26 response to the ongoing wave of prescription opioid abuse.”²⁴⁸ Specifically, PCF members
27

28 ²⁴⁸ Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public

1 spent over \$740 million lobbying in the nation's capital and in all 50 statehouses on an array
2 of issues, including opioid-related measures.²⁴⁹

3 822. Not surprisingly, each of the Racketeering Defendants who stood to profit from
4 lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.²⁵⁰ In
5 2012, membership and participating organizations included the HDA (of which all
6 Racketeering Defendants are members), Purdue, Actavis, and Teva.²⁵¹ Each of the
7 Manufacturer Defendants worked together through the PCF to advance the interests of the
8 enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants
9 actively participated, and continue to participate in the PCF, at a minimum, through their trade
10 organization, the HDA.²⁵² The State is informed and believes that the Distributor Defendants
11 participated directly in the PCF as well.

12 823. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing
13 on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates
14 that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis,
15 unless otherwise noted. Local members were "encouraged to attend in person" at the monthly
16 meetings. And, the meeting schedule indicates that the quarterly and year-end meetings
17 included a "Guest Speaker."

18 824. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the
19 Defendants participated in meetings on a monthly basis, either directly or through their trade
20 organization, in a coalition of drugmakers and their allies whose sole purpose was to shape
21 the national response to the ongoing prescription opioid epidemic, including the concerted
22 lobbying efforts that the PCF undertook on behalf of its members.

23
24
25 Integrity (September 19, 2017, 12:01 a.m.), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (emphasis added).

26 ²⁴⁹ *Id.*

²⁵⁰ PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), <https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf>.

27 ²⁵¹ *Id.* The State is informed and believes that Mallinckrodt became an active member of the PCF sometime after
28 2012.

²⁵² *Id.*

825. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the Racketeering Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis, Purdue, and Mallinckrodt, were members of the HDA.²⁵³ The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

826. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.”²⁵⁴ Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Distributors.

827. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Racketeering Defendants.²⁵⁵ The manufacturer membership application must be signed by a “senior company executive,” and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current

²⁵³ Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/membership/manufacturer>.

²⁵⁴ Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en>.

²⁵⁵ Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/~media/pdfs/membership/manufacturer-membership-application.ashx?la=en>.

distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.²⁵⁶

828. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

- a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."²⁵⁷
- b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.²⁵⁸
- c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.²⁵⁹
- d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.²⁶⁰
- e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes

²⁵⁶ *Id.*

²⁵⁷ Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/about/councils-and-committees>.

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ *Id.*

manufacturer members.²⁶¹

- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.²⁶²
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.²⁶³
- h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.²⁶⁴
- i. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation includes Distributor and Manufacturer Members.²⁶⁵

829. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise’s organization.

830. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to “bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues.”²⁶⁶ The conferences also gave the Manufacturer and Distributor Defendants “unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry.”²⁶⁷ The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.*

²⁶⁶ Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), <https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers>.

²⁶⁷ *Id.*

1 attending and sponsoring these events.²⁶⁸

2 831. Third, the Racketeering Defendants maintained their interpersonal relationships
3 by working together and exchanging information and driving the unlawful sales of their opioids
4 through their contractual relationships, including chargebacks and vault security programs.

5 832. The Manufacturer Defendants engaged in an industry-wide practice of paying
6 rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.²⁶⁹
7 As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the
8 HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors
9 rebates and/or chargebacks on their prescription opioid sales.²⁷⁰ On information and belief,
10 these contracts were negotiated at the highest levels, demonstrating ongoing relationships
11 between the Manufacturer and Distributor Defendants. In return for the rebates and
12 chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed
13 information regarding their prescription opioid sales, including purchase orders,
14 acknowledgements, ship notices, and invoices.²⁷¹ The Manufacturer Defendants used this
15 information to gather high-level data regarding overall distribution and direct the Distributor
16 Defendants on how to most effectively sell the prescription opioids.

17 833. The contractual relationships among the Racketeering Defendants also include
18 vault security programs. The Racketeering Defendants are required to maintain certain
19 security protocols and storage facilities for the manufacture and distribution of their opiates.
20 The State is informed and believes that manufacturers negotiated agreements whereby the
21

22 ²⁶⁸ 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September
23 14, 2017), <https://www.healthcaredistribution.org/events/2015-distribution-management-conference>.

24 ²⁶⁹ Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The
25 Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017),
26 <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letter
27 from Sen. Claire McCaskill, (July 27, 2017), <https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png>; Letters From Sen. Claire McCaskill, (March 28, 2017),
28 <https://www.mccaskill.senate.gov/opioid-investigation>; Purdue Managed Markets, Purdue Pharma, (accessed on
September 14, 2017), <http://www.purduepharma.com/payers/managed-markets/>.

²⁷⁰ *Id.*

²⁷¹ Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017),
<https://www.healthcaredistribution.org/resources/webinar-leveraging-edu>.

1 Manufacturers installed security vaults for Distributors in exchange for agreements to maintain
2 minimum sales performance thresholds. The State is informed and believes that these
3 agreements were used by the Racketeering Defendants as a tool to violate their reporting and
4 diversion duties under Nevada law,²⁷² in order to reach the required sales requirements.

