IN THE SUPREME COURT OF NEVADA

CITY OF RENO, Appellant, vs. TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN USA, INC.; ALLERGAN FINANCE, LLC K/K/A ACTAVIS INC. F/K/A WATSON PHARMACEUTICALS, INC.; ACTAVIS PHARMACY, INC. F/K/A WATSON PHARMA, INC.; AND ACTAVIS LLC, Respondents.	Electronically Filed Jun 05 2023 05:06 PM Elizabeth A. Brown Clerk of Supreme Court Supreme Court No. 85412 District Court Case No.: CV18-01895

APPENDIX TO RESPONDENTS' ANSWERING BRIEF
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618. The Manufacturer Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt 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. Manufacturer Defendants 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.

619. 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 opioids. The manufacturers negotiated agreements whereby the Manufacturer Defendants installed security vaults for the Distributor Defendants 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.

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

621. 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.

622. 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."[173] 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.[174]

623. Rather than abide by these public safety statutes, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[175]

624. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participants in the PCF. In 2012, membership and participating organizations included Endo, Purdue, and Actavis.[176] Each of the Manufacturer Defendants worked together through the PCF. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a

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

[174] *Id.*

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

[176] Mallinckrodt became an active member of the PCF sometime after 2012.

minimum, through their trade organization, the HDA.[177] The Distributor Defendants participated directly in the PCF as well.

625. 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, Endo, Purdue, and Mallinckrodt, were members of the HDA. The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including "strengthen[ing] . . . alliances."[178]

626. 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."[179] Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Manufacturer Defendants and Distributor Defendants.

627. 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.[180] For example, the manufacturer membership application must be signed by

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

[178] *Manufacturer Membership*, Healthcare Distribution Alliance, https://healthcaredistribution.org/about/membership/manufacturer (last accessed Apr. 25, 2018).

[179] *Id.*

[180] *Manufacturer Membership Application*, Healthcare Distribution Alliance,

a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

628. 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, Anda, Inc., Cardinal Health, McKesson, and their subsidiaries.

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

630. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[181] The conferences also gave the Manufacturer Defendants and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[182] The HDA and its conferences were and continue to be significant opportunities for the Manufacturer Defendants and Distributor Defendants to interact at a high-level of leadership. It is clear that the Manufacturer Defendants have embraced this opportunity by attending and sponsoring these events.[183]

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https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

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

[182] *Id.*

[183] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

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

1. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

2. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.

3. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributor and manufacturer members.

4. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

5. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.

632. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship

notices, and invoices.[184] 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.

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

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

635. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion. As the HDA (then the HDMA) explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.[185]

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

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

636. This statement by the HDA and the Industry Compliance Guidelines themselves support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under controlled substances laws. As John M. Gray, President/CEO of the HDA stated in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that all of the Defendants, working together, found the same balance – an overwhelming pattern and practice of failing to identify, report or halt suspicious orders and failure to prevent diversion, all the while obscuring naked profit motives with opaque concerns about drug "access."

637. The Defendants' scheme involved a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants 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 to identify, report or halt suspicious orders or report them to any appropriate agencies.

638. 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 Marketing and Distributor Defendants did this through their participation in the PCF and HDA.

639. 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 the production quotas for prescription opioids due to diversion of suspicious orders.

640. The Defendants also had reciprocal obligations 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.

641. 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 the continued appearance of consistency in their dealings with DEA.

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

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

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

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

645. This information includes the following facts:

1. Distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

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

3. Manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described elsewhere in this Complaint;

4. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

5. Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

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

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

648. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[186] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other 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.

649. 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.[187]

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

651. 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,

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[186] *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/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[187] 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).

[188] 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.

organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[189]

652. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.[190]

653. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities because Defendants have made it part of their collective business to know where those orders went and to whom.

654. Defendants refused to maintain effective controls to prevent diversion, and refused to identify, investigate and report suspicious orders to the DEA or the Nevada Board of Pharmacy when they became aware of the same, despite their actual knowledge of drug diversion rings. For instance, as described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[191] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six (76) actions involving orders to show cause and forty-one (41) actions involving immediate suspension orders, all for failure to report suspicious orders.[192]

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

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

[190] 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).

[191] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[192] *Id.*

656. 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?

657. Moreover, 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, Dr. Rand, operated a pill mill in Reno, Nevada, an activity for which he has been indicted, charged, and sentenced. Additionally, as discussed, *supra*, Dr. Steven Holper in Clark County, Nevada, has been indicted on charges related to the excessive Subsys prescriptions he has written to patients.

658. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this is an organized drug ring[.]"[193] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[194] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after

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

the clinic was shut down in 2010 to inform the authorities. This was a pattern and practice in the medical community of which Purdue was familiar and about which it did nothing.

659. As to Actavis, a Kadian prescriber guide discusses abuse potential of Kadian. It is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, 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." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.

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

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

662. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: "To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the

opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow / Grow = New Patient Starts and Conversions." In an example of how new patients plus a high-volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."

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

664. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturer Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[195]

665. 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.[196]

[195] Meier, *supra*, at 179.
[196] Harriet Ryan et al., *More Than 1 million OxyContin Pills Ended Up in the Hands of Criminals and Addicts, supra.*

666. As discussed below, Endo knew that Opana ER was being widely abused. Yet, as the New York Attorney General investigation into Endo revealed, 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. Worse, Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

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

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

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

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

670. For example, 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, 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."

671. McKesson further 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 CFR Part 1300 et seq., at the McKesson Distribution Centers." Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which, investigators found "were supplying pharmacies that sold to criminal drug rings."

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

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

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

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

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

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

677. Contrary to the representations of CVS, Viper was not a monitoring program. CVS's 30(b)(6) witness Mark Vernazza admitted at deposition that Viper "was not deemed an SOM report." Viper was no more than a theft report that provided no ability to evaluate specific orders of controlled substances placed by CVS pharmacies to McKesson. In reality, CVS had no policies, procedures or programs to monitor prescription opioid orders placed by its pharmacies to McKesson or any other outside vendor until 2014.

678. When McKesson sought to fulfill its responsibilities, efforts to monitor CVS pharmacies were resisted by CVS as early as 2008. In 2008 and 2010 CVS refused to provide McKesson sales or dispensing information for individual stores in order to establish accurate opioid thresholds. In March of 2012, Don Walker, the Senior Vice President of Distribution at McKesson and Tom McDonald, Director of Regulatory Affairs, met with CVS. At that

meeting, CVS was requested to provide information with regard to "cash sales ratio per store." Don Walker of McKesson acknowledged that this was "important information" to have to identify diversion. CVS refused to provide this information. Mr. Walker described this as a "business decision" on the part of CVS.

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

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

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

682. As a result of its misrepresentations, affirmative acceptance, and refusals outlined above, although CVS knew the importance of the data and responsibility for the monitoring of prescription opioid orders distributed from McKesson to CVS Pharmacies throughout the United States including Nevada and Plaintiff's communities specifically, CVS failed to make reasonable efforts to maintain effective controls against diversion of controlled substances and to monitor suspicious orders of controlled substances placed by CVS pharmacies to McKesson.

683. Similarly, in 2017, the Department of Justice fined Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled

substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."

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

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 CFR §1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 CFR §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 USC §842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 USC §828 and 21 CFR Part 1305."

685. In 2012, the State of West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws as well as for the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 million oxycodone pills during that time period. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or

to report and take steps to halt suspicious orders. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit for $16 million to the state; Cardinal Health settled for $20 million.

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

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

688. The sheer volume of prescription opioids distributed to pharmacies in the State of Nevada is excessive for the medical need of the community and facially suspicious.[197] Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[198]

689. Not only did Defendants fail to maintain effective controls to prevent diversion of controlled substances, they invested time, research, and funds to ensure the supply would be large enough for the excessive demand. Upon information and belief, J&J created and supplied a more potent strand of poppy that ultimately propped up the excessive, illegitimate, and harmful demand of opioids across the nation and in the State of Nevada, specifically.

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

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

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

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

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

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

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

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

696. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[199]

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

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

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

700. The Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity, and disseminated massive quantities of prescription opioids into the black market.

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

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

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

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

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

704. After being caught for failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even 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 promises not to do so.

705. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent 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."

706. 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."

707. 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 provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."

708. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, the HDMA (now HDA) and the National Association of Chain Drugstores ("NACDS"), filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements.[200]

1. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

2. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

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

710. 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 . . . ."

711. 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

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

"constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[201]

712. 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. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

713. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e 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 . . . ."[202] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[203] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[204]

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

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[201] 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-approved-label/; *Setting The Record Straight On Our Anti-Diversion Programs*, Purdue Pharma (July 11, 2016), http://www.purduepharma.com/news-media/get-the- facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[202] *Opioids With Abuse-Deterrent Properties*, Purdue Pharma, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids- with-abuse-deterrent-properties/.

[203] *Opioids & Corporate Responsibility*, Purdue Pharma, http://www.purduepharma.com/news- media/opioids-corporate-responsibility/.

[204] 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-antidiversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

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

715. 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.

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

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

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

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

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

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

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

721. Each participant in the supply chain of controlled substance distribution including, but not limited to, opioid and opioid cocktail drug distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

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

723. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

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

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

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

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

728. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted. As registrants, retail pharmacies are required to maintain effective controls and procedures to guard against theft and

diversion (*see* NAC §§ 453.400, 435.410; NRS §§ 639.500 – 639.515, 639.585) and to operate in compliance with all applicable federal, state and local laws and regulations. *See* NRS §§ 639.510. This would include reporting evidence of prescription diversion to the DEA. Furthermore, Nevada law requires retail pharmacies to adopt and abide by a marketing code of conduct, enforce policies regarding investigation into compliance and corrective actions, and submit and report certain information to the Board. NRS § 639.570

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

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

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

732. Upon information and belief, the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers

of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

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

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

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

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

b. National Retail Pharmacies Track Suspicious Orders and Possible Diversion Activities through Orders Delivered to their Locations and Dispensed by their Locations

737. The National Retail Pharmacies are responsible for the dispensing practices in their stores. The National Retail Pharmacies exerted day-to-day operational control from the top down, with the national, corporate entities designing and implementing uniform policies and procedures (to the extent they existed) that governed how all pharmacies in the chain were to

operate, including the exact conduct related to anti-diversion efforts at issue. The National Retail Pharmacies' control also intentionally resulted in a pharmacy environment that did not encourage, and in many instances did not even allow, pharmacists to fulfill their corresponding responsibility as pharmacists.

738. The State's claims are based on the National Retail Pharmacies' duties, their conduct in establishing dispensing policies and procedures, their failure to make use of the data they had regarding the dispensing of prescriptions, and their own failures to properly train their employees regarding their duties imposed by Nevada and federal law.

739. These laws and the related regulations, are intended to create a closed system for the delivery of controlled substances and prevent the distribution of controlled substances outside of the system. The National Retail Pharmacies have a duty to ensure that their pharmacies operate appropriately within the closed system in order to prevent diversion of dangerous drugs.

740. The National Retail Pharmacies have been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Several National Retail Pharmacies have been repeatedly penalized for their illegal practices related to prescription opioid sales.

741. In Nevada, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

742. Upon information and belief, the National Retail Pharmacies knew or reasonably should have known that there was a suspiciously large flow of opioids into Nevada and also the operation of "pill mills" within the State. "Pill mills" generated opioid prescriptions that, by their quantity, frequency, or nature, were signs of, or direct evidence of, illicit supply and diversion.

743. The National Retail Pharmacies knew or reasonably should have known about the ongoing opioid crisis and the devastating consequences of oversupply and diversion of prescription opioids, including the increased rates of opioid use disorder and opioid overdoses in the community.

744. Upon information and belief, because of regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others related to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were aware that their distribution and dispensing activities fell far short of legal requirements.

745. National Retail Pharmacies are responsible for developing SOM programs that track dispensing data in order to flag and review any retail locations where controlled substances are being dispensed in suspiciously high numbers. Upon information and belief, some National Retail Pharmacies relied solely upon such data for their SOM programs.

