IN THE SUPREME COURT OF THE STATE OF NEVADA

CITY OF RENO,

Appellant,

vs.

TEVA PHARMACEUTICALS USA, INC.; 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.; ACTAVIS PHARMACY, INC. F/K/A WATSON PHARMA, INC.; AND ACTAVIS LLC,

Respondents.

Supreme Court No. 85412

District Court Case No. CV18-01895

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APPELLANT'S APPENDIX VOLUME 7

Robert T. Eglet, Esq.
Robert M. Adams, Esq.
Cassandra S.M. Cummings, Esq.
Richard K. Hy, Esq.
EGLET ADAMS
400 S. 7th Street, 4th Floor
Las Vegas, NV 89101
Tel: (702) 450-5400
Fax: (702) 450-5451
Email: eservice@egletlaw.com

Bill Bradley, Esq.
Mark C. Wenzel, Esq.
BRADLEY, DRENDEL & JEANNEY
6900 S. McCarren Blvd., Suite 2000
Reno, NV 89509
Tel: (775) 335-9999
Email: office@bdjlaw.com

Docket 85412 Document 2023-11598

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 15th day of April 2023, I served a true and correct copy of the foregoing **APPELLANT'S APPENDIX VOLUME 7** upon each of the parties by electronic service through the E-Flex rules of service.

By: /s/ *Jennifer Lopez*
An Employee of EGLET ADAMS

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IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF WASHOE

CITY OF RENO,

Plaintiff,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC. d/b/a THE PURDUE FREDERICK COMPANY, INC.; PURDUE PHARMACEUTICALS, L.P; 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; DEPOMED, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, 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; INSYS THERAPEUTICS, INC.;

Caption continued on next page

Case No. CV18-01895

Dept. No. 8

OMNIBUS ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS; AND GRANTING LEAVE TO AMEND

MALLINCKRODT, LLC; MALLINCKRODT BRAND PHARMACEUTICALS INC.; and MALLINCKRODT US HOLDINGS, INC.; ROBERT GENE RAND, M.D. and RAND FAMILY CARE, LLC; DOES 1 through 100; ROE CORPORATIONS 1 through 100; and ZOE PHARMACIES 1 through 100, inclusive,

Defendants.

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OMNIBUS ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS; AND GRANTING LEAVE TO AMEND

Before the Court are several *Motions to Dismiss*, specifically:

(1) Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint;

(2) Distributors' Joint Motion to Dismiss First Amended Complaint;

(3) Defendant Mallinckrodt LLC's Joinder to Manufacturer Defendants' Joint Motion to Dismiss and Motion to Dismiss First Amended Compliant;

(4) Allergan USA, Inc.'s and Allergan Finance, LLC's Motion to Dismiss the Amended Complaint;

(5) Endo Health Solutions, Inc., and Endo Pharmaceuticals, Inc.'s Motion to Dismiss First Amended Complaint;

(6) Motion to Dismiss of Defendants Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc.; and

(7) Motion to Dismiss of Defendants Cephalon, Inc., and Teva Pharmaceuticals USA, Inc.

The matters have been briefed[1] and argued. Being fully apprised, the Court Grants in Part and Denies in Part the *Motions*.

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[1] Including Supplemental Briefs, a Sur-reply and a Response to Sur-reply. Also including various joinders.

I. LEGAL STANDARD

Pursuant to NRCP 12(b)(5), a Court may dismiss a cause of action that fails to state a upon which relief can be granted. Nevada is a "notice-pleading" jurisdiction and, therefore, a complaint need only set forth sufficient facts to demonstrate the necessary elements of a claim for relief so that the adverse party has "adequate notice of the nature of the claim and relief sought." *Hay v. Hay*, 100 Nev. 196, 198, 678 P.2d 672, 674 (1984). In reviewing motions to dismiss under NRCP 12(b)(5), the court must construe the pleadings liberally, accept all factual allegations in the complaint as true, and draw every fair inference in favor of the non-moving party. *See Blackjack Bonding v. City of Las Vegas Mun. Court*, 116 Nev. 1213, 1217, 14 P.3d 1275, 1278 (2000) (citing *Simpson v. Mars. Inc.*, 113 Nev. 188, 190, 929 P.2d 966, 967 (1997)).

If the Court grants a motion to dismiss, it must then decide whether it should grant leave to amend. The court should "freely give" leave to amend when justice so requires. NRCP 15(a); *Nutton v. Sunset Station, Inc.*, 131 Nev. 279, 284, 357 P.3d 966, 970 (Nev. App. 2015). The Nevada Supreme Court has held that "in the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant—the leave sought should be freely given." *Id.* (quoting *Stephens v. S. Nev. Music Co.*, 89 Nev. 104, 105–06, 507 P.2d 138, 139 (1973)).

II. ANALYSIS

A. Neither NRS 228.170 et seq. nor Common Law Dillion's Rule, or the Legislature's 2015 Enactment of NRS 268.001 et seq. Preclude Plaintiff's Action.

A threshold determination for the Court is whether Plaintiff may bring this action, as opposed to the State of Nevada[2] being the only party which the law empowers to seek the relief sought.

Defendants vigorously argue that only the State may proceed.

Plaintiff responds that it is not preempted and may sue on behalf of itself and its citizens.

For the following reasons, the Court agrees with the Plaintiff. The case may proceed.

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[2] Indeed, the State of Nevada is already a plaintiff in its own action, filed in Nevada's Eighth Judicial District (Clark County), as case number A-19-796755-B.

1. NRS 228-State Interest.

NRS 228.170 provides that when it is necessary "to protect and secure the interest of the State…the Attorney General shall commence [an] action or make [a] defense." Defendants argue that the mandatory language of this statute gives the Attorney General exclusive authority to bring actions affecting a statewide interest. The opioid epidemic—so the argument goes—is a matter not only of statewide but of nationwide concern. This larger context, of which Reno's alleged distress is only a small part, forecloses the City's ability to independently seek relief.

The Court finds Defendants' argument misplaced. The beginning and the end of the issue is simply this: the City of Reno did not bring this action on behalf of the State of Nevada. The City is not purporting to be protecting Nevada's interest. Rather, the City's concern, and its requested relief, is local. While there can be no doubt that the opioid epidemic reaches every corner of the nation, the extent of its magnitude is not dispositive. Instead, there is no reason to differentiate between the City's interest in fighting the crisis and the City's interest in addressing any number of other issues common to municipalities around the country. NRS 228.170 designates the Attorney General as the proper authority to bring suits protecting the State's interests. This is ongoing in Clark County. That filing does not, however, preclude the City's suit, filed on behalf of itself and alleging an independent and isolated injury.[3]

2. Dillon's Rule.

Named after the late Iowa Supreme Court Chief Justice John F. Dillon, Dillon's Rule refers to the reported cases of *City of Clinton v. Cedar Rapids & M.R.R. Co.*, 24 Iowa 455

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[3] Defendants are also concerned with the potential for double recovery. However, it is unclear what portion, if any, of the State's requested relief would benefit Reno. In addition, double recovery is governed by a different set of rules to be analyzed if at all, on the back end, and is immaterial to whether a case can be brought in the first place. Finally, this issue is not ripe in any event because the outcome of the State's case is yet uncertain.

(1868), and *Merriam v. Moody's Ex'rs*, 25 Iowa 163, 170 (1868),[4] and his treatises[5] thereafter discussing state versus municipal rule. Generally speaking, Dillon's rule was thus born as a common-law rule defining and limiting the powers of local governments.

Dillon's Rule was primarily a response to the absence of legal constraints on municipalities. Such municipalities had taken it upon themselves to, for example, borrow money to fund public improvements and railroads, which later failed and left its citizens footing the bill.[6] This, understandably, was a problem.

It is not a problem implicated by this case, however. Here, the City has not passed an ordinance or adopted a regulation. Nor has Plaintiff attempted to traverse a state law or make Nevada responsible for the City's obligations. Rather, the City has filed a lawsuit seeking to redress a perceived civil wrong visited upon its citizens.

Second, the codification of common law Dillon's Rule left open the prospect of seeking judicial relief independent of that sought by the State. Defendants emphasize NRS 268.001(4), which states, "Dillon's Rule also provides that if there is any fair or reasonable doubt concerning the existence of a power, that doubt is resolved against the governing body of an incorporated city and the power is denied." This might otherwise be dispositive, were it not for a later provision specifically included to alter the traditional application of the Rule:

> To provide the governing body of an incorporated city with the appropriate authority to address matters of local concern for the effective operation of city government, the provisions of NRS 268.001 to 268.0035, inclusive:
> . . .

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[4] *See also* Brian Chally, *Dillon's Rule in Nevada*, Nevada Lawyer, June 2013, at 6; Gregory Taylor, *Dillon's Rule: A Check on Sheriffs' Authority to Enter 287(g) Agreements*, 68 Am. U. L. Rev. 1053, 1060–61 (2019) (discussing a brief history of Dillon's Rule); Hugh Spitzer, *"Home Rule" vs. "Dillon's Rule" For Washington Cities*, 38 Seattle U.L. Rev. 809, 813–14 (2015) (discussing origins of Dillon's Rule).

[5] John F. Dillon, *Commentaries on the Law of Municipal Corporations* § 237, p. 448–51 (5th ed. 1911).

[6] *See generally* Clayton P. Gillette, *In Partial Praise of Dillon's Rule, or, Can Public Choice Theory Justify Local Governmental Law*, 67 Chi.-Kent L. Rev. 959 (1991).

> (b) Modify Dillon's Rule as applied to the governing body of an incorporated city so that if there is any fair or reasonable doubt concerning the existence of a power of the governing body to address a matter of local concern, it must be presumed that the governing body has the power unless the presumption is rebutted by evidence of a contrary intent by the Legislature.

NRS 268.001(6) and (6)(b). Defendants thus have the burden of rebutting the presumption that the City indeed does have the power to bring the instant suit and can only do so with "evidence of a contrary intent by the Legislature." Here, at least, the unequivocal intent of the Legislature was to reverse the presumption typically attributed to Dillon's Rule and expand the City's authority to act in matters of local concern.

Defendants argue that the opioid epidemic is not merely a matter of local concern because it has a significant impact or effect on areas located in other cities or counties. They also argue that the manufacture, distribution, sales, and the prescribing and dispensing of opioids is subject to substantial regulation by a federal or state agency. While this may be so, it does not end the inquiry but rather, merely dispenses with the presumption favoring the City. Thus, were this the end of the analysis, this lawsuit would not be deemed presumptively valid under Dillon's Rule. But the Court's analysis continues:

As set forth above, Dillon's Rule was the response to circumstances that do not exist here. Compounding this is the fact that the Court is unaware of persuasive authority in which Dillon's Rule has been utilized to limit a City's ability to litigate as opposed to the passage of local ordinances, signing of contracts, and the conduct of other non-litigious activities in which a city might participate. Indeed, it is rather axiomatic that cities must, and regularly do, commence and defend civil lawsuits. It would be nigh impossible for the legislature to explicitly enumerate every potential issue a city may face and define how a city must address it. Taking Defendants' argument to the extreme, the City would be limited by Dillon's Rule to commencing only those actions for which the Legislature has provided a statutory right. In other words, the lack of an express grant of power to prosecute and defend suits to which the City is a

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party would by omission imply that the power does not exist. This, it would seem, could not possibly be the Legislature's intent.[7]

Rather, the Court's consideration is furthered by a review of NRS 266.190(2)(e), which requires that the city's mayor "shall cause legal proceedings to be instituted or defended...where necessary or proper to protect the interests of the city." The Court therefore concludes that Dillon's Rule, at least with respect to the City's powers does not contemplate, and therefore does not limit, the City's ability to litigate. If it did, NRS 266.190 would be rendered meaningless.[8]

Finally, the Court observes, again, that the City of Reno is not seeking relief on behalf of the State, and further, the relief sought by the State addresses alleged wrongs, theories, and damages not pursued in this case. Rather, Reno states a cognizable local concern by virtue of the impact the alleged conduct has had on its citizens' health, safety and welfare, including the concomitant stress placed on its police, fire, and social services. This stress directly impacts the city's budget, finances, and expenditures.

For all these reasons, the Court finds that this action may proceed notwithstanding NRS 228, common law Dillon's Rule, and NRS 268.001 et seq.

B. The Municipal Cost Recovery Rule is Neither Binding nor Applicable Here.

Defendants argue that the City's claims for the recoupment of government costs fail under the cost recovery rule. They contend that under this rule, public expenditures made in the performance of governmental functions are not recoverable. However, while acknowledging that Nevada has yet to address the doctrine, Defendants argue that the cost recovery rule is akin

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[7] The Court is aware of the apparent incongruity between NRS 268 (municipalities) and NRS 244 (counties) in this regard. However, the Court does not find that distinction to be dispositive here.

[8] This conclusion is bolstered by NRS 268.0035 which holds, "the governing body of an incorporated city has: (a) All powers expressly granted to the governing body." As set forth above, the mayor, as a representative of the "governing body," has the power to initiate suits, such as the one here, which are deemed necessary or proper to protect the interests of the city.

to the underlying principles of the firefighter's rule[9] and would thus support adoption of the cost recovery rule. [10]

The municipal cost recovery rule, also known as the free public services doctrine, generally provides that "the cost of public services for protection from fire or safety hazards is to be borne by the public as a whole, not assessed against the tortfeasor whose negligence creates the need for the service." *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322, 323 (9th Cir. 1983). The rationale for this rule is that when such governmental services are provided to the public, the cost and thus the risk of certain losses is spread to the public through shifting the financial responsibility to taxpayers instead of making each and every individual bear the costs for calling necessary services. *See id.*; *see also City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1144 (Ill. 2004). However, even with this justification in mind, Nevada has never specifically adopted the cost recovery rule. This Court declines to do so now, finding its rationale inapposite to this matter.

Even if Nevada had adopted such rule, this is not the type of case to which it should apply; here, Plaintiff alleges intentional and wrongful conduct, over many years, effecting the whole community. The facts thus pled are inconsistent with those in which the rule has been invoked.

This Court is not alone in taking this approach. Courts around the country have declined to apply the rule, most notably those grappling with opioid litigation. *See In re Nat'l Prescription Opiate Litig.*, Case Nos. 1:17-md-2804; 1:18-op-45459;1:18-op-45749, 2019 WL 3737023, *7–8 (N.D. Ohio June 13, 2019) [hereinafter *National Prescription*][11] (stating that "[t]he Court finds that the municipal cost recovery rule does not apply in this case. In five

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[9] *See Moody v. Manny's Auto Repair*, 110 Nev. 320, 323–28, 871 P.2d 935, 937–40 (1994); *Steelman v. Lind*, 97 Nev. 425, 427–29, 634 P.2d 666, 667–68 (1981).

[10] The Court finds that the firefighter's rule is neither applicable to the present case nor does it compel a different result.

[11] The Court does not cite these cases for their binding effect, but only for their persuasive value.

separate courts, and in the multi-district federal litigation based in Ohio, judges have rejected the notion that the municipal cost recovery rule bars recovery for public costs.") (quoting *State ex rel. Jennings v. Purdue Pharma L.P.*, No. N18C-01-223MMJ CCLD, 2019 WL 446382, at *6 (Del. Super. Ct. Feb. 4, 2019)). The Court in *National Prescription* continued:

> The current trend among state court judges ruling in opioid-related cases around the country is that the municipal cost recovery rule does not apply when, as alleged here, an ongoing and persistent course of intentional misconduct creates an unprecedented, man-made crisis that a governmental entity plaintiff could not have reasonably anticipated as part of its normal operating budget for municipal, county, or in this case, tribal services. The Court concludes that the Oklahoma and Montana high courts would likely follow this trend and reject the municipal cost recovery rule's application to Plaintiffs' state law claims.

2019 WL 3737023, at *8.

Courts addressing the opioid epidemic are hardly the only courts to find the cost recovery rule inapplicable. The Court in *City of Gary ex rel. King v. Smith & Wesson Corp.* stated:

> ...but the mere fact that the City provides services as part of its governmental function does not render the costs of those services unrecoverable as a matter of law. We do not agree that the City, as a governmental entity, is necessarily disabled from recovering costs from tortious activity. Rather, we agree with those courts that have rejected the municipal cost doctrine as a complete bar to recovery.

801 N.E.2d 1222, 1243 (Ind. 2003). Some courts have even indicated that this rule should be abolished on the grounds that tortfeasors can use it as a shield to preclude them from liability. *See James v. Arms Tech., Inc.*, 820 A.2d 27, 48–49 (N.J. Super. Ct. App. Div. 2003). Considering what appears to be the majority view that the municipal cost recovery rule should not be a bar, and the persuasive argument against its implication here, the Court denies Defendants' *Motions* on this ground.[12]

[12] Defendants cite cases that are sufficiently distinguishable from the present case. That is, as the City points out, most involve a single emergency situation. *See e.g. Flagstafff*, 719 F.2d at 323 (railroad tank cars carrying liquified petroleum gas derailed, causing mass evacuations); *Walker Cty. v. Tri-State Crematory*, 643 S.E.2d 324, 325–26 (Ga. Ct. App. 2007) (discovery of improperly disposed, decaying bodies at crematorium). Nothing of the type is at issue here.

C. Plaintiff's Negligence and Unjust Enrichment Claims Sound in Fraud, Are Not Pled with Requisite Specificity, and Must be Amended.

The complaint alleges that Defendants' conduct amounted to negligence (Claims III and V) and unjust enrichment (Claim VI).

Actionable negligence requires proof by a preponderance of the evidence that: (1) the defendant owed the plaintiff a duty of care; (2) the defendant breached that duty; (3) the breach was the legal cause of the plaintiff's injuries; and (4) the plaintiff suffered damages. *See Foster v. Costco Wholesale Corp.*, 128 Nev. 773, 777, 291 P.3d 150, 153 (2012) (citing *DeBoer v. Sr. Bridges of Sparks Fam. Hosp.*, 128 Nev. 406, 412, 282 P.3d 727, 732 (2012)).

Unjust enrichment is recognized under Nevada law when an aggrieved party proves that: (1) the plaintiff conferred a benefit on the defendant; (2) the defendant appreciated such benefit; and (3) there is acceptance and retention by the defendant of such benefit under circumstances such that it would be inequitable for him to retain the benefit without payment of the value thereof. *See Certified Fire Prot. Inc. v. Precision Constr.*, 128 Nev. 371, 381, 283 P.3d 250, 257 (2012) (citing *Unionamerica Mtg. v. McDonald,* 97 Nev. 210, 212, 626 P.2d 1272, 1273 (1981)) (internal quotations omitted).

The parties disagree whether the elements of unjust enrichment and negligence have been—or could be—sufficiently pled under Rule 12(b)(5). Pursuant to the Court's reasoning below, as currently pled Plaintiff's claims cannot proceed.

Defendants cite over a dozen instances demonstrating the City's claims both sound in and are replete with averments of fraud, and thus are required to meet the heightened pleading standard required for fraud cases. Because the City's complaint does not comply with Rule 9(b), movants argue the complaint must be dismissed.

Responding, the City asserts its claims are based on negligent (only) conduct and do not implicate intentional or fraudulent action. It additionally argues that Defendants are attempting to circumvent the Rule 8 notice pleading standards by "recasting" the negligence and unjust

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Rather, the City alleges it has been required to address an ongoing health and social services crisis over many years. Thus, the argument additionally fails on these grounds.

enrichment claims so that they sound in fraud. The City cites *In re Daou Sys., Inc.*,[13] suggesting that a claim "sounds in fraud" only if there is a "unified course of fraudulent conduct" and "relies entirely" on that conduct. The City thus concludes it must only meet the NRCP 8 pleading standard.

NRCP 9(b), states: "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." *See also Rocker v. KPMG LLP*, 122 Nev. 1185, 1192, 148 P.3d 703, 707 (2006), *abrogated on other grounds by Buzz Stew, LLC v. City of N. Las Vegas*, 124 Nev. 224, 181 P.3d 670 (2008). The circumstances that must be detailed include averments to the time, the place, the identity of the parties involved, and the nature of the fraud or mistake. *Brown v. Kellar*, 97 Nev. 582, 583–84, 636 P.2d 874 (1981); *see also Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) ("averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged.") (internal quotations omitted).

Moreover, "where allegations in a complaint do not use the word 'fraud,' but 'sound in fraud,' are 'grounded in fraud,' or allege a 'unified course of fraudulent conduct,' the pleading standards of [FRCP] 9(b) still apply." *See Oaktree Capital Mgmt., L.P. v. KPMG*, 963 F. Supp. 2d 1064, 1075 (D. Nev. 2013). FRCP 9(b) contains identical language to NRCP 9(b),[14] and it is only "where fraud is not an essential element of a claim[] [that] only those allegations of a complaint which aver fraud are subject to [FRCP] 9(b)'s heightened pleading standard."[15] *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (citing *Vess*, 317 F.3d at 1105).

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[13] 411 F.3d 1006, 1027 (9th Cir. 2005).

[14] *See Rocker*, 122 Nev. at 1193, 148 P.3d at 708.

[15] This Court uses federal law to supplement its analysis of Nevada law where the rules are identical. *See Nelson v. Heer,* 121 Nev. 832, 835, 122 P.3d 1252, 1253 (2005) *as modified* (Jan. 25, 2006); *Executive Mgmt., Ltd. V. Ticor Title Ins. Co.*, 118 Nev. 46, 53, 38 P.3d 872, 876 (2002) (citing *Las Vegas Novelty, Inc. v. Fernandez*, 106 Nev. 113, 119, 787 P.2d 772, 776 (1990)) (stating that "[f]ederal cases interpreting the Federal Rules of Civil Procedure are strong persuasive authority, because the Nevada Rules of Civil Procedure are based in large part upon their federal counterparts.") (internal quotations omitted).

However, while such is the standard of heightened pleading for fraud, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." NRCP 9(b).

Upon close scrutiny of the City's complaint, it is evident that, regardless how styled, the City's negligence and unjust enrichment claims at the very least sound in fraud. Consider the following excerpts:

> 93. To take advantage of the lucrative market for chronic pain patients, **Defendants developed a well-funded marketing scheme based on deception**. Defendants used both direct marketing and unbranded advertising disseminated by purported independent third parties to **spread false and deceptive statements** about the risks and benefits of long-term opioid use.
>
> 131. To convince prescribing physicians and prospective patients that opioids are safe, **Defendants deceptively concealed the risks of long-term opioid** use, particularly the risk of addiction, **through a series of misrepresentations**. **Defendants manipulated** their promotional materials and the scientific literature **to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not**.
>
> 235. **Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud**, ill will, recklessness, or willful and intentional disregard of Plaintiff's rights, and, therefore, Plaintiff is entitled to punitive damages.
>
> 249. **Defendants intended and had reason to expect** under the operative circumstances **that the Plaintiff would be deceived** by Defendants' statements, concealments, and conduct as alleged herein and that **Plaintiff would act or fail to act in reasonable reliance** thereon.

Compl. at ¶¶ 93, 131, 235, 249 (emphasis added).

There are other examples. These include headings: **B. Defendants' Fraudulent Marketing**, and **F. The Consequences of Defendants' Fraudulent Scheme**.[16] In this case, while fraud is not necessarily an element of a claim, the City has chosen to allege that Defendants have engaged in fraudulent activity. This is more than merely alleging the "conditions of a person's mind." Thus, the Court finds the City's complaint alleges a unified

[16] *See* Compl. at 19:18, 37:5.

course of conduct such that it invokes the standards of NRCP 9(b) and warrants a heightened pleading standard required of fraud claims. The negligence and unjust enrichment claims are insufficient to withstand dismissal at this time. Accordingly, this Court **GRANTS** Defendants' *Motion to Dismiss* **WITH LEAVE TO AMEND.**[17]

D. Plaintiff's Public and Private Nuisance Claims Survive Dismissal.

The complaint alleges both statutory and common law public nuisance claims. For the reasons set out below, Plaintiff's claims survive the *Motions to Dismiss*.

1. Statutory Public Nuisance.

Succinctly stated, Defendants argue the City's statutory public nuisance claim must be dismissed because the Nevada public nuisance statute, NRS 202 et seq. deals with crimes. Defendants aver that its topic, "crimes and punishments" reflects the statute's limited applicability. That statute also identifies punishment for public nuisance as a criminal, not civil, misdemeanor. Thus, Defendants conclude that civil liability cannot be derived from a criminal statute.

Defendants further argue that *Coughlin v. Tailhook Ass'n, Inc.*,[18] supports this. *Coughlin* states in part, "there is no indication that § 202.450 et seq. was intended to create a private cause of action." *Id.* Finally, Defendants claim that a civil public nuisance claim is unprecedented under Nevada law.

In opposition, the City argues that the claim may proceed because, while not expressly stated, public nuisance as a civil cause of action is implied within the language of NRS 202.450 et seq. The City extrapolates from *Baldonado v. Wynn Las Vegas, LLC*,[19] to assert that an

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[17] Plaintiff may have ninety (90) days from the date of this order to file a Second Amended Complaint. In addition, pursuant to *Rocker v. KPMG LLP*, limited discovery on issues relative to the claims which sound in fraud may commence immediately. *See Rocker*, 122 Nev. at 1194-95, 148 P.3d at 709.

[18] 818 F. Supp. 1366, 1372 (D. Nev. 1993), *aff'd sub nom. Coughlin v. Tailhook Ass'n*, 112 F.3d 1052 (9th Cir. 1997).

[19] 124 Nev. 951, 958–59, 194 P.3d 96, 100–01 (2008).

implied right of action exists after considering the statutory scheme, reason, and public policy at issue and assessing *Baldonado's* three factor test for assessing an implied civil action.

The Court agrees with the City. While the statute does not directly address a civil cause of action for public nuisance, this is not the end of the Court's analysis. A fair reading of NRS 202's public nuisance statutes, as construed by the Court, suggest an implied right of the City to do so. For instance, NRS 202.480 is entitled "Abatement of nuisance; civil penalty." While NRS 202.480 seemingly applies to NRS 202.470, the Court is unaware of legislative intent to preclude a civil public nuisance claim by virtue of its absence.

Moreover, *Coughlin* is distinguishable. First, the facts are markedly different from the present case. In *Coughlin*, Plaintiff Lieutenant Paula Coughlin, was seeking redress from the Tailhook Association and Hilton Hotels based on being attacked while at the convention. *See Coughlin*, 818 F. Supp. at 1367. Lieutenant Coughlin, individually, does not present with the same concerns or allegations of harm as does a municipality. The Court notes as well that *Coughlin* did not find that there can *never* be a civil cause of action for a public nuisance. *See id.* at 1371–72. This also informs the Court's analysis. As the Court reads *Coughlin*, its holding must be construed narrowly.

Second, the Court is cognizant that, while often persuasive, federal district court decisions from Nevada are not binding on this Court. The Court must decide the issue as it interprets the law in this case, at this time.

The Court does not find Defendants' argument persuasive, and therefore **DENIES** the *Motions to Dismiss* this claim.

2. Common Law Public Nuisance.

Defendants next seek dismissal of Plaintiff's common law public nuisance claim. Specifically, Defendants argue Plaintiff does not allege there was interference with a public right (as opposed to interest), or that Defendants had control over the instrumentality of the nuisance at the time it was created. Defendants observe that the opioid crisis as a pressing public health problem does not implicate a public right. Rather, Defendants aver that the misconduct alleged implicates only private rights.

The City argues that the Restatement's definition of public nuisance is broad, and that it should be able to seek recovery against Defendants for the allegedly widespread harm and costs to it. Moreover, it asserts that the complaint sets forth facts alleging that Defendants have impacted the public health, which they reason, is a public right. Plaintiff thus maintains it is not an inherently novel theory, as the viability of such claims have been recognized by other jurisdictions handling their own opioid cases.

Under the Restatement:

> (1) A public nuisance is an unreasonable interference with a right common to the general public.
>
> (2) Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:
>
> (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or
>
> (b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or
>
> (c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

Restatement (Second) of Torts § 821B (1979).

While Nevada has not specifically adopted the Restatement's definition of public nuisance, case law indicates the Restatement may guide the Court's analysis. *See generally Land Baron Inv. v. Bonnie Springs Family LP*, 131 Nev. 686, 689, 356 P.3d 511, 514 (2015); *Layton v. Yankee Caithness Joint Venture, L.P.*, 774 F. Supp. 576, 577–78 (D. Nev. 1991). In doing so, the Court finds unpersuasive Defendants' argument that the opioid epidemic, as pled, does not allege a viable interference with a public right.

Nor is the omission of the control element determinative. As noted by the City in its Sur-Opposition and during oral argument, this was the product of clerical error. The Court agrees that satisfactory allegations are set forth in the First Amended Complaint, and as such they withstand—at the pleading stage—the heightened standard of dismissal. Therefore, Defendants' *Motion to Dismiss* as to the common law public nuisance claim is **DENIED**.

E. Plaintiff's Negligent Misrepresentation (Claim IV) and Punitive Damages (Claim VII) Claims are Dismissed Without Leave to Amend.

The City's complaint alleges that Defendants' conduct amounted to negligent misrepresentation (Claim IV), and appears to seek the remedy of punitive damages, among other relief on Claims III, IV, and VI. Oddly, the City also pleads punitive damages (Claim VII) as a standalone cause of action. But a review of applicable law informs the Court that these two claims must be dismissed.