5 834. Taken together, the interaction and length of the relationships between and
6 among the Manufacturer and Distributor Defendants reflects a deep level of interaction and
7 cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor
8 Defendants were not two separate groups operating in isolation or two groups forced to work
9 together in a closed system. The Racketeering Defendants operated together as a united entity,
10 working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The
11 HDA and the Pain Care Forum are but two examples of the overlapping relationships and
12 concerted joint efforts to accomplish common goals and demonstrate that the leaders of each
13 of the Racketeering Defendants were in communication and cooperation.

14 835. According to articles published by the Center for Public Integrity and The
15 Associated Press, the Pain Care Forum – whose members include the Manufacturers and the
16 Distributors’ trade association – has been lobbying on behalf of the Manufacturers and
17 Distributors for “more than a decade.”²⁷³ From 2006 to 2016 the Distributors and
18 Manufacturers worked together through the Pain Care Forum to spend over \$740 million
19 lobbying in the nation’s capital and in all 50 statehouses on issues including opioid-related
20 measures.²⁷⁴ Similarly, the HDA has continued its work on behalf of Distributors and
21 Manufacturers, without interruption, since at least 2000, if not longer.²⁷⁵

22 836. Defendants, individually and collectively through trade groups in the industry,
23 pressured the U.S. Department of Justice to “halt” prosecutions and lobbied Congress to strip
24

25 ²⁷² See, e.g., NRS § 453.231(a).

26 ²⁷³ Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Ctr.
for Pub. Integrity, <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic> (last updated Dec. 15, 2016, 9:09 AM).

27 ²⁷⁴ *Id.*

28 ²⁷⁵ HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017),
<https://www.healthcaredistribution.org/about/hda-history>.

1 the DEA of its ability to immediately suspend distributor registrations. The result was a “sharp
2 drop in enforcement actions” and the passage of the “Ensuring Patient Access and Effective
3 Drug Enforcement Act” which, ironically, raised the burden for the DEA to revoke a distributor’s
4 license from “imminent harm” to “immediate harm” and provided the industry the right to
5 “cure” any violations of law before a suspension order can be issued.²⁷⁶

6 837. As described above, the Racketeering Defendants began working together as
7 early as 2006 through the Pain Care Forum and/or the HDA to further the common purpose of
8 their enterprise. The State is informed and believes that the Racketeering Defendants worked
9 together as an ongoing and continuous organization throughout the existence of their enterprise.

10 **B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE**

11
12 838. The Racketeering Defendants conducted the Opioids Diversion Enterprise, and
13 participated in the enterprise, by engaging in a pattern of racketeering activity, as prohibited by
14 NRS § 207.400.

15 839. During the time period alleged in this Complaint, the Racketeering Defendants
16 exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by
17 fraudulently failing to comply with their obligations under Nevada law (and federal law, as
18 incorporated into Nevada law) to identify, investigate and report suspicious orders of opioids in
19 order to prevent diversion of those highly addictive substances into the illicit market, to halt
20 such unlawful sales as set forth below. In doing so, the Racketeering Defendants increased
21 production quotas and generated unlawful profits.

22 840. The Racketeering Defendants disseminated statements that were false and
23 misleading – either affirmatively or through half-truths and omissions – to the general public,
24 the State, Nevada consumers, and the Nevada Board of Pharmacy, claiming that they were
25 complying with their obligations to maintain effective controls against diversion of their
26

27 ²⁷⁶ See Bernstein & Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of*
28 *Control, supra*; Bernstein & Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement*
Slowdown Amid Opioid Crisis, supra; Eyre, *supra*.

1 prescription opioids.

2 841. The Racketeering Defendants disseminated statements that were false and
3 misleading – either affirmatively or through half-truths and omissions – to the general public,
4 the State, Nevada consumers, and the Nevada Board of Pharmacy, claiming that they were
5 complying with their obligations to design and operate a system to disclose to the registrant
6 suspicious orders of their prescription opioids.

7 842. The Racketeering Defendants disseminated statements that were false and
8 misleading – either affirmatively or through half-truths and omissions – to the general public,
9 the State, Nevada consumers, and the Nevada Board of Pharmacy claiming that they were
10 complying with their obligation to notify the DEA of any suspicious orders or diversion of their
11 prescription opioids.

12 843. The Opioid Diversion Enterprise worked to scale back regulatory oversight by
13 the DEA that could interfere with the Racketeering Defendants' ability to distribute their opioid
14 drugs in the State of Nevada. To distribute controlled substances in Nevada, the Racketeering
15 Defendants had to be able to demonstrate possession of a current Nevada registration. *See* NRS
16 § 453.226. Even if they held a current registration, the Racketeering Defendants' ability to
17 obtain a Nevada registration could be jeopardized by past suspension or revocation of their DEA
18 registration. NRS § 453.231(1)(g).

19 844. The Racketeering Defendants paid nearly \$800 million dollars to influence
20 local, state and federal governments throughout the United States and in Nevada, through joint
21 lobbying efforts as part of the Pain Care Forum. The Racketeering Defendants were all
22 members of the Pain Care Forum either directly or indirectly through the HDA. The lobbying
23 efforts of the Pain Care Forum and its members included efforts to pass legislation making it
24 more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors'
25 registrations for failure to report suspicious orders of opioids—protecting the Racketeering
26 Defendants' ability to distribute prescription opioids in Nevada.