746. Each of the National Retail Pharmacies has been subject to numerous fines, penalties, and lawsuits arising out of opioid dispensing and record keeping at their retail locations nationwide. The dispensing practices at retail locations and the training of staff at those locations is critical to tracking the sale of opioids, flagging suspicious orders, and stopping any suspicious orders.

747. The National Retail Pharmacies breached their duties to the State and violated State laws and regulations by failing to adequately track such data in a way that would allow the National Retail Pharmacies to flag and stop suspicious orders.

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

748. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly

penalized for their irresponsible and illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

i. CVS

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

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

751. As recently as July 2017, CVS entered into a $5 million settlement regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[205]

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

1. February 2016, CVS paid $8 million in a settlement in Maryland;
2. October 2016, CVS paid $600,000 in a settlement in Connecticut;

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

3. September 2016, CVS paid $795,000 in a settlement with the Massachusetts Attorney General;

4. June 2016, CVS agreed to pay $3.5 million arising out of allegations that it filled forged prescriptions;

5. August 2015, CVS paid $450,000 in a settlement with the U.S. Attorney's Office for the District of Rhode Island;

6. May 2015, CVS agreed to pay a $22 million penalty arising out of an investigation in Sanford, Florida;

7. September 2014, CVS paid $1.9 million in civil penalties;

8. August 2013, CVS was fined by $350,000 by the Oklahoma Pharmacy Board; and

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

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

ii. Walgreens

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

756. Walgreens also has been penalized for serious and flagrant violations of its duties to prevent diversion. Indeed, Walgreens agreed to pay $80 million to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[206]

[206] *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled*

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

758. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[207]

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

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

H. <u>The Opioids the Defendants Sold Migrated into Other Jurisdictions.</u>

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

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

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

764. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for

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Substances Act, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao- sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

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

transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price.[208] In Columbus, Ohio, in 2011, 16 individuals were prosecuted for being involved in the "oxycodone pipeline between Ohio and Florida."[209] When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and $80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. District Judge Michael Watson, contributing to a "pipeline of death."[210]

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

766. In yet another case, defendants who operated a pill mill in south Florida within Broward County were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward's] customers came from Florida. Instead, the clinic grew

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[208] Andrew Welsh-Huggins, *'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers*, NBC News (July 8, 2012), http://www.nbcnews.com/id/48111639/ns/us_news- crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71.

[209] *16 Charged in Pill Mill Pipeline*, Columbus Dispatch (June 7, 2011), http://www.dispatch.com/content/stories/loal/2011/06/07/16-charged-in-pill-mill-pipeline.html.

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

prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts."[211] The court further noted that the pill mill "gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents."[212]

767. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.[213] Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag.[214] If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.[215] Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the "Oxy Express."[216]

768. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.[217]

769. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California.[218] Another similar pipeline developed in Michigan. According

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[211] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).
[212] *Id.* at 861.
[213] John Temple, *American Pain* 171 (2016).
[214] *Id.* at 172
[215] *Id.* at 171.
[216] *Id.*; *see also* Welsh-Huggins, *supra*. Note that Interstate 75 was also called as the Oxy Express; for example, the Peabody Award-winning documentary named *The OxyContin Express* focuses on the transport of prescription opioids along I-75. https://www.youtube.com/watch?v=wGZEvXNqzkM.
[217] *The OxyContin Express.* YouTube (Feb. 26, 2014), http://www.youtube.com/watch?v=wGZEvXNqzkM.
[218] Nok-Noi Ricker, *Slaying of Florida Firefighter in Maine Puts Focus on Interstate 95 Drug Running*, Bangor Daily News (March 9, 2012), http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-

to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.[219]

770. Along the West Coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.[220] Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.[221] The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.[222]

I. Nevada's Opioid Epidemic

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

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

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maine-puts- focus-on-interstate-95-drug-running.

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

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

[221] *Id.*

[222] *Id.*

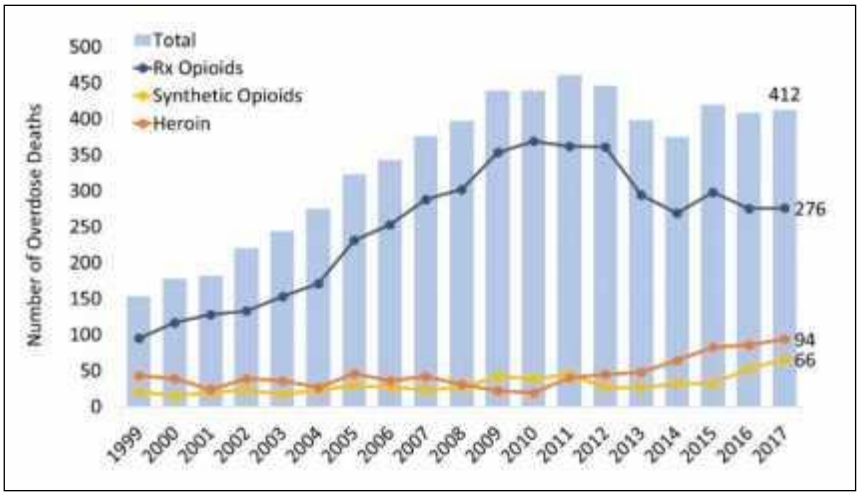


Figure 1. Number of overdose deaths involving opioids in Nevada, by opioid category. Drug categories presented are not mutually exclusive, and deaths might have involved more than one substance. Source: CDC WONDER.

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

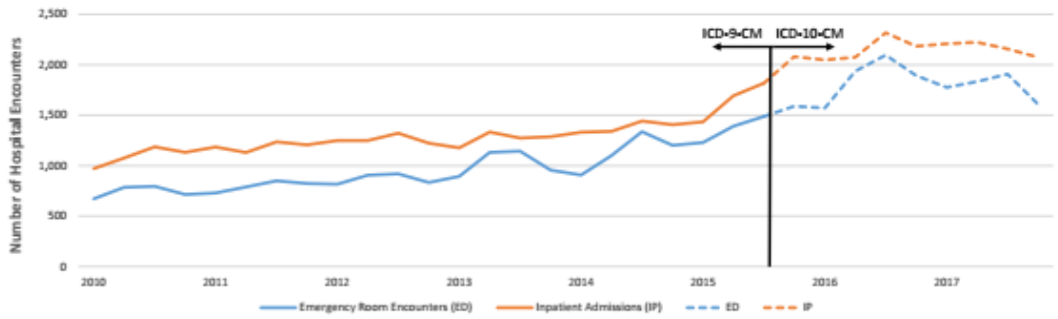
Opioid-Related Hospital Data, Nevada Residents, 2010-2017

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

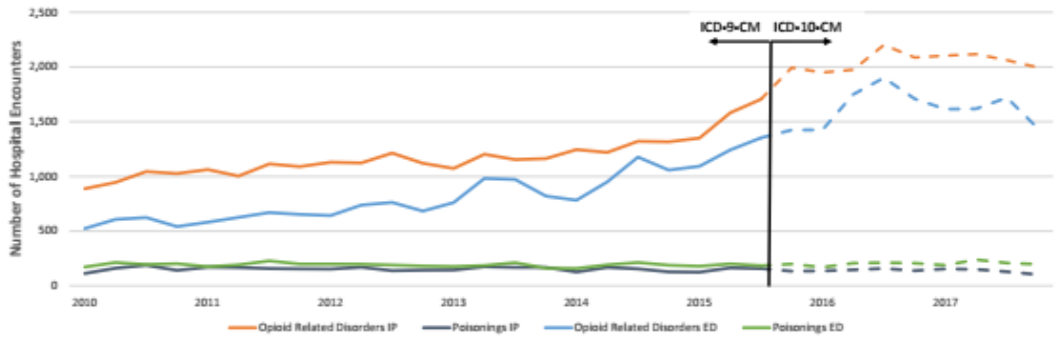
Year	Emergency Room Encounters (ED)	Emergency Room Crude Rates	Percent Change	Inpatient Admissions (IP)	Inpatient Crude Rates	Percent Change
2010	2,963	109.5		4,362	161.2	
2011	3,188	117.1	7%	4,755	174.7	8%
2012	3,473	126.3	8%	5,042	183.3	5%
2013	4,122	147.2	17%	5,067	180.9	-1%
2014	4,543	159.8	9%	5,517	194.0	7%
2015	5,695	196.5	23%	7,022	242.3	25%
2016	7,495	253.8	29%	8,621	291.9	20%
2017	7,125	238.7	-6%	8,661	290.1	-1%
Percent Change 2010-2017			118%			80%

Rates are per 100,000 Nevada Population.

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



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



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

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

Year	0-1	2-4	5-9	10-14	15-19	20-24	25+
2010	648	1,833	1,158	380	132	97	114
2011	691	1,977	1,339	403	132	74	139
2012	670	1,953	1,531	467	160	102	159
2013	754	1,952	1,483	411	192	111	164
2014	740	2,124	1,604	505	215	111	218
2015	880	2,771	2,196	592	245	117	221
2016	985	3,209	2,916	721	312	169	309
2017	1,104	3,357	2,725	705	322	182	266

773. In 2010, Nevada's opioid-related emergency room hospitalizations totaled 4,518 patients. In 2015, that number increased to 8,231 patients. Similarly, in 2010, the number of opioid-related inpatient admissions statewide totaled 3,095 hospitalizations. That number increased to 7,035 in 2015.

774. Nevada's death rate from drug overdose grew dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs. The State went from an age-adjusted drug overdose death rate of 11.5 in 1999 to 21.7 in 2016. Nevada has the fourth highest drug overdose mortality rate in the United States. Between 2010 and 2015, approximately 2,800 deaths in Nevada were attributed to opioid-related overdose. It is estimated that 55% of those deaths were caused by natural and semi-synthetic opioids.

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

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

778. Defendants' conduct in Nevada is much the same as their conduct around the country and includes, but is not limited to: sending detailers to speak to Nevada's medical

providers, leading classes and seminars in which Defendants and/or their representatives made misrepresentations regarding their opioid products, filling suspicious opioid orders, failing to report suspicious opioid orders, favoring those medical providers who were prescribing more opioids and stronger dosages of the drugs, and other conduct as discussed throughout this Complaint.

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

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

780. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[223]

781. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[224]

782. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[225]

[223] *See* Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[224] *See* Volkow & McLellan, *supra*.
[225] *See* Califf et al., *supra*.

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

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

785. Given the well-established relationship between the use of prescription opioids and the use of heroin, the State is informed and believes, and based thereon alleges, that the increase in opioid usage in the State of Nevada is dramatically increasing the rate of heroin addiction among Nevada residents.

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

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

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

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

790. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[226]

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

791. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[227]

792. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[228] Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the State of Nevada.

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

1. Conspiracy Among Manufacturer Defendants.

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

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

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

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

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

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

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

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

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

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

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

802. Manufacturer Defendants put their own twist on this method: they worked together to fabricate an entire ecosystem of misinformation, paid experts and Front Groups to legitimize, cite to, and create more of that misinformation, used legally-mandated medical education to spread and reinforce that misinformation, and then collected massive quantities of data to target for special attention those prescribers who were not playing along, all to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Manufacturer Defendants were able to create the illusion of consensus through their materials and references.

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

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

805. Manufacturer Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers that opioids were not a concern. The enormous impact of Manufacturer Defendants' 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." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy…

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

2. Conspiracy Among All Defendants.

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

808. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly-

knit industry. The Manufacturer Defendants and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

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

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

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

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

L. Statutes of Limitations are Tolled and Defendants Are Estopped From Asserting Statutes of Limitations as Defenses.

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

1. Continuing Conduct

814. Plaintiff, State of Nevada, contends it continues to suffer harm from the unlawful actions by the Defendants.

815. 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. Though the State has made efforts to abate the nuisance, the wrongdoing has not ceased and thus, the public nuisance remains, and the conduct causing the damages remains unabated.

2. Equitable Estoppel

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

817. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[229]

818. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[230]

819. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[231]

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

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

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

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

- "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

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

820. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. These Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community using literature and materials created at the direction of, and paid for by, the Defendants. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, and the State were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State of Nevada.

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

3. Intentional Concealment

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

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

824. As set forth herein, the Manufacturer Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Manufacturer Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations, and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Manufacturer Defendants' deceptions deprived the State of actual or implied knowledge of facts sufficient to put the State on notice of potential claims.