1. Negligent Misrepresentation is Not and Cannot be Pled.

Negligent misrepresentation is a close cousin of negligence and is found where the plaintiff shows by clear and convincing evidence that: (1) the defendant made a representation; (2) while in the course of his business, profession, employment or other action of pecuniary interest; (3) the defendant failed to exercise reasonable care or competence in obtaining or communication the representation to the plaintiff; (4) the representation was false; (5) the representation was supplied for the purpose of guiding the plaintiff in its business transactions; (6) the plaintiff justifiability relied on the false information; and (7) the plaintiff sustained a loss due to the false information. *See* Nev. Jury Instr. – Civ. 10.7 (2018); *Bill Stremmel Motors, Inc. v. First Nat. Bank of Nevada*, 94 Nev. 131, 134, 575 P.2d 938, 940 (1978).

Regardless of how couched by Plaintiff, the complaint is devoid of factual allegations which, if proven, could result in a verdict on any of these claims. Whatever else is disputed in this case, this much is not: the City of Reno did not enter into a business transaction with moving Defendants. It did not enter into a commercial transaction with moving Defendants. There were no direct representations or concealments made to or withheld from Plaintiff.

Without such hallmark factual allegations, there is no claim. Accordingly, Claim IV is **DISMISSED WITHOUT LEAVE TO AMEND.**[20]

[20] It is well-settled that where, as here, amendment would be futile, the Court may foreclose such opportunity. *See Allum v. Valley Bank of Nevada*, 109 Nev. 280, 287, 849 P.2d 297, 302 (1993) (citing *Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990)); *Halcrow, Inc. v. Eighth Jud. Dist. Ct.*, 129 Nev. 394, 398, 302 P.3d 1148, 1152 (2013), *as corrected* (Aug. 14, 2013). As set forth above, there are no set of facts which could establish all the elements of this claim, the Court declines to allow amendment. Because of this, the issue as to availability of punitive damages as a remedy is moot as to this claim.

2. Punitive Damages Are a Remedy Not a Separate Claim.

As to Claim VII, the law in Nevada is well-settled, as elsewhere,[21] that punitive damages are a remedy, not a cause of action. *See Massi v. Nobis*, No. 72546, 2016 WL 1565201, at *1 (Apr. 15, 2016) (*citing Doe v. Colligan*, 753 P.2d 144, 145 n.2 (Alaska 1988) ("Punitive damages do not constitute a cause of action.")). Accordingly, the Court **GRANTS** the *Motions to Dismiss* as to Claim VII **WITHOUT LEAVE TO AMEND**.[22]

IT IS SO ORDERED.[23]

DATED this 14 day of February, 2020.

BARRY L. BRESLOW
District Judge

[21] See *e.g., Murray v. Gencorp, Inc.*, 979 F.Supp.1045, 1050 (E.D. Pa. 1997) ("under Pennsylvania law there is no separate cause of action for punitive damages"); *Rhodes v. Sutter Health*, 949 F. Supp. 2d 997, 1011 n.8 (E.D. Cal. 2013) (quoting *McLaughlin v. Nat'l Union Fire Ins. Co.*, 29 Cal. Rptr. 2d 559, 579 (1994) ("In California there is no separate cause of action for punitive damages")); *Biggs v. Eaglewood Mortg., LLC,* 582 F. Supp. 2d 707, 711 n.5 (D. Md. 2008) ("[t]there is no separate cause of action for punitive damages apart from an underling cause of action upon which punitive damages can be grounded. This is true both as a matter of federal law and state law.") (internal citations omitted).

[22] Claim VII is dismissed as a stand-alone claim for relief. Plaintiff may pursue this remedy—if properly pled and otherwise available to claims not dismissed— in its Second Amended Complaint.

[23] To the extent not otherwise addressed by this Omnibus Order, the Court has considered and denies all other separate or collaborative grounds for dismissal brought by movants.

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I hereby certify that I am an employee of the Second Judicial District Court of the State of Nevada, County of Washoe; that on this 14 day of February, 2020, I electronically filed the following with the Clerk of the Court by using the ECF system which will send a notice of electronic filing to the following:

SARAH JOHANSEN, ESQ.
J. JORGENSEN, ESQ.
CHAD FEARS, ESQ.
JAMES PISANELLI, ESQ.
DANIEL POLSENBERG, ESQ.
RYAN LEARY, ESQ.
STEVEN GUINN, ESQ.
ABRAHAM SMITH, ESQ.
ROBERT ADAMS, ESQ.
PHILIP HYMANSON, ESQ.
BILL BRADLEY, JR., ESQ.
STEVEN BORANIAN, ESQ.
JAKE MILLER, ESQ.
AMANDA YEN, ESQ.
JEFFREY BENDAVID, ESQ.
ROSA SOLIS-RAINEY, ESQ.
JARROD RICKARD, ESQ.
STEVE MORRIS, ESQ.
MAX CORRICK II, ESQ.
PATRICIA LUNDVALL, ESQ.
JOEL HENRIOD, ESQ.

CHRISTINE KUHL
Judicial Assistant

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Jacqueline Bryant
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ACOM
ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
CASSANDRA S.M. CUMMINGS, ESQ.
Nevada Bar No. 11944
RICHARD K. HY, ESQ.
Nevada Bar No. 12406
EGLET ADAMS
400 S. 7th Street, 4th Floor
Las Vegas, NV 89101
Tel.: (702) 450-5400
Fax: (702) 450-5451
E-Mail: eservice@egletlaw.com
-and-
BILL BRADLEY, ESQ.
Nevada Bar No. 1365
BRADLEY, DRENDEL & JEANNEY
6900 S. McCarran Blvd., Suite 2000
Reno, Nevada 89509
Telephone: (775) 335-9999
Email: office@bdjlaw.com
Attorneys for Plaintiff, the City of Reno

IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA IN AND FOR THE COUNTY OF WASHOE

CITY OF RENO,

Plaintiff,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC. d/b/a THE PURDUE FREDERICK COMPANY, INC.; PURDUE PHARMACEUTICALS, L.P.; TEVA PHARMACEUTICALS USA, INC.; McKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; CARDINAL HEALTH 6 INC.;

Case No.: CV18-01895
Division No.: 8

SECOND AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

CARDINAL HEALTH TECHNOLOGIES LLC; CARDINAL HEALTH 108 LLC d/b/a METRO MEDICAL SUPPLY; DEPOMED, INC.; 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; INSYS THERAPEUTICS, INC., MALLINCKRODT, LLC; MALLINCKRODT BRAND PHARMACEUTICALS INC.; and MALLINCKRODT US HOLDINGS, INC.; ROBERT GENE RAND, M.D. AND RAND FAMILY CARE, LLC; DOES 1 through 100; ROE CORPORATIONS 1 through 100; and ZOE PHARMACIES 1 through 100, inclusive,

Defendants.

Plaintiff City of Reno, by and through the undersigned attorneys, files this Second Amended Complaint against the named Defendants seeking to recover its damages as a result of the opioid epidemic Defendants caused, and alleges as follows:

INTRODUCTION

1. Opioid addiction and overdose in the United States as a result of prescription opioid use has reached epidemic levels over the past decade.

2. The abuse of opioids is a widespread problem in the State of Nevada as well as the City of Reno specifically.

3. Nevada ranked as the sixth highest state for the number of milligrams of opioids distributed per adult, in 2016.

4. In 2016, Nevadans were prescribed opioids at a rate of 87 prescriptions per 100 residents.

5. In that same year, the rate of overdose deaths in Nevada exceeded the national average.

6. Nevada has had the fourth highest drug overdose mortality rate in the United States.

7. The dramatic increase in prescription opioid use over the last two decades, and the resultant public-health crisis, is no accident.

8. The crisis was precipitated by Defendants, who, through deceptive means, and using one of the biggest pharmaceutical marketing campaigns in history, carefully engineered and continue to support a dramatic shift in the culture of prescribing opioids by falsely portraying both the risks of addiction and abuse and the safety and benefits of long-term use.

9. Defendant drug companies named herein, manufacture, market, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like Oxycontin, Vicodin and Percocet, as well as generics like oxycodone and hydrocodone, which are powerful narcotic painkillers.

10. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines and arthritis), opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

11. Defendants' goal was simple: to dramatically increase sales by convincing doctors that it was safe and efficacious to prescribe opioids to treat not only the kind of severe and short-term pain associated with surgery or cancer, but also for a seemingly unlimited array of less severe, longer-term pain, such as back pain, headaches and arthritis.

12. Defendants knew that their opioid products were addictive, subject to abuse, and not safe or efficacious for long-term use.

13. Defendants' nefarious plan worked and they dramatically increased their sales and reaped billions upon billions of dollars of profit at the expense of millions of people who are now addicted and the thousands who have died as a result.

14. While Americans represent only 4.6% of the world's population, they consume over 80% of the world's opioids.

15. Since 1999, the amount of prescription opioids sold in the U.S. has nearly quadrupled. In 2010, 254 million prescriptions were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).

16. By 2014, nearly two million Americans either abused or were dependent upon opioids.

17. On March 22, 2016, the Food and Drug Administration (FDA) recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."

18. The Centers for Disease Control (CDC) reports that overdoses from prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths.

19. From 2000 to 2015, more than half a million people died from drug overdoses (including prescription opioids and heroin). The most recent figures from the CDC suggest that 175 Americans die every day from an opioid overdose (prescription and heroin).

20. Many addicts, finding painkillers too expensive or too difficult to obtain, have turned to heroin. According to the American Society of Addiction Medicine, four out of five people who try heroin today started with prescription painkillers.

21. County and city governments and the services they provide their citizens have been strained to the breaking point by this public health crisis.

22. Defendant drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live, because they know prescribing doctors and other health-care providers rely on their statements in making treatment decisions, and drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

23. Defendants broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the City of Reno and throughout Nevada.

24. Defendants falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support their claims.

25. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids.

26. As a result of the drug companies' marketing campaign, opioids are now the most prescribed class of drugs generating over $11 billion in revenue for drug companies in 2014 alone.

27. As a result of the drug companies' marketing campaign, the fatalities continued to mount while the living continue to suffer.

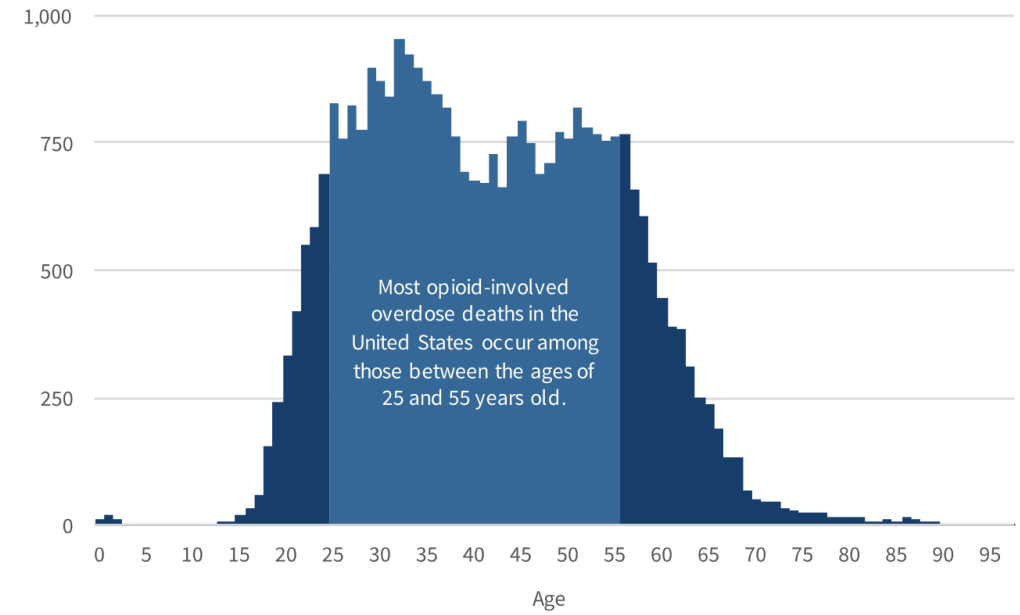
28. In 2017, a record number of drug overdoses claimed the lives of about 72,000 Americans, a 10.2 percent increase from 2016. According to the CDC the death toll from drug overdoses was higher than the peak yearly death totals from H.I.V., gun deaths, or car crashes. The increase of deaths related to drug overdoses was linked to two major factors: (i) a growing number of Americans are using opioids, and (ii) drugs are becoming deadlier.

29. This trend of increased opioid abuse has been well documented in the last several years. In 2015, over 33,000 Americans died of a drug overdose involving opioids with studies suggesting that these fatalities are statistically underreported. And in 2016, 2.1 million Americans had opioid use disorders, according to a government survey, but that figure could be as high as 4 million.

30. Most opioid related deaths occur among those between the ages of approximately 25 and 55 years old. Studies have shown that the overall fatality rate was 10.3 deaths per 100,000 population, and in the 25 to 55-year-old age group, fatality rates were much higher, ranging from 16.1 to 22.0 deaths per 100,000 population.

31. In 2015, the estimated economic impact of the opioid crisis was $504 billion, or 2.8 % of our U.S.'s gross domestic product that same year. Previous estimates of the economic cost of the opioid crisis greatly understate it by undervaluing the most important component of the loss—fatalities resulting from overdoses.

Figure 2. Opioid-involved Overdose Deaths by Age in 2015
(Number of deaths)



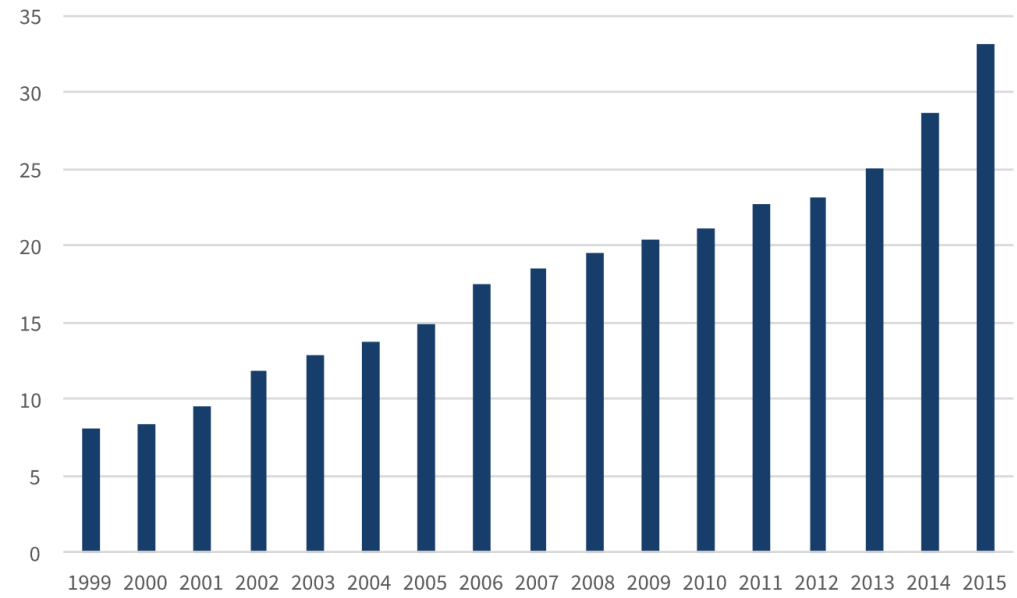
Source: CDC Wonder database, multiple cause of death files

32. In addition to the cost of fatalities each year, opioid misuse among the living imposes important costs as well. It is estimated that prescription opioid misuse increases healthcare and substance abuse treatment costs in the United States by $29.4 billion, increases criminal justice costs by $7.8 billion, and reduces productivity among those who do not die of overdose by $20.8 billion (in 2015 $). The total nonfatal cost of $58.0 billion divided by the 1.9 million individuals with a prescription opioid disorder in 2013 results in an average cost of approximately $30,000.[1] And when patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin, fueling the secondary drug market.

33. Further compounding the issue is that this problem is worsening at an alarming rate. According to a report published by the White House Council of Economic Advisors (CEA), opioid-involved overdose deaths have doubled in the past ten years and quadrupled in the past sixteen.

[1] Florence, C., Zhou, C., Luo, F. and Xu, L. 2016. "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013." *Medical Care*, 54(10): 901-906.

Figure 1. Opioid-involved Overdose Deaths, 1999-2015
(Thousands of Deaths)



Source: CDC Wonder database, multiple cause of death files

34. The crisis that Defendants caused has directly impacted the City of Reno as it bears the financial brunt of this epidemic as it unfolds in our community.

35. Apart from the toll on human life, the crisis has financially strained the services the City of Reno provides its residents and employees. Human services, social services, court services, law enforcement services, the office of the coroner/medical examiner and health services, including hospital, emergency and ambulatory services, have all been severely impacted by the crisis. For example, as a direct and foreseeable consequence of Defendants' egregious conduct, the City of Reno paid, and continues to pay, a significant amount for health care costs that stem from prescription opioid dependency. These costs include unnecessary and excessive opioid prescriptions, substance abuse treatment services, ambulatory services, emergency department services, and inpatient hospital services, among others. Defendants' conduct also caused the City of Reno to incur substantial economic, administrative and social costs relating to opioid addiction and abuse, including criminal justice costs, victimization costs, child protective services costs, lost productivity costs, and education and prevention program costs among others.

36. After creating a public health crisis, Defendants have not pulled their opioid products from the market, acknowledged the very real dangers of addiction and abuse even if the opioids are taken as prescribed, or acknowledged that opioids are inappropriate for long-term pain management. Instead, Defendants have taken the position that their opioid products are not dangerous and continue to sell these dangerous and addictive drugs, thereby continuing to fuel the crisis.

37. As a result, physicians, pharmacists and patients are not able to appropriately and adequately evaluate the relevant risks associated with opioids use, particularly the risks to patients who have been and are being exposed to, unnecessarily, including but not limited to the risk of severe and disabling addiction, actual addiction, the consequences of addiction, and other adverse medical conditions. Additionally, the rising numbers of persons addicted to opioids have led to a dramatic increase of social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids. Consequently, public health and safety have been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

38. As a result of Defendants' misconduct, physicians, pharmacists and patients have not been provided with accurate information about the appropriate uses, risks and safety of these drugs, thus causing the crisis before us as well as giving rise to this lawsuit.

39. Plaintiff files this Complaint naming the drug companies herein as Defendants and placing the industry on notice that the City of Reno is taking action to abate the public nuisance that plagues our community.

40. By its Complaint, the City of Reno seeks to recover from Defendants its damages as a result of the opioid public-health crisis Defendants caused. Namely, this action is brought by this Plaintiff pursuant to constitutional, statutory, common law and/or equitable authority for purposes of, *inter alia*:

a. recovering restitution and reimbursement for all the costs the City of Reno has incurred in paying excessive and unnecessary prescription costs related to opioids;

b. recovering restitution and reimbursement for all the costs expended by the City of Reno for health care services and programs associated with the diagnosis and treatment of adverse health consequences of opioids use, including but not limited to, addiction;

c. recovering restitution and reimbursement for all the costs consumers have incurred in excessive and unnecessary prescription costs related to opioids;

d. disgorgement;

e. recovering damages for all costs incurred and likely to be incurred in an effort to combat the abuse and diversion of opioids in the City of Reno;

f. recovering damages incurred as costs associated with the harm done to the public health and safety.

41. However, Plaintiff does not bring claims, as part of this action, for products liability nor does the City seek compensatory damages for death, physical injury to person, emotional distress, or physical damage to property.

PARTIES AND JURISDICTION

A. Plaintiff, City of Reno.

42. Plaintiff, City of Reno ("Reno" or "Plaintiff"), is a municipality organized under the laws of the State of Nevada.

43. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

44. Plaintiff has all the powers possible for a municipality to have under the constitution of the State of Nevada, the laws of the State of Nevada, and its city charter.

45. Plaintiff has standing to bring this litigation to provide for the orderly government of Reno and to address matters of local concern including the public health, safety, prosperity, security, comfort, convenience and general welfare of its citizens.

46. Reno declares that the unlawful distribution of prescription opiates, by the Defendants named herein, has created a serious public health crisis of opioid abuse, addiction, morbidity and mortality and is a public nuisance.

47. Plaintiff is authorized by law to abate any nuisance and prosecute in any court of competent jurisdiction, any person who creates, continues, contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance.

B. Defendants, Drug Manufacturers.

48. Defendant PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware and registered, and authorized, to do business in the State of Nevada, under the laws thereof. At all times relevant herein, PURDUE PHARMA L.P. takes and took advantage of the legislative, regulatory and tax schemes of the State of Nevada to own, maintain and defend drug patents. PURDUE PHARMA INC. is a corporation organized under the laws of both Delaware and New York, with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut. Defendant PURDUE PHARMACEUTICALS, L.P. is and was a limited partnership organized under the laws of the State of Delaware. At all times relevant hereto, the foregoing, (collectively, "PURDUE") are and were in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing OxyContin and have done so to and within the State of Nevada. At all times relevant herein, PURDUE hired "Detailers" in Reno, Nevada, to make personal contact with physicians and clinics to advocate for the purchase and use of opioid medications which were contrary to known safety concerns and sound medical advice.

49. Defendant TEVA PHARMACEUTICALS USA, INC. ("TEVA"), is a Delaware corporation with its principal place of business located in North Whales, Pennsylvania. Teva develops, makes, manufactures, and distributes generic opioid medications worldwide, including within Washoe County, Nevada.

50. Defendant DEPOMED, INC. is a corporation organized under the laws of the State of California and headquartered in Newark, California. At all times relevant herein, DEPOMED INC. was and is engaged in the manufacturing, distribution and the sale of opioid drugs into and within Washoe County, Nevada. At all times relevant herein, DEPOMED INC. hired "Detailers" in Washoe County, Nevada, to make personal contact with physicians and clinics to advocate for the purchase and use of opioid medications which were contrary to known safety concerns and

sound medical advice. Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

51. Defendant CEPHALON, INC., is Delaware corporation with its principal place of business located in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired CEPHALON, INC.

52. Defendant ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business located in Malvern, Pennsylvania. ENDO PHARMACEUTICALS, INC., is a wholly owned subsidiary of Endo Health Solutions Inc., and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc., and Endo Pharmaceuticals, Inc., collectively are referred to herein as "ENDO").

53. Defendant ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in Pennsylvania. Defendant ALLERGAN FINANCE, LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc. is a Nevada limited liability company. (ALLERGAN USA, INC. and ALLERGAN FINANCE, LLC collectively are referred to herein as "ALLERGAN"). ALLERGAN PLC (f/k/a Actavis plc, f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

54. Defendant WATSON LABORATORIES, INC. is, and was at all times relevant herein, a Nevada corporation with its principal place of business in Corona, California. At all times relevant herein, Watson Laboratories, Inc. takes and took advantage of the legislative, regulatory and tax schemes of the State of Nevada to own, maintain and defend drug patents. ACTAVIS PHARMA, INC. f/k/a Watson Pharma Inc. is a Delaware corporation with its principal place of business in New Jersey. ACTAVIS PHARMA, INC. f/k/a Watson Pharma Inc. was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic business to Teva. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey (Watson Laboratories, Inc., Actavis Pharma, Inc. f/k/a Watson Pharma Inc., and Actavis LLC, collectively are referred to herein as "ACTAVIS" and shall include the related ALLERGAN entities for the relevant time periods).

55. Defendant INSYS THERAPEUTICS, INC., is, and was at all times relevant herein, a Delaware corporation with its principal place of business located in Chandler, Arizona. At all times relevant herein, Defendant INSYS THERAPEUTICS, INC. was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling and/or distributing Subsys, a transmucosal immediate-release formulation of fentanyl, packed in a single-dose spray device intended for oral sublingual administration, and has done so to and within in the State of Nevada. At all times relevant herein, INSYS THERAPEUTICS, INC. hired "Detailers" in Washoe County, Nevada to make personal contact with physicians and clinics to advocate for the purchase and use of opioid medications which were contrary to known safety concerns and sound medical advice. At all times relevant herein, INSYS THERAPEUTICS, INC., used deceptive tactics to gain authorization for Subsys prescriptions from health insurance providers for off-label, high dosage uses.

56. Defendant MALLINCKRODT LLC is a Delaware corporation with its principal place of business in Hazelwood, Missouri. Defendant MALLINCKRODT BRAND PHARMACEUTICALS INC. is a Delaware corporation with its principal place of business in Hazelwood, Missouri. Defendant MALLINCKRODT US HOLDINGS, INC. is a Nevada corporation with its principal place of business in Hazelwood, Missouri. At all times relevant

herein, Mallinckrodt US Holdings, Inc. takes and took advantage of legislative, regulatory and tax schemes in Nevada for the purpose of holding, protecting and defending Mallinckrodt assets related to their pharmaceutical business.

57. Defendants Mallinckrodt LLC, Mallinckrodt Brand Pharmaceuticals Inc., and Mallinckrodt US Holdings, Inc. (collectively "MALLINCKRODT") operate in the United States under the name Mallinckrodt Pharmaceuticals, with its United States headquarters located in Hazelwood, Missouri. At all times relevant herein, Defendant MALLINCKRODT was in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing opioid products known as Exalgo, Roxicodone, and Xartemis XR, and has done so to and within the State of Nevada.

58. That at all times relevant herein, PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC. dba THE PURDUE FREDERICK COMPANY, INC.; PURDUE PHARMACEUTICALS, L.P.; DEPOMED, INC.; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICALS INDUSTRIES LTD; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, 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; INSYS THERAPEUTICS, INC.; MALLINCKRODT, LLC; MALLINCKRODT BRAND PHARMACEUTICALS INC.; and MALLINCKRODT US HOLDINGS, INC., (collectively "Defendant Manufacturers" or "Defendants") were, and currently are, regularly engaged in business in Washoe County. More specifically, Defendants were, and currently are, in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, and/or selling opioids throughout Washoe County.

C. Defendants, Wholesale Distributors.

59. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is, and at all times pertinent hereto, was, a foreign corporation authorized to do business in the County of Washoe, State of Nevada. Upon information and belief, and at all times relevant hereto, AMERISOURCEBERGEN DRUG CORPORATION's principal place of business is located in Chesterbrook, Pennsylvania, operating distribution centers in Ohio.

60. Defendant, CARDINAL HEALTH, INC. is, and at all times pertinent hereto, was, a foreign corporation with multiple wholly-owned subsidiaries incorporated under the laws of the State of Nevada and/or authorized to do business in said state, and conducting business in the County of Washoe, State of Nevada.

61. Upon information and belief, and at all times relevant hereto, CARDINAL HEALTH, INC.'s principal office is located in Dublin, Ohio, operating distribution centers in Ohio. CARDINAL HEALTH 6 INC. is a Nevada Domestic Corporation. CARDINAL HEALTH TECHNOLOGIES LLC is a Nevada Domestic LLC. At all times relevant herein, CARDINAL HEALTH TECHNOLOGIES LLC takes and took advantage of the legislative, regulatory and tax schemes of the State of Nevada to own, maintain and defend patents, including those relating to drug labeling, coding and distribution.

62. CARDINAL HEALTH 108 LLC d/b/a Metro Medical Supply is a foreign limited liability company incorporated under the laws of the state of Delaware and headquartered in Dublin, Ohio, and registered and authorized to conduct business within the State of Nevada. CARDINAL HEALTH 108 LLC d/b/a Metro Medical Supply operates a drug distribution center within the physical confines of the Washoe County, specifically at 6640 Echo Ave, Ste J, Reno, Nevada 89506. (Cardinal Health, Inc., Cardinal Health 6 Inc., Cardinal Health Technologies LLC, and Cardinal Health 108 LLC, collectively are referred to herein as "CARDINAL")

63. Defendant, McKESSON CORPORATION, is, and at all times pertinent hereto, was, foreign corporation authorized to do business in the County of Washoe, State of Nevada. Upon information and belief, and at all times relevant hereto, McKESSON CORPORATION's principal place of business is located in San Francisco, California, operating distribution centers in Ohio. At all times relevant herein, McKESSON CORPORATION takes and took advantage

of the legislative, regulatory and tax schemes of the State of Nevada to own, maintain and defend patents, including those relating to drug labeling, coding and distribution.

64. McKESSON CORPORATION, AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., CARDINAL HEALTH 6 INC.; and CARDINAL HEALTH TECHNOLOGIES LLC; CARDINAL HEALTH 108 LLC d/b/a Metro Medical Supply (collectively "Defendant Distributors" or "Defendants") distributed opioids or facilitated the distribution of opioids into Reno. The United States Drug Enforcement Administration has found it necessary to levy disciplinary action against these and each of these including large fines and suspension or permanent cancellation of their licenses for distribution of controlled substances, based on dangerous and abusive distribution practices as detailed herein and below.

65. Defendant Distributors purchased opioids from manufacturers, including the named Defendants herein, and distributed them to pharmacies throughout Reno, and the State of Nevada.

66. Defendant Distributors played an integral role in the chain of opioids being distributed throughout Reno, and the State of Nevada.

D. Defendants, Detailers.

67. Defendant Detailers (hereinafter "Detailers") are natural persons, and at all relevant times herein, were residents of Washoe County, Nevada and who are or were engaged in specialty drug sales on behalf of Defendant Manufacturers and Distributors named herein.

68. Upon information and belief, Defendant Detailers played an integral role in the chain of opioids being sold throughout Reno.

69. Defendant Detailers were trained to, and did in fact, make personal contact with physicians and clinics within Washoe County, Nevada for the purpose, and with the result, of encouraging them to prescribe opioid medications in a manner inconsistent with known safety concerns and contrary to sound medical practice.