27 845. The Racketeering Defendants exercised control and influence over the
28

distribution industry by participating and maintaining membership in the HDA.

846. The Racketeering Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”²⁷⁷

847. The Racketeering Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The State is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, the State is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants’ sales efforts to regions where prescription opioids were selling in larger volumes.

848. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Racketeering Defendants.

849. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Racketeering Defendants identify suspicious orders or customers who were likely to divert prescription opioids.²⁷⁸ On information and belief, the “know your customer” questionnaires informed the Racketeering Defendants of the number of pills that the

²⁷⁷ See HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>; Bernstein & Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, *supra*; Bernstein & Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, *supra*; Eyre, *supra*.

²⁷⁸ Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

1 pharmacies sold, how many non-controlled substances are sold compared to controlled
2 substances, whether the pharmacy buys from other distributors, the types of medical providers
3 in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment
4 facilities, among others, and these questionnaires put the recipients on notice of suspicious
5 orders.

6 850. The Racketeering Defendants refused to identify, investigate and report
7 suspicious orders to the DEA, the Nevada Board of Pharmacy, and the FDA when they became
8 aware of the same despite their actual knowledge of drug diversion rings. The Racketeering
9 Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing
10 final decisions against the Distributor Defendants in 178 registrant actions between 2008 and
11 2012²⁷⁹ and 117 recommended decisions in registrant actions from The Office of
12 Administrative Law Judges. These numbers include 76 actions involving orders to show cause
13 and 41 actions involving immediate suspension orders – all for failure to report suspicious
14 orders.²⁸⁰

15 851. Defendants' scheme had decision-making structure that was driven by the
16 Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer
17 Defendants worked together to control the State and Federal Government's response to the
18 manufacture and distribution of prescription opioids by increasing production quotas through
19 a systematic refusal to maintain effective controls against diversion and to identify suspicious
20 orders and report them to the DEA and State governments, including the State of Nevada.

21 852. The Racketeering Defendants also worked together to ensure that the Aggregate
22 Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed
23 high and to ensure that suspicious orders were not reported to the DEA. By not reporting
24 suspicious orders or diversion of prescription opioids, the Racketeering Defendants ensured
25 that the DEA had no basis for refusing to increase, or to decrease, the production quotas for
26

27 ²⁷⁹ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement*
28 *Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

²⁸⁰ *Id.*

prescription opioids due to diversion of suspicious orders. The Racketeering Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."²⁸¹
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The Racketeering Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The Racketeering Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The Racketeering Defendants withheld information regarding suspicious orders

²⁸¹ Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

and illicit diversion from the DEA because it would have revealed that the “medical need” for and the net disposal of their drugs did not justify the production quotas set by the DEA.

853. The scheme devised and implemented by the Racketeering Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, in intentional violation of Nevada law, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY

854. The Racketeering Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in NRS § 207.390, by at least two crimes related to racketeering (NRS § 207.360), trafficking in controlled substances (NRS §§ 207.360(22); 453.3395), and distribution of controlled substances or controlled substance analogues (NRS § 453.331), and punishable by imprisonment of at least one year, with the intent of accomplishing activities prohibited by § 207.400 of the Racketeering Act.

855. The Racketeering Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of NRS §§ 207.360), within a five-year period. The multiple acts of racketeering activity that the Racketeering Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Racketeering Defendants’ regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise.

856. The Racketeering Defendants committed these predicate acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the Opioids Diversion Enterprise by conducting activities prohibited by NRS §§ 207.360, 207.390, 207.400.

857. The predicate acts all had the purpose of generating significant revenue and

profits for the Racketeering Defendants while the State was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Racketeering Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

858. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, the Racketeering Defendants are distinct from the enterprise.

859. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

860. Many of the precise dates of the Racketeering Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

861. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the State of Nevada. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Nevada, Nevada consumers, or other Nevada citizens. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Racketeering Defendants were also aware that the State and the citizens of this jurisdiction rely on the Racketeering Defendants to maintain a closed system and to protect against the non-



1 medical diversion and use of their dangerously addictive opioid drugs.

2 862. By intentionally refusing to report and halt suspicious orders of their
3 prescription opioids, the Racketeering Defendants engaged in a fraudulent scheme and
4 unlawful course of conduct constituting a pattern of racketeering activity.

5 863. It was foreseeable to Defendants that refusing to report and halt suspicious
6 orders would harm the State by allowing the flow of prescription opioids from appropriate
7 medical channels into the illicit drug market.

8 864. The Racketeering Defendants did not undertake the predicate acts described
9 herein in isolation, but as part of a common scheme. Various other persons, firms, and
10 corporations, including third-party entities and individuals not named as defendants in this
11 Complaint, may have contributed to and/or participated in the scheme with the Racketeering
12 Defendants in these offenses and have performed acts in furtherance of the scheme to increase
13 revenues, increase market share, and /or minimize the losses for the Racketeering Defendants.