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

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

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

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

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

830. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the State filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

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

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

M. <u>Facts Pertaining to Civil Penalties and Punitive Damages</u>

833. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Manufacturer Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction

were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse- deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

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

835. Defendants' conduct was so willful, deceptive, and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. Through their ongoing course of conduct, Defendants knowingly, deliberately and repeatedly threatened, harmed, and created a risk of harm to public health and safety, and caused large-scale economic loss to communities and government liabilities across the country.

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

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

838. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay $19

million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

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

840. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' 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." 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.

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

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

- 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 that resulted in the suspension of its DEA registration;

- 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;

- On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

- On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

- On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

843. McKesson's conscious and deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[232] In the 2008 MOA, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[233]

844. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the Controlled Substances Monitoring Program ("CSMP") files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP. It failed to take these actions despite its awareness of the great probability that its failure to do so would cause substantial harm.

845. 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. McKesson's 2017 agreement with the DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its

[232] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. at 4 (Jan. 17, 2017), https://www.justice.gov/opa/press- release/file/928476/download.
[233] *Id.*

sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

846. 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."[234] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should 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)."[235] 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."[236] Due to these violations, McKesson agreed that its authority to distribute controlled substances from certain facilities would be partially suspended.[237]

847. As *The Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. 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";

[234] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press- release/file/928476/download.
[235] *Id.* at 4.
[236] *Id.*
[237] *Id.* at 6.

"[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

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

> DAVID SCHILLER: If they would [have] stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> [INTERVIEWER:] And they had none.
>
> DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[238]

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

[238] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-deaattorneys-went-easy-on-mckesson-the- countrys-largest-drug-distributor/.

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

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

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

852. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of

the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

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

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

855. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had continued to detail approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six- year period.

856. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that

Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).

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

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

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

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

V. LEGAL CAUSES OF ACTION

FIRST CAUSE OF ACTION
NRS § 202 et seq. and common law
(Against Manufacturer Defendants and Distributor Defendants)

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

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

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

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

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

866. The health and safety of the residents of the State, 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 to the State's citizens and residents.

867. 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.

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

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

870. 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.

871. 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.

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

873. 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, and the health and safety of those individuals in Nevada, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern.

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

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

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

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

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

879. Defendants' actions created and expanded and/or assisted in the creation and expansion of the abuse of opioids, which are dangerously addictive, and the ensuing associated

plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Nevada, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids. Such actions were inherently dangerous.

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

881. 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.

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

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

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

885. The public nuisance created by Defendants' actions is foreseeable, substantial, and unreasonable it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Distributor Defendants' abdication of their gate-keeping duties, and the Manufacturer Defendants' deceptive marketing activities, have caused harm to the entire community that includes, but is not limited to:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids made opioids a recreational drug of choice among Nevada teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those State residents who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and deceptive promotions. Many residents 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' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More pills sold by Defendants led to more addiction, with many addicts turning from prescription pills 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 increased number of individuals who abuse or are addicted to opioids increased the demands on the State's Medicaid program.

i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the State.

j. Defendants' interference with the comfortable enjoyment of life in Nevada is unreasonable because there is no social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

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

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

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

889. 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.

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

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

SECOND CAUSE OF ACTION

Violation of Nevada's Deceptive Trade Practices Act (NRS §§ 598.0903 to 598.0999)
(Against Manufacturer Defendants and Distributor Defendants)

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

893. At all times relevant herein, the Defendants violated the Nevada Deceptive Trade Practices Act, §§ 598.0903 to 598.0999, by repeatedly and willfully committing deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce, both of which are violations of the Act.

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

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

896. The Distributor Defendants willfully committed deceptive trade practices because of false representations as well as omission of material facts. *See* NRS § 598.0915(5); *see also*§§ 598.0915(2) ("[k]knowingly makes a false representation as to the source, sponsorship, approval or certification of goods or services for sale…"), 598.0915(3) ("[k]knowingly makes a false representation as to affiliation, connection, association with or

certification by another person"), and 598.0915(15) ("[k]nowingly makes any other false representation in a transaction").

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

898. As alleged herein, each Manufacturer Defendant, at all times relevant to this Complaint, violated the Deceptive Trade Practices Act by committing deceptive trade practices by representing that the opioid prescription pills "have … characteristics, … uses, [or] benefits …" that they do not have. NRS § 598.0915(5).

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

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

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

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

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

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

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

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

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

b. Upon information and belief, within Nevada, distributing materials that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

c. Disseminating misleading statements nationally that reached doctors and prescribers within Nevada concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers, including consumers in Nevada;

d. Distributing brochures to doctors, patients, and law enforcement officials nationally, and upon information and belief, in Nevada, that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications nationally that were available and distributed to doctors within Nevada, that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications nationally that were distributed, upon information and belief, to doctors within Nevada, that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements, available to doctors and patients in Nevada, concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials available nationally, and upon information and belief, in Nevada, concerning the use of opioids to treat chronic non-cancer pain;

i. Assisting in the distribution of guidelines nationally and within Nevada, that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

j. Endorsing and assisting in the distribution of CMEs, attended by or made available to doctors licensed in Nevada, containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies nationally, and upon information and belief, within Nevada 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;

l. Assisting in the dissemination of literature nationally and within Nevada, written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials nationally, and upon information and belief, within Nevada, that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

n. Targeting veterans nationally, and upon information and belief, in Nevada, by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

o. Targeting the elderly nationally, and upon information and belief, in Nevada, 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;

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

q. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to Nevada prescribers through in-person detailing; and

r. Withholding from Nevada law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

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

a. Creating, sponsoring, and assisting in the distribution of patient education materials nationally, and upon information and belief, in Nevada, that contained deceptive statements;

b. Creating and disseminating advertisements nationally, and upon information and belief, in Nevada, 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. Creating and disseminating paid advertisement supplements in academic journals that were made available to and, upon information and belief, distributed to doctors licensed in Nevada, promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements nationally, and upon information and belief, in Nevada, that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements nationally and in Nevada, concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated that were available to consumers and doctors licensed in Nevada;

f. Endorsing, directly distributing, and assisting in the distribution of publications nationally, and upon information and belief, in Nevada, that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements available to doctors and patients in Nevada concerning the use of opioids to treat chronic non-cancer pain;

h. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious misrepresentations – that made deceptive statements, including in patient education materials, available nationally, and upon information and belief, in Nevada, concerning the use of opioids to treat chronic non-cancer pain;

i. Targeting the elderly nationally, and upon information and belief, in Nevada, 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;

j. Endorsing and assisting in the distribution of CMEs, attended by or made available to doctors licensed in Nevada, containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Developing and disseminating scientific studies that were available nationally, and upon information and belief, in Nevada, that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

l. Directly distributing and assisting in the dissemination of literature nationally and in Nevada, written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials available nationally, and upon information and belief, in Nevada, that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

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

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

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

b. Creating and disseminating advertisements nationally and, upon information and belief, in Nevada, that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements nationally and, upon information and belief, in Nevada, that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies nationally that reached doctors and prescribers in Nevada, that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

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

a. Creating, sponsoring, and assisting in the distribution of patient education materials throughout the United States—including, upon information and belief, Nevada prescribers—that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients throughout the United States— including, upon information and belief, in Nevada;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids that, upon information and belief, reached Nevada doctors and prescribers, to treat chronic non-cancer pain and breakthrough chronic non-cancer pain; and

d. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials that, upon information and belief, reached Nevada doctors and prescribers, concerning the use of opioids to treat chronic non-cancer pain.

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

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

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

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

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

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

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

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

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

THIRD CAUSE OF ACTION

Violation of the Nevada Racketeering Act (NRS §§ 207.350 to 207.520)

(Against Defendants Purdue and The Sackler Defendants, J&J, Endo, Mallinckrodt, Actavis, McKesson, Cardinal and AmerisourceBergen)

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

920. The State, both as a "person" who has sustained injury ***and*** on behalf of Nevada residents who have been injured, brings this claim for civil remedies under the Racketeering Act, NRS §§ 207.350 to 207.520, against the following Defendants, as defined above: Purdue and the Sackler Defendants, J&J, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and

AmerisourceBergen (collectively, for purposes of this Count, the "Racketeering Defendants"). The Attorney General has the specific statutory authority to bring this action pursuant to NRS §§ 207.415 and 207.490.

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

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

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

924. For over a decade, the Racketeering Defendants 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, the Racketeering Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the Racketeering Defendants operated and continue to operate within the nationwide "closed-system" created under the Controlled Substances Act, 21 USC § 821, *et seq.* (the "CSA") and the Nevada Controlled Substances Act, §§ 453.005 to 453.730. Together, the CSA and Nevada Controlled Substances Act restrict the Racketeering Defendants' ability to manufacture or distribute Schedule II substances like opioids nationally and in Nevada by requiring them to: (1) register

to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA, the Nevada Pharmacy Board, and the FDA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

925. The nationwide closed-system, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[239]

926. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their duty under Nevada law to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA, the Nevada Board of Pharmacy, and the FDA of suspicious orders.[240] As discussed in detail below, through the Racketeering Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas throughout the United States for opioids allowed by the DEA.[282] In doing so, the Racketeering Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

927. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the Racketeering Defendants were associated with, and conducted or participated in, the affairs of the racketeering enterprise (defined below

[239] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[240] 21 USC § 823(a)(1), (b)(1); 21 CFR § 1301.74(b)-(c).

and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and to deceive the public, and federal and state regulators into believing that the Racketeering Defendants were faithfully fulfilling their statutory obligations. The Racketeering Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Racketeering Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the State of Nevada experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the Racketeering Defendants' misconduct violated § 207.400 of the Racketeering Act and the State is entitled to treble damages for its injuries under NRS § 207.410.

928. J&J, was not only a manufacturer of the opioid products, but supplied, through the deceptive means, the raw materials that became the opioid products manufactured by the other Defendant Manufacturers who are Racketeering Defendants.

929. Alternatively, the Racketeering Defendants were members of a legal entity enterprise within the meaning of NRS § 207.380 through which the Racketeering Defendants conducted their pattern of racketeering activity in Nevada and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[241] is a distinct legal entity that satisfies the definition of a racketeering enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in § 207.380 because it is a corporation and a legal entity.

[241] Health Distribution Alliance, History, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

930. On information and belief, each of the Racketeering Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

931. Each of the Racketeering Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Racketeering Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Racketeering Defendants exists separately from the HDA. Therefore, the HDA may serve as a racketeering enterprise.

932. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the Racketeering Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association- in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

A. THE OPIOID DIVERSION ENTERPRISE

933. Throughout the United States—and within the State of Nevada—the Racketeering Defendants have operated at all relevant times under a "closed distribution system" of quotas that governs the production and distribution of prescription opioid drugs. The Opioids Diversion Enterprise is an ongoing and continuing business organization that created and maintained systemic links for a common purpose: To protect and maximize their profitability under this quota system through the unlawful sale of opioids. The Racketeering Defendants participated in the Opioids Diversion Enterprise through a pattern of racketeering activity, which includes multiple violations of Nevada state criminal law.

934. Recognizing that there is 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.[242] The CSA and its implementing

[242] Joseph T. Rannazzisi Decl. ¶4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

regulations created a closed-system of distribution for all controlled substances and listed chemicals.[243] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[244] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[245] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[246] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[247] All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[248] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[249] The result is the scourge of addiction that has occurred.

935. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of

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[243] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

[244] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 USC § 801(20; 21 USC §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[245] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

[246] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[247] *See* Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).

[248] *Id.*; 16.19.8.13(F) NMAC (requiring anyone licensed to distribute Schedule II controlled substances in Nevada to "report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and where applicable, to the DEA."); 16.19.20.48(A) NMSA ("All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.").