70. That the true names and the capacities, whether individual, agency, corporate, associate or otherwise, of Defendant Detailers, are unknown to Plaintiff. Plaintiff will ask leave

of the Court to amend this Complaint to show the true names and capacities of these Defendants, when they become known to Plaintiff.

E. Defendants, Pharmacies.

71. Defendant pharmacies (collectively "Defendant Pharmacies" or "Defendants") sold opioids to residents of Reno giving rise to the opioid crisis.

72. Upon information and belief, Defendant Pharmacies played an integral role in the chain of opioids being sold throughout Reno.

73. That the true names and the capacities, whether individual, agency, corporate, associate or otherwise, of Defendant Pharmacies, are unknown to Plaintiff. Plaintiff will ask leave of the Court to amend this Complaint to show the true names and capacities of these Defendants, when they become known to Plaintiff.

F. Defendants, Health Care Providers

74. Defendant ROBERT GENE RAND, M.D. is, and was at all times relevant herein, a resident of Washoe County, Nevada and was a licensed medical doctor in the State of Nevada. Upon information and belief, and at all times relevant hereto, Defendant ROBERT GENE RAND, M.D., conducted business and provided medical services as RAND FAMILY CARE, LLC, a Nevada Domestic Limited Liability Company in Gardnerville, Nevada.

75. Defendants ROBERT GENE RAND, M.D. AND RAND FAMILY CARE, LLC (collectively "Defendant Providers" or "RAND") diverted and distributed addictive and potentially lethal opioid medications, including, but not limited to, OxyContin, to residents of Washoe County, Nevada (including the City of Reno), operating a "pill mill" out of a local car dealership.

76. Defendant RAND prescribed an excessive amount of opioid medication in reckless regard for his patients' lives. For example, Defendant RAND prescribed approximately 23,645 pills of opioid medication to a single patient.[2] Unfortunately, this was not an isolated incident.

[2] UNITED STATES ATTORNEY'S OFFICE, DISTRICT OF NEVADA, Reno Doctor Sentenced To 10 Years In Prison For Involuntary Manslaughter Of Patient And Unlawful Distribution Of Large Quantities Of Prescription Drugs

77. Defendant RAND was investigated by the Board of Medical Examiners ("BME or Board"). The Board discovered that Defendant RAND constantly, and on a regular basis, over-prescribed opioid medication to his patients, increased opioid medication doses to patients without appropriate medical examinations, and on a regular basis prescribed additional opioid medication to patients who, due to one reason or another, needed extra medication.[3]

78. On November 20, 2018, Defendant RAND and several of his associates, and/or individuals under his employment, pleaded guilty to various criminal counts in the United States District Court, District of Nevada for their involvement in illegal activities. Defendant RAND was sentenced to ten (10) years in prison.[4]

79. Defendant RAND was able to over-prescribe copious amounts of opioid medication due to the abundant supply from Defendant Manufacturers and Defendant Distributors.

G. Defendants, Does, Roes and Zoes.

80. That the true names and the capacities, whether individual, agency, corporate, associate or otherwise, of Defendant DOES 1 through 100, inclusive, are unknown to Plaintiff. Plaintiff will ask leave of the Court to amend this Complaint to show the true names and capacities of these Defendants, when they become known to Plaintiff. Plaintiff believes each Defendant named as DOE was responsible for the misconduct alleged herein.

81. That the true names and the capacities, whether individual, agency, corporate, associate or otherwise, of Defendant ROE CORPORATIONS 1 through 100, are unknown to Plaintiff. These Defendants include the manufacturer(s), distributor(s) and any third party that may have developed, manufactured, produced, sold, altered or otherwise distributed the subject drug, which caused Plaintiff's injuries as complained herein. Plaintiff will ask leave of the Court to amend this Complaint to show the true names and capacities of these Defendants, when they

(November 20, 2017), available at http:// www.justice.gov/usao-nv/pr/reno-doctor-sentenced-10-years-prison-involuntary-maslaughter-patient-and-unlawful (last visited on 2018-08-22).

[3] In the Matter of Charges and Complaint Against Robert Rand, M.D., No. 17-25704-1 (February 02, 2017), available at http://www.medboard.nv.gov/Resources/Public/2017_Public_Filings/ (last visited on 2018-08-22).

[4] Reno Doctor Sentenced To 10 Years In Prison For Involuntary Manslaughter Of Patient And Unlawful Distribution Of Large Quantities Of Prescription Drugs, supra note 2.

become known to Plaintiff. Plaintiff believes each Defendant named as ROE CORPORATION was responsible for contributing to the misconduct alleged herein.

82. That the true names and the capacities, whether individual, agency, corporate, associate or otherwise, of Defendant ZOE PHARMACIES 1 through 100, are unknown to Plaintiff. These Defendants include the pharmacies or similarly situated retailers that may have developed, manufactured, produced, sold, altered or otherwise distributed opioids which caused Plaintiff's injuries as complained herein. Plaintiff will ask leave of the Court to amend this Complaint to show the true names and capacities of these Defendants, when they become known to Plaintiff. Plaintiff believes each Defendant named as ZOE PHARMACY was responsible for contributing to the misconduct alleged herein.

83. That Plaintiff is informed and believes, and based upon such information and belief, alleges that each of the Defendants herein designated as DOES, ROES and/or ZOES are in some manner responsible for the misconduct alleged herein.

84. Plaintiff is informed and believes and thereon alleges that at all relevant times herein mentioned Defendants, and each of them, were the agents and/or servants and/or partners and/or joint venture partners and/or employers and/or employees and/or contractors of the remaining Defendants and were acting within the course and scope of such agency, employment, partnership, contract or joint venture and with the knowledge and consent of the remaining Defendants at the time of the event leading to the misconduct alleged herein.

H. Jurisdiction & Venue.

85. That exercise of the jurisdiction by this Court over each and every Defendant in this action is appropriate because each and every Defendant has done, and continues to do, business in the State of Nevada, and committed a tort in the State of Nevada. Additionally, this Court has jurisdiction over the claims alleged herein as they arise under Nevada statutes and Nevada common law.

86. Venue is proper in the Second Judicial District Court of Washoe County, Nevada where part of the claims alleged herein occurred.

GENERAL FACTUAL ALLEGATIONS

A. Opioids Generally

87. Defendants design, manufacture, distribute, sell, market, and advertise prescription opioids, including brand-name drugs like Oxycontin and Subsys, and generics like oxycodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines and arthritis), opioids were used only to treat short-term acute pain cancer patients or for palliative (end-of-life) care.

88. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

89. In the 1970s and 1980s, studies were conducted that made clear the reasons to avoid opioids. By way of example, the World Health Organization ("WHO") in 1986 published an "analgesic ladder" for the treatment of cancer pain. The WHO recommended treatment with over the counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, then use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted. The WHO ladder pertained only to the treatment of cancer pain and did not contemplate the use of narcotic opioids for chronic pain - because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

90. Due to concerns about their addictive qualities, opioids have been regulated as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as a result of an excessive dose.

91. Yet, as Defendant Manufacturers like Purdue developed their opioid products, they sought to expand their market and profits.[5] Therefore, Defendant Manufacturers had to change the perception of opioids to permit and encourage long-term opioid use for widespread, chronic conditions like back pain, migraines, and arthritis. Defendant Purdue, along with other Defendant

[5] Purdue is in Bankruptcy. The City of Reno cites to the factual background involving Purdue to provide facts necessary to describe the history of opioid marketing and sales.

Manufacturers began to promote opioids as a class of drugs as well as their own opioid products as safe, effective, and appropriate for long-term use to treat common pain conditions. Part of this strategy involved misrepresenting the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

92. As is clear in the City of Reno, the Defendant Manufacturers' scheme was resoundingly successful. Chronic opioid therapy—the prescription of opioids long-term to treat chronic pain—has become commonplace and is often the first-line treatment. The Defendant Manufacturers' deceptive marketing has caused prescribing to skyrocket—both for whatever particular opioid they manufacturer and for opioids as a class of drugs.

93. Instead of compassionately helping patients, the explosion in opioid use, and Defendants' profits along with it, has come at the expenses of chronic pain patients. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. According to the CDC, one of every 550 patients started on opioid therapy die from opioid-related causes a median of 2.6 years after their first opioid prescription.[6] Further, for patients receiving 200 morphine milligram equivalents per day, the number increases to 1 in 32. The then CDC director summed it up well: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[7]

94. Once the Defendant Manufacturers, employing the help of Defendant Distributors, created a mass market for prescription opioids, McKesson Corporation, AmerisourceBergen Drug Corporation, and Defendant Cardinal, along with Defendant Manufacturers' help, flooded the market. Defendant Distributors are responsible for delivering opioids marketed and made by the Defendant Manufacturers to pharmacies and other customer throughout the country and in the City of Reno. Additionally, and as will be described further, Defendant Distributors entered into agreements with Defendant Manufacturers to market the Defendant Manufacturers' opioid products to Defendant Distributors' customers. Defendants – Manufacturers and Distributors -

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[6] 4 Thomas R. Frieden, M.D. and Debra Houry, M.D., Reducing the Risks of Relief –The CDC Opioid-Prescribing Guideline at 1503, NEJM, April 21, 2016.

[7] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General,
August 2016, available at http://turnthetiderx.org.

have a duty under state and federal law to report and to not ship suspicious orders of controlled substances into the Plaintiff's community. Yet, these Defendants repeatedly shipped suspicious orders of opioids – often in quantities that they knew or should have known exceeded any legitimate market for opioids, and exceeded even the wider market for chronic pain, and ignored red flags of suspicious orders of these drugs in Plaintiff's community, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

B. The Resurgence of Opioid Use in the United States

95. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, like the one operated by Dr. Rand, issue high volumes of opioid prescriptions under the guise of medical treatment. Pill mills in the City of Reno directly supplied illicit opioids into Plaintiff's community. Prescription opioid pill mills and rogue prescribers would not have been able to channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

96. Defendant Purdue was uniquely positioned to execute the fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of $13 billion back in 2016. The company's profits go to Sackler family trusts and entities. Yet, the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as spokespeople for the company.

97. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. Arthur Sackler created the pharmaceutical advertising industry as we know it, laying the groundwork for the promotion of OxyContin that would make billions of dollars for the Sackler family.

98. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical educations ("CME") courses. He also harnessed the persuasive power of recommendations from fellow physicians, but he was willing to manipulate information when necessary. For example, one promotional brochure produced by his firm for

Pfizer showed business cards of physicians from various cities, presenting them as testimonials, yet when a journalist tried to contact the doctors, he discovered that they did not exist.

99. Arthur Sackler knew how to advertise for his own clients, but he also published a bi-weekly newspaper called the Medical Tribune, distributed for free to doctors across the nation. He also created a company, now called IMS Health Holdings, Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like the Defendant Manufacturers, who utilize it to target and tailor their sales pitches to individual physicians.

100. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company and had grand ambitions for the company. According to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean really big."[8] Richard believed Purdue should develop another use for its "Contin" timed-release system.

101. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that

[8] Christopher Glazek, The Secretive Family Making Billions from the Opioid Crisis, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.

oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[9]

102. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. Although Purdue did not find or generate any such evidence, that did not stop Purdue from making that claim regardless, opening a huge untapped market of patients with non-end-of-life, non-acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[10]

103. Beginning around 1996, Purdue poured massive resources into OxyContin's sales force and advertising, and advertised to a broader audience of primary care physicians who treated patient with chronic pain complaints.[11] In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

104. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million. Yet Purdue had its aim on even greater profits. Under the name of

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[9] *Id.*

[10] Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204 (Rodale 2003), at 156 (hereinafter "Meier").

[11] U.S. General Accounting Office, *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters, at 22 (Dec. 2003), http://www.gao.gov/new/items/d04110.pdf.

Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.[12]

105. Purdue's recent pivot to untapped markets through Mundipharma—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

106. Once Defendant Purdue created the market for use of opioids for a range of common aches and pains by misrepresenting the risks and benefits, other Defendant Manufacturers positioned themselves to take advantage of the opportunity created in large part by Purdue, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products.

107. Defendant Endo, which already sold Percocet and Percodan, was the first to submit an application for a generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect.[13] Endo withdrew oral Numorphan from the market in 1979.

108. However, two decades later, when communities began to raise concern about prescription opioids and Purdue executives were being called to testify to Congress regarding

[12] Letter from Members of Congress to Dr. Margaret Chan, Director-General, World Health Organization (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-lettersignatures.pdf.

[13] John Fauber and Kristina Fiore, Abandoned Painkiller Makes a Comeback, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448.

OxyContin, Endo essentially dusted off the Numorphan, previously shelved for widespread abuse, and pushed it out into the market stream with a new name, Opana.

109. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, thereby skewing the test results, and obtained approval. Endo began marketing Opana and Opana ER in 2006. Despite the knowledge that the drug was highly susceptible to abuse, Endo did not provide any information in their marketing regarding that danger, and in fact, misled others regarding the safety of the drug.

110. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "[t]his is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[14] On July 6, 2017, Endo agreed to withdraw Opana ER from the market.

111. By adding additional opioids or expanding the use of their existing opioid products, the other Defendant Manufacturers took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the $1 billion mark in sales of Duragesic in 2009.

C. Defendant Manufacturers' Deceptive Marketing by Promotion of Falsehoods about Opioids

112. Defendant Manufacturers spent hundreds of millions of dollars on promotional activities and materials, including advertising and websites that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and misleading information derived from seminars, treatment guidelines, and other publications and

[14] Press Release, U.S. Food & Drug Administration, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Defendants.

113. While it would be impossible to precisely list every one of the Defendant Manufacturers' misrepresentation, the Defendant Manufacturers' misrepresentations generally fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low;

b. Signs of addictive behavior are "pseudo addiction," requiring more opioids;

c. To the extent there is a risk of addiction, it can be easily identified and managed;

d. Opioid withdrawal can be avoided by tapering;

e. Long-term opioid use improves functioning;

f. Opioid doses can be increased without limit or greater risks;

g. Alternative forms of pain relief pose greater risks than opioids;

h. OxyContin provides twelve hours of pain relief; and

i. New formulations of certain opioids successfully deter abuse.

114. Each of the above-listed representations were false. The Defendant Manufacturers knew the representations were false, but they set out to convince physicians, patients, , and citizens and officials of the City of Reno the truth of each of these representations in order to expand the market for their opioids, and in turn, their profits.

115. These nine (9) categories of misrepresentations are not meant to be a checklist for assessing each Defendant's liability. While each Defendant Manufacturer deceptively promoted their opioids specifically, and, together with other Defendant Manufacturers, opioids generally, not every Defendant propagated (or needed to propagate) each misrepresentation. Each Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Second Amended Complaint attempts to document examples of each Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. At this point, the Second Amended Complaint is not, and cannot be, an exhaustive catalog of the nature and manner of each deceptive statement by each Defendant. Yet, upon information and

belief, all of the messages described below were disseminated to prescribers and patients in Plaintiff's community.

Falsehood # 1: The risk of addiction from chronic opioid therapy is low

116. To convince prescribers and patients that opioids are safe, Defendant Manufacturers deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

117. Defendant Manufacturers undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. These Defendant Manufacturers also minimized the difficulty of withdrawal in their marketing material and promotional programs. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days.[15] However, this claim is at odds with the experience of patients addicted to opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

118. When it launched OxyContin, Purdue knew it would need data to overcome decades of resistance to using opioids. Although Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin, Purdue (and, later, the other Defendants) found "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980. In the letter, Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with

opioids.[16] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records. Dr. Jick later explained to a journalist that he submitted the statistics to NEJM as a letter because the data was not robust enough to be published as an actual study.[17] In fact, Dr. Jick elaborated that using the citation to assert that opioids were not addictive was "not in any shape or form what we suggested in our letter."

119. Purdue specifically used the Porter and Jick letter in its 1998 promotional video, "I got my life back," in which Dr. Alan Spanos says, "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*." [18] Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent."[19]

120. Other Defendant Manufacturers relied on and disseminated the same distorted messaging. The enormous impact of Defendant Manufacturers' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented."[20] "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[21]

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[16] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[17] Meier at 174.

[18] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited Feb. 27, 2020) (emphasis added).

[19] Patrick Radden Keefe, *The Family That Built an Empire of Pain,* New Yorker (Oct. 30, 2017).

[20] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

[21] Painful words: How a 1980 letter fueled the opioid epidemic, STAT (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

121. Purdue further disseminated deceptive messages through their own materials stating falsehoods like the fear of addiction being "exaggerated"[22] or that addiction, overdose, and death would not befall "legitimate" patients.[23]

122. Purdue specifically trained sales representatives to overcome doctors' objections to prescribing opioids and to assuage their fears regarding addiction.[24]

123. Endo also falsely represented that addiction is rare in patients who are prescribed opioids. Until April 2012, Endo's website for Opana, *www.opana.com*, stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." Another Endo website, *PainAction.com*, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

124. Upon information and belief, Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo's training materials for its sales representatives in 2011 also prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.[25]

125. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC") and its website *Painknowledge.com*,

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[22] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/; see also Partners Against Pain consists of both an unbranded website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

[23] OxyContin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.; see also Purdue's brochure about OxyContin "A Guide to Your New Pain Medicine and How to Become a Partner gainst Pain."

[24] Keefe, *Empire Of Pain;* Meier, *Pain Killer*, at 102; David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontinwas-sold-to-the-masses.

which claimed that "[p]eople who take opioids as prescribed usually do not become addicted." A brochure available on *Painknowledge.com* titled "*Pain: Opioid Facts*," Endo-sponsored NIPC stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." Endo continued this deceptive message in its patient education pamphlets. Furthermore, Endo funded a 2009 patient education publication that omitted addiction from the "common risks" of opioids.[26]

126. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.[27]

127. A Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003 taught that chronic pain was undertreated due to the "continued stigmatization of opioids" and the "unfounded and self-imposed" fears with which doctors approached opioids. It went on to state that there was "confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse."[28]

128. Upon information and belief, Cephalon also trained sales representatives to tell prescribers that addiction was uncommon in patients with no personal or family history of abuse, that few patients using opioids for a "legitimate" purpose become addicted, and that drug dependence is easily overcome with scheduled dose increases.[29]

129. Actavis claimed in its "Learn More about customized pain control with Kadian" material that although it is possible to become addicted to morphine-based drugs like Kadian, it is "less likely" to happen in those who "have never had an addiction problem." In line with the

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[28] Michael J. Brennan, et al., Pharmacologic Management of Breakthrough or Incident Pain, Medscape, http://www.medscape.org/viewarticle/449803 (last visited Oct. 10, 2017).

uniform message of the other Defendants, Actavis further stated that the need for a "dose adjustment" is the result of tolerance, and "not addiction."[30]

130. Upon information and belief, Actavis trained their sales force to push out the deceptive messages regarding low addiction risk by attributing addiction to family history or psychiatric disorders, highlighting the difference between substance dependence and substance abuse, and using the term "pseudo addiction" to dismiss evidence of addiction as undertreatment of pain that they urge requires more and higher doses of opioids.

131. In Actavis's market study on takeaways from prescriber interactions with Kadian sales representatives, the doctors had a strong recollection of the sales representatives' discussion of the low-abuse potential. Actavis's sales representatives' misstatements on the low abuse potential was considered an important factor to doctors and was most likely repeated and reinforced to their patients. Numerous marketing surveys of doctors in 2010 and 2012 confirmed that Actavis's messaging about Kadian conveyed a low addiction potential and that it had less abuse potential than other similar opioids.

132. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements convey both that Kadian is less addictive and is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

133. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient

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safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

134. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book entitled *Defeat Chronic Pain Now!*, still available online. The false claims and misrepresentations in this book include statements that addiction to opioids is rare without a prior history of addiction, that every chronic pain patient with moderate to severe pain should be viewed as a potential opioid candidate, that chronic pain patients rarely develop a true addiction, and that only a minority of chronic pain patients taking long-term opioids develop tolerance.

135. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

136. Upon information and belief, Mallinckrodt worked to secure a media message related to its Exalgo product that there is a need for extended-release opioid options for treatment of chronic pain; this message was published in *Managed Healthcare Executive* magazine in 2011.

137. Studies have shown that at least 8 - 12%, and as many as 30- 40% of long-term users of opioids experience problems with addiction. According to one study, nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.[31] Addiction can result from the use of any opioid, "even at prescribed doses" [32] and the risk

[31] Jennifer M. Hah, et al., Chronic Opioid Use after Surgery: Implications for Perioperative Managment in the Face of the Opioid Epidemic, Anesth. Analg. 2017 Nov.; 125(5): 1733-40 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6119469/ (last visited Feb. 28, 2020).
[32] *Id.*

increases with chronic (more than three months) use. The CDC has emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[33]

138. Upon information and belief, the misinformation described above was distributed to and targeted patients and prescribers in the City of Reno, Nevada.

Falsehood # 2: Signs of addiction are "pseudo addiction," requiring more opioids

139. Defendants covered up the occurrence of addiction by attributing it to an imaginary condition they called "pseudo addiction." Signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

140. Purdue, through its unbranded *Partners Against Pain*, promoted the concept of pseudo addiction through at least 2013 on its website. It disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of an American Pain Society ("APS") consensus statement through the website, where APS, who received funding from Defendants, defined pseudo addiction in the same terms endorsed by Purdue.

141. The Federation of State Medical Boards ("FSMB"), a trade organization representing state medical boards, finances opioid- and pain-specific programs through grants from Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudo addiction. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

142. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which

[33] CDC Training Document, Module 6: Dosing and Titration of Opioids: How Much, How Long, and How and When to Stop?, available at https://www.cdc.gov/drugoverdose/training/dosing/accessible/index.html (last visited Feb. 28, 2020).

promoted pseudo addiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo held control in NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. Upon information and belief, APF viewed the NIPC as an "opportunity to generate new revenue" given Endo's funding commitment.

143. The FAQs section of *pain-topics.org*, a no longer active website to which Mallinckrodt provided funding, also contained misleading information about pseudo addiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudo addiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

144. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, rejects the concept of pseudo addiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[34] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[35]

145. Upon information and belief, the misinformation described above was distributed to and targeted patients and prescribers in the City of Reno, Nevada.

Falsehood # 3: To the extent there is addiction risk, it can be easily identified and managed

146. Defendant Manufacturers falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to

[34] CDC Guideline at 13.
[35] *Id.* at 25.

safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendant Manufacturers advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else. These misrepresentations were especially dangerous because Defendant Manufacturers aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations created the impression that opioid addiction was simply the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs—if the focus was on blaming other doctors and blaming "problem" patients, the heat was off Defendant Manufacturers.

147. Defendant Manufacturers conveyed these safe prescribing messages in nationally distributed marketing materials. A catalogue distributed by Purdue to prescribers across the country and, on information and belief, in the City of Reno, included information on screening tools. On information and belief, none of the Defendant Manufacturers disclosed the lack of evidence for efficacy of these tools. Defendant Manufacturers also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by or were available online, to Reno prescribers.

148. For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation **d**eceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

149. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), supporting scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented a disproportionate number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of

Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, from the City of Reno, attended these conferences.

150. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers' bureau (group of doctors paid to give talks, typically manufacturers' largest prescribers) in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

151. The CDC Guideline confirmed the falsity of Defendant Manufacturers' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies like screening tools or patient contracts "for improving outcomes related to overdose, addiction, abuse, or misuse."[36] The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[37]

Falsehood # 4: Opioid withdrawal can be avoided by tapering

152. Upon information and belief, all Defendants' profits depend on keeping patients on opioids on an ongoing basis, and recurring prescriptions is a key component of each Defendants' business model. To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. Upon information and belief, Defendants pushed the purported benefits of long-term opioid use, while falsely suggesting the benefits were supported by scientific evidence.

[36] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, at 5.
[37] *Id.* at 28.

153. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[38] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[39] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well controlled studies of opioids use longer than 12 weeks."[40] As a result, the CDC recommends that opioids not be used in the first instance and for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments.

154. The American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Defendant Manufacturers. According to a letter from U.S. Senate Committee on Finance Ranking Member Ron Wyden to Secretary Thomas Price of the U.S. Department of Health & Human Services, as recently as May 2017, the Corporate Council of AAPM included Endo, Janssen, Purdue and Teva, along with several other pharmaceutical drug companies.[41] Upon information and belief, these Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The coauthor of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. Key Opinion Leader Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

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[38] *Id.* at 2.
[39] *Id.* at 15.
[40] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[41] Letter from Ron Wyden, Ranking Member, U.S. Senate Committee on Finance, to Honorable Thomas E. Price, Secretary, U.S. Health & Human Services (May 5, 2017), https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf.

155. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Defendant Manufacturers in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

156. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite low quality of evidence and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. At least one panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.[42]

157. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature. These Guidelines were available to Reno prescribers.

158. Purdue published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse side effects or ineffective treatment. Despite relating to a chronic condition, opioids were

[42] This sentiment was confirmed by Dr. Gilbert Fanciullo, retired professor of Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, who described the Guidelines as "skewed" by drug companies and "biased in many important respsects."

provided only short-term. The authors even acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[43] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[44] A conclusion not supported by the data as a substantial proportion of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term. The dissemination of these misleading studies led to the spread of misinformation regarding the safety and efficacy of opioids like OxyContin.

159. The FDA expressly limited Teva's opioids Actiq and Fentora to the treatment of cancer pain in opioid-tolerant individuals. Despite the FDA's limitation, Teva has worked to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. This campaign included the use of CMEs, speaker programs, Key Opinion Leaders, and journal supplements to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

160. For example, Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

161. Upon information and belief, Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

162. In December 2011, Teva widely disseminated a journal supplement entitled *"Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal*

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[43] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).
[44] *Id.*

Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in the City of Reno. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

163. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can develop when the medications are used as prescribed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq or Fentora.

Falsehood # 5: Long-term opioid use improves functioning

164. Defendant Manufacturers claimed—with no evidence—that long-term opioid use could help patients resume their lives and jobs.

165. Defendant Manufacturers' materials that, upon information and belief, were distributed or made available in the City of Reno, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving" "[d]aily function" and "[o]verall health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, starting in at least May of 2011, Endo distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

166. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

167. Purdue and Teva sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

168. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement, and Endo closely tracked visits to the site. Endo also through a series of CMEs titled Persistent Pain in the Older Patient, claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

169. Mallinckrodt followed suit, stating on its website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[45]

170. The FDA, other federal agencies, and independent researchers have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[46] The CDC Guideline, following a "systematic review of the

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[45] Mallinckrodt Pharmaceuticals, Responsible Use, http://www.mallinckrodt.com/corporateresponsibility/responsible-use.

[46] See, Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-makingpain-patients-worse*?;* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that opioid manufacturer Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.").

best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[47] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[48]

Falsehood # 6: Alternative forms of pain relief pose greater risks than opioids

171. In materials Defendant Manufacturers produced, sponsored, or controlled, Defendant Manufacturers omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or NSAIDs. None of these claims were corroborated by scientific evidence. In fact, several studies have shown that ibuprofen and acetaminophen taken together are better than opioids at relieving pain such as dental pain, low back pain, and moderate acute traumatic pain.[49]

172. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Defendant Manufacturers routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[50] in which the patient experiences some of the following symptoms: heightened sensitivity to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions often accompanying chronic pain).

173. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication

[47] CDC Guideline at 2, 18.
[48] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline*, NEJM, Apr. 21, 2016 at 1503
[49] Donald Teater, M.D., *Evidence for the Efficacy of Pain Medication,* National Safety Council, October 2014.
[50] Bradley C Martin, et al, Long-term chronic opioid therapy discontinuation rates from the TROUP study, J. Gen. Intern. Med .2011; 26(12): 1450-1457.

inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids). This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

174. APF's *Exit Wounds*, sponsored by Purdue and Endo and aimed at veterans, omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder.

175. Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

176. Defendant Manufacturers frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

177. In reality, a Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22.9% of patients in opioid trials dropped out before the study began because of the "adverse effects" of opioids.[51]

178. These omissions are significant and material to patients and prescribers. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

Falsehood # 7: Opioid doses can be increased without limit or greater risks.

[51] Meredith Noble M., *Long-Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

179. Defendant Manufacturers falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

180. Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.[52]

181. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." Endo also distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . .. You won't 'run out' of pain relief."

182. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[53] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[54]

183. Upon information and belief, this misinformation was distributed to and targeted patients and prescribers in the City of reno.

Falsehood # 8: OxyContin provides twelve hours of pain relief

184. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality,

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[52] Through at least June 2015, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors who would; A Policymaker's Guide, the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but it did not disclose the risks from high dose opioids; Purdue-sponsored CME, Overview of Management Options, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

[53] CDC Guidelines at 19.

[54] *Id.* at 16.

OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

185. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours. Purdue has affirmatively claimed in its general marketing, including, upon information and belief, to prescribers in the City of Reno, that OxyContin lasts for 12 hours and that this is a key advantage of OxyContin, implying that most or all patients would in fact experience continuous pain relief for the full 12 hour dose period. Purdue has also failed to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue continues to make, are particularly dangerous because inaccurate dosing helps fuel addiction.

186. Yet, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue doses"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

187. 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."[55] 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.

[55] Harriet Ryan, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, L.A. Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

188. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.,* every 8 hours) because 12-hour dosing was "a significant competitive advantage."

189. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks. According to a CDC clinical evidence review, higher opioid doses are related to increased risks of motor vehicle injury, opioid use disorder, and overdoses, and the increased risk increases in a dose-dependent manner.[56] With higher doses, patients experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[57]

Falsehood # 9: New formulations of certain opioids successfully deter abuse

190. Defendants Purdue and Endo seized widespread abuse and addiction to opioids as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded their sales and influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in the City of Reno.

191. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. However, the FDA made clear that abuse deterrent

[56] Mark J. Edlund, *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Non-cancer Pain,* 30 Clin. J. Pain 557–564 (2014); Woodcock Letter, *supra*.
[57] CDC Guideline at 16.

properties do not stop tampering but only make it harder to modify the pills. ADF pills can still be snorted and injected if tampered with, and these pills are still sought after by abusers because of their high likability when snorted. Further, ADF properties do not reduce oral abuse—the most common form of abuse—in any way. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations.

192. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

193. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks these powerful medications create . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse."[58]

194. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[59] and is still regularly tampered with and abused. Additionally, they knew or should have known that there was widespread information on websites such as bluelight.org and reddit.com discussing numerous ways to tamper with OxyContin and Hysingla ER.

195. 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

[58] Purdue website, Opioids With Abuse-Deterrent Properties, available at http://www.purduepharma.com/healthcareprofessionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/.

[59] Hr'g Test. of Dr. Mohan Rao at 1615:7-10, In re OxyContin, No. 1:04-md-01603-SHS (SDNY Oct. 7, 2013), ECF No. 613.

opioid abuse, and can still be abused by non-oral routes."[60] Tom Frieden, the 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 death."[61]

196. 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."[62] 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.

197. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids like OxyContin that were being introduced as ADFs, also made abuse-deterrence a key to its marketing strategy.

198. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse."[63] In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that the new formulation of Opana ER was not proven to be less subject to addiction, overdoes, diversion, abuse, or misuse.

199. Nonetheless, in August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant,

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[60] CDC Guideline at 22 (emphasis added).

[61] Matthew Perrone, Drugmakers Push Profitable, but Unproven, Opioid Solution, AP (Jan. 2, 2017), https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution.

[62] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

[63] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-2228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Like Purdue, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug.

200. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[64] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[65]

201. In a departure from their position regarding discontinuation of the previous formulation, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its "dangers". In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[66]

202. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation, according to the FDA's findings. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure. In 2009, only 3% of Opana ER abuse was by intravenous means.

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[64] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al., No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012.

[65] Defendants' Response to the Court's November 30, 2012 Order, Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al., No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[66] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.., No. 1:12-cv-01936 ,Doc. 18-4(D.D.C. Dec. 9, 2012).

Since the reformulation, injection of Opana ER has drastically increased. Yet, Endo continued to market their drug as tamper-resistant and abuse-deterrent, failing to disclose evidence that Opana ER was actually easier to abuse intravenously.

203. In its written materials, Endo marketed Opana ER as having been *designed* to be crush resistant, knowing that this would imply that Opana ER actually *was* crush resistant and thus less likely to be abused. For example, a June 14, 2012, Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[67] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[68] While journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant."

204. In a 2016 settlement with Endo, the New York Attorney General found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New \ York Attorney General also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to insurers and pharmacy benefit managers, which also would have impacted the availability of Opana ER in the City of Reno.

205. Upon information and belief, a guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide claims that Kadian's unique formulation will protect against extraction and may be less likely to be abused due to its slow onset of action. Kadian was not approved by the FDA as abuse-deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

206. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and

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[67] Ex. E to Rurka Decl., Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al., No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[68] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.., No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

chemical tampering, including chewing, crushing and dissolving."[69] However, as one member of the FDA's Controlled Substance Staff noted in 2010, hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[70]

207. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that it had "technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[71] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[72]

208. In sum, each of the nine categories of Defendant Manufacturers' misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by, or was contrary to, the scientific evidence and were misleading or contrary to the Defendant Manufacturers' own labels. Upon information and belief, each one of these misrepresentations or omissions were directed to and reached the City of Reno.

D. Defendants Manufacturers Used Multiple Channels to Disseminate Falsehoods about Opioids

209. To take advantage of the lucrative market for chronic pain patients, Defendants developed a well-funded marketing scheme based on deception. Defendant Manufacturers used both direct marketing and unbranded advertising disseminated by purported independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use. They targeted, not only the medical community, but the patients who experienced chronic pain.

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[69] Press Release, Covidien, FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-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.

[70] 2010 Meeting Materials, Anesthetic and Analgesic Drug Products Advisory Committee, at 157-58, FDA, https://wayback.archiveit.org/7993/20170403223634/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/ucm/193298.htm.

[71] Mallinckrodt, Responsible Use of Opioid Pain Medications (Mar. 7, 2014).

[72] Samantha Liss, Mallinckrodt Banks on New Painkillers for Sales, St. Louis Bus. J. (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/.

210. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from federal agencies such as the Food and Drug Administration ("FDA") and Centers for Disease Control and Prevention ("CDC") based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including the elderly and veterans.

211. Defendant Manufacturers also used kickback systems, prior authorization systems, and incentives to encourage health care providers to prescribe the opioid medications.

Direct Marketing Efforts

212. Defendant Manufacturers' direct marketing of opioids generally proceeded on two tracks. First, Defendants conducted, and continue to conduct, promotional campaigns extolling the purported benefits of their branded drugs. Advertisements were branded to deceptively portray the benefits of opioids for chronic pain. For instance, Defendant Purdue commissioned series of ads in medical journals, called "Pain vignettes," for Oxycontin in 2012. These ads featured chronic pain patients and recommended opioids for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that Oxycontin would help the writer work more effectively. Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but no similar order has been issued in Nevada. Defendant Mallinckrodt marketed its products, Exalgo and Xartemis as specially formulated to reduce abuse and published information on its website minimizing addition risk as well as advocating access to opioids. Defendant Insys provided health care providers with false and misleading information in order to deceive such providers into believing the FDA had approved Subsys for more uses than the FDA had actually approved. The Defendant Manufacturers published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Defendant Manufacturers collectively spent more than $14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

213. The first track not only targeted doctors but also targeted consumers in advertising. Defendant Manufacturers knew that physicians are more likely to prescribe a drug if a patient specifically requests it.[73] Defendant Manufacturers also knew that this willingness to acquiesce to patient requests holds true even for opioids not approved for conditions being treated.[74] Endo's research, for example, also found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. Defendant Manufacturers thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials in the form of pamphlets, videos, or other publications that patients could view in their physician's office.

214. Second, Defendant Manufacturers promoted, and continue to promote, the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendant Manufacturers' detailing to doctors is effective. By establishing close relationships with prescribing physicians, Defendant Manufacturers' sales representatives are able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain.

215. Defendant Manufacturers devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendant Manufacturers spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.[75]

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[73] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., Effects of Patient Medication Requests on Physician Prescribing Behavior, 52(2) Med. Care 294 (2014).

[74] *Id.*

[75] Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of more than $27 million in 2007. Endo's quarterly spending went from the $2 million to $4 million range in 2000- 2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year). Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011). Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), continuing to rise through 2016.

216. These direct techniques were also accompanied by kickbacks, prior authorization systems, and the use of other incentives to encourage health care providers, to prescribe the opioid medication for chronic pain.

217. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Defendants devoted, and continue to devote, massive resources to direct sales contacts with doctors.

218. Defendant Manufacturers paid sham "speaker fees" to doctors to run educational events to discuss the use of their products, but the fees were actually intended to reward those doctors for prescribing Defendant Manufacturers' products and incentivize them to prescribe more of those products to patients. In fact, often times the speakers spoke at events with minimal to no attendance simply to collect the fee. These kickbacks increased as the number of prescriptions written by the speakers increased.

219. In accordance with common industry practice, the Defendant Manufacturers purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management and analytics corporation. 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 and disseminated the misinformation and materials described herein.

220. Upon information and belief and at all times relevant herein, Defendant Manufacturers ensured, and continue to ensure, marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Upon information and belief, Defendant Manufacturers' sales representatives and physician speakers were required to adhere to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

221. Upon information and belief and at all times relevant herein, Defendant Manufacturers employed, and continue to employ, the same marketing plans and strategies and deployed the same messages in Nevada as they did nationwide.

222. As the opioid epidemic spread, many health care providers recognized the dangers of opioid medication, including health risks and the risk of addiction. Others, however, continued to prescribe such medication for off-label purposes without adequately warning patients of the dangers associated with opioids.

223. Upon information and belief, Defendant Providers received financial incentives to continue writing prescriptions for such opioid medication despite the dangers associated with same.

224. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendant Manufacturers' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Defendant Manufacturers consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

Speakers' Bureaus and Programs

225. In addition to making sales calls, Defendant Manufacturers' detailers also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Defendant Manufacturers. 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; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Defendant Manufacturers grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon, and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating on speakers' bureaus, providing consulting services, and other services.

Unbranded/Third-Party Marketing by Defendant Manufacturers

226. In addition to direct communications, Defendant Manufacturers utilized third-party marketing to promote their line of prescription opiates. This "unbranded" marketing refers not to a specific drug, but more generally to a disease state or treatment. For instance, these marketing materials generally promoted opioid use but did not name a specific opioid. Through these unbranded materials, Defendant Manufacturers presented information and instructions concerning opioids that were generally contrary to, or at best, inconsistent with, information and instructions listed on Defendant Manufacturers' branded marketing materials and drug labels and with Defendant Manufacturers' own knowledge of the risks, benefits and advantages of opioids. An example of such unbranded marketing techniques is Defendant Mallinckrodt's Collaborating and Acting Responsible to Ensure Safety (C.A.R.E.S.) Alliance, which promoted a book "Defeat Chronic Pain Now!" minimizing the risk of opioid addiction and emphasizing opioid therapy for regular use for moderate chronic pain.

227. Unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product's limits and risks. In contrast, a pharmaceutical company's "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label. Through unbranded materials, the Defendant Manufacturers expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

228. Many of the Defendant Manufacturers utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue's pain-management website, *www.inthefaceofpain.com*. The website contained testimonials from several dozen "advocates," including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars

229. Using "Key Opinion Leaders" (KOLs) and "Front Groups," Defendant Manufacturers disseminated their false and misleading statements regarding the efficacy of opioids. These KOLs and Front Groups were important elements of Defendants' marketing plans, because they appeared independent and therefore outside of FDA oversight. However, Defendants did so knowing that unbranded materials typically were not submitted or reviewed by the FDA. By acting through third parties, Defendant Manufacturers were able both to avoid FDA scrutiny and to give the false appearance that these messages reflected the views of independent third parties. Afterwards, Defendant Manufacturers would cite to these sources as corroboration of their own statements.

230. Defendant Manufacturers worked, and continue to work, in concert with the Front Groups and KOLs which they funded and directed to carry out a common scheme to deceptively market the risks, benefits, and superiority of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to Nevada prescribers and patients.

Defendant Funded, Edited, and Distributed Publications

231. Defendant Manufacturers created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks. They created this body of literature, sometimes through third-party consultants and/or Front Groups, by commissioning, editing, and arranging for the placement of favorable articles in academic journals.

232. The plans for these materials originated in the marketing departments of Defendant Manufacturers—not in the departments responsible for research, development, or any other specialized area regarding drugs or their effects on patients.

233. Defendant Manufacturers made sure that favorable articles were disseminated and cited widely in the medical literature, despite their knowledge that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The

Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence. The Defendant Manufacturers also published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

234. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[76] published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed below) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients.[77]

Key Opinion Leaders (KOLs)

235. Upon information and belief and at all times relevant herein, Defendant Manufacturers recruited, as part of their unbranded marketing efforts, a cadre of doctors who were financially sponsored because of their preference to aggressively treat chronic pain with opioids. KOLs were retained by Defendant Manufacturers to influence their peers' medical practice, including but not limited to their prescribing behavior. KOLs gave lectures, conducted clinical trials, and occasionally made presentations at regulatory meetings or hearings. KOLs were carefully vetted to ensure that they were likely to remain on message and supportive of Defendant Manufacturers' agenda.

[76] Donald R. Taylor, et al., Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ), 8(3) Pain Med. 281-88 (Mar. 2007).

[77] *Id.*

236. Defendant Manufacturers' financial support helped these doctors become respected industry experts. Upon information and belief, these doctors repaid Defendant Manufacturers by extolling the benefits of opioids to treat chronic pain as quid pro quo. Defendant Manufacturers would cite to these sources later on as corroboration of their own false and misleading statements regarding opioids.

237. Although these KOLs were funded by the Defendant Manufacturers, 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. These pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

238. Once the Defendant Manufacturers identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the false position that opioids were safe and effective for treatment of chronic pain, Defendant Manufacturers poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. Defendant Manufacturers cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Defendant Manufacturers did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

239. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[78] He went on to state that the problems with long-term administration of opioid drugs

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

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."[79]

240. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Defendant Manufacturers, 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, cofounder 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.'"[80]

241. 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."[81]

242. Dr. Portenoy was also a critical component of the Marketing 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.

243. 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."[82] 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 . . ."[83] 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 have always to live with that one."[84]

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[79] *Id.*
[80] Sam Quinones, Dreamland: The True Tale of America's Opiate Epidemic 314 (Bloomsbury Press 2015).
[81] *Id.* at 136.
[82] Thomas Catan and Evan Perez, A Pain-Drug Champion Has Second Thoughts, The Wall Street Journal (Dec. 17, 2012, 11:36am), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[83] *Id.*
[84] Meier, at 277.

244. 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 was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. 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 Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

245. Dr. Webster created and promoted the Opioid Risk Tool ("ORT"), a five question, one-minute screening tool relying on patient self-reports that would supposedly allow doctors to manage the risk that their patients would become addicted to or abuse opioids. The claimed ability to presort 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 ORT appear on, or are linked to, websites run by Endo, Janssen, 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 the City of Reno.

246. 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 Defendants' promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

247. 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 experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets

in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP." This CME effectively amounted to off-label promotion of Cephalon's opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

248. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

249. Another KOL was Dr. Perry Fine. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescriptions for non-cancer patients. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS/AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was on the board of directors of APF.

250. Dr. Fine has acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under $5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's website states that the company paid him $32,017 for consulting, promotional talks, meals, and travel that year.

251. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction.[85]

252. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic

[85] Perry G. Fine, MD and Russell K. Portenoy, MD, A Clinical Guide to Opioid Analgesia 20 and 34, McGraw-Hill Companies (2004), http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

Pain: An 18-Month Study."[86] In that article, Dr. Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[87] The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse related events was "small."[88]

253. 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.[89] He states 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 entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He 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."[90]

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[86] Perry G. Fine, et al., Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

[87] *Id.*

[88] *Id.*

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

[90] *Id.*

254. Another KOL, Dr. Scott Fishman, 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." He has authored publications, including the seminal guides on opioid prescribing, which were funded by the Defendant Manufacturers.[91] He has also worked to oppose legislation requiring 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."[92]

255. 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."[201] The guide also continues to present symptoms of addiction as symptoms of "pseudo addiction."[93]

Front Groups

256. Defendant Manufacturers also entered into arrangements with seemingly unbiased and independent patient advocacy groups and professional organizations to promote opioids for the treatment of chronic pain. Under their direction and control, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy while understating the risks. They also assisted Defendant Manufacturers by refuting negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendant Manufacturers.

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[91] Scott M. Fishman, Responsible Opioid Prescribing: A Guide for Michigan Clinicians, 10-11 (Waterford Life Sciences 2012). In 2007, Dr. Fishman authored a physician's guide on the use of opioids to treat chronic pain titled Responsible Opioid Prescribing, which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain. In 2012, Dr. Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created. 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.

[92] 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-treatmenthave-long-ties-to-drug-industry (hereinafter "Weber, Two Leaders in Pain").

[93] Scott M. Fishman, Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication 45 (Oxford University Press 2012).

257. These Front Groups depended on Defendant Manufacturers for funding and, in some cases, for survival. Defendant Manufacturers exercised significant control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In so doing, Defendant Manufacturers made sure that these Front Groups would generate only favorable messages. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients. In reality, by funding, directing, editing, approving, and distributing these materials, Defendant Manufacturers exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front groups to deceptively promote the use of opioids for the treatment of chronic pain.

258. "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.'"[94] "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.'"[95] Indeed, the U.S. Senate's report, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*,[96] which arose out of a 2017 Senate investigation and, drawing on disclosures from Purdue, Janssen, 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 area of opioids policy,"[97] found that the Defendant Manufacturers made millions of dollars of contributions to various Front Groups.

[94] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("Fueling an Epidemic"), at p. 2.
[95] *Id.*
[96] *Id.* at 1.
[97] *Id.*

259. The Defendant Manufacturers also "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[98]

260. As the Senate *Fueling an Epidemic* Report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[99] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescribing and misbranding."[100]

261. While Defendant Manufacturers utilized many Front Groups, one of the most prominent of was the American Pain Foundation ("APF"). While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen and Cephalon. APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF's largest donor and provided more than half of its $10 million in funding from 2007 to 2012.

262. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Nevadans.

263. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain*, and distributed 17,200 copies of this

[98] *Id.* at 10.
[99] *Id.* at 12-15
[100] *Id.* at 12.

guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use.

264. APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, *www.painknowledge.com*. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of "dinner dialogues." But it was Endo that substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo's control of NIPC was such that Endo listed it as one of its "professional education initiative[s]" in a plan Endo submitted to the FDA. Yet, Endo's involvement in NIPC was nowhere disclosed on the website pages describing NIPC or *www.painknowledge.org.* Endo estimated it would reach 60,000 prescribers through NIPC.

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

266. This alignment of interests was especially evident in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the

Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

267. APF's Board of Directors was largely comprised of doctors who were on the Defendant Manufacturers' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Defendant Manufacturers demonstrates APF's clear lack of independence, in its finances, management, and mission, and its willingness to allow these Defendant Manufacturers to control its activities and messages supports an inference that each Defendant Manufacturer that worked with it was able to exercise editorial control over its publications—even when Defendant Manufacturers' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy.

268. On or about May 2012, the U.S. Senate Finance Committee began investigating APF to determine the relationship, financial and otherwise, between the organization and the manufacturers of opioid analgesics. The investigation caused considerable damage to APF's credibility as an objective and neutral third party. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization and APF ceased to exist.

269. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[101] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy, who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

270. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Dr. Scott Fishman

[101] The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at http://www.stgeorgeutah.com/wp-content/uploads/2016/05/OPIOIDES.DOLORCRONICO.pdf (as viewed August 18, 2017).

("Fishman") (2005), Dr. Perry G. Fine ("Fine") (2011) and Dr. Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented. Fishman, who also served as a Key Opinion Leader for Defendant Manufacturers, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[102]

271. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held at resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids—37 out of roughly 40 at one conference alone.

272. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines"). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including Key Opinion Leader Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

273. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug

[102] 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.

companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

274. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who also 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.

275. 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 period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines—upon information and belief this includes doctors in the City of Reno. For that reason, the CDC has recognized that treatment guidelines can "change prescribing practices."[103]

276. Defendant Manufacturers widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

277. 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, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

[103] 2016 CDC Guideline at 2.

278. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies." The 1998 Guidelines that the pharmaceutical companies helped author taught, not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in the City of Reno.

279. FSMB's 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo and Cephalon. The publication also received support from the APF and the AAPM. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as "the leading continuing medical education (CME) activity for prescribers of opioid medications." This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

280. Defendant Manufacturers relied on the 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to chronic pain patients.

281. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization claiming to be "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical

care."[104] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[105] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Janssen, Endo, Mallinckrodt, Purdue and Cephalon.

282. APA's board members have also directly received substantial funding from pharmaceutical companies.[106] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids' side effects, including from defendants Endo, Purdue and Cephalon. Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

283. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[107] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are

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[104] About AfPA, The Alliance for Patient Access, http://allianceforpatientaccess.org/ about-afpa/#membership (last visited Jan. 4, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[105] Mary Chris Jaklevic, Non-profit 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 patientaccess-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, Non-profit Alliance for Patient Access").

[106] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/.

[107] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp content/uploads/2013/12/PT_WhitePaper_Finala.pdf.

burdensome, not user friendly, and of questionable efficacy.[108] The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills like the requirements for a pain management center to be owned by physicians or professional corporations, have a medical director who is Board certified, and subject to record keeping, reporting, and inspection requirements.[109] Further, the white paper coins the stigma associated with prescribing and taking pain medication as "opiophobia."[110] 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."[111]

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

285. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act").[112] The AAPM is also a signatory to this letter. An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "could actually result in increased diversion, abuse, and public health and safety consequences"[113] and, according to DEA chief administrative law judge John J. Mulrooney

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[108] *Id.* at 4-5.
[109] *Id.* at 5-6
[110] *Id.* at 6.
[111] *Id.* at 7.
[112] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf
[113] Bill Whitaker, Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry") (internal quotations omitted).

("Mulrooney"), the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like the defendants here, in the federal courts.[114] The law passed both houses of Congress and was signed into law in 2016.

286. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Defendants. The USPF was one of the largest recipients of contributions from the Defendant Manufacturers, collecting nearly $3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Defendants' lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Marketing Defendants, listing opioid manufacturers like Teva, Depomed, Endo, Purdue, McNeil *(i.e.*, Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[115] Industry Front Groups like the AAPM, the AAM, and APS are also members of varying levels in the USPF.

287. The American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Defendants. AGS was a large recipient of contributions from the Defendant Manufacturers, including Endo, Purdue and Janssen. AGS contracted with Purdue, Endo and Janssen 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,[116] hereinafter "2009 AGS Guidelines"). According to news reports, AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[117] AGS's complicity in the common purpose with the Marketing Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug

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[114] John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/ documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.

[115] *Id.* at 12; Transparency, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last accessed on March 9, 2018).

[116] 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 accessed on March 9, 2018).

[117] John Fauber & Ellen Gabler, "Narcotic Painkiller Use Booming Among Elderly," Milwaukee J. Sentinel, May 30, 2012.

companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

288. 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.[118] These Guidelines further recommended that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

289. The deceptive messages of each of the previously described Front Groups, upon information and belief, were meant to and did reach the City of Reno.

Continuing Medical Education (CMEs)

290. CMEs are ongoing professional education programs required for physicians. Physicians must 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 to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered by KOLs who are highly-respected in their fields and are thought to reflect their medical expertise, they can be especially influential with doctors. Therefore, Defendants aggressively distributed their deceptive messages and false body of "literature" through thousands of CMEs.

291. By utilizing CMEs, Defendants sought to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly

[118] AGS 2009 Guidelines at 1342.

dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions. Defendants sponsored CMEs that promoted chronic opioid therapy.[119]

292. The American Medical Association ("AMA") recognized the impropriety that pharmaceutical company-funded CMEs creates, stating that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter."[120]

293. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

294. Upon information and belief and at all times relevant herein, CMEs paid for or sponsored by Defendants were intended to and did reach prescribing physicians in the City of Reno, Nevada, and physicians who attended or reviewed these CMEs were misled by them.

Defendant Manufacturers Utilize Kickbacks to Encourage Prescriptions

295. Upon information and belief, Defendant Manufacturers utilized a system of kickbacks to encourage health care providers to write prescriptions for, and deliver, the opioid medications. Kickbacks took the form of "speaker fees" paid to health care providers that spoke at programs regarding the purported benefits and safety of using opioid medications to treat chronic pain. Such speakers were recruited by Defendant Manufacturers based upon the number of prescriptions the providers wrote for opioid medications. The more prescriptions written, the

[119] Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false information to physicians across the country. See, e.g., Daniel S. Bennett, Breakthrough Pain: Treatment Rationale With Opioids, Medscape, http://www.medscape.org/viewarticle/461612 (last visited Oct. 10, 2017) (available on Medscape starting September 16, 2003 and given by a pain management doctor who lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process, failing to mention its FDA limitation to treatment of cancer-related pain). Teva also paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. Responsible Opioid Prescribing was sponsored by Purdue, Endo and Teva, and more than 163,000 copies have been distributed nationally.

[120] Opinion 9.0115, Financial Relationships with Industry in CME, Am. Med. Ass'n (Nov. 2011).

more times the speaker was asked to appear at a program, and the more "speaker fees" were paid to the provider. Defendant Manufacturers' employees were rewarded when their "speakers" increased the prescriptions they wrote. These speaking programs did not result in other health care providers writing a significant number of prescriptions for Defendant Manufacturers' products, but the "speakers" continued to be paid to speak so long as they increased their own prescriptions. Many of the speaker programs had few or no attendees that would actually be able to write prescriptions for Defendant Manufacturers' products. Upon information and belief, Defendant Providers, benefitted from such programs.

Prior Authorization Programs

296. Upon information and belief, Defendant Manufacturers developed prior authorization programs in order to gain authorization and approval from insurance companies to cover the costly opioid products for off-label uses. These programs involved representatives from Defendant Manufacturers contacting insurance companies and representing that they are from a health care provider's office rather than from the Defendant manufacturer or distributor; providing inaccurate diagnosis information on the authorization requests; and drafting Letters of Medical Necessity for health care providers to sign-off on for purposes of receiving authorization from health insurance providers. Upon information and belief, Defendant Providers also participated in misleading the health insurance providers to authorize the numerous prescriptions written for opioid medications, including, but not limited to, Subsys.

Medication Switch Programs

297. Upon information and belief, Defendant Manufacturers encouraged and incentivized detailers and salespeople to convince health care providers to substitute stronger, more expensive opioid medications for medications that patients were already prescribed. Detailers and salespeople were informed that they would receive higher pay and/or bonuses by convincing health care providers to change prescriptions. These programs ignored any warnings that one opioid drug could not be substituted on a one-for-one basis with another opioid medication. Each opioid medication is unique in its dosing and has a different approved dosage level. Switch programs encouraged a one-for-one substitution despite the differences in the original and substitute medication.

Defendant Manufacturers Utilized Marketing Targeting Vulnerable Populations

298. In their pursuit of profit, Defendant Manufacturers targeted vulnerable segments of the population suffering from chronic pain including veterans and the elderly.

299. Defendant Manufacturers' targeted marketing to the elderly and the absence of cautionary language in their promotional materials creates a heightened risk of serious injury. Studies have shown that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. Additionally, elderly patients taking opioids have been found to suffer elevated fracture risks, greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression.

300. The Defendant Manufacturers promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. For example, the AGS 2009 Guidelines, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "*exceedingly low* in older patients with no current or past history of substance abuse." (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried "possibly less potential for abuse than in younger patients." Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

301. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old and treated Medicare part D patients among their most valuable customer segments. Since then, upon information and belief, a pharmaceutical benefits management company has recommended against the use of Opana ER with elderly patients asserting that Opana ER is not safe for the elderly population.

302. Defendant Manufacturers' efforts have been successful. Since 2007, opioid prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. Based on anecdotal evidence, many of these elderly patients started on opioids for chronic back pain or arthritis.

303. Veterans are also suffering greatly from the effects of Defendant Manufacturers' targeted marketing. Opioids are particularly dangerous to veterans. According to a study

published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, like overdoses and self- inflicted and accidental injuries, than the general U.S. population. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as nonveterans to die from an opioid overdose.

304. *Exit Wounds*, a 2009 publication sponsored by Defendants Purdue, Endo, and Janssen, and distributed by APF, written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

305. *Exit Wounds* downplays and minimizes the risks from chronic opioid therapy and does not disclose the risk that opioids may cause fatal interactions with benzodiazepines taken by a significant number of veterans. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together. *Exit Wounds* is not the unbiased narrative of a returning war veteran; it is another form of marketing, sponsored by Defendants Purdue, Endo, and Janssen.

306. The deceptive nature of *Exit Wounds* is made obvious in comparing it to guidance on opioids published by the U.S. Department of Veterans Affairs and the Department of Defense in 2010 and 2011. The VA's Taking Opioids Responsibly describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol.

307. Upon information and belief, Defendant Manufacturers targeted the elderly and veterans in the City of Reno and distributed these deceptive messages in the City of Reno.

E. Defendant Manufacturers Had a Duty to Educate Doctors and Prevent Harm

308. Even in the face of growing evidence of the overuse, abuse, addition to, and overdose from opioids, Defendant Manufacturers failed to take appropriate actions to protect

public health and safety. Responsible companies marketing and selling highly addictive controlled substances would have, among other steps: (1) pulled in their marketing to avoid the overuse and oversupply of opioids; (2) ramped up efforts to detect, prevent, and address diversion and indications of improper or over-prescribing and dispensing; (3) ensured that doctors, pharmacists, and patients understood the appropriate use of opioids and accurately conveyed the risks and benefits of their drugs, correcting their years of misinformation. Using language identical to that approved by the FDA with respect to the brand-name labels, Defendant Manufacturers could have used the same mechanisms used to disseminate their fraudulent marketing—CMEs, speaker programs, sales representatives—among others, to stop the near-literal bleeding their promotional efforts had caused, and would continue to cause.

309. Instead of taking these steps, Defendant Manufacturers participated in an industry effort to water down a federally and state mandated Risk Evaluation and Mitigation Strategies.

F. Defendant Manufacturers' Misrepresentations

310. To convince prescribing physicians and prospective patients that opioids are safe, Defendants deceptively concealed the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations and disseminated those misrepresentations to Nevada and the City of Reno. Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not.

311. These misrepresentations regarding opioids include but are not limited to:

a. Starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed;

b. Patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs;

c. The use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and

d. Abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

312. Upon information and belief, Defendants have not only failed to correct these misrepresentations, they continue to make them today.