14 865. The Racketeering Defendants aided and abetted others in the violations of NRS
15 §§ 207.360, 207.390, and 207.400, while sharing the same criminal intent as the principals who
16 committed those violations, thereby rendering them indictable as principals in the offenses.

17 866. The last racketeering incident occurred within five years of the commission of
18 a prior incident of racketeering.

19 **1. The Racketeering Defendants Conducted the Opioid Diversion Enterprise**
20 **through Acts of Fraud.**

21
22 867. Fraud consists of the intentional misappropriation or taking of anything of value
23 that belongs to another by means of fraudulent conduct, practices or representations.

24 868. The Racketeering Defendants' fraudulent conduct, practices, and
25 representations include, but are not limited to:

- 26 a. Misrepresentations to facilitate Defendants' DEA registrations, which could be a bar
27 to their registrations with the Nevada Board of Pharmacy;
28 b. Requests for higher aggregate production quotas, individual production quotas, and

procurement quotas to support Defendants' manufacture and distribution of controlled substances they knew were being or would be unlawfully diverted;

- c. Misrepresentations and misleading omissions in Defendants' records and reports that were required to be submitted to the DEA and the Nevada Board of Pharmacy pursuant to Nevada Administrative Code provisions;
- d. Misrepresentations and misleading omissions in documents and communications related to the Defendants' mandatory DEA reports that would affect Nevada registrant status; and
- e. Rebate and chargeback arrangements between the Manufacturers and the Distributors that Defendants used to facilitate the manufacture and sale of controlled substances they knew were being or would be unlawfully diverted into and from Nevada.

869. Specifically, the Racketeering Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Racketeering Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

870. At the same time, the Racketeering Defendants misrepresented the superior safety features of their order monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

871. The Racketeering Defendants intended to and did, through the above-described fraudulent conduct, practices, and representations, intentionally misappropriate funds from the State and from private insurers, in excess of \$500, including, for example:

- a. Costs of prescriptions provided under Nevada's Medicaid Program;



- 1 b. Public employees' health insurance prescription coverage costs;
- 2
- 3 c. Retired public employees' group insurance costs;
- 4
- 5 d. Public employees and school board retirees' group health insurance costs; and
- 6
- 7 e. Prescription benefits paid by private insurers for opioid prescriptions.
- 8

9 872. Many of the precise dates of the fraudulent acts and practices have been
10 deliberately hidden and cannot be alleged without access to Defendants' books and records.
11 But, the State has described the types of, and in some instances, occasions on which the
12 predicate acts of fraud occurred.

13 **2. The Racketeering Defendants Unlawfully Trafficked in and Distributed**
14 **Controlled Substances.**

15
16 873. Defendants' racketeering activities also included violations of the Nevada
17 Controlled Substances Act, § 453.3395, and each act is chargeable or indictable under the laws
18 of Nevada and punishable by imprisonment for more than one year. *See* NRS § 207.360(22).

19 874. Under Nevada law (NRS § 453.3395), it is unlawful to "knowingly or
20 intentionally sell[], manufacture[], deliver[] or bring[] into this state"—prescription opioids,
21 which are Schedule II controlled substances that are narcotic drugs, except as authorized by the
22 Nevada Controlled Substances Act.

23 875. The Racketeering Defendants intentionally trafficked in prescription opioid
24 drugs, in violation of Nevada law, by manufacturing, selling, and/or distributing those drugs in
25 Nevada in a manner not authorized by the Nevada Controlled Substances Act. The
26 Racketeering Defendants failed to act in accordance with the Nevada Controlled Substances
27 Act because they did not act in accordance with registration requirements as provided in that
28

Act.

876. Among other infractions, the Racketeering Defendants did not comply with
21

USC § 823 and its attendant regulations (*e.g.*, 21 CFR § 1301.74)²⁸² which are incorporated into Nevada state law, or the Nevada Pharmacy Board regulations. The Racketeering Defendants failed to furnish notifications and omitted required reports to the Nevada Board.

877. The State is informed and believes that the Racketeering Defendants failed to furnish required notifications and make reports as part of a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA, as required by 21 CFR § 1301.74, throughout the United States.

878. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.²⁸³

879. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of their duty to report suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.²⁸⁴ The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales

²⁸² Once again, throughout this Count and in this Complaint Plaintiff cites federal statutes and federal regulations to state the duty owed under Nevada tort law, *not* to allege an independent federal cause of action or substantial federal question. *See, e.g., Herrera*, 2003-NMSC-018, ¶7.

²⁸³ McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), <http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/>.