[249] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[controlled substances], and the requirement of order forms for all transfers of these drugs."[250] When evaluating production quotas, the DEA was instructed to consider the following information:

- Information provided by the United States Department of Health and Human Services;
- Total net disposal of the basic class by all manufacturers;
- Trends in the national rate of disposal of the basic class;
- An applicant's production cycle and current inventory position;
- Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- 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.[251]

936. Under the CSA, as incorporated into Nevada law, it is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[252]

937. At all relevant times, the Racketeering Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their duty under Nevada law to identify, investigate, halt or report suspicious orders of opioids and diversion of their drugs into the illicit market, *see generally* **IV.E.1** *supra*, in order to

[250] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[251] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[252] *Id.* (citing 21 USC 842(b)); NRS § 453.385 (regulations must ensure "compliance with, but may be more stringent than required by, applicable federal law governing controlled substances and the rules, regulations and orders of any federal agency administering such law.")); NRS § 453.146 (the Nevada Board of Pharmacy may consider findings of "the federal Food and Drug Administration or the Drug Enforcement Administration as prima facie evidence relating to one or more of the determinative factors.").

unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Racketeering Defendants conducted their pattern of racketeering activity in Nevada and throughout the United States through this enterprise.

938. The Racketeering Defendants conspired together to target specific doctors to prescribe more opioids for longer durations, thus increasing the flow of opioids into the market and contributing to the crisis.

939. The Racketeering Defendants further conspired together to pressure the FDA to move away from restrictions on opioid marketing and sales so that their own profits would continue to increase, regardless of dangers to the community.

940. The Racketeering Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the Racketeering Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

941. The Racketeering Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and illegal trafficking in and distribution of prescription opioids, in violation of Nevada law.

942. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding reports and representations about their systems for controlling against diversion, and refusal to report suspicious orders.

943. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, nationwide per capita purchases of methadone, hydrocodone, and oxycodone increased 13-fold, 4- fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of hydrocodone

every 4 hours for 1 month.[253] On information and belief, the Opioid Diversion Enterprise has been ongoing nationally and in Nevada for at least the last decade.[254]

944. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that State and federal regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public and the State of Nevada and its residents.

945. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Racketeering Defendant; (b) was separate and distinct from the pattern of racketeering in which the Racketeering Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Racketeering Defendants; (d) characterized by interpersonal relationships among the Racketeering Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Racketeering Defendants would have a larger pool of prescription opioids from which to profit.

946. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there may be some legitimate uses and/or needs for prescription opioids, the Racketeering Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal

[253] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. *Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States*. Am J Public Health. 2014;104(2):e52-9.

[254] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy- amid-drug-epidemic.

laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

947. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Racketeering Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

948. Each of the Racketeering Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The Racketeering Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Racketeering Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

949. The Racketeering Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum ("PCF"), the HDA, and through their contractual relationships.

950. PCF has been described as a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. 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.

951. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[255] 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.[256]

952. Not surprisingly, each of the Racketeering Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[257] In 2012, membership and participating organizations included the HDA (of which all Racketeering Defendants are members), Endo, Purdue, J&J, Actavis, and Teva.[258] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[259] The State is informed and believes that the Distributor Defendants participated directly in the PCF as well.

953. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

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[255] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy- amid-drug-epidemic (emphasis added).

[256] *Id.*

[257] PAIN CARE FORUM 2012 Meetings Schedule, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings- Schedule-amp.pdf.

[258] *Id.* The State is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

[259] *Id.*

954. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

955. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the Racketeering Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis, Purdue, and Mallinckrodt, were members of the HDA.[260] The HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

956. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[261] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Distributors.

[260] Manufacturer Membership, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

[261] Manufacturer Membership Benefits, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership- benefits.ashx?la=en.

957. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Racketeering Defendants.[262] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[263]

958. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[264]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e- commerce." Participation in this committee includes distributors and manufacturer members.[265]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[266]

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[262] Manufacturer Membership Application, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.
[263] *Id.*
[264] Councils and Committees, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and-committees.
[265] *Id.*
[266] *Id.*

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[267]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.[268]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[269]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[270]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[271]

i. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[272]

959. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

960. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences

[267] *Id.*
[268] *Id.*
[269] *Id.*
[270] *Id.*
[271] *Id.*
[272] *Id.*

to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[273] 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."[274] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[275]

961. Third, the Racketeering Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

962. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[276] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[277] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed

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[273] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for- manufacturers.

[274] *Id.*

[275] 2015 Distribution Management Conference and Expo, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015- distribution-management-conference.

[276] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter- manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter- manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed- markets/.

[277] *Id.*

information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[278] 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 the prescription opioids.

963. The contractual relationships among the Racketeering Defendants also include vault security programs. The Racketeering Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The State is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. The State is informed and believes that these agreements were used by the Racketeering Defendants as a tool to violate their reporting and diversion duties under Nevada law,[279] in order to reach the required sales requirements.

964. 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 Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Racketeering Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum 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 Racketeering Defendants were in communication and cooperation.

965. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum – whose members include the Manufacturers and the Distributors' trade association – has been lobbying on behalf of the Manufacturers and

[278] Webinars, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.
[279] *See, e.g.*, NRS § 453.231(a).

Distributors for "more than a decade."[280] From 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[281] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[282]

966. Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[283]

967. As described above, the Racketeering Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to further the common purpose of their enterprise. The State is informed and believes that the Racketeering Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

968. The Racketeering Defendants conducted the Opioids Diversion Enterprise, and participated in the enterprise, by engaging in a pattern of racketeering activity, as prohibited by NRS § 207.400.

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[280] Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Ctr. for Pub. Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro ainkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last updated Dec. 15, 2016, 9:09 AM).

[281] *Id.*

[282] HDA History, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

[283] *See* Bernstein & Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, *supra*; Bernstein & Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, *supra*; Eyre, *supra.*

969. During the time period alleged in this Complaint, the Racketeering Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their obligations under Nevada law (and federal law, as incorporated into Nevada law) to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales as set forth below. In doing so, the Racketeering Defendants increased production quotas and generated unlawful profits.

970. The Racketeering Defendants disseminated statements that were false and misleading – either affirmatively or through half-truths and omissions – to the general public, the State, Nevada consumers, and the Nevada Board of Pharmacy, claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

971. The Racketeering Defendants disseminated statements that were false and misleading – either affirmatively or through half-truths and omissions – to the general public, the State, Nevada consumers, and the Nevada Board of Pharmacy, claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

972. The Racketeering Defendants disseminated statements that were false and misleading – either affirmatively or through half-truths and omissions – to the general public, the State, Nevada consumers, and the Nevada Board of Pharmacy claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

973. The Opioid Diversion Enterprise worked to scale back regulatory oversight by the DEA that could interfere with the Racketeering Defendants' ability to distribute their opioid drugs in the State of Nevada. To distribute controlled substances in Nevada, the Racketeering Defendants had to be able to demonstrate possession of a current Nevada registration. *See* NRS § 453.226. Even if they held a current registration, the Racketeering Defendants' ability to

obtain a Nevada registration could be jeopardized by past suspension or revocation of their DEA registration. NRS § 453.231(1)(g).

974. The Racketeering Defendants paid nearly $800 million dollars to influence local, state and federal governments throughout the United States and in Nevada, through joint lobbying efforts as part of the Pain Care Forum. The Racketeering Defendants were all members of the Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids—protecting the Racketeering Defendants' ability to distribute prescription opioids in Nevada.

975. The Racketeering Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

976. The Racketeering Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[284]

977. The Racketeering Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. The State is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, the State is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

[284] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and- finance/hdma-now-healthcare-distribution-alliance/; Bernstein & Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, *supra*; Bernstein & Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, *supra*; Eyre, *supra.*

978. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the Racketeering Defendants.

979. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Racketeering Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[285] On information and belief, the "know your customer" questionnaires informed the Racketeering Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are 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.

980. The Racketeering Defendants refused to identify, investigate and report suspicious orders to the DEA, the Nevada Board of Pharmacy, and the FDA when they became aware of the same despite their actual knowledge of drug diversion rings. The Racketeering Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[286] and 117 recommended decisions in registrant actions from The Office of

[285] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[286] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders – all for failure to report suspicious orders.[287]

981. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants 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 to identify suspicious orders and report them to the DEA and State governments, including the State of Nevada.

982. The Racketeering Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and to ensure that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the Racketeering Defendants ensured that the DEA had no basis for refusing to increase, or to decrease, the production quotas for prescription opioids due to diversion of suspicious orders. The Racketeering Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

[287] *Id.*

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[288]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The Racketeering Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The Racketeering Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

j. The Racketeering Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

983. The scheme devised and implemented by the Racketeering Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, in intentional violation of Nevada law, and all designed and operated to ensure the continued unlawful sale of controlled substances.

[288] Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

C. PATTERN OF RACKETEERING ACTIVITY

984. The Racketeering Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in NRS § 207.390, by at least two crimes related to racketeering (NRS § 207.360), trafficking in controlled substances (NRS §§ 207.360(22); 453.3395), multiple transactions involving deceit in the course of an enterprise (NRS §§ 207.360(35); 205.377) and distribution of controlled substances or controlled substance analogues (NRS § 453.331), and punishable by imprisonment of at least one year, with the intent of accomplishing activities prohibited by § 207.400 of the Racketeering Act.

985. The Racketeering Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of NRS §§ 207.360), within a five-year period. The multiple acts of racketeering activity that the Racketeering Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Racketeering Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise.

986. The Racketeering Defendants committed these predicate acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the Opioids Diversion Enterprise by conducting activities prohibited by NRS §§ 207.360, 207.390, 207.400.

987. The predicate acts all had the purpose of generating significant revenue and profits for the Racketeering Defendants while the State was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Racketeering Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

988. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, the Racketeering Defendants are distinct from the enterprise.

989. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

990. Many of the precise dates of the Racketeering Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise alleged herein depended upon secrecy.

991. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the State of Nevada. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Nevada, Nevada consumers, or other Nevada residents. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Racketeering Defendants were also aware that the State and the residents of this jurisdiction rely on the Racketeering Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

992. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Racketeering Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

993. It was foreseeable to Defendants that refusing to report and halt suspicious orders would harm the State by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

994. The Racketeering Defendants did not undertake the predicate acts described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Racketeering Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Racketeering Defendants.

995. The Racketeering Defendants aided and abetted others in the violations of NRS §§ 207.360, 207.390, and 207.400, while sharing the same criminal intent as the principals who committed those violations, thereby rendering them indictable as principals in the offenses.

996. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

1. The Racketeering Defendants Conducted the Opioid Diversion Enterprise through Acts of Fraud.

997. Fraud consists of the intentional misappropriation or taking of anything of value that belongs to another by means of fraudulent conduct, practices or representations.

998. The Racketeering Defendants' fraudulent conduct, practices, and representations include, but are not limited to:

a. Misrepresentations to facilitate Defendants' DEA registrations, which could be a bar to their registrations with the Nevada Board of Pharmacy;

b. Requests for higher aggregate production quotas, individual production quotas, and procurement quotas to support Defendants' manufacture and distribution of controlled substances they knew were being or would be unlawfully diverted;

c. Misrepresentations and misleading omissions in Defendants' records and reports that were required to be submitted to the DEA and the Nevada Board of Pharmacy pursuant to Nevada Administrative Code provisions;

d. Misrepresentations and misleading omissions in documents and communications related to the Defendants' mandatory DEA reports that would affect Nevada registrant status; and

e. Rebate and chargeback arrangements between the Manufacturers and the Distributors that Defendants used to facilitate the manufacture and sale of controlled substances they knew were being or would be unlawfully diverted into and from Nevada.

999. Specifically, the Racketeering Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Racketeering Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

1000. At the same time, the Racketeering Defendants misrepresented the superior safety features of their order monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

1001. The Racketeering Defendants intended to and did, through the above-described fraudulent conduct, practices, and representations, intentionally misappropriate funds from the State and from private insurers, in excess of $500, including, for example:

a. Costs of prescriptions provided under Nevada's Medicaid Program;

b. Public employees' health insurance prescription coverage costs;

c. Retired public employees' group insurance costs;

d. Public employees and school board retirees' group health insurance costs; and

e. Prescription benefits paid by private insurers for opioid prescriptions.

1002. Many of the precise dates of the fraudulent acts and practices have been deliberately hidden and cannot be alleged without access to Defendants' books and records. But, the State has described the types of, and in some instances, occasions on which the predicate acts of fraud occurred.

2. The Racketeering Defendants Unlawfully Trafficked in and Distributed Controlled Substances.

1003. Defendants' racketeering activities also included violations of the Nevada Controlled Substances Act, § 453.3395, and each act is chargeable or indictable under the laws of Nevada and punishable by imprisonment for more than one year. *See* NRS § 207.360(22).