313. Upon information and belief and at all times relative herein, Defendants made and/or disseminated deceptive statements related to opioids, including, but not limited to, in the following ways:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to Reno consumers that contained deceptive statements;

b. Creating and disseminating advertisements 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. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

d. Developing and disseminating scientific studies that misleadingly 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;

e. Targeting the elderly and veterans by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

f. Exclusively disseminating misleading statements in education materials to Nevada hospital doctors and staff while purportedly educating them on new pain standards; and

g. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Reno prescribers through in-person detailing.

G. Defendant Manufacturers' Scheme Created a Public Health Epidemic

314. Defendant Manufacturers necessarily expected a return on the enormous investment they made in their deceptive marketing scheme and worked to measure and expand their success. Upon information and belief, 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.

315. Endo, for example, directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER's uses; virtually all of Endo's opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. Similarly, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have high correlation to sales.

316. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[121] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[122]

317. Upon information and belief, each of the Defendant Manufacturers tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. Their purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs, for instance. Defendant Manufacturers continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As

[121] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.
[122] *Id.*

described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, like abuse-deterrent formulas.

318. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior. 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 versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures.[123]

319. Defendant Manufacturers spent millions of dollars to market their drugs to prescribers and patients 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.[124] These results are directly due to Defendant Manufacturers' deceptive marketing campaign—as shown by Defendant Manufacturers' own tracking as well as independent studies.

320. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[125] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

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[123] Ian Larkin, et al., Association between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing, JAMA 2017; 317(17): 1785-1795, available at https://jamanetwork.com/journals/jama/fullarticle/2623607.

[124] Catherine S. Hwang, et al., Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA 2015; 175 (2): 302-304, available at https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1984247.

[125] 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).

321. 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."[126] Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[127]

322. Defendant Manufacturers failed to prevent diversion, or otherwise control the supply of opioids following into communities across the United States, including in the City of Reno, Nevada. Defendant Manufacturers further failed to report and halt shipment of suspicious orders. Defendant Manufacturers continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders. Governmental agencies and regulators have confirmed (and in some cases these Defendants have admitted) that Defendant Manufacturers did not meet their obligations and have uncovered especially blatant wrongdoing.

323. Defendant Manufacturers have breached their duties under federal and state law (duties related to suspicious order monitoring is explained more fully below) by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids; and/or (e) perform due diligence on orders which they had reason to believe were suspicious, and instead shipping those orders without review.

i. PURDUE

324. Defendant Purdue breached its duties under federal and state law. As shown by the Arcos Data, Purdue sold an extraordinary amount of prescription opioids into the Plaintiff's community. Purdue's excessive sales were made possible by, and are evidence of, Purdue's failures to comply with its duties under the CSA and Nevada statutes.

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[126] Rose A. Rudd, et al., Increases in Drug and Opioid Overdose Deaths – United States 2000-2014, CDC Morbidity and Mortality Weekly Report, Jan. 1, 2016, 64(50); 1378-82, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

[127] *Id.*

325. Purdue comprised 2.2% of the market share for manufacturers in Washoe County, and it distributed around 5,260,015 total dosage units from 2006 to 2014 to Washoe County.[128]

326. Purdue failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's Community.

327. Purdue failed to fulfill its responsibilities under state and federal law with respect to control of the supply chain of opioids. Purdue was required to set up a system to prevent diversion, including excessive volume and other suspicious orders. This includes reviewing Purdue's own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Purdue failed to do this. Part of Purdue's duties under the statute require that all suspicious orders must be reported to relevant enforcement authorities. Purdue was required to stop shipment of orders which were flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels. Purdue failed to comply with its obligations under the statute. Despite these failures, Purdue's former Head of National Accounts, Steve Seid testified that Purdue had a "state of the art" and very "robust" SOM system. Purdue was so proud of its SOM system, that the Chair of the SOM Committee and member of General Counsel's office, Robin Abrams, gave a presentation to HDMA outlining the details of Purdue's SOM system so as to serve as an example to members in the industry.[431] Curtis Wright, likewise testified that abuse and diversion are inherent in opioids and at all points of the distribution chain there would be a "leak" and this is a function of volume.

328. Purdue's SOM system provides two streams of data providing total visibility down the chain –Purchasing Data and Prescribing Data. Purdue has specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Purdue to observe

[128] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

the signs of suspicious prescribing and dispensing—lines of seemingly healthy patients, out of-state license plates, and cash transactions, to name only a few. In addition, Purdue regularly mined data, including chargeback data, that allowed it to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, which would have alerted Purdue, independent of their sales representatives, to suspicious prescribing. These information points gave Purdue insight into prescribing and dispensing conduct that enabled them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

ii. CEPHALON and TEVA

329. Defendant Cephalon, currently owned by Teva, breached its duties under federal and state law. As shown by the Arcos Data, Cephalon/Teva sold an extraordinary amount of prescription opioids into the Plaintiff's community. Cephalon/Teva's excessive sales were made possible by, and are evidence of, Cephalon/Teva's failures to comply with its duties under the CSA and Nevada statutes.

330. Cephalon/Teva products comprised 1.3% of the market share for manufacturers in Washoe County, and it distributed around 3,002,800 total dosage units from 2006 to 2014 to Washoe County.[129]

331. Cephalon and Teva failed to meet their suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

332. Although Cephalon acknowledges that it was always under a regulatory obligation equal to that of the distributors to monitor and stop suspicious orders, it did not implement a SOM program until 2013.

[129] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

333. In 2012, Cephalon hired Buzzeo to perform a review of its systems. The subsequent audit report described the existing SOMS systems as "rudimentary" and noted that no suspicious orders had ever been reported up to that point.

334. Cephalon did not report a single suspicious order until 2013. From 2013 to 2016, it made only six suspicious order reports.

335. Cephalon failed to meet its suspicious order monitoring requirements by failing to have proper policies and procedures in place that would have ensured its ability to stop shipment on suspicious orders. Because of this, it failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

iii. ENDO

336. Defendant Endo breached its duties under federal and state law. As shown by the Arcos Data, Endo sold an extraordinary amount of prescription opioids into the Plaintiff's community.[130] Endo's excessive sales were made possible by, and are evidence of, Endo's failures to comply with its duties under the CSA and Nevada statutes.

337. Endo products comprised 0.5% of the market share for manufacturers in Washoe County, and it distributed around 1,107,980 total dosage units from 2006 to 2014 to Washoe County.[131]

338. Endo failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

339. Endo had a duty to monitor for suspicious orders, but upon information and belief, Endo never implemented a robust SOM program (including, for example, independence from commercial departments, use of due diligence, use of chargeback data, etc.) and never reported any orders to the DEA or blocked any orders as suspicious. Even when Endo went through the

[130] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.
[131] *Id.* See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

motions to put a more "robust" SOM system in place on the generic side, it appears that was largely a paper process in which personnel were looking to check the boxes and clear orders, especially when it came to orders funneled through the major wholesalers. Very few orders were reported to the DEA and/or halted.

iv. ACTAVIS

340. Defendant Actavis breached its duties under federal and state law. As shown by the Arcos Data, Actavis sold an extraordinary amount of prescription opioids into the Plaintiff's community. Actavis's excessive sales were made possible by, and are evidence of, Actavis's failures to comply with its duties under the CSA and Nevada statutes.

341. Actavis comprised 27.3% of the market share for manufacturers in Washoe County, and it distributed around 64,940,100 total dosage units from 2006 to 2014 to Washoe County.[132]

342. Actavis failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's Community.

343. Before the 2012 acquisition by Watson of Actavis, each maintained its own SOM system. Each conflicted with the guidance provided in a letter from former DEA Agent Joe Rannazzisi sent in 2007 outlining the responsibilities of drug companies to track orders and shipments of opioids for purposes of identifying any suspicious orders so that they could be stopped and investigated. Until 2012, Actavis' SOM protocols were run by a single employee in the customer service group, Nancy Baran, who sent a 2009 email explaining that the process was inadequate to "prevent shipping excess product" because the report permitted a customer with a monthly usage threshold of 3000 units to order 2999 every day of the month and "[i]f we stopped to question and put on hold every one of the" flagged orders, "it would be crippling." She concluded: "The intent of the DEA suspicious order report was designed to prevent excessive shipments of controlled products. In my opinion, it does a lousy job at even that." Although

[132] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

Actavis produced documents reflecting approximately 7,000 orders flagged as suspicious, Baran testified that she believed the company determined that only one of the orders it flagged was ultimately reported to the DEA.

344. During integration discussions in 2012, Watson's SOM expert, Mary Woods, documented the Actavis system as "Not nearly as compliant as we could be" because it was a "[t]hreshold based report system" based on a six-month order average; noted Actavis has "no current SOP [standard operating procedures] on the current process;" commented that Actavis does "not investigate all, only some, since there is no SOP, they don't investigate;" and concluded that the system was a "[d]efinite risk right now today, current system is not acceptable to Watson."

345. Actavis U.S. CEO Doug Boothe's testimony confirms the inadequacy of Actavis' SOM program: "I don't think we had responsibility for, accountability for preventing diversion." Boothe testified that, so long as the order was from a licensed pharmacy and within the SOM threshold, "we have no capability or responsibility or accountability . . . . So, once we ship an order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point."

346. Upon information and belief, on September 12, 2012, the DEA hosted a meeting with Actavis. Michael Clarke, Vice President of Ethics and Compliance, and Baran (among others), attended. During the meeting, the DEA criticized Actavis for flooding the market with oxycodone. In a follow-up meeting one month later, the DEA asked Actavis to reduce its oxycodone quota. CEO Boothe rejected the request.

347. Actavis made efforts to improve its SOM system during 2012, including contracting with Buzzeo PDMA, a Cegedim Company ("Buzzeo"), and a new Buzzeo-based system was implemented in October 2012. But within three months, the combined Watson/Actavis company (renamed Actavis, Inc.) decided to use the previously existing Watson SOM system.

348. Watson's system was similarly deficient. Watson DEA Compliance Chief Officer Thomas Napoli criticized the system's threshold-based approach as being inferior to a "total SOM model" that would "dynamically evaluate[] a variety of order characteristics." Not only was Watson's system threshold-based, it also affirmatively allowed customers to avoid violations of

the thresholds by cancelling the order or reducing the order quantity – also violations of the 2007 Rannazzisi letter. Watson's system also allowed orders to be shipped if a Watson employee (including someone from the sales team) provided mere email justification of the order.

349. Like pre-merger Actavis, pre-merger Watson hired Buzzeo to create a new system. The system, however, was never implemented due to the merger. Pre-merger Watson's SOM system remained in place after the merger through 2016, when the sale of the generics business of the now-combined companies to Teva closed.

350. In summary, Actavis maintained one of the largest market shares for prescription opioids nationally and by far the largest market share for Washoe County and used SOM systems that employed improper threshold-based protocols, permitted orders to be modified to fit within the improper thresholds, and reported a grand total of approximately one suspicious order to the DEA

vii. MALLINCKRODT

351. Defendant Mallinckrodt breached its duties under federal and state law. As shown by the Arcos Data, Mallinckrodt sold an extraordinary amount of prescription opioids into the Plaintiff's community. Mallinckrodt's excessive sales were made possible by, and are evidence of, Mallinckrodt's failures to comply with its duties under the CSA and Nevada statutes.

352. Mallinckrodt comprised 42.9% of the market share for manufacturers in Washoe County, and it distributed around 102,039,648 total dosage units from 2006 to 2014 to Washoe County.[133]

353. Mallinckrodt failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's community.

354. Mallinckrodt is one of the largest manufacturers of prescription opioids in the country, with over $18 billion in sales between 1996 and 2017. Mallinckrodt stoked the fires of the opioid epidemic by shipping hundreds of millions of opioid pills with little regard to where

[133] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

they ended up or how they were used. It is, thus, not surprising that during a meeting with Mallinckrodt in 2010, the DEA referred to the Company as "the kingpin within the drug cartel."

355. Typifying Mallinckrodt's attitude toward its duties under the CSA is an email from Victor Borelli, a former Mallinckrodt National Account Manager. In January 2009—a year in which, according to the CDC, over 18,000 people died from opioid overdoses—Mr. Borelli emailed Steve Cochrane, the VP of Sales of wholesale distributor client Keysource Medical to let him know that 1200 bottles of Mallinckrodt oxycodone had been shipped: "Keep'em comin'! Flyin' out of there. It's like people are addicted to these things or something. Oh, wait, people are . ." Mr. Borelli responded: "Just like Doritos, keep eating. We'll make more."[134]

356. Mr. Borelli's crass response is typical of his communications with Mr. Cochrane. The relationship speaks volumes about Mallinckrodt's cavalier attitude about the sale of controlled substances. Indeed, Mr. Borelli worked closely with Mr. Cochrane to help him grow his business, notwithstanding obvious red flags. As was the case with several Mallinckrodt wholesale distributor customers, the DEA eventually suspended Keysource Medical's license to distribute opioids because the company constituted an imminent danger to public health and safety. Mallinckrodt ignored this danger—and sold opioids to Keysource and its other wholesale distributor customers up until the day their licenses were suspended by the DEA.

357. Mallinckrodt did not punish or discipline its sales team for selling opioids recklessly to companies that posed an imminent danger to public health and safety. To the contrary, Mallinckrodt rewarded them with hefty volume-based bonuses. Between 2008 and 2011, Mallinckrodt flooded Florida with more than 500 million oxycodone pills alone, and Mallinckrodt's director of compliance, Karen Harper, admitted that she had direct knowledge that these pills were migrating to other areas of the country. The company also rewarded ever-increasing sales objectives.

[134] See Email between Victor Borelli of Mallinckrodt and Scott Cochrane from Keysource Medical (Mallinckrodt client) dated January 2009; see also Scott Higham, et al., Internal drug company emails show indifference to opioid epidemic, WASHINGTON POST, Jul. 19, 2019, available at https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html.

358. Mallinckrodt's poor documentation practices were an impediment to the company's efforts to establish an effective anti-diversion program. Mallinckrodt used the artifice of "peculiar orders" to avoid reporting suspicious orders to the DEA. Mallinckrodt's SOM program was flawed both in its design and implementation rendering it ineffective to detect suspicious orders.

359. Mallinckrodt did not have a draft written SOM policy until 2008, at the earliest. From 2008 to 2015, Mallinckrodt modified its SOM policies fifteen times, and in 2008, 2011, and 2012, there were three or more revisions per year. Mallinckrodt's approach to its SOM policies and procedures was outside of the norms of good corporate governance and resulted in drafts with gaps and inconsistencies that were used in place of final written standards for years.

360. While these revisions were made to purportedly improve Mallinckrodt's ability to stop suspicious orders, Mallinckrodt simply failed to execute a compliant SOM program. Karen Harper, Mallinckrodt's director of compliance, admitted that revision of the SOM policy was at times a "train wreck." She even admitted that Mallinckrodt released and shipped orders prior to completing due diligence. Moreover, the "due diligence" that Mallinckrodt did conduct was simply to ask the National Account Managers (NAM) to investigate, and whatever reason the NAM provided for the unusual order pattern was accepted and the order shipped. The results of this blind eye towards identifying and stopping suspicious orders were predictably dismal: upon information and belief, from 2003 to 2011, Mallinckrodt shipped a total of 53 million orders, flagged 37,817 as potentially suspicious, and stopped a grand total of 33 orders. This was in the face of skyrocketing sales, including to Florida— a region that was known at the time by Mallinckrodt's own sales managers as the "pill mill capital" of the Country—and Mallinckrodt's direct knowledge that these pills were migrating to other regions of the country.

361. In addition, despite recognizing by at least 2007 that its chargeback data would allow detailed monitoring of its downstream customers—showing the pharmacy name and DEA registration number, the pharmacy address, and the volume of product—Mallinckrodt's compliance department did not consider using chargeback data at all until 2009. The first effort at systematic use of chargeback data occurred in 2010, but the data was not formally incorporated into Mallinckrodt's SOM policies and procedures until January 2011. Meanwhile, Mallinckrodt

continued shipping millions of pills to wholesale distributor customers whose actions screamed diversion.

362. Based on the available evidence it is no surprise that in 2017, Mallinckrodt entered into an agreement with DEA and DOJ. According to the DEA, Mallinckrodt failed to:

a. Conduct adequate due diligence of its customers;

b. Detect and report to the DEA orders of unusual size and frequency;

c. Use "chargeback" information from its distributors to evaluate suspicious orders; and

d. Take effective action to prevent recurrences of diversion by downstream customers despite receiving concrete information of diversion by those customers.

363. As part of this agreement, Mallinckrodt conceded that "at certain times [between January 1, 2008 and January 1, 2012], certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters" from the DEA in 2006 and 2007.[135]

364. Mallinckrodt's conduct is all the more egregious considering that for decades Mallinckrodt has been the leading manufacturer of methadone, which has been used to treat addiction since the 1960s. By the 1990s Mallinckrodt supplied, either directly or indirectly, 80 to 90 percent of all methadone used in drug treatment clinics in the U.S. Promoting its expertise gained from decades in the addiction treatment business, Mallinckrodt offered continuing education programs on the history and science of addiction, teaching that opioid drugs fit receptors in the brain like keys in locks, that opioids "hijack" the brain, and that as a result of the changes in brain structure and function, treatment (including medication like methadone) may be required for a lifetime. Mallinckrodt clearly knew the harm its products were capable of causing. It just didn't care.

365. 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

[135] See 2017 Mallinckrodt Memorandum of Agreement ("MOA"), at 4.

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."[136]

H. Duty of Drug Distributors as Gate Keepers

366. In Nevada, opioids are a controlled substance and are categorized as "dangerous drugs." Therefore, Defendant Distributors have a duty to exercise reasonable care under the circumstances. Defendants Distributors had a duty to exercise reasonable care in distributing dangerous narcotic substances. Defendant Pharmacies further had a duty to exercise reasonable care in supervising the sale of such drugs. By flooding Nevada, Washoe County, and the City of Reno with opioids and failing to effectively prevent diversion, including failing to monitor for red flags, Defendant Distributors and Defendant Pharmacies breached their duties. By filling and failing to report or halt orders that they knew or should have realized were likely being diverted for illicit uses, Defendant Distributors further breached their duties. These breaches both created and failed to prevent a foreseeable risk of harm to the Plaintiff and the Plaintiff's Community

367. Pursuant to NAC 453.400, Distributor Defendants must establish and maintain effective controls and procedures to prevent or guard against theft and misuse of controlled substances. They are also bound to federal duties to register as manufacturers, distributors, or dispensers pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11. Distributor Defendants have violated their duties arising under state and federal law.

368. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct-and thereafter realizes or should realize that such conduct

[136] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay record-150- million-settlement-failure-report-suspicious-orders.

has created an unreasonable risk of harm to another-is under a duty to exercise reasonable care to prevent the threatened harm.

369. All opioid distributors are required and have a duty to maintain effective controls against opioid diversion. They are also required and have a duty to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency.

370. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

371. Defendant Distributors each have an affirmative duty to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs.

372. Defendant Distributors each have a non-delegable duty to identify and track suspicious orders of controlled substances.

373. In addition, Defendant Distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.

374. Defendant Distributors have a duty to detect questionable and suspicious orders to prevent the diversion of opioids into Reno, which include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency.

375. Defendant Distributors not only have a duty to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.

376. In so doing, this is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

377. When speaking publicly about opioids and their efforts and commitment to combat diversion of prescription opioids, each of the Defendant Distributors and Defendant Pharmacies assumed a duty to speak accurately and truthfully. They have violated this duty as well.

378. Notwithstanding these duties and obligations, the DEA has been required to take administrative action against Defendant Distributors to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[137] Some of these actions include the following:

(a) On April 24, 2007, the DEA issued *an Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

(b) On November 28, 2007, the DEA issued an *Order to Show Cause and 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;"

[137] The Drug Enforcement Administration's Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, 1-2014-003 (May 2014).

(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; Valencia, California; and Denver, Colorado;

(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 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 against its Lakeland, Florida Distribution Center;

(j) On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA; and

(k) On July 11, 2017, Mallinckrodt agreed to pay the DEA $35 million to settle allegations for the company's failure to report suspicious orders of opioids and allegations of faulty record keeping. The investigation originally began in 2011 and federal investigators reportedly found 44,000 violations potentially exposing Mallinckrodt to $2.3 billion in fines.

379. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between Defendant McKesson and the DEA in January 2017, McKesson admitted that it breached its duties to monitor, report, and prevent suspicious orders and that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017), it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[138] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should

[138] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[139] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers."

380. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[140] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[141] Investigators found certain warehouses "were supplying pharmacies that sold to criminal drug rings."[142]

381. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[143]

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[139] *Id.*

[140] Lenny Bernstein and Scott Higham, "'We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017).

[141] *Id.*

[142] *Id.*

[143] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay record-150- million-settlement-failure-report-suspicious-orders.

382. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],'" as a DEA official working on the case noted.[144] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[145] 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 frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[146] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[147]

383. Further, in a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendant Distributors' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die."[148] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[149]

384. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[150] He further explained that "I can tell you with 100

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[144] Lenny Bernstein and Scott Higham, "'We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017), https://www.washingtonpost.com/investigations/mckesson-dea-opioids-fine/2017/12/14/ab50ad0e-db5b-11e7-b1a8- 62589434a581_story.html?utm_term=.d6e92f349f47.

[145] *Id.* (quoting a March 30, 2015 DEA memo).

[146] *Id.*

[147] *Id.*

[148] Bill Whitaker, Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress.

[149] *Id.*

[150] *Id.*

percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[151]

385. The Distributor Defendants were not alone in failing to live up to their reporting obligations. As discussed above, Mallinckrodt recently paid a $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[152] In addition, Mallinckrodt 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."[153]

386. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[154]

387. Among the allegations resolved by the settlement, the government alleged "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

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[151] *Id.*

[152] See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspiciousorders.

[153] 2017 Mallinckrodt MOA, https://www.justice.gov/usao-edmi/press-release/file/986026/download.

[154] See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspiciousorders.

U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[155]

388. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer including its failure to: conduct adequate customer due diligence, detect and report orders of an unusual size or frequency, detect and report orders that deviated substantially from normal patterns (e.g., disproportionate amount of opioids going to a geographic region of known diversion, disproportionate amount of opioids as compared to other products, orders from customers known to be purchasing from multiple distributors), using "chargeback" information to evaluate suspicious orders, and taking sufficient action to prevent recurring diversion after receiving concrete evidence of diversion.[156]

389. Mallinckrodt acknowledged that at certain times prior to January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letter from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[157] Mallinckrodt also agreed that, from its chargeback data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[158]

390. Because Defendant Distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on these distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.

391. The sheer volume of prescription opioids distributed to pharmacies in Reno is excessive for the medical need of the community and facially suspicious. Some red flags are so

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[155] *Id.*

[156] 2017 Mallinckrodt MOA, https://www.justice.gov/usao-edmi/press-release/file/986026/download, at 2-3.

[157] *Id.* at 3-4.

[158] *Id.* at 5.

obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.

392. Over the course of a decade, Defendant Distributors failed to detect suspicious orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Reno.

393. Defendants ignored the law, paid the fines, and continued to unlawfully fill suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Reno, and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into Reno.

I. Defendant Distributors Disregarded Their Duties to Maintain Effective Controls Against Diversion

394. The Defendant Distributors facilitated the supply of far more opioids that could have been justified to serve the legal and appropriate market. The failure of the Defendant Distributors to maintain effective controls, and of the Defendant Distributors to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, breached both their statutory and common law duties.

395. For over a decade, the Defendant Distributors aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendant Distributors are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendant Distributors are subject to various duties to prevent oversupply and diversion into the illicit market.

396. As facilitated and caused by Defendant Distributors' actions, opioids as a class of prescription drugs have skyrocketed. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015 nationally. The Department of Health and Human Services Estimates that, on an average day, more than 650,000 opioid prescriptions are dispensed in the U.S.

ARCOS/DADS DATA

397. The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[159] system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.[160]

398. All manufacturers and distributors of prescription opiates are required under federal law to report each transaction to a national database, the ARCOS/DADS database.[161] This database can be used, along with other information, to identify unlawful sales of prescription opiates to every pill mill in America. However, the data has been concealed behind a curtain of "trade secret" until recently.

399. ARCOS/DADS data has become public knowledge from 2006 to 2014 and reveals that the top three drug wholesalers sold Washoe County pharmacies over 154 million total dosage units during that time frame. The data does not disclose the distributions per pharmacy nor the monthly shipments. Specifically, the data reveals as follows the following about sales of opioids into Washoe County over an eight-year period:

Company Name	Market Share	Total Dosage Units	2006	2007	2008	2009	2010	2011	2012	2013	2014
Amerisource Bergen Drug	27.90%	66,422,004	5,823,417	8,322,917	9,799,112	10,014,375	10,052,990	8,868,332	5,507,825	3,661,031	4,372,005
McKesson Corporation	23.82%	56,706,808	5,222,038	4,891,963	5,072,607	5,554,501	6,068,298	6,156,645	6,191,293	8,053,497	9,495,966
Cardinal Health	13.29%	31,646,412	2,000,978	2,196,573	1,791,668	2,212,133	2,133,443	3,104,168	5,405,929	5,771,877	7,029,643

[159] ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. See United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), Background: What is ARCOS and What Does it Do?, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017).

[160] 21 U.S.C. 826(d).

[161] 69 FR 51104-02.

400. ARCOS software enables the Drug Enforcement Administration ("DEA") to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.[162]

401. The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances. Pursuant to 69 FR 51104-02, all automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is located at DEA, 700 Army Navy Drive, Arlington, VA 22202.

402. The ARCOS/DADS system has access to all of the data submitted by each DEA registrant from the across the country.[163] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.[164] Additionally, the DEA provides internet access to summary data from this system.

403. Ironically, many distributors have complained to Congress and the federal courts that the DEA does not permit registrants to gain access to competitor data from ARCOS for purposes of ensuring a customer is not purchasing controlled substances from multiple suppliers.

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[162] See ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, ARCOS Defined (Version 1.0 August 1997).

[163] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. Keysource Med., Inc. v. Holder, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

[164] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html.

Yet, these same distributors sell their data through "chargebacks" to manufacturers. So too could they voluntarily share data with each other or, simply, consent to disclosure.[165]

404. Each registrant has full visibility of its own controlled substance transactions, often down to the pharmacy, physician, and patient level. The ARCOS data reveals the extraordinary and escalating amounts of prescription opioids being sold into Nevada and nationwide. Such excessive distribution was not supported by medical need or population growth and would not have happened, but for the Defendants' failures to fulfill their legal duties.

Duty to Detect, Report, and Halt Suspicious Orders

405. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. 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.

406. All registrants – which includes all manufacturers, distributors, and dispensers of controlled substances – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

407. The DEA has repeatedly, unequivocally emphasized: 1) that the purpose of the Controlled Substances Act and its federal regulations is to prevent diversion; 2) that diversion is foreseeable if registrants fail to comply with federal law; 3) that failure to comply with federal

[165] 28 CFR § 16.7(e) (2015).

law enables more diversion; 4) that the unlawful entry of more pills int o the market results in more diversion; and 5) that diversion is detrimental to public health and safety.

408. The Defendant Distributors' legal duties with respect to controlled substances are set out under federal statutes, federal regulations, Nevada state law (incorporating relevant federal law), and DEA guidance. These laws and regulations establish a common law duty with which Defendants must comply.

409. Defendant Distributors owe a duty to maintain effective controls and procedures against the diversion of prescription opiates into the illicit market.[166] The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution and dispensing of controlled substances.[167]

410. The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[168]

411. The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[169] Any entity that seeks to become involved

[166] 21 U.S.C.A. § 823(b)(1); 21 U.S.C. § 802(10); 21 U.S.C. § 822(a)(2)); and 21 C.F.R. § 1301.71.
[167] See 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009).
[168] Gonzales v. Raich, 545 U.S. 1, 12–14 (2005) (internal citations omitted).
[169] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); see 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

in the production or chain of distribution of controlled substances must first register with the DEA.[170]

412. The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.[171]

413. Part of the process to providing effective controls against the theft and diversion of controlled substances is by developing and implementing a system to identify and report suspicious prescriptions based on known red flags, such as pattern prescriptions: the same types of drugs in the same quantities from the same prescriber.[172]

414. Supply Chain Defendants must also "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[173] This nonexclusive definition of "suspicious order" has been codified in the CSA.[174] Other red flags indicating suspicion may include, for example, "[o]rdering the same controlled substance from multiple distributors."[175]

415. The criteria for identifying suspicious orders are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern,

[170] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.
[171] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).
[172] See, e.g., Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision and Order, 77 FR 62316-01 (Oct. 12, 2012) (noting that certain red flags, such as "the red flags presented by the circumstances of patients travelling from Kentucky or Tennessee to South Florida to obtain prescriptions, including for a schedule II narcotic, which by definition has the highest potential for abuse of any drug that may be prescribed lawfully, see 21 U.S.C. 812(b)(2), and then travelling to Respondents to fill them, are so obvious that only those who are deliberately ignorant would fill these prescriptions.").
[173] 21 C.F.R. § 1301.74(b) (1971).
[174] 21 U.S.C. § 802. Definitions, 21 USCA § 802.
[175] 21 C.F.R. § 1301.74(b) (1971).

is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region, including into Washoe County and the City of Reno.