²⁸⁴ Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

1 manager spoke with company officials in 2009 about the prescriber, asking “Shouldn’t the
2 DEA be contacted about this?” and adding that she felt “very certain this is an organized drug
3 ring.”²⁸⁵ Despite knowledge of the staggering amount of pills being issued in Los Angeles, and
4 internal discussion of the problem, “Purdue did not shut off the supply of highly addictive
5 OxyContin and did not tell authorities what it knew about Lake Medical until several years
6 later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills
7 had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”²⁸⁶

8 880. Finally, Mallinckrodt was recently the subject of a DEA and Senate
9 investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt,
10 arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills
11 ended up in Florida between 2008 and 2012.²⁸⁷ After six years of DEA investigation,
12 Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors
13 summarized the case by saying that Mallinckrodt’s response was that everyone knew what was
14 going on in Florida, but they had no duty to report it.²⁸⁸

15 881. The Racketeering Defendants’ pattern and practice of willfully and intentionally
16 omitting information from their mandatory reports is evident in the sheer volume of
17 enforcement actions available in the public record against the Distributor Defendants.²⁸⁹ For
18 example:

19 a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate*
20 *Suspension Order* against the AmerisourceBergen Orlando, Florida distribution
21 center (“Orlando Facility”) alleging failure to maintain effective controls
22 against diversion of controlled substances. On June 22, 2007,
23 AmerisourceBergen entered into a settlement that resulted in the suspension of
24 its DEA registration;

25 b. On November 28, 2007, the DEA issued an *Order to Show Cause and*

26 ²⁸⁵ *Id.*

27 ²⁸⁶ *Id.*

28 ²⁸⁷ Bernstein & Higham, *The government’s struggle to hold opioid manufacturers accountable, supra*. This number
accounted for 66% of all oxycodone sold in the state of Florida during that time.

²⁸⁸ *Id.*

²⁸⁹ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep’t of Justice, *The Drug Enforcement
Administration’s Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";
- g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");
- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken



1 against its Lakeland, Florida Distribution Center; and

- 2 j. On January 5, 2017, McKesson Corporation entered into an *Administrative*
3 *Memorandum Agreement* with the DEA wherein it agreed to pay a \$150,000,000
4 civil penalty for violation of the 2008 MOA as well as failure to identify and
5 report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ,
6 LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen
7 MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento
8 CA.

9 882. These actions against the Distributor Defendants confirm that the Distributors
10 knew they had a duty to maintain effective controls against diversion, design and operate a
11 system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions
12 also demonstrate, on information and belief, that the Manufacturer Defendants were aware of
13 the enforcement against their Distributors and the diversion of the prescription opioids and a
14 corresponding duty to report suspicious orders.

15 883. Many of the precise dates of Defendants' criminal actions at issue herein were
16 hidden and cannot be alleged without access to Defendants' books and records. Indeed, an
17 essential part of the successful operation of the Opioid Diversion Enterprise depended upon the
18 secrecy of the participants in that enterprise.

19 **D. DAMAGES**

20 884. The Racketeering Defendants' violations of law and their pattern of racketeering
21 activity directly and proximately caused the State of Nevada and its citizens injury in their
22 business and property because the State paid for costs associated with the opioid epidemic, as
23 described above in allegations expressly incorporated herein by reference.

24 885. The State's injuries, and those of its citizens, were proximately caused by
25 Defendants' racketeering activities. But for the Racketeering Defendants' conduct, the State
26 would not have paid the health services and law enforcement services and expenditures
27 required as a result of the plague of drug-addicted residents.

28 886. The State's injuries and those of its citizens were directly caused by the

1 Racketeering Defendants' racketeering activities.

2 887. The State was most directly harmed and there is no other plaintiff better suited
3 to seek a remedy for the economic harms at issue here.

4 888. The State of Nevada seeks all legal and equitable relief as allowed by law,
5 including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed
6 proper by the Court, attorney's fees and all costs and expenses of suit (NRS § 207.470), and pre-
7 and post-judgment interest.

8 **FOURTH CAUSE OF ACTION**
9 **VIOLATION OF NEVADA**
10 **FALSE CLAIMS ACT NRS §§ 357.010 to 357.250**
11 **(Against All Defendants)**

12 889. The State re-alleges all prior paragraphs of this Complaint as if set forth fully
13 herein.

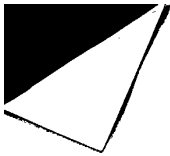
14 890. Defendants' willful and repeated conduct related to opioid sales, as described
15 above, violates the Nevada False Claims Act, NRS § 357.040.

16 891. As detailed above, the Manufacturer Defendants willfully misrepresented opioids
17 as an appropriate, beneficial, and non-addictive treatment for chronic pain, and Defendants'
18 course of conduct caused the State of Nevada to pay for drugs that were worthless in that they
19 had no beneficial value, and in fact, were harmful to patients.

20 892. The Distributor Defendants secured and renewed licenses from *inter alia* the
21 Nevada Board of Pharmacy under false pretenses when, in fact, the Distributor Defendants
22 were not abiding by their non-delegable legal duties. As further described above, the Distributor
23 Defendants made false public statements representing that they were operating a closed system
24 safeguarding against diversion of dangerous opioids into illicit channels when, in truth, the
25 Distributor Defendants were ignoring their legal duties for profit.

26 893. Each Defendant knowingly presented, or caused to be presented, to the State
27 false or fraudulent claims for payment or approval, in violation of NRS § 357.040(1)(a).

28 894. Each Defendant knowingly made, used, or caused to be made or used, false,



1 misleading or fraudulent statements or records to obtain or support the approval of, or the
2 payment on, false or fraudulent claims, in violation of NRS § 357.040(1)(b).

3 895. By engaging in the wrongful conduct described herein, Defendants conspired to
4 defraud the State by obtaining approval or payment on false or fraudulent claims.