1004. Under Nevada law (NRS § 453.3395), it is unlawful to "knowingly or intentionally sell[], manufacture[], deliver[] or bring[] into this state"— prescription opioids, which are Schedule II controlled substances that are narcotic drugs, except as authorized by the Nevada Controlled Substances Act.

1005. The Racketeering Defendants intentionally trafficked in prescription opioid drugs, in violation of Nevada law, by manufacturing, selling, and/or distributing those drugs in Nevada in a manner not authorized by the Nevada Controlled Substances Act. The Racketeering Defendants failed to act in accordance with the Nevada Controlled Substances Act because they did not act in accordance with registration requirements as provided in that Act.

1006. Among other infractions, the Racketeering Defendants did not comply with 21 USC § 823 and its attendant regulations (*e.g.*, 21 CFR § 1301.74)[289] which are incorporated into Nevada state law, or the Nevada Pharmacy Board regulations. The Racketeering Defendants failed to furnish notifications and omitted required reports to the Nevada Board.

1007. The State is informed and believes that the Racketeering Defendants failed to furnish required notifications and make reports as part of a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA, as required by 21 CFR § 1301.74, throughout the United States.

1008. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[290]

1009. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of their duty to report suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.[291] The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug

[289] Once again, throughout this Count and in this Complaint Plaintiff cites federal statutes and federal regulations to state the duty owed under Nevada tort law, *not* to allege an independent federal cause of action or substantial federal question. *See, e.g., Herrera,* 2003-NMSC-018, ¶7.

[290] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson / Newsroom / Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press- releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/.

[291] Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

ring."[292] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[293]

1010. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt, arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012.[294] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.[295]

1011. The Racketeering Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports is evident in the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[296] For example:

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 that 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;

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[292] *Id.*
[293] *Id.*
[294] Bernstein & Higham, *The government's struggle to hold opioid manufacturers accountable*, *supra*. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.
[295] *Id.*
[296] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 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.

1012. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

1013. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

D. DAMAGES

1014. The Racketeering Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the State of Nevada and its residents injury in their business and property because the State paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

1015. The State's injuries, and those of its residents, were proximately caused by Defendants' racketeering activities. But for the Racketeering Defendants' conduct, the State would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

1016. The State's injuries and those of its residents were directly caused by the Racketeering Defendants' racketeering activities.

1017. The State was most directly harmed and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

1018. The State of Nevada seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit (NRS § 207.470), and pre- and post-judgment interest.

FOURTH CAUSE OF ACTION
Violation of Nevada False Claims Act NRS §§ 357.010 to 357.250
(Against All Defendants)

1019. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

1020. Defendants' willful and repeated conduct related to opioid sales, as described above, violates the Nevada False Claims Act, NRS § 357.040.

1021. Collectively, and individually, Defendants engaged in false and misleading marketing regarding the safety, efficacy, and appropriate use for prescription opioids; intentionally manipulated suspicious order monitoring systems, or failed to implement such systems, in order to allow for ever-increasing orders of prescription opioids; intentionally misled and made misrepresentations to government agencies regarding the appropriate use of prescription opioids and their monitoring systems to track orders of prescription opioids; and developed relationships with each other in order to continue fueling the prescription opioid crisis.

1022. In so doing, Defendants manufactured, sold, ordered, shipped, and distributed excessive quantities of prescription opioids, which were then prescribed to individuals whose claims for payment were submitted to the State Medicaid system. Many of the prescriptions would not have been written without the wrongdoing by Defendants in their marketing schemes and many should not have been filled had Defendants properly engaged SOM systems. Accordingly, thousands of Medicaid claims for prescription opioids would have never been

made but for the Defendants' wrongdoing as detailed in the State's Third Cause of Action for Violation of Nevada's Racketeering Act above, and further detailed below.

A. Manufacturer Defendants' Actions that Led to False Medicaid Claims

1023. As detailed above, the Manufacturer Defendants willfully misrepresented opioids as an appropriate, beneficial, and non-addictive treatment for chronic pain, and Defendants' course of conduct caused the State of Nevada to pay for drugs that were worthless in that they had no beneficial value, and in fact, were harmful to patients.

1. Endo / Par Pharmaceuticals

1024. Endo manufactured and sold two (2) primary opioid products between 2006 and 2017: Percocet and Opana. Percocet has long been known as a widely used and abused drug. Opana was previously sold and marketed in the 1960s, but was pulled from the market due its addictive nature. An article from 1962 documented the addictive nature of Oxmorphone (Opana) and that it was being abused.

a. Endo Intentionally Engaged in Misleading Marketing to Sell its Opioids

1025. Endo was aware of the addictive nature of Opana and the history of the drug, which is evident from Endo's internal Powerpoint titled "Corporate Reputation Management" dated May 2005, in which it specifically discussed that it would be problematic for the public to ever learn of the 1962 article and history of Opana, thereby demonstrating that Endo knew that it was putting an addictive product back on the market while actively trying to conceal the dangers of the drug.

1026. Endo's internal Powerpoint also included concerns from Endo that it may be named in litigation related to its Opana product.

1027. In a separate Powerpoint from October 2005 titled "Endo Commercial Capabilities Overview," Endo is referred to as "The Company that Percocet Built," and clearly demonstrates that the company's scientific affairs and marketing departments are closely intertwined. Endo laid out its intent to use scientific data in an "efficient and persuasive manner."

1028. Endo's Powerpoint also included a "Pyramid of Influence," demonstrating that Endo intended to influence from National Advisory Board down to Broad-scale Educational Initiatives. This campaign to influence others to use its opioid products had been developed over several years. In 2000, Endo laid out its intent to influence individuals through relationships, peers, and information.

1029. Endo's intent to influence included the plan to infiltrate the Physician Organization to Expand Pain Management and to conquer what Endo refers to as "opiophobia," or the fear of prescribing opioids, which Endo noted was a serious problem that needed to be dealt with. In a 2000 Powerpoint, Endo also discussed participating in industry organizations, "speaker placement" to discuss Endo's products, rapid publications, influencing textbooks, and influencing continuing medical education. Endo intended to market its opioid drugs in such a way that involved downplaying the dangers associated with the opioids.

1030. Endo continued its intentional misrepresentations in marketing its opioid products. Endo's internal marketing materials and Powerpoint demonstrations document Endo's intent to market Opana ER as a "low abuse potential" alternative to oxycontin, thereby concealing the addictive nature of the drugs.

1031. In 2017, Endo continued to market Opana ER at a discount. At that time, Opana ER had been discontinued due to objections by the FDA. Endo misrepresented that it voluntarily withdrew Opana ER, but documents reveal that the DEA was going to remove Opana ER from the market due to the risks associated with the drug.

1032. Endo's former Vice President of Pharmacovigilance and Risk Management and Chief Medical Officer, Mr. Shusterman, testified that Endo was absolutely aware that their opioid products were abused. Additionally, he testified that Endo was aware that its opioids were being diverted, but only through media reports.

1033. Par's former CEO and Endo's current CEO, Paul Campanelli, testified that he is aware of the problems associated with opioid abuse. He testified that Endo was pushing Percocet out of its intended market (moderate to moderately severe pain) into the market for mild and moderate pain.

1034. Mr. Campanelli further testified that Endo funded CMEs informing physicians that they would be sued for Malpractice if they failed to prescribe opioids.

1035. Additionally, Mr. Campanelli testified that, although Opana was marketed as a "low addiction alternative," there was no study to support that claim. Just the opposite, Endo had conducted studies with its manufacturing partner for Opana that the drug was easily abused. In fact, he testified that Endo was very aware of Opana's potency and addiction potential. Endo's low potency, low abuse potential message, was pushed in order to address the hesitations physicians had in prescribing Opana and to increase Endo's sales. Opana was so addictive that the FDA requested Endo voluntarily withdraw the drug from market and Endo did eventually pull the original formulation from the market.

1036. Endo intentionally deceived the public, members of the medical community, and governmental agencies regarding the safety and efficacy of its opioid products. Endo had a goal to increase its presence in the opioid market. As a result of Endo's misrepresentations, patients received prescriptions for opioids that would not have been written absent Endo's misrepresentations. As a further result of Endo's misrepresentations, the State Medicaid system was billed for prescriptions that would not have been written, filled, or invoiced without Endo's misrepresentations related to opioid drugs.

b. Endo and Par Failed to Operate an Effective SOM System

1037. Endo and Par did not maintain a SOM system that sufficiently tracked orders of opioids and did not operate a due diligence system to review any suspicious orders, thus leading to filling opioid orders and prescriptions that would not have otherwise been filled.

1038. In 2013 Endo and Qualitest (now known as Par), received an audit report from a Qualitest facility in Alabama, which identified several problems with Qualitest's SOM system including: (1) a lack of reporting; (2) selling quantities of controlled substances under Qualitest's thresholds to pharmacies that had already reached thresholds set by other distributors; (3) a complete lack of a pain management policy; and (4) a failure to review appropriate sources to determine whether prescriptions were valid.

1039. Endo's internal emails in 2013 regarding a DEA Compliance Initiative Presentation, includes a statement from Endo that it has an inadequate SOM system, thus leading Endo and Par to fear that the DEA will start focusing on Endo and Par's operations.

1040. Endo's Senior Director of Distribution and Customer Service testified that Endo is not a DEA registrant under the controlled substances act. Accordingly, Endo's SOM system is outsourced to UPS Logistics. The Senior Director testified that Endo was aware that UPS was not capable of performing SOM due diligence, thus leaving that task to Endo. The Senior Director further testified that Endo was solely responsible for providing the SOM information to UPS.

1041. In addition to utilizing UPS to operate the SOM system, based upon information received from Endo, Endo does not have a standard operating procedure for SOM system compliance. The Senior Director testified that Endo does not perform due diligence in opioid hot spots, including the State of Nevada, nor does it report orders to the DEA. Endo also did not track whether Endo's customers have SOM programs. In fact, the Senior Director testified that Endo's SOM system was so deficient, it had to be updated in 2014.

1042. Endo and Par failed to adequately monitor orders of controlled substances from their companies, thus leading to excessively large orders, and frequent orders, of opioids that

would not have otherwise been filled. Had Endo and Par put an effective SOM system in place, numerous opioid orders would not have been filled, and thus, the prescriptions would not have been sold and would not have been billed to the State's Medicaid system.

2. Teva/Cephalon/Actavis/Allergan

a. Teva Deceptively Marketed Opioids

1043. Upon information and belief, although Teva did not invent the opioid products it ultimately sold and promoted, it joined into the market by buying opioid business or by producing generic versions of successful opioid drugs.

1044. The Teva Defendants are a major Manufacturer of opioid drugs. For example, from 2012 to 2016, Teva's products were used to fill one in six opioid prescriptions in the United States.

1045. Upon information and belief, the Teva Defendants' 2016 acquisition of the Actavis generic business from Allergan plc made them the single largest prescription generic opioid manufacturer in the United States.

1046. Upon information and belief, in 1998 the FDA approved the opioid product Actiq, initially sold and manufactured by Anesta Corp. and later by Cephalon and Teva USA, solely for the management of "breakthrough pain" in opioid-tolerant cancer patients.

1047. Upon information and belief, the FDA placed a tight restriction on Actiq because it delivered a very powerful narcotic, fentanyl, in the form of a fast-dissolving lollipop, a Transmucosal Immediate-Release Fentanyl product ("TIRF"). These tight restrictions included a Risk Minimization Action Plan to ensure that any prescribing doctor fully understood the narrow indication as well as the increased risks of misuse, abuse, addiction, and overdose before prescribing the product. Therefore, the Teva Defendants were not only bound by the FDA regulations but also the Risk Minimization Action Plan developed by the FDA.

1048. When Cephalon purchased Anesta, it set extremely high sales goals for Actiq, pressuring employees to generate large volume sales.

1049. Cephalon succeeded by increasing sales by 36 times the volume of six years prior—volumes that would only be possible by selling outside the drug's indication.

1050. Upon information and belief, the increased sales were largely due to fraudulent marketing outside the drug's indication and not in compliance with the Risk Minimization Action Plan of the FDA.