416. The regulatory duty can be broken down in the following subparts: a security requirement to identify the suspicious order, a reporting requirement to the DEA, and a shipping requirement—to prevent the order from shipment until the distributor is able to determine that the order is not likely to be diverted into illegal channels.[176]

417. Of course, a registrant's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order nonsuspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed."[177] Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence."[178]

418. The DEA has repeatedly reminded the Defendant Distributors of their regulatory obligations. For example, in 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 by educating them on their duties to report and decline to fill suspicious orders. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Upon information and belief, many of the

[176] Masters Pharm., Inc. v. Drug Enf't Admin., 861 F.3d 206, 212–13 (D.C. Cir. 2017).
[177] Masters Pharmaceuticals, Inc., Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).
[178] Masters Pharmaceuticals, 861 F.3d at 212. "The Decision and Order was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In Masters Pharmaceutical, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the Decision and Order."

Manufacturer Defendants and the majority of the Distributor Defendants, if not all of them, 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.

419. The DEA sent another letter to all entities registered to distribute or manufacture controlled substances 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." 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). The letter explains that the Defendants had an independent duty to analyze whether controlled substances are likely to be diverted from legitimate channels and reporting an order as suspicious does not absolve that registrant of responsibility. 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."

420. The DEA has emphasized that manufacturers also have a duty to report suspicious orders, as plainly stated in the statutes and regulations. This duty was recently reaffirmed when, in 2017, Mallinckrodt was fined $35 million for failing to report suspicious orders of controlled substances and for violating recordkeeping requirements. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances" and noted that "[m]anufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands."[179]

[179] Drug Enforcement Administration Press Release, Mallinckrodt Agrees to Pay $35 Million Settlement, July 11, 2017.

421. In addition to the duties of Defendant Distributors clear from a review of applicable federal laws and regulations, the Defendant Distributors and Defendant Pharmacies have duties, previously identified, under Nevada state law.

Defendant Distributors' Duty to Apply Specialized Knowledge to Prevent Diversion

422. As set forth above, Defendant Distributors have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must design and operate a system that detects and stops suspicious transactions by, among other things, reviewing and analyzing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Further, with regard to Defendant Distributors, all suspicious orders must be reported to relevant enforcement authorities and shipment of any order which is flagged as suspicious must be stopped. Defendant Distributors can only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

423. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent registrants would not fall. Together, these laws and industry guidelines make clear that all Defendant Distributors possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled

424. Further, these laws and industry guidelines make clear that the Defendant Distributors have a duty and responsibility to exercise the specialized and sophisticated knowledge, information, skill, and understanding they possess by virtue of their role in the supply chain to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

425. For example, both because distributors handle such large volumes of controlled substances, and because they are "uniquely positioned," based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, a 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.

426. The Federal Trade Commission has recognized the unique role of distributors. Since their inception, distributors have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, distributors also offer their pharmacy, or dispensing, customers a broad range of added services. For example, distributors offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributors are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.[180] As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, distributors have a unique insight into the ordering patterns and activities of their dispensing customers.

427. Manufacturers also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from the data they purchase from commercial sources, such as IMS Health (now IQVIA). Their extensive boots-on-the-ground through their sales force, allows Manufacturer Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in this Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants regularly mine data, including, upon information and belief, chargeback data, that allows them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusually high dose prescribing, that would have alerted them, independent of their sales representatives, to suspicious prescribing. Manufacturers also have access to significant data through their procurement of "chargeback data," as discussed further herein. These information points give

[180] See Fed. Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anticompetitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.).

Manufacturer Defendants insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

428. In connection with its recent 2017 settlement with the DEA, Mallinckrodt 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."[181]

429. Moreover, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from the direct customer sales of controlled substances to 'downstream' registrants."[182] This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well. The practice of obtaining "chargeback" data should have enabled Mallinckrodt not only to see red flags in the orders it filled itself as a wholesaler, but also additional red flags from the added data it received from its distributor customers.

430. As part of the settlement, Mallinckrodt agreed that it could and would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[183]

Defendants Knew of Obligation to Prevent, Report, and Halt Suspicious Orders

431. The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Defendant Distributors were well aware they had an important role

[181] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 4 (July 10, 2017), available at https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").
[182] *Id.* at 5.
[183] *Id.*

to play in this system, and they also knew or should have known that their failure to comply with their obligations would have serious consequences.

432. Trade organizations to which the Defendant Distributors belong have acknowledged the importance of maintaining systems to prevent diversion, including, with respect to Defendant Distributors, systems to identify, halt, and report suspicious orders.[184] The Healthcare Distribution Alliance ("HDA") [185] a trade association of pharmaceutical distributors that also includes affiliate manufacturer members, as well as the National Association of Chain Drug Stores ("NACDS")[186], have both long taken the position that these Defendants have 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."

433. As previously discussed, the DEA has repeatedly reminded the Defendant Distributors of their obligations to report and decline to fill suspicious orders.

434. Upon information and belief, Defendant Distributors, like McKesson, have internal documents that describe the closed system of distribution designed to create checks and balances between registered entities to protect public health and safety. Upon information and belief, Defendant Distributors had presentations that highlighted the importance of having a system that actually worked to prevent diversion.

435. 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 (some, but not all, relevant information has been made public). The data necessary to identify with specificity

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[184] See Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration, 2012 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) (stating that regulations "in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA . . .") (emphasis omitted)

[185] From 2001 to 2016, the HDA was known as the Healthcare Distribution Management Association ("HDMA"). Prior to 2001, HDMA was named the National Wholesale Druggists' Association ("NWDA").

[186] NACDS is a trade organization whose members include "over 80 chain member companies," including regional chains with a minimum of four stores and national companies. NACDS members also include more than 900 supplier partners. NACDS's current Board includes Walgreens, CVS, Rite Aid, and Kroger. See National Association of Chain Drug Stores, "Leadership," available at https://www.nacds.org/.

the transactions that were suspicious is in possession of the Defendant Distributors but has not been fully disclosed to the public

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

437. This information includes the following facts:

a. 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;

b. Manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. 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 above;

d. Defendant Distributors, 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

e. 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.

438. The conclusion that the Defendant Distributors 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 wider market for chronic pain. At all relevant times, these 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").

439. The Defendant Distributors 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.[187] The "know your customer" questionnaires informed the Defendant Distributors 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 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.

440. 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.[188] IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[189]

[187] Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances, Drug Enforcement Admin. Diversion Control 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/newsresources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[188] 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).

[189] 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.

441. 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.[190] **T**his 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.[191]

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

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

443. Moreover, Manufacturer Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson

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

[191] 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).

was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."

444. Defendants' obligation 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.

445. Upon information and belief, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers to meet and exceed their quota. They further explained that all of the quota could be achieved by one high volume physician initiating Kadian for two or three new patients each week.

446. Similarly, Teva directed its sales representatives to make a minimum number of Fentora calls each day and focus on the high prescribers so that they could maintain and grow their business. Upon information and belief, Cephalon ensured that the majority of their highest volume prescribers were detailed at least five times every ten months.

447. The focus on marketing to the highest prescribers has two obvious implications: it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids and it demonstrates that instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

448. Defendant Manufacturers were not the only drug companies engaged in marketing and interested in driving up sales of opioids. Defendant Distributors entered into marketing agreements with Defendant Manufacturers in which Defendant Distributors agreed to utilize Defendant Manufacturers' materials to market Defendant Manufacturers' products to Defendant Distributors' customers. Together, Defendants developed a strategy to increase opioid sales throughout the country, including in the City of Reno, regardless of the danger to public health.

449. Whenever examples of opioid diversion and abuse have drawn media attention, 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."

450. 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.

451. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

452. 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.

Defendants Breached Their Duty to Prevent Diversion

453. Defendant Distributors failed to prevent diversion, or otherwise control the supply of opioids following into communities across the United States, including in Washoe County and the City of Reno, Nevada. Defendant Distributors further failed to report and halt shipment of suspicious orders. Despite the notice described above, and in disregard of their duties, Defendant

Distributors and Defendant Pharmacies continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders. Governmental agencies and regulators have confirmed (and in some cases these Defendants have admitted) that Defendant Distributors did not meet their obligations and have uncovered especially blatant wrongdoing.

454. Defendant Distributors breached their above-stated duties under federal and state law by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids; and/or (e) perform due diligence on orders which Supply Chain Defendants had reason to believe were suspicious, and instead shipping those orders without review.

i. AMERISOURCE BERGEN

455. Defendant AmerisourceBergen breached its duties under federal and state law. As shown by the ARCOS Data, AmerisourceBergen distributed an extraordinary amount of prescription opioids into Plaintiff's community. AmerisourceBergen's excessive distribution was made possible by, and is evidence of, AmerisourceBergen's failures to comply with its duties under state and federal law, including the CSA and applicable Nevada statutes.

456. AmerisourceBergen comprised 27.9% of the market share for distributors in Washoe County, and it distributed around 66,422,004 total dosage units from 2006 to 2014 to Washoe County.[192]

457. AmerisourceBergen failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's Community

458. AmerisourceBergen's breaches of its duties have persisted for many years, dating back to before 2007, when the DEA shut down one of AmerisourceBergen's distribution centers as part of an enforcement action. As of 2007, AmerisourceBergen's suspicious order monitoring

[192] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

system wholly failed the security requirement set forth in 21 C.F.R. § 1301.74(b). Specifically, AmerisourceBergen's pre-2007 policies constituted a failure to design and operate a system to identify suspicious orders because they only identified "excessive" orders that exceeded a three times threshold, which only took into consideration prior orders of that specific pharmacy. AmerisourceBergen's system did not take into consideration other relevant factors such as order frequency patterns, order averages of similar pharmacies, or comparisons of sales of Schedule II or III controlled substances with the sales of other controlled substances. AmerisourceBergen's also specifically failed to identify suspicious orders from internet pharmacies that the DEA concluded should have been identified.

459. AmerisourceBergen further violated the Reporting Requirement, violated the No-Shipping Requirement, and failed to perform meaningful due diligence. Pre-2007, while certain orders that exceeded the three times threshold were reported to the DEA, they were only reported *after* being shipped. AmerisourceBergen had no meaningful due diligence process in place to investigate whether "excessive" orders otherwise qualified as suspicious, other than an effort to make sure a customer was licensed with the state and registered with the DEA. AmerisourceBergen's official national policy from 1990 up until the DEA Settlement 2007, was to ship *all* orders of controlled substances, regardless of size, frequency, deviations from prior orders, deviations from averages, deviations from defined thresholds, or whether that order was determined to be suspicious.

460. Upon information and belief, the 2007 enforcement action by the DEA was based on AmerisourceBergen filling and shipping orders from pharmacies, which according to the DEA, AmerisourceBergen knew to be suspicious. The enforcement action shut down AmerisourceBergen's Orlando distribution center. On June 22, 2007, AmerisourceBergen and the DEA reached a settlement agreement in which AmerisourceBergen acknowledged it had failed to maintain effective controls at the Orlando Facility against diversion of certain controlled substances into illegitimate channels by sales to certain customers. According to the April 19, 2007, Order to Show Cause and Immediate Suspension of Registration issued by the DEA, AmerisourceBergen distributed hydrocodone to pharmacies in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers, distributed hydrocodone

to pharmacies even though they ordered small amounts of other drug products relative to those purchases, distributed hydrocodone to pharmacies much more frequently than AmerisourceBergen's other customers, and shipping to pharmacies that AmerisourceBergen knew or should have known many prescriptions were issued by physicians who did not conduct a medical examination of its customers, and instead wrote prescriptions for controlled substances ordered by customers over the internet.

461. The problems with AmerisourceBergen's suspicious monitoring policies and procedures, or lack thereof, were systemic and nation-wide leading to the implementation of new policies and procedures.

462. Even after AmerisourceBergen implemented program changes like adding a more in-depth due diligence process and requiring stop-shipment on suspicious orders, AmerisourceBergen still did not meet its obligations under state and federal law.

463. Post-2007, AmerisourceBergen still failed to design and operate an adequate system to identify suspicious orders because it continued to employ a "threshold-based system," which was based on an arbitrary three times multiplier among drug families and, which continued to ignore other relevant information. AmerisourceBergen also left critical discretion to identify suspicious orders with its distribution center employees, without putting in place any concrete rules or criteria on how suspicious orders should be identified. Accordingly, AmerisourceBergen failed to identify and grossly underreported suspicious orders.

464. Further, while AmerisourceBergen purported to change its system in 2007 pursuant to its settlement agreement with the DEA, it still did not fully comply with the No Shipping Requirement after that date. In certain cases, even orders reported to the DEA were shipped anyway, rather than being held or cancelled.

465. An Audit Report performed of AmerisourceBergen's SOM system in 2015 cited numerous problems with AmerisourceBergen's SOM system, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs, which contributed to "gaps and risks" in AmerisourceBergen's ability to identify orders as suspicious and prevent diversion.

466. AmerisourceBergen's efforts of due diligence in identifying suspicious orders at this time also fell well short of effective. Specifically, AmerisourceBergen's "Know Your Customer" due diligence policy was based on a form filled out by AmerisourceBergen's own sales representatives in conjunction with AmerisourceBergen's pharmacy customers, creating a conflict of interest in identifying accurate information. As AmerisourceBergen acknowledged internally regarding its targeted pharmacy visits, its true goal was always to maintain ABC customers. Additionally, AmerisourceBergen's chain retail pharmacy customers were exempt from the requirement to provide certain information, which improperly abdicated AmerisourceBergen's duty to identify suspicious orders to the customers themselves. Further, AmerisourceBergen's due diligence program itself was inconsistently implemented, leaving a lack of current and historical documentation of due diligence efforts that renders a robust, effective due diligence system impossible. Internally, AmerisourceBergen admitted to having an average of about 10% of the required customer due diligence documents, acknowledging that such a failure put AmerisourceBergen at risk with regulators.

467. Rather than focusing on putting effective controls to prevent diversion in place and designing and operating a system to detect suspicious orders and stopping those orders, AmerisourceBergen circumvented the requirements and coached customers on how to avoid being detected by the system and being the subject of an enforcement action by the DEA. Upon information and belief, a July 2013 AmerisourceBergen document entitled "Sales Talking Points" warned an AmerisourceBergen customer that it had a high volume and percentage of C2 orders that might be flagged as suspicious by either AmerisourceBergen's system or regulators. The goal was to prevent any AmerisourceBergen customer from being investigated or regulated. AmerisourceBergen then counseled the customer not to order fewer controlled substances, but to strategically format their ordering patterns so that they would not get flagged by SOMs programs or regulators.

468. AmerisourceBergen knew the consequence of failing to meet its obligations under the CSA. Upon information and belief, AmerisourceBergen's chief compliance officer admitted that if AmerisourceBergen did not adhere to the SOM system, diversion would occur. As discussed above, however, the evidence shows that AmerisourceBergen consistently ignored

critical red flags and warning signs from its customers in what amounts to a structural break-down of its diversion prevention obligations under state and federal law, which had real consequences in the communities where AmerisourceBergen shipped dangerous drugs, like prescription opioids, including in Plaintiff's community.

ii. CARDINAL

469. Defendant Cardinal breached its duties under federal and state law. As shown by the ARCOS Data, Cardinal distributed an extraordinary amount of prescription opioids into Plaintiff's community. Cardinal's excessive distribution was made possible by, and is evidence of, Cardinal's failures to comply with its duties under state and federal law, including the CSA and applicable Nevada statutes.

470. Cardinal comprised 13.3% of the market share for distributors in Washoe County, and it distributed around 31,646,412 total dosage units from 2006 to 2014 to Washoe County.[193]

471. Cardinal failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's Community.

472. Cardinal's greed caused it to ignore its obligations to protect against diversion, distributing billions of opioid pills without anything resembling an adequate suspicious order monitoring system until at least 2008. To the extent Cardinal's suspicious order monitoring program has improved, it has done so only as a result of the investigations and fines levied by the DEA and state attorneys general, in spite of having nearly unlimited resources and knowledge at its fingertips.

473. Cardinal's attempts at compliance with the Controlled Substances Act is historically reactionary; modifications and changes to Cardinal's suspicious order monitoring and reporting systems over the last two decades came only as a result of the governmental investigations, fines levied by the DEA and state attorneys general, and Congressional Hearings.

[193] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

Despite being one of the largest corporations in the United States, Cardinal failed to implement a system that would comply with the Controlled Substances Act.

474. As a DEA registrant and wholesale distributor, Cardinal was required by Congress to maintain effective control against diversion of prescription opiates and required by the DEA to identify, block and report suspicious orders from pharmacies. Cardinal blatantly failed in each regard resulting in the widespread diversion of prescription opioids.

475. From 1996 to 2008, Cardinal did not have an anti-diversion program that could adequately monitor and detect suspicious orders of opioids or timely report any suspicious orders.

476. Upon information and belief, Cardinal adopted a DEA Compliance Manual as early as April 4, 2000, which contained a corporate policy on suspicious order reporting. The policy provided for after-the-fact reporting and a cage vault rule placing a cap on individual sales. The policy was in effect at least through June 15, 2006.

477. Upon information and belief, Cardinal's policies and procedures required them to identify suspicious orders prior to shipment via each distribution center's cage/vault personnel responsible for physically picking customers' orders from warehouse shelves for packaging and checking the contents of the package to ensure the order was filled correctly. Upon information and belief, these "pickers and checkers" were responsible for policing individual orders that appeared excessive in relation to other customers' ordering patterns or that customer's order history. Cardinal developed and posted in the distribution centers' cage/vault areas a guide for pickers and checkers to use to identify suspicious orders.

478. Cardinal implemented daily limits that the pickers and checkers were to use for identifying suspicious orders. Schedules of these limits were implemented across the entire United States in the late 1990's. The charts identify daily limits for multiple drugs including several categories of opioids for Cardinal customers.

479. Upon information and belief, any orders exceeding these limits should have been stopped, reported to the DEA, and due diligence should have been conducted and documented to dispel suspicion of diversion before the order was allowed to ship. Upon information and belief, this was never done for orders going to Plaintiff's community.

480. The warehouse employees at each distribution center had the task of monitoring the millions of orders received each month by Cardinal, comparing those orders to the Dosage Limit Chart, and reporting any excessive orders to the DEA. Cardinal documents show that in a single month in 2009, for example, Cardinal shipped more than 146 million dosage units of fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone dosage units across United States. This procedure simply was not followed at Cardinal to any meaningful degree.

481. From at least 1996 to 2008 Cardinal's other method for reporting suspicious orders was through the submission of Ingredient Limit Reports (ILR) to the DEA. These were retrospective monthly summaries for the prior month related to all controlled substances including opioids. These reports showed which orders of controlled substances Cardinal received that exceeded a pre-determined average that had been multiplied by 4. Cardinal's submission of ILRs did not satisfy its obligation to report suspicious orders under 21 C.F.R. 1301.74(b) as they were only submitted after the orders had already shipped. Cardinal knew the reports did not satisfy Cardinal's suspicious order reporting obligations because both the DEA and the National Wholesale Druggists Association – predecessor of the Healthcare Distribution Alliance – had made it clear as early as 1984 that they did not. In an April 27, 1984, letter to NWDA Vice President of Government Affairs, Ronald Streck, Acting Chief of the Diversion Operations Section of the DEA, G. Thomas Gitchell, advised Streck that a post-shipment print out of sales data does not relieve a registrant's responsibility to report excessive or suspicious orders when discovered. The NWDA's Suspicious Order Monitoring System guidelines, issued to all its members including Cardinal in June of 1993, re-states the DEA's position. In other words, it was Cardinal's policy to ship orders it knew were suspicious without conducting any due diligence or investigation. Further, the ILR system failed because it did not account for orders of unusual frequency or orders deviating from a normal pattern. Upon information and belief, despite having around 30,000 employees, Cardinal had only 3 employees that were responsible for reviewing Ingredient Limit Reports, and even according to Cardinal employees, three individuals was insufficient to review all Ingredient Limit Reports.

482. Despite Cardinal's awareness that after-the-fact shipment print outs of sales data were insufficient to comply with diversion requirements, Cardinal continued to report suspicious orders after the fact. Additionally, Cardinal was on notice that shipping a suspicious order, rather than blocking the order, was irresponsible and a failure to comply with its duty to prevent diversion. Yet, Cardinal continued to ship suspicious orders.

483. Cardinal met with the DEA on August 22, 2005, as part of a DEA Distributor Initiative. Cardinal was reminded to report suspicious orders upon discovery and that reporting a suspicious order does not relieve the distributor of the responsibility to maintain effective controls against diversion. Regardless, Cardinal continued to ship suspicious orders and report after-the fact.

484. In 2007 the DEA initiated a prosecution of multiple Cardinal distribution centers due to their failure to operate an adequate suspicious order monitoring systems (SOMS) and violations of the CSA. The DEA found that Cardinal Health failed to "maintain adequate controls against the diversion of controlled substances on or prior to September 30, 2008, at all distribution facilities" operated, owned, or controlled by Cardinal Health in the United States. This encompassed all 27 of Cardinal's distribution facilities.

485. Cardinal knew its suspicious order monitoring system (SOMS) was defective. In the face of sanctions from the DEA, Cardinal commissioned Cegedim Dendrite to perform an investigation into its suspicious order monitoring system (SOMS). Upon information and belief, a report from January 23, 2008, found that Cardinal Health's SOMS was not compliant with federal law and made several recommendations. Cardinal did not timely implement many of the recommendations.

486. Upon information and belief, in 2008, for the first time, Cardinal implemented a written policy to stop shipment of orders suspected of diversion. The policy was implemented more than a year following the receipt of Joseph Rannazzisi's September 27, 2006, letter reminding Cardinal of its obligation to stop shipments of suspicious orders. As Cardinal has recognized, suspicious orders must not be shipped without first conducting due diligence to dispel the suspicion of diversion. Yet even prior to 2012, Cardinal's approach to reporting suspicious

orders was only to report customers with orders suspicious enough to warrant Cardinal terminating the customer as an unreasonable risk for diversion.

487. Cardinal entered into an Administrative Memorandum of Agreement, following the DEA's issuance of immediate suspension orders or orders to show cause ("ISO" or "OSC") on Cardinal distribution centers in Washington, Florida, New Jersey, and Texas.[194] Cardinal distributed massive amounts of opioids to pharmacies across the country that Cardinal knew or should have known were diverting opioids. The DEA found that Cardinal failed to maintain effective controls to detect and prevent diversion of controlled substances at each distribution center.

488. Some examples of the conduct which the DEA found to be systemic across the United States includes:

a. The DEA found that Cardinal's Auburn, Washington distribution center distributed in excess of 600,000 dosage units of hydrocodone over seven months to its largest customer, Horen's Drugstore, which was a "rogue drugstore" filling illegitimate prescriptions from internet pharmacies.[195]

b. Cardinal Health's Lakeland, Florida distribution center was found to have distributed over 8,000,000 dosage units of combination hydrocodone products to pharmacies Cardinal knew or should have known were diverting opioids.[196] At that time, retail pharmacies in Florida averaged less than 8,400 dosage units per month.[197] Cardinal shipped many, many times that average to Florida pharmacies it knew or should have known were diverting opioids.

c. The DEA found that Cardinal's Swedesboro, New Jersey distribution center had distributed 4.5 million dosage units of hydrocodone products to customers it new or should have known were diverting the drug.[198]

d. Finally, the DEA found that Cardinal's Stafford, Texas distribution center distributed almost 21 million dosage units of hydrocodone to retail pharmacy customers "under circumstances that clearly indicated that the pharmacies were

[194] See DOJ Press Release, Cardinal health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act, Dec. 23, 2016, available at https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.
[195] In re: National Prescription Opiate Litigation, Exhibit 215 at CAH_MDL_PRIORPROD_DEA12_00013071-00013072, available at https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Exhibit-215-S-r-and-MOA/ohnd-1:2017-md-02804-01964-003.
[196] *Id.* at 00013075.
[197] *Id.* at 00013076.
[198] *Id.* at 00013080.

> engaged in the widespread diversion of controlled substances," frequently distributed hydrocodone in excess of 800 dosage units per day without reporting these incidents to the DEA or conducting any investigation, which violated Cardinal's own policy.[199]

489. Cardinal paid millions to the U.S. government to resolve the investigation and was also required to implement a suspicious order monitoring program wherein it would determine whether a suspicious order should either not be filled and reported to the DEA or based on a detailed review the order is for a legitimate purpose and not likely to be diverted – obligations with which Cardinal did not comply.

490. Upon information and belief, in light of the DEA crackdown in 2007, Cardinal hired Deloitte to create a threshold system, which set thresholds for each base code for each customer based on 1) the customer's designation as small, medium, or large (based on the customer's sales), 2) the average orders for the prior year of all customers in that size designation, and 3) multiplied by a factor of three. Deloitte's calculation of initial thresholds was based on the previous twelve months' worth of ordering data. These numbers were significantly inflated due to the fact the United States was in the middle of a deadly opioid epidemic. Almost immediately Cardinal began increasing thresholds far and above the levels established by Deloitte. Cardinal took no steps to consider the opioid epidemic when setting or increasing these thresholds.

491. Due in part to Cardinal's history of failing to monitor, detect, and report suspicious orders, average distribution of opioids had increased dramatically across the country over the previous decade. Cardinal calculated the thresholds amid the opioid epidemic, benefiting from an artificially high average upon which to base its calculations. These thresholds, which would become the centerpiece of Cardinal's anti-diversion program going forward, were premised on faulty reasoning.

492. Under Cardinal's threshold system after 2008, if a customer ordered more than its established threshold in any given month, Cardinal would be notified, the order would be held, and a due diligence review of the customer's profile and order history was triggered. If an order tripped a pharmacy's threshold, a review of the circumstances surrounding the order should be documented and maintained in that pharmacy's due diligence file. According to Cardinal's

[199] *Id.* at 00013085-86.

policies neither the orders triggering the pharmacy's threshold nor any other orders for drugs from the same drug family should have been shipped to the pharmacy without first conducting due diligence to verify that the orders were not suspicious. Upon information and belief, in spite of its policies, Cardinal continued to fill orders for the same controlled substances without regard to the prior threshold breaches. Cardinal failed to conduct due diligence in response to these threshold events. Cardinal also continued to ship the customer the same drug that triggered a threshold event without any evidence that the order had been investigated or that the suspicion had been dispelled.

493. Cardinal had a policy and practice of providing preferential treatment to chain pharmacies differently than retail-independent pharmacies, in many respects, including setting thresholds and conducting due diligence. Cardinal refused to impose the same requirements on chain customers because it knew the national chains could take their billions of dollars in business elsewhere. Cardinal did not calculate thresholds for chain pharmacies in the same manner as described above; instead, this was a process that was conducted outside the Anti-Diversion Department at Cardinal. Cardinal also failed to conduct due diligence on its retail pharmacy chain customers, and instead, relied on the chains to report this information.

494. After 2008, Cardinal ceased submitting Ingredient Limit Reports as its suspicious order reports but continued to manually submit suspicious order reports. Upon information and belief, Cardinal reported no more than a few dozen suspicious orders per year from 2008 to 2011. The Baltimore, Maryland DEA office found that between 2008 and October 1, 2011, Cardinal's Swedesboro, New Jersey distribution center failed to report any suspicious orders at all. In 2012, the DEA began another prosecution of Cardinal Health for "blatantly" violating the terms of its 2008 MOA and shipping suspicious orders.

495. The DEA served another ISO on Cardinal's distribution facility in Lakeland, Florida – one of the facilities at issue in the 2008 action – for distributing excessive amounts of oxycodone to retail pharmacies. Steve Morse, who Cardinal hired following the 2008 DEA action, was demoted for failing to timely terminate the pharmacies despite finding evidence of suspected diversion. Morse was removed from his position as a Director of Investigations to a position in regulatory management. A 2013 report of the Special Demand Committee of Cardinal's Board of

Directors cited his questionable judgment as part of the reason for this demotion and the fact that Morse failed to review pharmacy site visit report as required by Cardinal's 2008 SOPs.[200] Similar to Steve Morse, as a result of the 2012 ISO and DEA investigation, Mr. Moné was moved from his position as Vice President of Anti-Diversion into a position as an attorney with the company's regulatory group where he remains today as a VP Associate General Counsel. The Special Demand Committee report states that Mr. Moné was moved as part of Cardinal's transition to "assessing customers based more on objective criteria;" under Moné evaluation of customers was a subjective standard.[201]

496. Cardinal entered a second MOA with the DEA in 2012 (2012 MOA) and again assured the DEA that they would come into compliance and operate within the confines of the CSA. Cardinal indicated that this time it was going to get it right and remove all subjectivity from the process to prevent poor decision making.[202]

497. While Cardinal again attempted to make changes to its SOMS systems, it still did not ensure that it was maintaining effective controls to prevent the diversion of controlled substances. Cardinal continued to operate with the same threshold system that was previously in operation, with several changes.

498. Around the same time Cardinal entered the 2012 MOA with the DEA it moved Todd Cameron into the position of Senior Vice-President of Supply Chain Integrity. Mr. Cameron has testified that Cardinal's new threshold system focused on prescription volume of each specific customer to determine its threshold. The significant problem with this approach was that Cardinal no longer considered population or comparison to similarly situated customers when setting thresholds.

499. Cardinal also devised a system where pharmacy customers were provided buffers above their previously set thresholds and used a coding scheme to identify which pharmacies had this built-in buffering system. However, Cardinal made no mention of any such buffering system

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[200] In re: National Prescription Opiate Litigation, Exhibit 220 at CAH_MDL_PRIORPROD_HOUSE_00003331, 0003367, available at https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Exhibit-220-Report/ohnd-1:2017-md-02804-01964-008.