5 896. As a result of the Manufacturer Defendants' fraudulent marketing of opioids,
6 and the Distributor Defendants' abdication of non-delegable duties to prevent opioids from
7 being diverted into illicit channels, the State of Nevada paid millions of dollars for opioids. As
8 a result, Defendants were illegally enriched at the expense of the State of Nevada. Further, the
9 State of Nevada was required and will be required to pay the costs of treatment for State of
10 Nevada participants actively harmed by the Defendants' actions.

11 897. Each claim for opioid prescriptions for improper purposes; for longer periods
12 than appropriate; and in quantities inappropriate for approved use, presented to the State of
13 Nevada or to a contractor, grantee or other recipient of state funds constitutes a separate
14 violation pursuant to NRS § 357.040.

15 898. Claims submitted for rehabilitation services for individuals with opioid
16 dependency and/or addiction; claims for sustained opioid use for non-cancer and non-hospice
17 patients; claims for treating Neonatal Abstinence Syndrome; as well as any and all claims
18 arising out of the use of opioids in Nevada by individuals for non-cancer and non-hospice
19 purposes, constitute separate violations pursuant to NRS § 357.040.

20 899. In addition to, or in the alternative, each exposure of a state employee or
21 contractor, Nevada health care professional or State of Nevada participant to Defendants'
22 misleading and deceptive information, communicated in any manner by Defendants,
23 constitutes a separate violation pursuant to NRS § 357.040.

24 900. In addition to, or in the alternative, each opioid prescription written in Nevada in
25 connection with State of Nevada programs constitutes a separate and distinct violation pursuant
26 to NRS § 357.040.

27 901. Plaintiff, State of Nevada seeks all legal and equitable relief as allowed by law,
28

1 including *inter alia* actual damages, treble damages, civil penalties of not less than \$5,500 and
2 up to \$11,000 for each violation, attorney fees and all costs and expenses of suit, and pre- and
3 post-judgment interest.

4 **FIFTH CAUSE OF ACTION**
5 **NEGLIGENCE**
6 **NEVADA COMMON LAW**
7 **(Against All Defendants)**

8 902. The State re-alleges all prior paragraphs of this Complaint as if set forth fully
9 herein.

10 903. Each Defendant had a duty to exercise reasonable care in manufacturing and
11 distributing highly dangerous opioid drugs in the State of Nevada.

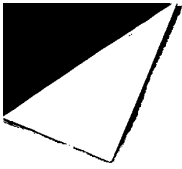
12 904. Each Defendant owed a duty to the State, and to the public health and safety in
13 Nevada, because the injury was foreseeable, and in fact foreseen, by the Defendants.

14 905. Reasonably prudent wholesale drug distributors would have anticipated that the
15 scourge of opioid addiction would wreak havoc on communities. As explained above, the
16 system whereby wholesale distributors are the gatekeepers between manufacturers and
17 pharmacies exists *for the purpose* of controlling dangerous substances such as opioids.
18 Moreover, Defendants were repeatedly warned by law enforcement.

19 906. Reasonably prudent manufacturers of pharmaceutical products would know that
20 aggressively pushing highly addictive opioids for chronic pain would result in the severe harm
21 of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently
22 turning to the illegal drug market as a result of a drug addiction that was foreseeable to the
23 Manufacturer Defendants.

24 907. The escalating amounts of addictive drugs flowing through Defendants'
25 business, and the sheer volume of these pills, further alerted all of the Defendants that addiction
26 was fueling increased consumption and that legitimate medical purposes were not being served.

27 908. As described above in language expressly incorporated herein, Distributor
28 Defendants breached their duties to exercise due care in the business of wholesale distribution



1 of dangerous opioids, which are Schedule II Controlled Substances, by filling highly suspicious
2 orders time and again. Because the very purpose of these duties was to prevent the resulting
3 harm diversion of highly addictive drugs for non-medical purposes – the causal connection
4 between Defendants’ breach of duties and the ensuing harm was entirely foreseeable.

5 909. As described above in language expressly incorporated herein, Manufacturer
6 Defendants breached their duties to exercise due care in the business of pharmaceutical
7 manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by
8 misrepresenting the nature of the drugs and aggressively promoting them for chronic pain. The
9 causal connection between Defendants’ breach of duties and ensuing harm was entirely
10 foreseeable.

11 910. As described above in language expressly incorporated herein, Defendants’
12 breach of duty caused, bears a causal connection with, and/or proximately resulted in, harm and
13 damages to the State.

14 911. Defendants’ conduct was willful, wanton, malicious, reckless, oppressive,
15 and/or fraudulent. Here, Defendants were selling dangerous drugs statutorily categorized as
16 posing a high potential for abuse and severe dependence. NAC § 435.520(a). Thus, Defendants
17 knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or
18 diverted to other than medical, scientific, or industrial channels.

19 912. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by
20 law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory
21 and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney
22 fees and costs, and pre- and post-judgment interest.