1051. Cephalon, purchased by Defendant Teva, conducted an internal audit in 2003 after a whistleblower came forward with concerns about patient safety due to the manner in which the company was selling their opioid product, Actiq. The audit found that the company was not in compliance with its risk management program.

1052. Internal documents from the Teva Defendants praised the marketing team pushing Actiq, stating that the hard work of marketing would be evidenced in paychecks and bonuses.

1053. Cephalon's marketing teams were pushing the message that Actiq was safe and effective for any breakthrough pain (rather than the approved cancer-only breakthrough pain) and that Actiq's potential for abuse and addiction was minimal.

1054. Upon information and belief, Cephalon admitted to fraudulent marketing, plead guilty to criminal charges, and paid around $425 million dollars in fines and settlements.

1055. The improper sales tactics were intended to and did reach the State of Nevada, and the Teva Defendants marketed to doctors in Nevada that were not pain specialists or oncologists.

1056. A September 2008 Department of Justice press release discussed the guilty plea and settlement by Cephalon and confirmed the company's off-label promotion of drugs, including its opioid product, Actiq.

1057. Despite the Department of Justice investigation and its recent admission of off-label promotion, leadership at Cephalon joked in a speech in front of the company about the ability to pay the enormous $425 million dollar fine thanks to past sales revenue. Despite the recent lesson in fraudulent marketing, due to the decline in Actiq sales, leadership continued to

encourage the sales team to push the opioid product Fentora to reach the 200 million dollar sales mark in 2008. Although the speech urged the sales team to make the most of Fentora under its current indication, the speaker noted that they should prepare for a broader indication in the future—one that Fentora never achieved.

1058. Upon information and belief, the Teva Defendants also paid third parties to encourage general opioid use through unbranded marketing. For example, Teva sponsored the APF guide *Treatment Options: A Guide for People Living with Pain* (2007), that claims addiction is rare and limited to extreme cases of unauthorized dose escalations, shopping opioids from multiple sources, or theft. The Guide urges that restriction from opioid medications will not be a solution to drug abuse or addiction. Furthermore, the Guide dissuades readers from referring to opioids as "narcotics" so that the "myths and misunderstandings" about the potential for abuse are not emphasized.

1059. Actiq's patent was set to expire in 2006, leading Cephalon sales staff members to worry about the loss in revenue and even hosted a fake funeral for the drug that had made the company so much money.

1060. Upon information and belief, the company then created the fentanyl-based Fentora that, despite efforts to market the drug beyond breakthrough cancer pain, was again restricted by the FDA to a limited indication for breakthrough cancer pain in opioid-tolerant patients and a very restrictive risk minimization action plan.

1061. Cephalon continued to push Fentora in almost the same manner as Actiq. Despite the Teva Defendants' knowledge that most Actiq prescriptions had been written for non-cancer pain conditions, the marketing team presented Fentora as an alternative to any Actiq already in use.

1062. Fentora training materials falsely stated that patients taking opioids to manage their pain may be at lower risk for addiction because pain reduces the euphoric effects of opioids. Therefore, these sales materials falsely claimed that patients in pain do no usually become addicted to opioids.

1063. Upon information and belief, despite the knowledge that Fentora was also not approved for non-cancer break-through pain, Cephalon's internal documents showed that a May 2007 Department of Justice investigation into the company continued to show improper promotion outside of the labeled indications despite allegedly increased compliance efforts.

1064. In September 2007, after receiving numerous reports of serious adverse events, the FDA issued a Public Health Advisory regarding Fentora.

1065. By 2009, the FDA had issued a Drug Marketing, Advertising, and Communications Letter stating that Fentora links on internet search engines were misleading consumers because they promoted efficacy information while omitting risk information. Additionally, the FDA said that the company's "sponsored links" did not adequately convey Fentora's indication.

1066. After the Teva Defendants purchased Cephalon in 2011 for $16 billion, they continued the company's misleading marketing practices.

1067. Upon information and belief, the Teva Defendants' internal documents lauded the positive effect marketing messages had on prescribers, noting the huge return on investment of "detailing."

1068. The Teva Defendants continued and expanded Cephalon's practice of funding front groups, speaker programs, and spreading misleading marketing materials to minimize addiction and misuse risks with Fentora.

1069. Upon information and belief, the Teva Defendants paid their clinical communications department to ghost-write letters for doctors to be submitted to insurers to override insurance company decisions to refuse to pay for non-cancer uses of Fentora.

1070. The Teva Defendants widely disseminated a journal supplement, *Oral Transmucosal Fentanyl Citrate (ACTIQ)*, to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* that openly promoted Fentora for multiple causes of pain, not the limited indication for cancer pain.

1071. Upon information and belief, the Teva Defendants made large payments to third-party pain groups for their advocacy regarding pain and opioid product treatment options, but the Teva Defendants sought to hide the affiliation with these groups.

1072. Upon information and belief, the Teva Defendants made substantial payments to speakers who promoted the unbranded opioid marketing scheme.

1073. Upon information and belief, Teva contributed educational grants to promote the use of opioids to treat chronic pain.

1074. Teva lobbied to dilute legislation that would combat the opioid epidemic and curb the rampant use and prescription of opioid products.

1075. The Teva Defendants contributed large amounts of money to disseminate misleading, unbranded pain publications like *Exit Wounds* that targeted veterans and falsely assured that people not predisposed to addiction were unlikely to become addicted to opioids.

1076. The Teva Defendants created a video presented as a documentary called *Pain Matters* that stated the importance of opioid prescription for many people living with chronic pain. Additionally, this production falsely claimed that risk of abuse or addiction was low for patients without a previous history of addiction.

1077. Upon information and belief, the Teva Defendants spread unbranded promotional material at major conferences and actively recruited and paid key opinion leaders to spread these same misleading marketing messages.

1078. Internal Teva documents laid out a roadmap for recruiting front groups to spread Teva and Cephalon's unbranded marketing messages to push opioids for the treatment of chronic pain.

1079. The Teva Defendants engaged in targeted, misleading marketing with the intent to grow the opioid market, thus leading to opioid prescriptions being written in Nevada that would not have been written but for the misrepresentations made by the Teva Defendants. Had the prescriptions not been written and filled, they would not have been billed to the State's Medicaid system.

1080. Thus, the Teva Defendants' marketing misrepresentations led to an increase in prescriptions that were written because of the false information and an influx of Medicaid payments for those prescriptions.

b. Teva Failed to Implement an Effective SOM System

1081. Teva was specifically notified of the severe inadequacies of its suspicious order management system after a 2012 outside audit.

1082. Upon information and belief, instead of hiring an expert to craft a new suspicious order monitoring system, Teva decided to save money by letting one Teva employee, with no prior experience at a drug manufacturer, design the entire system. This new system took almost two years to implement.

1083. Even the new SOM system relied on salespeople to report suspicious orders—salespeople who were paid based on volume shipped.

1084. Internal Teva communications in 2015 demonstrate that, even after the telling audit, management pushed to release suspicious orders from volume purchasers so that they would not put the reward at risk.

1085. Furthermore, upon information and belief, Teva never reported a single suspicious order to the DEA before September 2012.

1086. Internal Teva documents from 2011 and 2012 show leadership showing callous disregard for the ever-increasing opioid epidemic, forwarding a jingle about opioid addiction and pill mills to the tune of the Beverly Hillbillies song and editing a Kellogg's Smack cereal box to read "Oxycontin for Kids."

1087. Internal Teva documents from 2017 show knowledge of ongoing conflicts between DEA compliance and the Teva sales department.

1088. Upon information and belief, the suspicious order monitoring systems in place for Actavis were just as inadequate, if not more so.

1089. Upon information and belief, when employees of Defendant Actavis sought to replace the inadequate SOM system with an effective system, they were rejected by upper management.

1090. The Teva Defendants' failure to implement an effective SOM system allowed orders to be filled that would not have otherwise been filled had there been appropriate order monitoring, reporting, flagging, and reviewing.

1091. As a direct result of the Teva Defendants' lack of SOM system, claims were made to the State's Medicaid System for opioid prescriptions that would not have been filled but for the improper monitoring at the manufacturer level.

1092. Moreover, as a DEA registrant, the Teva Defendants made representations that it was in compliance with all DEA regulations and the controlled substances act, which was an intentional misrepresentation because Teva's SOM system was not in compliance with any regulations

B. Distributor and Retail Pharmacy Defendants' Actions that Led to False Medicaid Claims

1093. The Distributor Defendants secured and renewed licenses from *inter alia* the Nevada Board of Pharmacy under false pretenses when, in fact, the Distributor Defendants were not abiding by their non-delegable legal duties. As further described above, the Distributor Defendants made false public statements representing that they were operating a closed system safeguarding against diversion of dangerous opioids into illicit channels when, in truth, the Distributor Defendants were ignoring their legal duties for profit.

1094. At all times relevant herein, state a federal regulatory frameworks required distributors of controlled substances a) to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); b) to report suspicious order when discovered to appropriate regulators (the "reporting duty"); and c) to decline to ship any order identified as suspicious unless and until, through due diligence investigations, the registrant is

able to determine that the order is not likely to be diverted into illegal/improper channels (the "no-shipping duty").

1095. Distributors and Retail Pharmacies failed to implement and maintain appropriate systems to prevent the diversion of controlled substances into Nevada. In failing to comply with their obligations to comply with its identification, reporting, or no-shipping duties with respect to the distribution of controlled substances into Nevada. These failures constitute actions and omissions in violation of Nevada False Claims Act, NRS § 357.040.

1. AmerisourceBergen Drug Company (ABDC)

a. ABDC Failed to Implement an Adequate SOM System

1096. Through its actions and omissions, ABDC willfully and repeatedly violated the Nevada False Claims Act, NRS § 357.040.

1097. Based on internal communications and previous sworn depositions, ABDC knew and understood the duties each distributor of controlled substances is charged with yet refused to implement an appropriate system to prevent the diversion of these substances into Nevada. ABDC has failed to comply with its identification, reporting, or no-shipping duties with respect to the distribution of controlled substances into Nevada.

1098. ABDC's diversion control procedures were the same at all its distribution centers.

1099. Prior to 2007, ABDC operated a rudimentary Suspicious Order Monitoring system using thresholds to identify "excessive" orders.

1100. Prior to 2007, ABDC did not have any system in place to evaluate the frequency of orders of controlled substances placed by its customers.

1101. Prior to 2007, all orders identified as excessive were reported to the DEA after they were shipped to the customer.

1102. Prior to 2007, to the extent ABDC conducted any investigation regarding possible suspicious orders, the investigations were conducted after the orders had been shipped.

1103. Prior to 2007, ABDC reported excessive orders to the DEA in a monthly report, but again, such reports were not sent until after the orders had been shipped.

1104. Between 1990 and 1998, ABDC calculated and set customer thresholds by dividing the total amount of sales of a controlled substance by all pharmacies within a category by the total number of pharmacies within that category to create an average. That average was then multiplied by three. Specifically, according to ABDC, the company would "take all the pharmacies within the category and divide by the number of pharmacies to come up with an average volume for the month per drug category. And there was a multiplier of three. Any order that was over the threshold amount would be produced [sic] an excessive order report."

1105. The three times multiplier used by ABDC for its customer thresholds was taken from the Chemical Handler's Manual.

1106. Between 1990 and 1998, any order that exceeded the threshold calculation was determined to be excessive.

1107. Such a policy constitutes a clear failure to maintain effective controls against diversion, as it entails shipping controlled substance orders identified as suspicious (or in this case, "excessive"), was not designed to identify orders of unusual frequency, or those that deviated from normal ordering patterns. Further, this system improperly utilized a factor of "3" and "6" to establish thresholds well above the calculated average for ABDC's customers.

1108. ABDC's 1999 Regulatory Compliance & Security Services Policy and Procedures document for "Suspicious Order Reporting Policy and Procedure" states, "you must contact DEA to report the order before actually shipping the merchandise. This must be done even if you decide to cut the order back for business reasons. Again in this case, it is the order that is suspicious, not the actual shipment."

1109. In 2001, Amerisource and Bergen Brunswig merged and the newly formed AmerisourceBergen Corporation adopted the suspicious order monitoring system used by Bergen Brunswig.