[201] *Id.*

[202] See 2012 Cardinal Health Memorandum of Agreement, https://www.thehealthlawfirm.com/uploads/Cardinal%20Health%20-%20Memo%20of%20Agreement.pdf.

in its SOP's that were the policies Cardinal indicated to regulators, including the DEA, it was operating by.

500. Even after the 2012 DEA investigation, Cardinal continued to fail to report suspicious orders. Cardinal Director of Quality and Regulatory Affairs Chris Forst has testified that after 2012, Cardinal only reported orders that the company believed had a high potential for diversion instead of orders of unusual size, of unusual frequency, or deviating substantially from a normal pattern. From 2012 through 2015, Cardinal admittedly failed to report approximately 14,000 suspicious orders from across the country to the DEA, and the vast majority of those orders involved opioids. Cardinal only recognized the unreported suspicious orders retrospectively during an audit process in 2015.

iii. MCKESSON

501. Defendant McKesson breached its duties under federal and state law. As shown by the ARCOS Data, McKesson distributed an extraordinary amount of prescription opioids into Plaintiff's community. McKesson's excessive distribution was made possible by, and is evidence of, McKesson's failures to comply with its duties under state and federal law, including the CSA and applicable Nevada statutes.

502. McKesson comprised 23.8% of the market share for distributors in Washoe County, and it distributed around 56,706,808 total dosage units from 2006 to 2014 to Washoe County.[203]

503. McKesson failed to meet its suspicious order monitoring requirements, failed to stop shipment on suspicious orders, and failed to effectively prevent diversion in breach of its duties under state and federal law. These breaches contributed substantially to the public nuisance and harms alleged in the Plaintiff's Community.

504. McKesson is a sophisticated pharmaceutical distributor that has amassed great wealth from the delivery of pharmaceutical products, including prescription opioids. In fact, McKesson has claimed to deliver 1 out of every 3 prescriptions in the United States. This prowess in the pharmaceutical arena currently has McKesson seated at number 7 on the Fortune 500 list.

[203] See https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/.

However, as the company acknowledges, its size and infiltration into various aspects of the pharmaceutical industry have also provided the company with a unique national perspective on the diversion of controlled substances, including opioids.

505. McKesson has admitted its well-established duties under the Controlled Substances Act (hereinafter "CSA") to prevent diversion through its monitoring of controlled substances, which has been consistent since 1970.[204] As part of this suspicious order monitoring system, McKesson has a duty to report suspicious orders and to halt shipment of any orders that are deemed suspicious.[205] Further, McKesson has conceded that violations of these CSA requirements result in a substantial and detrimental effect on the health and general welfare of the American people.[206]

506. Importantly, McKesson has also known since it began distributing opioids that this class of drugs has a high potential for abuse and can lead to severe psychological and physical dependence.[207] Upon information and belief, McKesson has acknowledged in internal presentations that the opioid epidemic is the deadliest drug epidemic this country has ever faced. Unfortunately, opioid addiction is also a direct gateway to the initiation of illicit heroin use.[208] Therefore, the prescription opioid epidemic has only served to spawn additional epidemics.

507. McKesson admits that the societal costs of the opioid epidemic have been massive, in the tens of billions of dollars each year. McKesson has further conceded that McKesson is partially responsible for the societal costs of the opioid epidemic this country faces today.[209]

508. McKesson has consistently failed to comply with its obligations under the CSA. Upon information and belief, McKesson has had SOM policies in place dating at least back to 1997. Under the former policy, which remained in effect until 2007, a daily and monthly Controlled Substance Suspicious Order Warning Report was generated at the distribution center.

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[204] See In re: National Prescription Opiate Litigation, Exhibit 12, 7/31/18 Hartle Depo. at 78:4-10; 85:2-9, available at https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Exhibit-12-Depo-Excerpts/ohnd-1:2017-md-02804-01957-012.

[205] *Id.* at 36:14-37:4; 38:5-19.

[206] *Id.* at 43:22-44:5.

[207] *Id.* at 50:3-7; 50:22-51:3

[208] See In re: National Prescription Opiate Litigation, 8/1/18 Hartle Depo. at 37:4-38:17, available at https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Hartle-Nate-McKesson-08-01-18-Redacted/ohnd-1:2017-md-02804-01978-004.

[209] See 7/31/18 Hartle Depo. at 285:6-286:15.

To qualify for placement on this report the controlled substance order had to be 3 times the rolling 12 month average for that drug at that distribution center.[210] While McKesson claims that these reports were provided to the DEA, McKesson has not yet provided any evidence that this claim is true. Further, orders listed on this report were not held or halted, but were shipped without review. McKesson's own regulatory employees have conceded that these reports did not satisfy the requirements of the CSA to report suspicious orders.[211]

509. In late 2005, DEA began investigating McKesson for filling large quantities of hydrocodone and oxycodone orders for internet pharmacies. Upon information and belief, in January 2006, the DEA notified McKesson that it had identified excessive doses of hydrocodone delivered by McKesson to several internet pharmacies during a 3 week period. During discussions with the DEA, McKesson conceded that these extremely large orders were not flagged, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes. These excessive and suspicious purchases ultimately led to DEA seeking a show cause order against the distribution center supplying these pills. McKesson ultimately resolved these violations as part of the 2008 settlement.

510. Due in large part to the violations referenced above, in May 2007 McKesson created the Lifestyle Drug Monitoring Program ("LDMP"). The LDMP set thresholds of 8,000 doses a month for oxycodone and hydrocodone containing products.[212] Yet, upon information and belief, these thresholds were not strictly adhered to, and orders exceeding these levels would not be blocked and were not reported to DEA. Additional problems with the LDMP were uncovered during routine auditing of the program. First, it was noted that not all of the products containing one of the generic ingredients would likely have been included in the reports generated as part of the LDMP. The second flaw noted was that the Daily Dosage Summary Report generated under the LDMP was organized by distribution center, and therefore a customer could both exceed the

[210] See In re: National Prescription Opiate Litigation, 1/10/19 Hilliard Depo. at 163:21-169:7, available at https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Hilliard-Gary-McKesson-01-10-19-Redacted/ohnd-1:2017-md-02804-01978-012.

[211] *Id.* at Gary Hilliard Depo. at 176:8-22.

[212] See Sarah Le, Congressional Report Finds Millions of Opioids Sent to Small-Town Pharmacies in West Virginia, De. 22, 2018, available at https://www.theepochtimes.com/congressional-report-finds-millions-of-opioids-sent-to-small-town-pharmacies-in-west-virginia_2746085.html.

monthly 8,000 dosage unit threshold and avoid detection by spreading its purchases across multiple distribution centers. McKesson employees have alleged the company continued using the DU45 reports during this time period to report excessive orders as defined above.

511. While McKesson's first written policy aimed at preventing diversion dates back to at least 1997, the company has shown an unwillingness to comply with that policy and those that followed it. By 2008, the DEA and DOJ felt compelled to punish McKesson for its flagrant noncompliance with the CSA. On May 2, 2008, McKesson entered into a settlement agreement with the DEA and DOJ and paid $13,250,000 in fines for numerous violations of the CSA concerning the distribution of opioids.[213] The scope of the violations at issue were sprawling. The settlement covered conduct occurring at distribution centers in Maryland, Florida, Texas, Colorado, Utah, and California.[214] Further the violations at issue were egregious as McKesson delivered millions of doses of hydrocodone to a small number of pharmacies.

512. In May 2008, McKesson launched the Controlled Substances Monitoring Program ("CSMP"). The CSMP has remained in effect in some form since 2008. Given that the CSMP was created as a result of the DOJ settlement, it would be expected that the program would serve to make it more difficult for customers to improperly obtain opioids. However, upon information and belief, when the program was launched McKesson made sure to notify all of its pharmacy customers that business would remain the same as it pertained to those customers' ability to obtain controlled substances, including opioids.

513. Thresholds were set under the CSMP utilizing the customer's last 12 months of orders for a given product and adding a buffer to that amount. Upon information and belief, McKesson took the highest of the preceding 12 months orders for a given product and added a 10% buffer to that number and set that as the running threshold for the customer. Upon information and belief, retail national accounts received even more leeway on their thresholds, generally being given a 20-25% buffer rather than 10%. Thresholds were also routinely increased with little or no justification given to support the increase. Customers were also notified as they

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[213] See Department of Justice Press Release, McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications, May 2, 2008, available at https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html.

[214] *Id.*

approached their threshold, so they could request an increase without any interruption in receiving the product.

514. While customers rarely reached their thresholds under the CSMP, if they did the orders would be blocked until a threshold increase was approved. Once the orders were blocked under the CSMP a three-level review was also triggered. This three-level review was designed to assess whether the order was suspicious and whether further orders from the customer should be blocked. Orders were only reported as suspicious if the review made it to level 3.

515. The settlement with DEA & DOJ in 2008 and the implementation of the CSMP program did nothing to curb McKesson's flagrant violations of the CSA. The DEA has testified that McKesson blatantly violated the terms of its 2008 MOU with the DEA.[215]

516. The DEA and DOJ began investigating McKesson again in 2013 and quickly discovered that McKesson had developed a policy of not reporting suspicious orders. In fact, the CSMP in effect actually instructed McKesson employees to avoid using the word suspicious so as to avoid the requirement to report suspicious orders to the DEA. This policy, and others, ensured that McKesson reported almost no suspicious orders of opioids nationally from 2008 to 2013.

517. McKesson also manipulated the threshold system it established to ensure that it would not have to block customer orders or engage in any due diligence involving customer orders. First, McKesson set thresholds so high that they would never be exceeded thus ensuring that no higher level due diligence would be required by McKesson. Second, McKesson would routinely increase opioid thresholds preemptively despite a well-established policy that threshold increases should always be customer generated. Third, McKesson would also increase thresholds for the flimsiest of reasons or for no reason at all. For example, upon information and belief, in November 2008, employees of McKesson permanently increased opioid thresholds for 200 customers by 30% for no reason other than it was around the Thanksgiving holidays.

[215] See Department of Justice Press Release, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, Jan. 17, 2017, available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

518. McKesson also deferred completely to retail national account customers to dictate when their thresholds would be increased. McKesson's Senior Director of Distribution Operations, Donald Walker, readily acknowledged that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.[216]

519. Ultimately, the DEA and DOJ concluded that McKesson's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders and jeopardized the health and safety of people around the country. DEA and DOJ saw McKesson's due diligence failures as to opioids as nationwide and systemic. As a result of these broad sweeping due diligence failures, McKesson agreed to a $150,000,000 settlement with the DEA and DOJ.[217] Additionally, McKesson accepted responsibility for nationwide failures of due diligence as to opioid distribution spanning 2009 to 2017.[218] It would be expected that such a harsh financial penalty would have dramatically altered McKesson's practices. However, before the ink of the settlement agreement was even dry, McKesson was already re-assuring customers concerned about the flow of opioids that there shouldn't be a change in business at McKesson.

520. After renewed investigations by the DEA and DOJ beginning in late 2013, McKesson appeared to begin to try and tighten up its SOM policies. Included within those efforts was a massive threshold reduction initiative wherein McKesson reduced the oxycodone thresholds for most customers. McKesson also began working with a consulting company tasked with creating a new SOM policy for McKesson. On or about 2017, McKesson established both a benchmark threshold as well as a same-customer threshold, and the customer was bound by the lower of these two thresholds.

521. On January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for, *inter alia*,

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[216] See In re: National Prescription Opiate Litigation, 1/10/19 Donald Walker Depo. at 190-193, available at https://www.docketbird.com/court-documents/In-re-National-Prescription-Opiate-Litigation/Walker-Donald-McKesson-01-10-19-Redacted/ohnd-1:2017-md-02804-01985-011.

[217] See Settlement Agreement and Release between the DOJ/DEA and McKesson Corporation, Jan. 5, 2017, available at https://www.justice.gov/opa/press-release/file/928471/download.

[218] *Id.*

failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[219]

J. Defendants Delayed a Response to the Crisis by Pretending to Cooperate

522. When a registrant manufacturer, distributor, or dispenser of 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 by those involved in the supply chain, law enforcement may be delayed in taking action – or may not know to take action at all.

523. After being caught for failing to comply with particular obligations at particular facilities, Defendant Distributors 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 though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

524. More generally, the Defendant Distributors publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent

[219] *Id.* at 5.

diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription-controlled medications that do not meet [its] strict criteria." Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[220]

525. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also 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."

526. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies 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 **p**rovided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

527. 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

[220] https://www.cardinalhealth.com/en/about-us/corporate-citizenship.html.

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. 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."[221]

528. 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 "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[222] At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion.

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

K. Defendants Worked Together to Sustain the Market and Boost Profits

530. Finding it impossible to legally achieve their ever-increasing sales ambitions within the confines of their quotas, Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

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[221] http://www.mallinckrodt.com/about/news-and-media/news-detail/?id=7176.

[222] Purdue, Setting The Record Straight On OxyContin's FDA-Approved Label (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda approvedlabel/; Purdue, Setting The Record Straight On Our Anti-Diversion Programs, (July 11, 2016) http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversionprograms/.

531. 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 trade channels 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." When evaluating production quotas, the DEA was instructed to consider the following information:

> a. Information provided by the Department of Health and Human Services;
> b. Total net disposal of the basic class [of each drug] 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 [of drug] 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.

532. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

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

534. Defendant Distributors had financial incentives from the Manufacturer Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious

orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

535. The Defendant Manufacturers engaged in the practice of paying rebates and/or chargebacks to the Defendant Distributors for sales of prescription opioids as a way to help them boost sales. The *Washington Post* has described the practice as industry-wide, and the HAD includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt, a prescription opioid manufacturer, acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Defendant Manufacturers buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

536. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The manufacturers negotiated agreements whereby the Defendant Manufacturers installed security vaults for the Defendant Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

537. Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum ("PCF") and the HDA.

538. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described

in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

539. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[223] 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.[224]

540. 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 and Mallinckrodt were members of the HDA. Additionally, 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."[225]

541. 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."[226] 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 the Distributor Defendants.

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[223] 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-drugepidemic. (Last Updated Dec. 15, 2016, 9:09 AM).

[224] *Id.*

[225] Id; The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, 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).

[226] *Id.*

542. 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.[227] For example, 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.

543. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year end net sales" through wholesale distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health, and McKesson and their subsidiaries.

544. The closed meetings of the HDA's councils, committees, task forces, and working groups provided the Defendant Manufacturers and Distributors with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise. 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 Defendant Manufacturers 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."[228] 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."[229] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[230]

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227 Manufacturer Membership Application, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membershipapplication.ashx?la=en.

228 Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.

229 *Id.*

230 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

545. After becoming members of the HDA, Defendants were eligible to participate on councils, committees, task forces, and working groups, including the Industry Relations Council who provided leadership regarding pharmaceutical distribution and supply chain issues; the Business Technology Committee that focused on developing collaborative e-commerce business solutions; the Logistics Operation Committee that helped members with productivity, efficiency, and customer satisfaction; the Manufacturer Government Affairs Advisory Committee that provides a forum to brief members on federal and state legislative and regulatory measures affecting pharmaceutical distribution; and the Contracts and Chargebacks Working Group that explored streamlining the contract administration process through process improvements and technical efficiencies.

546. The Defendant Distributors and Defendant Manufacturers 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.[231] For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and 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.

547. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Defendant Manufacturers and Distributors 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.

548. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrate that the leaders of each of the Defendants were in communication and cooperation.

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

549. Publications and guidelines issued by the HDA nevertheless 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 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.

550. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA explained to the Energy and Commerce Subcommittee on Health in April 2014, it is difficult to ensure proactive anti-diversion efforts while avoiding inadvertent limitations on access to appropriately prescribed and dispensed medications. Here, it is apparent that all of the Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders, and failure to prevent diversion.

551. The Defendants' scheme had a decision-making structure driven by the Defendant Manufacturers and corroborated by the Defendant Distributors. The Defendant Manufacturers worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

552. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Defendant Manufacturers and Distributors did this through their participation in the PCF and HAD.

553. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially

high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

554. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

555. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

556. Not only did the Defendant Distributors distribute, supply, and sell prescription opioids without fulfilling their duties to maintain effective controls against diversion, but also, the Defendant Distributors further increased the flood of opioids into Plaintiff's community by actively assisting manufacturers in marketing their opioid products.

557. Distributors' efforts to assist manufacturers in increasing opioid prescriptions date back decades. For example, a 1991 article entitled "New Spirit of Partnering Rejuvenates Wholesalers" described efforts by the National Wholesale Druggists Association ("NWDA"), the predecessor entity to the HDMA/HDA, to work collaboratively with wholesalers, noting how "wholesalers and manufacturers showed their optimism about the future of wholesale drugs," in light of a "spirit of intercompany teamwork open[ing] up new opportunities for everyone involved…."[232] Outgoing NWDA chairman Joseph Polastri was also quoted as stating that "suppliers and wholesalers have a common economic incentive to work more closely together."[233]

558. In 1991, the NWDA organized official, high-level meetings between wholesalers and manufacturers. These visits, which were reported to have prompted discussions about using wholesaler sales representatives "to pass along technical product information to pharmacists,

[232] Val Cardinale, New Spirit of Partnering Rejuvenates Wholesalers, 135 Drug Topics 23 (Dec. 16, 1991).
[233] *Id.*

hospitals, third-party payers and perhaps even to selected doctors," and several manufacturers also expressed interest "in tapping into wholesaler telemarketing capabilities."[234]

559. Manufacturers such as Purdue were members of the NWDA starting from the early 1990s. Upon information and belief, manufacturers like Purdue would prepare statements at the request of the NWDA to acknowledge the role that distributors' marketing efforts played in the successful launch of its drugs—distributors would offer promotional programing like deal catalogs, retail tote stuffers, telemarketing, etc. Defendant Distributors also helped facilitate the promotion of Defendant Manufacturers' products at the retail level. For example, in describing services offered by McKesson and AmerisourceBergen's predecessor entity, Bergen Brunswig, Purdue noted that incentives were offered to facilitate placement of OxyContin at the retail level. These Distributor marketing activities were an integral part of the Manufacturer Defendants' deceptive scheme to spread misrepresentations about opioids and increase opioid prescribing.

560. Defendant Manufacturers worked with Defendant Distributors to develop marketing activities and paid Defendant Distributors for their efforts.

561. As the Defendant Distributors' marketing activities drove dramatic increases in opioid prescriptions, Defendant Distributors continued to distribute unconscionable quantities of opioids and both Distributor and Manufacturer Defendants continued to ignore their obligations to monitor, report, and stop suspicious orders. Distributors acted as more than middlemen or mere delivery services; on the contrary, they inserted themselves directly into doctor-patient relationships. The Defendant Distributors marketed opioids directly to patients, including for off label and unsafe uses, and they also consulted with patients about using opioids. Together, the Defendant Manufacturers and Distributors worked to overcome insurers' resistance to covering opioids outside of the uses for which they had been approved. For example, upon information and belief, AmerisourceBergen and its Xcenda division paid in-house scientists to publish articles downplaying the risks of opioids. Defendant Distributors also engaged in marketing efforts by providing discount cards to induce consumers to purchase the Defendant Manufacturers' opioids. Upon information and belief, Defendant Manufacturers like Purdue knew of the evidence

[234] NWDA Senior Management Teams Will Visit 30 Drug Companies By End Of Year; Wholesaler-Only Advisory Boards Have Been Established By 14 Drug Firms, The Pink Sheet (Nov. 25, 1991).

associating cash payment with opioid abuse and recognized that discount cards could lower costs for a cash prescription without revealing the cardholder's identity. Moreover, as alleged in the Massachusetts Attorney General Complaint, internal Purdue documents also revealed that opioid savings cards had the "highest return on investment" because they caused patients to stay on Purdue's product for much longer. In sum, the Defendant Distributors continually engaged in marketing efforts for the Defendant Manufacturers for decades.

562. Upon information and belief, Defendant Distributors, entered into Marketing Agreements with Defendant Manufacturers, in order to continue spreading misinformation regarding the safety and efficacy of opioids while also manipulating suspicious order monitoring systems as well as law enforcement to increase the threshold opioid order quantities.

563. The marketing initiatives and agreements were created to target healthcare providers and pharmacists through various means including, but not limited to: email campaigns; manufacturer advertisements included in Defendant Distributor publications distributed regularly to their pharmacy customers; targeted telemarketing; targeted direct mailing; and ad placement at pharmacies.

564. Through these marketing agreements, Defendant Distributors were well aware of the marketing plans developed by Defendant Manufacturers and helped disseminate the Defendant Manufacturers' misleading marketing to a greater audience, thus leading to increased orders of the opioids and increased distribution by Defendant Distributors.

565. By furthering and facilitating the misleading marketing, Defendant Distributors breached their duties to act reasonably to prevent the foreseeable harm caused by their conduct – the indiscriminate filling of opioid orders – and, in fact, actively worked to increase those orders thorugh marketing.

566. By way of example, upon information and belief**:**

a. Defendant Actavis entered into an agreement with Defendant McKesson, which included McKesson promoting Actavis products through phone and fax campaigns and providing Actavis with pharmacy data so that Actavis would know which pharmacies to target with promotional materials. In turn, Actavis provided McKesson

with talking points to utilize when speaking with McKesson customers related to Actavis opioid products.

b. McKesson also entered into a Product Promotional Agreement with Purdue, under which McKesson agreed to post Purdue drug advertisements on the McKesson online ordering portal, McKesson Connect, and to include the link to Purdue's product website on McKesson Connect.

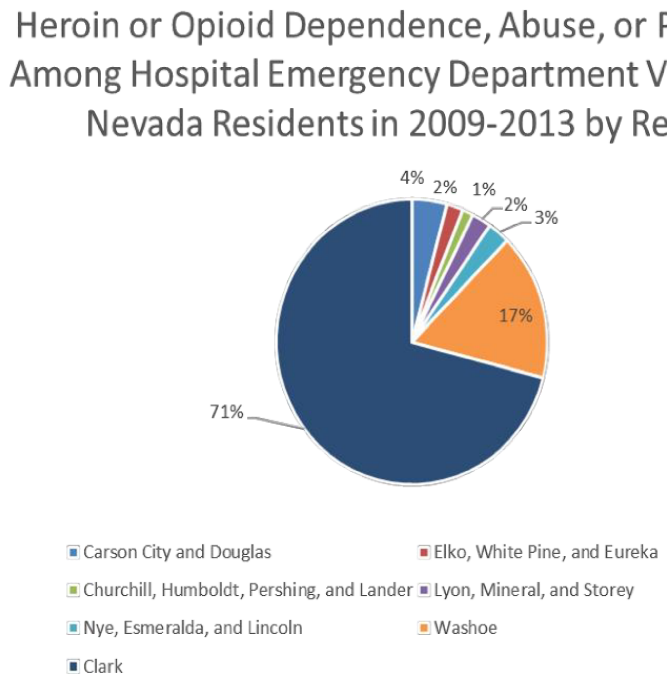
567. Upon information and belief, Defendant Distributors also entered into distribution agreements with Defendant Manufacturers, by which Defendant Distributors were incentivized to increase sales of Defendant Manufacturers' specific opioid products – both brand name and generic forms. McKesson entered into such agreements with Mallinckrodt and Actavis.

568. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

569. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

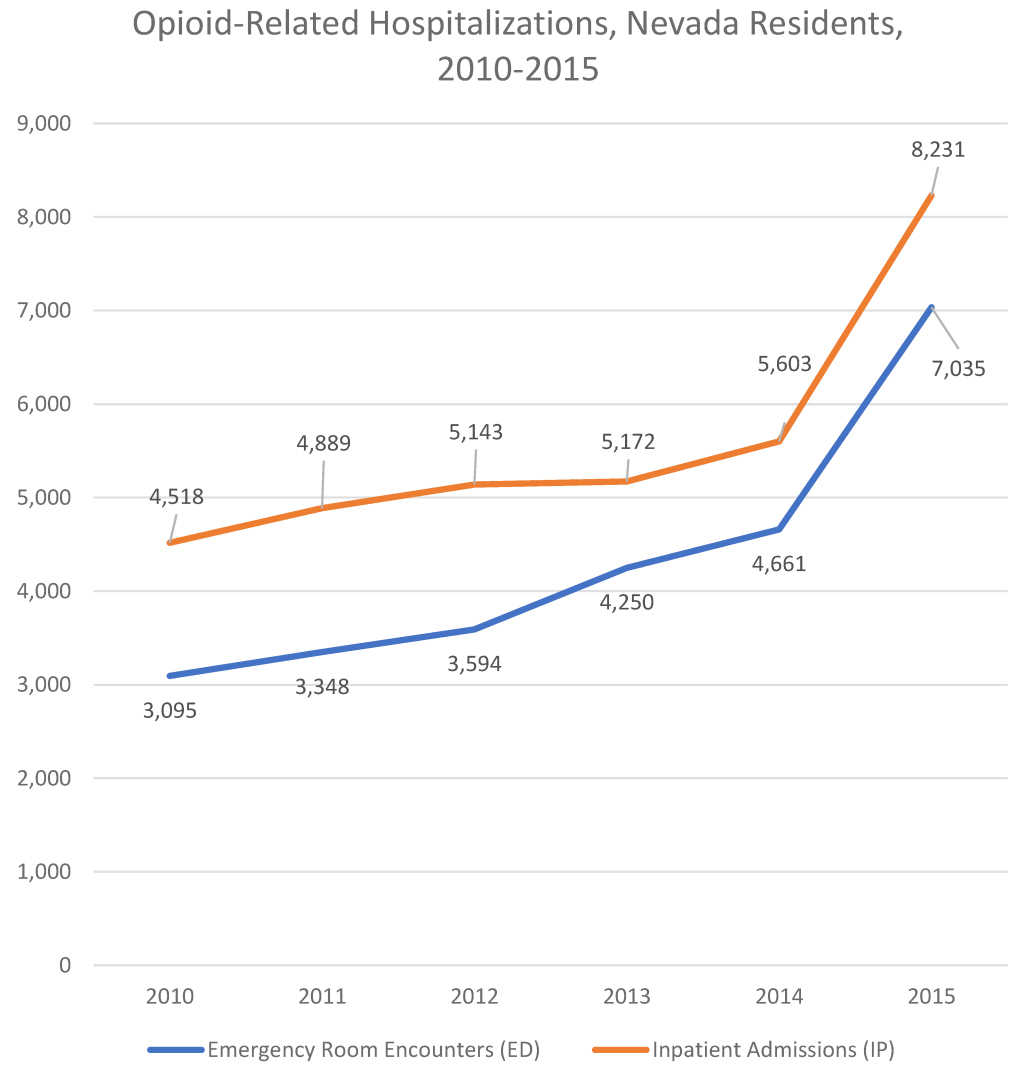
L. Opioid Addiction in Nevada

570. In 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. From 2009 to 2013, hospitals across the State had patients presenting to emergency rooms for heroin or opioid dependence, abuse, or poisoning. Of those visits, 17% occurred in Washoe County.



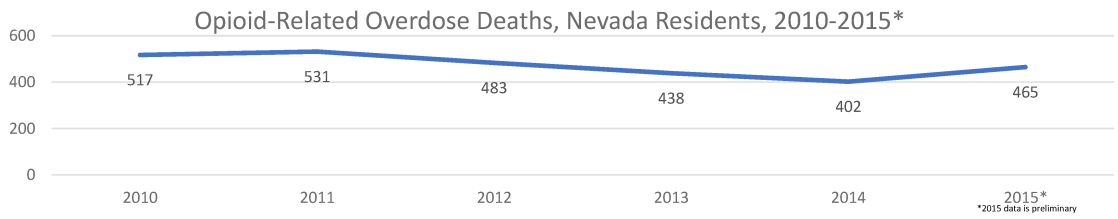
571. According to data from the Nevada Division of Public and Behavioral Health, the total number of opioid-related hospitalizations in Nevada nearly doubled from 2010 to 2015. In 2010, the number of opioid-related emergency room hospitalizations in Nevada totaled about 4,518 patients. By comparison, that number rose steeply to about 8,231 visits in a mere five years. Similarly, in 2010, the number of opioid-related inpatient admissions statewide totaled 3,095 hospitalizations. However, in a span of only five years, that number exponentially increased to 7,035 visits in 2015. From 2010 to 2015, over 26% of opioid-related emergency room hospitalizations in Nevada were among patients aged 55 years and older. Over 36% of opioid-related inpatient admissions in the State were among that same age group.

572. Opioid-induced hospitalizations and emergency room visits are a significant area of health expenditure.



573. In addition to hospitalizations, the total number of opioid-related deaths continues to mount. According to the Centers for Disease Control, nearly half of all U.S. opioid overdose deaths involve a prescription opioid. In 2015, more than 15,000 people in the U.S. died from overdoses involving prescription opioids.

574. Nevada has the fourth highest drug overdose mortality rate in the United States. From 2010 to 2015, approximately 2,800 deaths in Nevada have been attributed to opioid-related overdose. It is estimated that 55% of those deaths were caused by natural and semi-synthetic opioids.



M. The Consequences of Defendants' Deceptive Scheme

575. Through direct promotional marketing, in conjunction with third-party Front Groups and KOLs, Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, Nevada doctors began prescribing opioids long-term to treat chronic pain - something most would never have considered prior to Defendants' extensive marketing campaign.