23 **SIXTH CAUSE OF ACTION**
24 **NEGLIGENCE PER SE**
25 **NEVADA COMMON LAW**
(Against All Defendants)

26 913. The State re-alleges all prior paragraphs of this Complaint as if set forth fully
27 herein.
28

914. Nevada recognizes the doctrine of negligence per se. Negligence per se consists of four elements: (1) A duty to exercise due care with respect to a plaintiff as defined by a statute or administrative regulation; (2) plaintiff is in the class of persons the statute or regulation was designed to protect; (3) defendant breached the duty by violating the statute or regulation, constituting negligence as a matter of law; and (4) causation and damages. *Atkinson v. MGM Grand Hotel, Inc.*, 98 P.3d 678, 680 (Nev. 2004).

915. NRS 453.005 to 453.730 and NAC §§ 453.010 to 453.740 are public safety laws that define a standard of conduct. As such, these laws were intended to protect the public welfare and safety, and the State is the proper Plaintiff to enforce these laws. Each Defendant had a duty under *inter alia* these laws to prevent diversion of prescription opioids for non-medical and non-scientific purposes and to guard against, prevent, and report suspicious orders of opioids.

916. Nevada's minimum requirement for controlled substance manufacture and wholesale drug distribution is that they must comply with applicable laws and regulations.

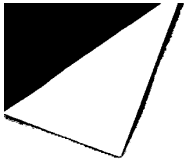
917. Nevada laws and regulations require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs.

918. Defendants have violated their duties under the Nevada Controlled Substances Act and the Nevada Administrative Code.

919. Defendants' violations of these public safety laws are prima facie evidence of negligence per se. Each Defendant had a duty under, *inter alia*, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

920. The State is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

921. It was foreseeable that the breach of duty described herein would result in the



1 damages sustained by the State.

2 922 Defendants' conduct was willful, wanton, malicious, reckless, and/or
3 oppressive, as described above.

4 923. As described above in language expressly incorporated herein, Defendants
5 breached their duties to maintain effective controls against diversion of dangerously addictive
6 opioids, including violating public safety statutes requiring that as wholesale drug distributors,
7 Defendants could only distribute these dangerous drugs under a closed system – a system
8 Defendants were responsible for guarding.

9 924. As described above in language expressly incorporated herein, Defendants'
10 breach of statutory and regulatory duties caused, bears a causal connection with, is and was a
11 substantial factor contributing to, and proximately resulted in, harm and damages to the State.
12 The harm at issue is the type of harm that the legislature sought to prevent in promulgating the
13 public safety statutes at issue.

14 925. Defendants' violations of the Nevada statutes and public safety regulations cited
15 herein were and are substantial factors in the injuries and damages sustained.

16 926. It was foreseeable that Defendants' breaches of statutory and regulatory duties
17 described herein would result in the damages sustained.

18 927. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by
19 law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory
20 and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney
21 fees and costs, and pre- and post-judgment interest.

22
23 **SEVENTH CAUSE OF ACTION**
24 **VIOLATIONS OF 2007 CONSENT JUDGMENT**
25 **(Against Purdue Defendants)**

26 928. The State re-alleges and incorporates by reference each of the allegations
27 contained in the preceding paragraphs as though fully alleged herein.

28 929. The 2007 Consent Judgement, as referenced above, prohibited Defendant

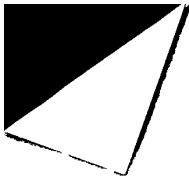
Purdue from engaging in certain conduct and required certain affirmative measures by Purdue with respect to the marketing, promotion, and sale of the branded opioid OxyContin.

930. Purdue, by making written and/or oral claims that are false, misleading, or deceptive, has violated, continues to violate, and failed to cure, Section II(2) of the 2007 Consent Judgement, which provides that “Purdue shall not make any written or oral claim that is false, misleading or deceptive.”

931. Purdue, by failing, after identifying suspicious prescribers, prescribing patterns, orders, distributions or distribution patterns, to provide notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities, has violated, continues to violate, and failed to cure, section II(13) of the 2007 Consent Judgement, which requires Purdue to sufficiently “establish, implement, and follow an OxyContin Abuse and Diversion Detection Program.” Specifically, in failing to report suspicious prescribers to Nevada law enforcement or regulatory authorities, Purdue failed to carry out its obligation to “take such further steps as may be appropriate [to combat opioid abuse and unlawful diversion] based on the facts and circumstances” and information learned through the OxyContin Abuse and Diversion Detection Program, including “providing notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities.”

932. Purdue, under the guise of education, by sending deceptive materials directly to health care professionals, violated and failed to cure section II(15) of the 2007 Consent Judgement, which requires Purdue to provide to health care professionals “written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics.” Specifically, Purdue violated and failed to cure section II(15) by (1) sending Nevada health care providers the first, second, and third editions of *Providing Relief, Preventing Abuse* and (2) creating and maintaining the website www.inthefaceofpain.com, both of which disseminated information to Nevada health care providers, misrepresenting the signs of opioid abuse.