1110. Between 1998 and 2005, ABDC changed the threshold calculation to create a rolling four-month average of each customer's purchases and then multiplying that number by three.

1111. Prior to 2005, to the extent ABDC conducted due diligence, all the company did was check a customer's license and DEA registration.

1112. Pursuant to what a policy summary generated by ABDC after 2015 describes as its "Legacy Diversion Control Program," ABDC shipped all orders of controlled substances before ruling out the possibility of the orders being suspicious.

1113. Only after shipping the orders did ABDC report any orders that it deemed to be suspicious to the DEA through an "excessive order report." ABDC sent these reports on a monthly basis to the DEA. ABDC took no other actions with regards to excessive orders prior to 2005, meaning that ABDC shipped all orders - including orders that may have been suspicious – without any further investigation or due diligence.

1114. In December 2005, ABDC implemented an "Excessive/Suspicious Order Investigation Program" to review the ordering activity of its customers to identify possible excessive or suspicious orders of controlled substances and listed chemicals, but to the extent this review occurred, it only occurred after orders were shipped and ABDC did not change its practice of shipping orders identified as excessive before reporting them to the DEA.

1115. In 2007, after DEA suspended the registration of ABDC's Orlando distribution center, ABDC made changes to its Order Monitoring Program ("OMP").

1116. As established in 2007, ABDC's threshold system grouped customers by DEA classification (i.e., hospital/clinic, retail pharmacy, practitioner, or distributor). Within each group, customers are further classified as small, medium, or large, based on the total dollar value of prescription sales. Then, ABDC uses a twelve-month average of each customer group's purchases and multiplies that by three to develop a threshold.

1117. Under ABDC's 2007 OMP, if orders exceeded the threshold, it was ABDC's policy to hold the orders and not ship them to customers, pending an inquiry by ABDC's national

CSRA investigatory group - referred to as CSRA Review. Furthermore, it was ABDC's policy that these orders should not be shipped unless ABDC's CSRA Department could confirm that they were not suspicious orders.

1118. ABDC's 2007 Order Monitoring Program purported to include a Know Your Customer Due Diligence program which ABDC conducted using a form called the Form 590. These forms were supposed to provide the basis for ABDC's due diligence investigation and a baseline to measure a pharmacy's ordering habits and to determine any deviation from expected purchasing practices.

1119. An ABDC presentation titled "Prescription Drug Diversion[:] Recognizing the Red Flags" states, among other things, "We are mandated to 'Know Our Customer'" and that "Complete and thorough information on the form 590 is essential."

1120. The Know Your Customer Due Diligence requirements, however, did not apply to "chain pharmacies," which were pharmacies with either 10 or more locations in one state, or any number of locations in more than one state.

1121. Instead of collecting due diligence information from each pharmacy location of a retail chain, ABDC "collected one questionnaire for an entire chain of stores."

1122. In 2009, in response to a news article with the headline "Rite Aid pays $5 million in fines in drug case," ABDC's Bruce Gundy, forwarded the article to the diversion control team, stating, "Interesting article. Brings to the surface that we can not (sic) ignore chain pharmacies for OMP and diversion investigations."

1123. In August 2013, ABDC Corporate Investigator Elizabeth Garcia stated, "we discussed the importance of gathering the 590 questionnaire demographic information from our chain customers, given the regulatory environment resulting from the DEA/Walgreens action. As a wholesale distributor and DEA registrant, AmerisourceBergen is mandated to 'know' [its] customers. This process normally begins with the completion of a questionnaire that contains compliance related questions and information prior to servicing the pharmacy. The forms are

kept on file and serve as the basis to satisfy our 'Know Your Customer' mandate and as reference for future activity."

1124. In connection with ABDC's efforts to develop an algorithm for identifying suspicious orders in 2015, ABDC's head of diversion control, David May, stated, "[t]here has been so much manipulation of the thresholds under the current system that has not necessarily been based on actual consumption data."

1125. In July 2016, the CSRA Diversion Control Team at ABDC started working on a project called "the CSRA Form 590 Validation Project." The purpose of project was to "validate that all current ABDC customers authorized to purchase controlled substances have the required due diligence documentation in file." "The first phase of this project was to conduct a full review of every ABDC customer authorized to purchase controlled substances and identify any with deficiencies." "A substantial number of customer[s] [were] identified who will be required to have their 590 documentation updated." By July 7, 2017, ABDC had "only received about 10% of the required customer due diligence documents." ABDC said the continued deficiency put ABDC at risk with regulators.

1126. ABDC's lack of an effective SOM system led to an influx of excessively large orders into the State of Nevada, which resulted in numerous prescriptions being filled and billed to the State Medicaid system that would not have been filled had ABDC properly monitored, flagged, and reviewed opioid orders.

1127. Moreover, as a DEA registrant, ABDC made representations that it was in compliance with all DEA regulations and the controlled substances act, which was an intentional misrepresentation because ABDC's SOM system was not in compliance with any regulations.

b. <u>ABDC's Contracts and Agreements with Other Defendants to Disseminate Misinformation</u>

1128. ABDC entered into marketing agreements with these opioid manufacturers to disseminate and propagate these blatant misrepresentations throughout the United States, including Nevada.

1129. For example, ABDC, as required by Nevada law, submitted a Marketing Code of Conduct (the Code) applicable to certain activities conducted by ABDC in Nevada. ABDC represented that "compliance with [the code] will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with healthcare fraud and abuse laws." On information and belief, ABDC violated the code by disseminating erroneous information concerning the use and hazards associated with opioid products, and thereby profited from the failure to disclose accurate information concerning the addictive nature of the products or actively promoting inappropriate use of the products.

1130. Upon information and belief, ABDC offered marketing services to opioid manufacturers, Purdue Pharma, L.P., Depomed, Inc., and Mallinckrodt LLC between October 1, 2014 and May 29, 2018, and Defendant ABDC has indicated that additional marketing services may have been provided before October of 2014. ABDC Response to First Set of Request for Production, #16. On information and belief, ABDC, in offering these services facilitated the dissemination of disinformation originally crafted by the manufacturers to boost sales of opioid narcotics to reach a much broader audience with higher frequency. On information and belief, these marketing services were varied in form and format but in each instance, ABDC played a critical role in the dissemination of misinformation to the benefit of ABDC and its partner manufacturers, including the distribution of false information concerning Schedule II drugs (opioid narcotics). For example, at one point, ABDC offered Enhanced Marketing Services for a fee to "increase awareness of the Fentanyl Transdermal system" and to advocate on behalf of Mallinckrodt LLC. ABDC was to be paid additional fees based on a percentage of product sales. On information and belief, marketing material disseminated in this campaign was false and misleading and ABDC knew of should have known as much. Through the dissemination of this fraudulent marketing material, additional inappropriate sales resulted, and ABDC profited accordingly.

1131. It is evident that ABDC actively and knowingly participated in many opioid related representations on behalf of many manufacturers helping create the impression that opioid narcotics were an appropriate, beneficial, and non-addictive treatment for chronic pain.

These actions by Defendant ABDC constitute willful and repeated violations of the Nevada False Claims Act.

1132. ABDC engaged in marketing efforts with Manufacturers thereby adopting and furthering Manufacturers' misleading marketing, deliberately concealing the dangers associated with prescription opioids and selling them for long-term use despite those dangers.

1133. ABDC made misrepresentations to the DEA and Nevada's agencies by continuing to register and confirm that it was in compliance with all regulations and requirements that it monitor orders of the controlled substances it distributed.

1134. By marketing and distributed opioids at high volume and filling orders that should have never been filled, ABDC contributed to the influx of Medicaid claims for such medication that would not have been written or filled absent ABDC's wrongdoing.

2. Cardinal Health

a. Cardinal Health Failed to Implement an Adequate SOM System

1135. Through its actions and omissions, Cardinal Health willfully and repeatedly violated the Nevada False Claims Act.

1136. Based on internal communications and previous sworn depositions, Defendant Cardinal Health knew and understood the duties each distributor of controlled substances is charged with following, yet refused to implement an appropriate system to prevent the diversion of these substances into Nevada. Defendant Cardinal has failed to comply with its identification, reporting, or no-shipping duties with respect to the distribution of controlled substances into Nevada. These failures constitute actions and omissions in violation of Nevada False Claims Act.

1137. By way of example and not limitation, from 1996 to 2008 Cardinal Health's suspicious order monitoring system fell woefully short of the required regulatory framework. Cardinal Health utilized "Ingredient Limit Reports" (ILR) to identify suspicious orders. These reports would list each pharmacy that ordered and received an amount of opioid narcotics that

exceeded a predetermined average shipment size, multiplied by a factor of four. While this approach is woefully inadequate and fails to comply with the basic regulatory duty to identify suspicious orders, it was Cardinal's only attempt to identify suspicious orders of opioid narcotics during period of time.

1138. While Cardinal would collect these ILRs for orders placed and even, at times, provide them to regulators, no attempt was made to investigate the legitimacy of these flagged orders or conduct any due diligence to determine that the order was not likely to be diverted into illegal/improper channels. In fact, the ILRs were not even generated until after each order listed on the report had been shipped.

1139. Cardinal's ILR approach to monitoring suspicious orders was wholly retrospective and did nothing to prevent diversion of opioid narcotics, falling far short of the suspicious order monitoring system required of opioid distributors and unquestionably causing and contributing to the submission of false claims to the State of Nevada. Based on internal documents and direct communication with federal regulators, it is clear that Cardinal was specifically aware of its obligation to identify, report, and not to ship suspicious orders but continued to do so, prioritizing profits over the lives of Nevadans.

1140. In the years following, Cardinal abandoned its ILR approach for a "threshold" system supposedly more targeted to suspicious orders of opioid narcotics. Based on internal documents and expert analysis of the same, what is clear is that the very structure of the "threshold" system was fundamentally flawed and had no grounding whatsoever in the regulatory safeguards against diversion of opioid narcotics. However, even if the framework of the threshold system had been reasonably constructed, its practical implementation would have totally destroyed the purpose of its creation. The threshold system was little more than a framework by which otherwise "suspicious orders" could be recharacterized as non-suspicious, as threshold limits were routinely elevated from artificially inflated baselines to justify larger and larger orders that would otherwise have been flagged as suspicious.

1141. In addition to Cardinal's failures to identify, report, and stop shipments of suspicious orders, Cardinal also treated orders made by certain large, pharmacy chains differently than it did other customers. For example, Cardinal totally surrendered its obligation to monitor orders placed by Defendant CVS, instead allowing CVS to order and receive shipments from Cardinal, unmonitored. Cardinal's total resignation of its duties to Co-Defendant CVS unquestionably cause and contribute to the submission of false claims to the State of Nevada. Making matters worse, based on internal communications, Cardinal understood that these CVS orders were not being subjected to the internal Cardinal review or any independent review by CVS prior to order fulfillment; meaning that the majority of orders shipped to CVS by Cardinal occurred without being subjected to any suspicious order monitoring system at all.

1142. Cardinal continues to violate the basic principles of the required regulatory framework and continues to case and contribute to the submission of false claims.

1143. Cardinal failed to implement a SOM system despite knowing of its legal obligations to do so. Its documents and the testimony of Cardinal employees demonstrate the goal to ship more prescription opioids to increase profits, without regard for the size of the orders or the ever-growing opioid crisis.

b. Cardinal's Contracts and Agreements with Other Defendants to Disseminate Misinformation

1144. Cardinal entered into marketing agreements with opioid manufacturers to disseminate and propagate these blatant misrepresentations throughout the United States, including Nevada.

1145. Cardinal routinely offered marketing services to opioid manufacturers, allowing the disinformation originally crafted by the manufacturers to boost sales of opioid narcotics to reach a much broader audience with higher frequency. Based on internal communications, these marketing services were varied in form and format but in each Cardinal played a critical role in the dissemination of misinformation to the benefit of Cardinal and its partner manufacturers, including the distribution of false information concerning Schedule II drugs (opioid narcotics).