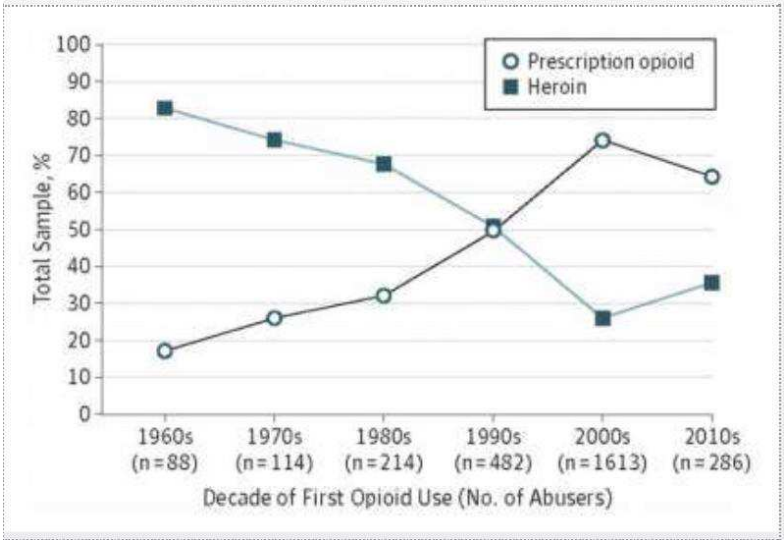
576. But for the misleading information disseminated by Defendants, prescribing physicians would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain. The impact of Defendants' deceptive marketing on doctors' prescribing and patients' use of opioids is evidenced by the increase in opioid prescribing nationally in concert with Defendants' marketing, and the consequences of opioid over-prescription - including addiction, overdose, and death.

N. Prescription Opioids Fueling Secondary Market of Illegal Drugs

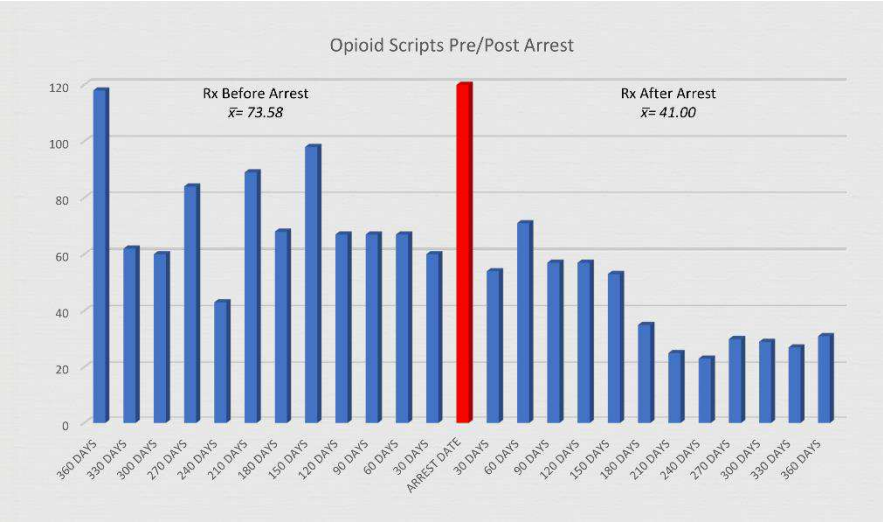
577. Defendants' successful efforts in expanding the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction and abuse. Defendants' behavior supplies both ends of the secondary market for opioids – producing both the inventory of narcotics to sell and the addicts to buy them. It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Thus, prescription drug abuse is fueling the rise of heroin usage in Nevada.

578. As a result, self-reported heroin use nearly doubled in the U.S. between 2007 and 2012, from 373,000 to 669,000 individuals and, in 2010, more than 3,000 people in the U.S. died

from heroin overdoses, also nearly double the rate in 2006; nearly 80% of those who used heroin in the past year previously abused prescription opioids.



579. Between 2011 to 2015, the Reno Police Department arrested approximately 735 individuals related to heroin use. Of those arrested, 53% were prescribed opioids. While records indicate that aggregate opioid prescriptions for those arrested decreased following their arrests, opioid addiction and illegal heroin use persist.



580. While the use of opioids continues to take an enormous toll on Reno and its residents, pharmaceutical companies reap blockbuster profits.

581. In 2014 alone, opioids generated $11 billion in revenue for drug companies, Defendants experienced a material increase in sales, revenue, and profits from their fraudulent advertising and other unlawful and unfair conduct as described above.

582. Defendants should be held accountable for their misrepresentations and the harms caused to Reno as well as its residents thus giving rise to this lawsuit.

FIRST CAUSE OF ACTION

(Public Nuisance Against All Defendants)

583. Plaintiff repeats and reiterates the allegations previously set forth herein.

584. This action is brought by the City for violations of statutory provisions concerning public nuisance under NRS 202 *et seq.* Nevada law provides that a where a controlled substance, including but not limited to opioids, is "unlawfully sold, served, stored, kept, manufactured, used or given away" constitutes a public nuisance.

585. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused, and continues to cause, significant harm to the community. The rates of opioid use resulting from Defendants' deceptive marketing efforts have caused harm to the community

586. As a result of Defendants' conduct, Plaintiff has incurred substantial costs including but not limited to law enforcement action opioid-related to drug crimes, for addiction treatment, and other services necessary for the treatment of people addicted to prescription opioids.

587. Defendants, and each of them, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of Reno citizens, "renders a considerable number of persons insecure in life" and/or interferes with the comfortable enjoyment of life in violation of Nevada law.

588. Defendants knew or should have known that their marketing of opioid use would create a public nuisance.

589. Defendants' actions were, and continue to be, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, and continue to be, a

substantial factor in prescribing physicians and prospective patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

590. The health and safety of the citizens of Reno, 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.

591. Defendants' conduct has affected and continues to affect a considerable number of people within the physical boundaries of Reno and is likely to continue to cause significant harm to people who take opioids, their families, and the community at large.

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

593. Defendants created an absolute nuisance. Defendants' actions created and expanded 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 Reno, 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.

594. 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 Reno.

595. Defendants' actions also created a qualified nuisance. 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.

596. Defendants acted with actual malice 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.

597. The damages available to the Plaintiff include, inter alia, recoupment of governmental costs, flowing from an "ongoing and persistent" public nuisance which the government seeks to abate.

598. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

599. As a direct result of Defendants' conduct, Reno has suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. Reno here seeks recovery for its own harm.

600. Reno has sustained specific and special injuries because its damages include, *inter alia,* health services, law enforcement expenditures, costs related to opioid addiction treatment and overdose prevention, and related costs.

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

602. The public nuisance created by Defendants' actions is 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 prescription opioid abuse and heroin use resulting from Defendants' abdication of their gate-keeping duties has caused harm to the entire community that includes, but is not limited to:

a. The high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids has made opioids a recreational drug of choice among teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those City residents who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' failure to maintain effective controls against diversion of dangerously addictive prescription opioids for non-medical use and abuses has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. Increased supply, due to Defendants' conduct, led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on health care services and law enforcement in the City.

i. The significant unreasonable interference with the public rights caused by Defendants' conduct has taxed the human, medical, public health, law enforcement, and financial resources of the City.

j. Defendants' interference with the comfortable enjoyment of life in the City is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

603. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* abatement, compensatory damages, and punitive damages from the Defendant Wholesale Distributors for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

604. 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 wrongdoing has not ceased. The public nuisance remains unabated.

605. 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.

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

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

SECOND CAUSE OF ACTION

(Common Law Public Nuisance against all Defendants)

608. Plaintiff repeats and reiterates the allegations previously set forth herein.

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

610. The public nuisance created by Defendants' actions is 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 use resulting from Defendants' marketing efforts have caused harm to the community.

611. Defendants, and each of them, knew or should have known that their promotion of opioid use would create a public nuisance.

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

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

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

615. The health and safety of those individuals in Reno, 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.

616. The public nuisance created, perpetuated, and maintained by Defendants can be abated and further reoccurrence of such harm and inconvenience can be prevented.

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

618. 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.

619. That as a result of the aforesaid occurrence, Plaintiff has suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid, including necessary medical, hospital, and concomitant expenses.

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

621. Defendants created an absolute nuisance. Defendants' actions created and expanded 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 Reno, 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.

622. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids without maintain 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 Reno.

623. Defendants' actions also created a qualified nuisance. 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.

624. Defendants acted with actual malice 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.

625. The damages available to the Plaintiff include, inter alia, recoupment of governmental costs, flowing from an "ongoing and persistent" public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

626. As a direct result of Defendants' conduct, the City has suffered actual injury and damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections and other services. The City here seeks recovery for its own harm.

627. The City has sustained specific and special injuries because its damages include, *inter alia,* health services, law enforcement expenditures, costs related to opioid addiction treatment and overdose prevention, and related costs.

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

629. The public nuisance created by Defendants' actions is 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 prescription opioid abuse and heroin use resulting from Defendants' abdication of their gate-keeping duties has caused harm to the entire community that includes, but is not limited to:

a. The high rates of use have led to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids has made opioids a recreational drug of choice among Reno teenagers; opioid use among teenagers is only outpaced by marijuana use. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those City residents who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' failure to maintain effective controls against diversion of dangerously addictive prescription opioids for non-medical use and abuses has created an

abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. Increased supply, due to Defendants' conduct, led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has increased the demands on health care services and law enforcement in the City.

i. The significant unreasonable interference with the public rights caused by Defendants' conduct has taxed the human, medical, public health, law enforcement, and financial resources of Reno.

j. Defendants' interference with the comfortable enjoyment of life in Reno is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

630. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* abatement, compensatory damages, and punitive damages from the Defendant Wholesale Distributors for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

631. 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 wrongdoing has not ceased. The public nuisance remains unabated.

632. 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.

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

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

THIRD CAUSE OF ACTION

(Negligence against Defendant Manufacturers & Detailers)

635. Plaintiff repeats and reiterates the allegations previously set forth herein.

636. Defendants had a duty to exercise reasonable care in the manufacture, marketing, promotion, and/or sale of opioids.

637. In the course and furtherance of Defendants' business in Reno, Defendants breached their duty by manufacturing, marketing, promoting, and/or selling opioids in an improper manner.

638. Defendant Manufacturers further owe a duty to Plaintiff to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks, and in light of Defendant Manufacturers' knowledge of the dangers inherent in opioid use.

639. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for its residents and using City resources in relation to opioid use and abuse.

640. Defendant Manufacturers developed a marketing scheme specifically to deceive the medical community and the public at large in order to minimize the dangers of opioids and to tout their off-label uses and benefits. *See* paragraph 453; see also paragraphs 131 through 134 and 207 related to Defendant Actavis; paragraphs 111-113, 119, 125-127, 144, 152, 157-158, 167, 170-171, 176-177, 183, 192, 199-206 as to Defendant Endo; paragraphs 135-138, 208-29 related to Defendant Mallinckrodt; and paragraphs 128-130, 156, 161-169, and 175 related to Defendants Teva and Cephalon.

641. Defendant Manufacturers' actions and involvement in the creation of the deceptive marketing schemes are detailed in the factual background sections, *supra*, which included developing a regular pattern of misinformation related to the efficacy, safety, and appropriate use of their opioid medications.

642. Defendant Manufacturers utilized various marketing strategies as set forth, *supra*, including utilizing Defendant Detailers to promote opioids directly to physicians. Additionally, Defendant Manufacturers utilized Key Opinion Leaders, CMEs, and purported third-party publications to spread their deceptive marketing all in breach of their duty to the City of Reno. *See* Footnote 75 and paragraph 288; *see also* paragraphs 215, 217, 246-247, 251, 263, 266, 269, 273-275, 281, 283-284, 302-303, 307-317 related to Defendant Endo; paragraphs 214, 227-228, 283-284 related to Defendant Mallinckrodt; and paragraphs 217, 227, 236, 246, 249-250, 254, 263, 265, 273-275, 281, 283-284, 318, 331, and Footnote 119 related to Defendants Teva and Cephalon.

643. However, as detailed, *supra*, Defendants continued to design manufacture, market, promote and sell opioids so as to maximize sales and profits at the expense of the health and safety of the public, in conscious disregard of the foreseeable harm caused by the opioid drugs.

644. Additionally, Defendant Manufacturers had a duty to track and identify suspicious orders of opioids in order to conduct investigations into those orders and to combat diversion of their dangerous products. *See* paragraph 344 related to Defendant Actavis; paragraph 340 related to Defendant Endo; paragraph 355 related to Defendant Mallinckrodt; and paragraph 334 related to Defendants Teva and Cephalon.

645. Defendant Manufacturers not only failed to track and report suspicious orders, but as described, *supra*, encouraged ever increasing orders of their dangerous opioid products thereby breaching their duty to the City of Reno. *See* paragraphs 345-352, 447related to Defendant Actavis; paragraph 341 related to Defendant Endo; paragraphs 356-367, 387-391 related to Defendant Mallinckrodt; and paragraphs 335-337, 448 related to Defendants Teva and Cephalon.

646. Defendant Manufacturers' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with other Defendants.

647. A negligent violation of this trust poses distinctive and significant dangers to the City and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

648. Defendant Manufacturers were negligent in not acquiring and utilizing special knowledge that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

649. Defendant Manufacturers are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids arising out of the sale of their opioids.

650. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, or willful and intentional disregard of Plaintiff's rights, and, therefore, Plaintiff is entitled to punitive damages.

651. 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 wrongdoing has not ceased. The public nuisance remains unabated.

652. Plaintiff is without fault and the injuries to the City and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture and sale of opioids.

653. 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.

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

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

FOURTH CAUSE OF ACTION

(Negligence against Defendant Distributors & Defendant Providers)

656. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

657. Defendant Distributors owe a duty to exercise reasonable care in the distribution and/or sale of opioids.

658. Defendants Distributors further owe a duty to Plaintiff to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

659. Defendant Distributors had a duty to track and identify suspicious orders of opioids in order to conduct investigations into those orders and to combat diversion of their dangerous products.

660. Defendant Distributors not only failed to track and report suspicious orders, but as described, *supra*, encouraged ever increasing orders of dangerous opioid products thereby breaching their duty to the City of Reno. *See* paragraphs 380 and 385-386 related to all Distributor Defendants. *See also* paragraphs 457-470, 528 related to Defendant Amerisource Bergen; paragraphs 471-502, 526 related to Defendant Cardinal; and paragraphs 381-384, 503-523, 525, 527 related to Defendant McKesson.

661. Defendant Distributors further breached this duty by actively participating in the deceptive marketing designed by Defendant Manufacturers in order to increase opioid sales throughout the City of Reno. *See* paragraphs 535, 549, 556, 568, and 559-563 related to Distributor Defendants' participation in deceptive marketing.

662. Defendant Providers owed a duty to exercise reasonable care in the prescription of opioids.

663. Defendant Providers further owe a duty to Plaintiff to conform their behavior to the legal standard of reasonable conduct under the circumstances, in light of the apparent risks, and in light of Defendant Providers' knowledge as it relates to the inherent dangers in the use of opioids.

664. Defendant Providers breached this duty by, not only failing to recognize the risk of writing increased numbers of prescriptions for opioids, but by actively disregarding the dangers

associated with opioid use, particularly for off-label purposes and in dosages far exceeding those recommended.

665. Defendant Providers further breached their duty by providing false information to health insurance providers in order to obtain authorization and coverage for the opioid prescriptions.

666. As a proximate result, Defendant Distributors, as well as Defendant Providers, and their agents have caused Plaintiff to incur significant damages, including but not limited to costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids. Reno has borne the massive costs of these illnesses and conditions by having to provide necessary medical care, facilities, and services for treatment of City residents.

667. Defendant Distributors and Defendant Providers were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct. *See* paragraph 443.

668. Defendant Distributors were negligent in disclosing to Plaintiff suspicious orders for opioids. *See* paragraph 443.

669. Defendant Providers were negligent in writing improper prescriptions for opioids.

670. Defendant Distributors and Defendant Providers' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with other Defendants.

671. A negligent violation of this trust poses distinctive and significant dangers to the City and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

672. Defendant Distributors and Defendant Providers were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

673. Defendant Distributors are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

674. Defendant Providers are required to exercise a high degree of care to prescribe appropriate medications in appropriate dosages to avoid harm to patients and their communities.

675. Defendant Distributors breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

676. Defendant Providers breached their duty to exercise the degree of care required to protect their patients and their communities.

677. Defendant Distributors are in exclusive control of the distribution management of opioids that it distributed and/or sold in Reno.

678. Defendant Providers were active in providing patients within Reno with the prescriptions for opioids that were supplied by the Defendant Distributors.

679. Plaintiff is without fault and the injuries to the City and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.

680. 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 wrongdoing has not ceased. The public nuisance remains unabated.

681. 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.

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

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

FIFTH CAUSE OF ACTION

(Unjust Enrichment against all Defendants)

684. Plaintiff repeats and reiterates the allegations previously set forth herein.

685. Plaintiff has expended substantial amounts of money to fix or mitigate the societal harms caused by Defendants' conduct.

686. Such conduct by Defendants include Manufacturers' deceptive marketing flooding the market with opioids; Distributors' failure to report suspicious orders and participation in deceptive marketing; and the Providers' excessive prescribing of opioids to patients within the City of Reno. *See* the allegations set forth in the Third and Fourth Causes of Action, *supra*.

687. The expenditures by Plaintiff in providing healthcare services to people who use opioids have added to Defendants' wealth. These expenditures have helped sustain Defendants' businesses. *See* paragraphs 334-337, 340-341, 344-352, 355-367, 380-391, 447, 448, 457-502, 526, 528, 535, 549, 556, 559-563, and 568.

688. Plaintiff has conferred a benefit upon Defendants, by paying for what may be called Defendants' externalities - the costs of the harm caused by Defendants' negligent distribution and sales practices.

689. Plaintiff's payment of these externalities allowed Defendants to continue operating their businesses without impact on their profit or bottom line.

690. Defendants made substantial profits while fueling the prescription drug epidemic into Reno.

691. Defendants continue to receive considerable profits from the distribution of controlled substances into the City.

692. Defendants appreciated the benefit of their substantial profits without bearing the expense of their wrongdoing as all such expenses were being paid for by the City of Reno. *See* paragraphs 35 and 572-576.

693. Defendants' retention of the benefit – increased profits without penalty for wrongdoing – is unjust. *See* paragraphs 334-337, 340-341, 344-352, 355-367, 380-391, 447, 448, 457-502, 526, 528, 535, 549, 556, 559-563, and 568. *See also* Footnote 75 and 119.

694. Defendants have been unjustly enriched by their negligent, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing.

695. It would be inequitable to allow Defendants to retain benefit or financial advantage.

696. Plaintiff demands judgment against each Defendant for restitution, disgorgement, and any other relief allowed in law or equity.

697. Plaintiff is without fault and the injuries to the City and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.

698. The continued tortious conduct by the Defendants caused 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 wrongdoing has not ceased. The public nuisance remains unabated.

699. 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.

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

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

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against the Defendants as follows:

1. General damages in an amount in excess of $15,000.00;
2. Special damages in an amount in excess of $15,000.00;
3. For punitive damages in such amount as will sufficiently punish Defendants for their wrongful conduct in Nevada as well as serve as an example to prevent a repetition of such conduct in Nevada in the future;
4. For a fund establishing a medical monitoring program due to the increased susceptibility to injuries and irreparable threat to the health of opioid users resulting from their exposure to opioids, which can only be mitigated or addressed by the creation of a Court-supervised fund, financed by Defendants, and which will:
    a. Notify individuals who use or used opioids of the potential harm from opioids;

b. Aid in the early diagnosis and treatment of resulting injuries through ongoing testing and monitoring of opioid use;

c. Fund studies and research of the short- and long-term effects of opioids and the possible cures and treatments for the detrimental effects of using opioids;

d. Accumulate and analyze relevant medical and demographic information from opioid users, including but not limited to the results of testing performed on them;

e. Gather and forward to treating physicians information related to the diagnosis and treatment of injuries which may result from using opioids.

5. For restitution and reimbursement sufficient to cover all prescription costs the City has incurred related to opioids due to Defendants' wrongful conduct, with said amount to be determined at trial;

6. For restitution and reimbursement sufficient to cover all costs expended for health care services and programs associated with the diagnosis and treatment of adverse health consequences of opioids use, including but not limited to addiction due to Defendants' wrongful conduct, with said amount to be determined at trial;

7. For restitution and reimbursement for all prescription costs incurred by consumers related to opioids;

8. For such other and further extraordinary equitable, declaratory and/or injunctive relief as permitted by law as necessary to assure that the Plaintiff has an effective remedy and to stop Defendants' promotion and marketing of opioids for inappropriate uses in Nevada, currently and in the future;

9. For disgorgement;

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/ / /

10. Costs of suit, reasonable attorney fees, interest incurred herein; and

11. For such other and further relief as is just and proper.

DATED this 14th day of May, 2020.

EGLET ADAMS

/s/ Robert M. Adams

ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
CASSANDRA S.M. CUMMINGS, ESQ.
Nevada Bar No. 11944
RICHARD K. HY, ESQ.
Nevada Bar No. 12406
400 S. 7th Street, 4th Floor
Las Vegas, NV 89101
Tel.: (702) 450-5400
Fax: (702) 450-5451
E-Mail eservice@egletlaw.com
-and-
BILL BRADLEY, ESQ.
Nevada Bar No. 1365
6900 S. McCarran Blvd., Suite 2000
Reno, Nevada 89509
Telephone: (775) 335-9999
Email: office@bdjlaw.com
Attorneys for Plaintiff, City of Reno

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DEMAND FOR JURY TRIAL

Plaintiff, by and through her attorneys of record, hereby demands a jury trial of all of the issues in the above matter.

DATED this 14th day of May, 2020.

EGLET ADAMS

/s/ Robert M. Adams

ROBERT T. EGLET, ESQ.
Nevada Bar No. 3402
ROBERT M. ADAMS, ESQ.
Nevada Bar No. 6551
CASSANDRA S.M. CUMMINGS, ESQ.
Nevada Bar No. 11944
RICHARD K. HY, ESQ.
Nevada Bar No. 12406
400 S. 7th Street, 4th Floor
Las Vegas, NV 89101
Tel.: (702) 450-5400
Fax: (702) 450-5451
E-Mail eservice@egletlaw.com
-and-
BILL BRADLEY, ESQ.
Nevada Bar No. 1365
6900 S. McCarran Blvd., Suite 2000
Reno, Nevada 89509
Telephone: (775) 335-9999
Email: office@bdjlaw.com
Attorneys for Plaintiff, City of Reno

CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I certify that I am an employee of EGLET ADAMS, and that on the 14th day of May, 2020, I caused the foregoing document entitled **SECOND AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL** to be served upon those persons designated by the parties in the E-Service Master List for the above-referenced matter in the Second Judicial District Court eFiling System in accordance with the mandatory electronic service requirements of Administrative Order 14-2 and the Nevada Electronic Filing and Conversion Rules:

Steven E. Guinn Ryan W. Leary LAXALT & NOMURA, LTD. 9790 Gateway Dr., Ste. 200 Reno, NV 89521 Rocky Tsai ROPES & GRAY LLP Three Embarcadero Center San Francisco, CA 94111-4006 William T. Davison ROPES & GRAY LLP Prudential Tower 800 Boylston Street Boston, MA 02199 *Attorneys for Mallinckrodt LLC; Mallinckrodt US Holdings, Inc.*	LAWRENCE J. SEMENZA, III, CHRISTOPHER D. KIRCHER, JARROD L. RICKARD, ESQ., SEMENZA KIRCHER RICKARD 10161 Park Run Drive, Ste. 150 Las Vegas, Nevada 89145 Telephone: (702) 835-6803 Facsimile: (702) 891-8763 SARAH B. JOHANSEN, ESQ., REED SMITH LLP 355 South Grand Avenue, Suite 2900 Los Angeles, CA 90071 Telephone: (213) 457-8000 Facsimile: (213) 457-8080 *Attorneys for AmerisourceBergen Drug Corp.*
Pat Lundvall Amanda C. Yen McDONALD CARANO LLP 100 W. Liberty Street, 10th Floor Reno, NV 89501 John D. Lombardo *(pro hac vice forthcoming)* Jake R. Miller *(pro hac vice forthcoming)* Tiffany M. Ikeda *(pro hac vice forthcoming)* ARNOLD & PORTER KAYE SCHOLER LLP 777 S. Figueroa St., 44th Floor Los Angeles, CA 90017-5844 *Attorneys for ENDO Health Solutions, Inc. & ENDO Pharmaceuticals, Inc.*	Steve Morris Rosa Solis-Rainey MORRIS LAW GROUP 411 E. Bonneville Ave., Ste. 360 Las Vegas, NV 89101 Nathan E. Shafroth (pro hac vice pending) COVINGTON & BURLING, LLP One Front Street San Francisco, CA 94111 *Attorneys for McKesson Corporation*

Max E. Corrick II OLSON, CANNON, GORMLEY, ANGULO & STOBERSKI 9950 W. Cheyenne Ave Las Vegas, NV 89129 Martin Louis Roth Donna Marie Welch Timothy William Knapp Erica Zolner KIRKLAND & ELLIS, LLP 300 N. LaSalle Chicago, Illinois 60654 Jennifer Gardner Levy KIRKLAND & ELLIS, LLP 1301 Pennsylvania Ave., N.S. Washington, DC 20004 *Attorneys for Allergan USA, Inc. and Allergan Finance LLC fka Actavis Inc. fka Watson Pharmaceutic, Allergan USA, Inc.*	Philip M. Hymanson HYMANSON & HYMANSON PLLC 8816 Spanish Ridge Avenue Las Vegas, Nevada 89148 Steven A. Reed MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, Pennsylvania 19103 Collie F. James, IV MORGAN, LEWIS & BOCKIUS LLP 600 Anton Blvd., Suite 1800 Costa Mesa, California 92626-7653 Brian M. Ercole MORGAN, LEWIS & BOCKIUS LLP 200 South Biscayne Blvd., Suite 5300 Miami, Florida 33131 *Attorneys for Teva Pharmaceuticals USA, Inc.; Cephalon, Inc; Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. fka Watson Pharma, Inc.*
Chad Fears Kelly A. Evans Hayley E. Miller EVANS FEARS & SCHUTTERT LLP 2300 W. Sahara Ave, 3950 Las Vegas, Nevada 89102 Mark S. Cheffo Hayden A. Coleman Mara Cusker Gonzalez DECHERT LLP Three Bryant Park, 1095 Ave of the Americas New York, New York 10036-6797 *Attorneys for Purdue Pharmaceuticals, L.P.; The Purdue Frederick Company, Inc.; Purdue Pharma, Inc.; Purdue Pharma, L.P.*	Abran Vigil Brianna Smith BALLARD SPAHR LLP One Summerlin 1980 Festival Plaza Dr., Suite 900 Las Vegas, Nevada 89135-2658 J. Matthew Donohue Joseph L. Franco Heidi A. Nadel HOLLAND & KNIGHT 2300 U.S. Bancorp Tower 111 S.W. Fifth Ave Portland, Oregon 97204 *Attorneys for Insys Therapeutics, Inc.*
Lawrence Semenza III Christopher D. Kircher	Daniel F. Polsenberg J. Christopher Jorgensen

Jarrod Rickard Katie L. Cannata SEMENZA KIRCHER RICKARD 10161 Park Run Drive, Suite 150 Las Vegas, Nevada 89145 Scott D. Powers David Arlington BAKER BOTTS 98 San Jacinto Blvd Austin, Texas 78701 Kevin Sadler BAKER BOTTS 1001 Page Mill Road, Bldg. One, Ste. 200 Palo Alto, California 94304 *Attorneys for Assertio Therapeutics, Inc. fka Depomed, Inc.; Cardinal Health, Inc.; Mallinckrodt Brand Pharmaceuticals Inc.; Mallinckrodt, LLC; Ortho-McNeil-Janssen Pharmaceuticals, Inc. nka Janssen Pharmaceutica, Inc. nka Actavis, Inc, fka Watson Pharmaceuticals, Inc.; Abbvie, Inc.; Carindal Health 108 LLC dba Metro Medical Supply; Robert Gene Rand, MD; Rand Family Care, LLC*	LEWIS ROCA ROTHGERBER CHRISTIE LLP 3993 Howard Hughes Pkwy, Ste. 600 Las Vegas, Nevada 89169 *Attorneys for Cardinal Health, Inc., Cardinal Health 6, Inc.; Cardinal Health Technologies LLC; Cardinal Health 414 LLC; and Cardinal Health 200 LLC*

/s/ Makaela Otto
An Employee of EGLET ADAMS

SECOND JUDICIAL DISTRICT COURT
COUNTY OF WASHOE, STATE OF NEVADA

AFFIRMATION
Pursuant to NRS 239B.030 and 603A.040

The undersigned does hereby affirm that the preceding document, _____

Second Amended Complaint and Demand for Jury Trial
(Title of Document)

filed in case number: CV18-01895

☒ Document does not contain the personal information of any person.

- OR -

☐ Document contains the social security number of a person as required by:

☐ A specific state or federal law, to wit:

_____
(State specific state or federal law)

- or -

☐ For the administration of a public program

- or -

☐ For an application for a federal or state grant

- or -

☐ Confidential Family Court Information Sheet
(NRS 123.130, NRS 125.230, and NRS 125B.055)

Date: 5/14/2020

_____
(Signature)

Robert M. Adams, Esq.
(Print Name)

City of Reno
(Attorney for)