933. Purdue, by making misrepresentations with respect to OxyContin’s potential for



1 addiction, and by claiming that abuse-deterrent formulations of OxyContin are not subject to
2 abuse, despite knowing that the abuse-deterrent features of reformulated OxyContin have not
3 been effective to prevent abuse, has violated, continues to violate, and failed to cure, section
4 II(20) of the 2007 Consent Judgement, which provides that:

5 All material used in promoting OxyContin, regardless of format (audio,
6 internet, video, print) and whether directed primarily to patients or Health
7 Care Professionals, shall, not be inconsistent with the Package Insert, contain
8 only information that is truthful, balanced, accurately communicated, and
9 not minimize the risk of abuse, addiction or physical dependence associated
10 with the use of OxyContin.

11 934. Purdue's violations of the 2007 Consent Judgement affected and continue to
12 affect the public interest, caused and continue to cause injury to numerous Nevada consumers,
13 political subdivisions, and the State, and contributed to a public health crisis, which has cost
14 consumers, political subdivisions, and the State substantial financial and social harm.

15 935. Purdue's violations of the 2007 Consent Judgement, on information and belief
16 were, in some cases, also directed toward elderly persons or persons with a disability.

17 936. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by
18 law, including *inter alia* all relief and damages set forth in the 2007 Consent Judgment. Plaintiff
19 specifically incorporates the 2007 Consent Judgment as if restated fully herein and avails itself
20 of each and every remedy contained therein, in addition to the remedies available by statute,
21 common law, an equity.

22 VI. PUNITIVE DAMAGES

23 937. The State re-alleges all prior paragraphs of this Complaint as if set forth fully
24 herein.

25 938. The acts, conduct and omissions of Defendants, as alleged throughout this
26 complaint, were willful, malicious, oppressive and/or were done with conscious disregard of
27 the rights and safety of Plaintiff and for the primary purpose of increasing Defendants' profits
28

1 from the sale and distribution of the subject drug.

2 939. Defendants' outrageous and unconscionable conduct warrants an award of
3 exemplary and punitive damages against each Defendant in an amount appropriate to punish
4 and make an example of each Defendant.

5 940. The continued tortious conduct by the Defendants causes a repeated or
6 continuous injury. The damages have not occurred all at once but have increased as time
7 progresses. The tort is not completed nor have all the damages been incurred until the
8 wrongdoing ceases. The State has made efforts to abate the nuisance, but, the wrongdoing has
9 not ceased and, thus, the public nuisance remains unabated.

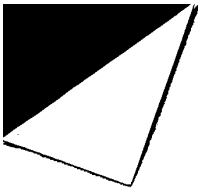
10 941. Here, Defendants were selling dangerous drugs statutorily categorized as posing
11 a high potential for abuse and severe dependence. NAC § 435.520(a). Thus, Defendants
12 knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or
13 diverted to other than legitimate medical, scientific, or industrial channels. Because of the
14 severe level of danger posed by, and indeed visited upon the State by, these dangerous drugs,
15 Defendants owed a high duty of care to ensure that these drugs were only used for proper
16 medical purposes. Defendants chose profit over patients, and the safety of the community, and
17 an award of punitive damages is appropriate, as punishment and a deterrence

18 942. Defendants' conduct was despicable, and so contemptible that it would be
19 looked down upon and despised by ordinary, decent people, and was carried on by Defendants
20 with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary
21 damages.

22 943. Therefore, Plaintiff's claims are subject to equitable tolling, stemming from
23 Defendants' wrongful concealment and from Plaintiff's inability to obtain vital information
24 underlying its claims.

25 944. Plaintiff is entitled to punitive damages, for the sake of example and by way of
26 punishing Defendants in an amount in excess of \$15,000.00.

27
28



945. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

VII. RELIEF

WHEREFORE, the State of Nevada, by and through its Attorney General, respectfully prays that this Court grant the following relief:

1. Entering Judgment in favor of the State in a final order against each of the Defendants;

2. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in deceptive practices in violation of Nevada law and ordering temporary, preliminary or permanent injunction;

3. Order that Defendants compensate the State for its future costs to abate the ongoing public nuisance caused by the opioid epidemic;

4. Declaring that each act and omission of each of the Defendants described in this Complaint constitute multiple, separate violations of the Deceptive Trade Practices Act;

5. Imposing actual damages as well as civil penalties of up to \$5,000, per Defendant, for each repeated and willful violation of the Deceptive Trade Practices Act;

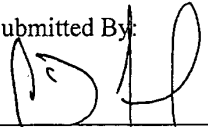
6. Awarding actual damages, treble damages, and civil penalties of not less than \$5,500 and up to \$11,000 for each violation of the False Claims Act;

7. Awarding the State its past and future damages caused by the opioid epidemic, including money wrongfully paid for opioids through government-funded insurance;

8. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

- 1 9. Granting the State:
- 2 a. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;
- 3 b. Pre-judgment and post-judgment interest; and,
- 4 c. All other relief as provided by law and/or as the Court deems appropriate and
- 5 just.
- 6 d. Plaintiff asserts claims herein in excess of the minimum jurisdictional
- 7 requirements of this Court.

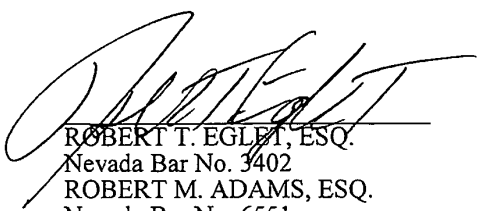
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