1146. While the specific scope and substantive nature of these representations made by Cardinal may be subject to confidentiality, it is clear that Defendant Cardinal actively and knowingly participated in many opioid related representations on behalf of many manufacturers helping create the impression that opioid narcotics were an appropriate, beneficial, and non-addictive treatment for chronic pain. These actions by Defendant Cardinal Health constitute willful and repeated violations of the Nevada False Claims Act.

1147. Additionally, Defendant Cardinal, as required by Nevada law, submitted a Marketing Code of Conduct (the Code) applicable to certain activities conducted by Cardinal in Nevada. Cardinal represented that compliance with [the code] will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with healthcare fraud and abuse laws. On information and belief, Cardinal violated the code by disseminating erroneous information concerning the use and hazards associated with opioid products, and thereby profited from the failure to disclose accurate information concerning the addictive nature of the products or actively promoting inappropriate use of the products.

1148. Cardinal participated in marketing efforts with Manufacturers, thereby adopting and furthering Manufacturers' misleading marketing, deliberately concealing the dangers associated with prescription opioids and selling them for long-term use despite those dangers.

1149. Cardinal made misrepresentations to the DEA and Nevada's agencies by continuing to register and confirm that it was in compliance with all regulations and requirements that it monitor orders of the controlled substances it distributed and sold.

1150. By marketing, ordering, and distributing opioids at high volume and filling orders that should have never been filled, Cardinal contributed to the influx of Medicaid claims for such medication that would not have been written or filled but for Cardinal's wrongdoing.

3. CVS

a. CVS Failed to Design and Implement a Viable SOM System

1151. The requirement that distributors of controlled substances design and operate a system to disclose suspicious orders has been in place since the 1970s.

1152. CVS was aware of the requirements of registered controlled substance distributors to design and implement a SOM system, and to report suspicious orders of controlled substances to federal and state governmental authorities as far back as the inception of the federal CSA and enactment of corresponding Nevada Statutes reciting the same or similar obligations.

1153. In 2006 and 2007 CVS received correspondence from the DEA reaffirming the non-delegable duties of all registered controlled substance distributors, including CVS, to design and operate a suspicious order monitoring system to disclose to the registrant suspicious orders of controlled substances, and to inform the DEA of suspicious orders when discovered by the registrant. Suspicious orders included orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

1154. Internal CVS documents and communications demonstrate that at all times relevant, CVS did not comply with its duties to design and operate a SOM system.

1155. During all relevant periods leading up to December 2008 CVS relied upon each CVS controlled substance distribution center's pickers and packers to identify potential suspicious orders of controlled substances including opioids it distributed to its CVS pharmacies. The pickers and packers had:

a. No standard operating procedures to guide them;

b. No policies and procedures to guide them;

c. No organized SOM training provided to them; and

d. No criteria, tools, historical ordering data, threshold measurements, electronically or otherwise, to determine whether any single order by any single

pharmacy on a particular date was of unusual size, unusual frequency or deviated from a normal pattern, so the order could be stopped and investigated with due diligence to rule it out as suspicious before the order was shipped to a Nevada CVS pharmacy for retail sale to consumers, including consumers who paid for those drugs with Medicaid benefits.

1156. CVS falsely claimed it maintained this picker and packer program as a SOM system when in fact it is not and never has been a viable SOM system.

1157. CVS's ostensible reliance upon pickers and packers for SOM resulted in no suspicious orders of controlled substances made by any Nevada CVS pharmacy to any CVS distribution center being identified and reported by CVS to any federal or state governmental agency.

1158. During all relevant periods leading up to December 2008 and beyond CVS ostensibly relied upon a theft software program called Viper PDMR (Visual Improvements Profit Execution & Results Prescription Drug Monitoring Report) to augment its otherwise nonviable pickers and packers SOM system. Viper PDMR was not a SOM system. Viper PDMR was a once a month generated theft detection report showing a historical lookback at the difference between the volume of drugs supplied to a pharmacy over the course of the past month compared to the volume of those same drugs dispensed by that same pharmacy during that same month. Viper PDMR did not flag or determine whether any single order by any single pharmacy on a particular date was of unusual size, unusual frequency or deviated from a normal pattern, so the order could be stopped and investigated with due diligence before the order was shipped to a CVS pharmacy for retail sale in Nevada.

1159. CVS's ostensible reliance upon Viper PDMR as a SOM system or as an augmentation to an otherwise non-existent SOM system resulted in no suspicious orders of controlled substances from any Nevada CVS pharmacy to any CVS distribution center being identified and reported by CVS to any Nevada state governmental agency or federal governmental agency.

1160. CVS falsely claimed it maintained this Viper PDMR program as part of a SOM system when in fact it was not a viable SOM system or SOM tool. It was purely theft detection software.

1161. During periods leading up to December 2008 and beyond CVS used a centralized store ordering system called AIM (Automated Inventory Management) through which CVS pharmacies electronically placed overnight orders of controlled substances, including orders of opioids CVS's DCs supplied to CVS pharmacies. The CVS DC workers picked those orders in a controlled drug cage within the distribution centers, packed those orders into controlled drug totes and shipped those totes for current or next day delivery to CVS pharmacies. AIM was simply an electronic ordering system through which orders could be either automatedly entered or manually entered. It was not a SOM tool or SOM system.

1162. CVS never filtered any controlled substance orders entered into AIM through the Viper PDMR software for daily output and review to flag or determine whether any single order by any single pharmacy on a particular date was of unusual size, unusual frequency or deviated from a normal pattern, so the order could be stopped and investigated to rule it out as suspicious, before the order was shipped to the pharmacy for retail sale to Nevada consumers. Viper PDMR was not capable of flagging or measuring whether any single order by any single pharmacy on a particular date was of unusual size, unusual frequency or deviated from a normal pattern.

1163. In December 2008 CVS took delivery of its first ever electronic algorithm-based SOM software system from a consultant, Cegedim Dendrite Compliance Solutions, designed to produce a daily report showing controlled substance orders the algorithm measured and flagged as fitting the description of an order of unusual size, an order deviating substantially from a normal pattern or and an order of unusual frequency made by CVS pharmacies to CVS distribution centers.

1164. The electronic software system was designed to measure attributes of each controlled drug order, including opioid orders made by a CVS pharmacy to a CVS DC, through a mathematical algorithm resulting in an overall score. The SOM algorithm-based software

model designer's instructions expressly stated the "model is designed such that any order with a score of .15 or higher should be identified as suspicious, pended, and should be further investigated."

1165. CVS was responsible through its information technology department and indendent contractors for incorporating the software into its ordering process systems so that controlled substance orders, including opioid orders, made by CVS pharmacies through its ordering system could be filtered through and measured by the algorithm based SOM system formulas and its weighted attributes, to determine its overall score. If the score of an order exceeded a threshold level, that order, the weighted score of each attribute and the overall score was flagged by the algorithm and output onto a printable SOM Report, later renamed Item Review Report or IRR.

1166. CVS delayed viable implementation of this electronic algorithm-based SOM software system while its pharmacies continued ordering controlled substances from CVS distribution centers without an effective SOM system in place to determine whether any single controlled substance order by any single pharmacy on a particular date was of unusual size, unusual frequency or deviated from a normal pattern so the order could be stopped and investigated to rule it out as suspicious before the order was shipped to CVS pharmacies for retail sale to consumers, including consumers who paid for those drugs with Medicaid benefits.

1167. Prior to August 25, 2010 CVS did not have a written SOM SOP (Suspicious Order Monitoring, Standard Operating Procedure). CVS uploaded its August 25, 2010 final draft of it first ever CVS DEA SOM SOP into its corporate DEA SOP Manual while the DEA was on site inspecting the Indiana Indianapolis DC. The SOM SOP was window dressing for the DEA since the CVS Indiana DC personnel and most CVS DC personnel nationwide were unfamiliar with the SOM SOP.

1168. Upon information and belief, August 24, 2010 through September 13, 2010 the DEA inspected CVS's Indiana distribution center. CVS employee, Terrance Dugger then and there represented to the DEA that CVS's controlled substance SOM program was centrally

operated by one CVS employee, John Mortelliti, out of the CVS Lumberton, NJ DC; then falsely represented to the DEA that Mortelliti operated the SOM system through AIM and Viper; that all orders generated through AIM were run through the Viper Program, and if cleared, the order was shipped to the DC; that Viper generated a daily and weekly "suspicious Item Review Report" (IRR) for Mortelliti to review; that a copy of that IRR was forwarded daily to the CVS Indiana DC and other CVS DCs nationwide, and that the Loss Prevention Manager of each DC was contacted daily about each "order of concern" that flagged onto that IRR.

1169. Based upon what was written in the August 25, 2010 CVS SOM SOP, CVS drafted a slide deck approved by its legal counsel dated August 27, 2010 called CVS DEA Speaking Points, containing a description of how CVS supposedly operated its controlled drug SOM system. An internal email sent by CVS's Director of Asset Protection Supply Chain to multiple CVS DCs stated in part: "These are the final approved speaking points for the DEA agents if they come to one of your facilities and questions suspicious monitoring. It is OK to share this document. Please be sure your team understands it before presenting so it doesn't look like a prop instead of a tool". The DEA Speaking Points were in fact a prop and more window dressing to supply to the DEA so CVS could further falsely claim that it was operating and fully implementing a SOM system in the manner described in the DEA Speaking Points.

1170. CVS allowed its pharmacies to supplement supplies of controlled substances ordered from CVS DCs, by also ordering the same or similar drugs from outside vendor sources such as McKesson, Cardinal Health Care and Amerisource Bergen Drug Corporation. Yet those outside vendor orders, including opioid orders were not filtered through or counted within the threshold measurements of CVS's algorithm based SOM system until CVS purchased and slowly rolled out a new algorithm based SOM system between March 2014 and October, 2014. CVS knew in the interim that this failure effectively permitted CVS pharmacies nationwide to order opioids from CVS DCs, then supplement that supply with orders of opioids made directly to outside vendors over and above the supplies received from CVS DCs, which effectively oversupplied CVS pharmacies with opioids for retail sale to consumers, including consumers who paid for those drugs with Medicaid benefits.

1171. Internal communications show that CVS intentionally refused to monitor for suspicious orders of controlled substances supplied to its pharmacies by outside vendors and intentionally shirked its obligation to report those suspicious orders to federal and state governmental authorities.

1172. When CVS installed, tested and ultimately attempted to implement its algorithm based SOM system between 2009 and 2014, CVS manipulated and tweaked the flagging score of the SOM model and system to a level much higher than the consultant's original design for the formulas within that system without informing the DEA. This effectively desensitized the SOM model and system so that fewer orders were flagged by the system as either suspicious or potentially suspicious.

1173. In August 2013, the DEA inspected CVS's Indianapolis Indiana distribution center where CVS operated its centralized, albeit deficient, controlled drug SOM system for all CVS DCs and all CVS pharmacies nationwide. CVS misrepresented to the DEA that it operated a viable DEA compliant SOM system for controlled substances it distributed to CVS pharmacies. Following that inspection, the DEA issued a scathing report of its investigation finding, among other deficiencies, that CVS failed to design and maintain a system to detect suspicious orders to detect and report suspicious orders of controlled substances.

1174. Up until CVS's new SOM model was rolled out for operation at individual CVS distribution centers between March 2014 and October 2014, the prior CVS SOM models were centrally run out of one distribution center instead of each individual distribution center.

1175. On October 6, 2014, the FDA's rescheduling of hydrocodone to a Schedule 2 controlled substance resulted in CVS ceasing its opioid distribution operations to its CVS pharmacies, but continued to distribute controlled substances including opioid cocktail drugs to its CVS pharmacies. However, CVS just as it had done prior to then, continued in its efforts to aid CVS pharmacies in being oversupplied with opioids from outside vendors.

1176. Even when controlled drug orders, including opioid orders were flagged by the CVS SOM system, CVS did not subject the vast majority of those orders to full due diligence investigations and instead shipped those orders to CVS pharmacies.

1177. On several occasions when the DEA inspected and questioned employees at CVS distribution centers about its controlled drug SOM system, CVS misrepresented its SOM system to the DEA to convince the DEA that it operated a viable SOM system.

1178. CVS failed to implement a SOM system despite knowing of its legal obligations to do so. Its internal communications and external communications with Manufacturer and Distributor Defendants demonstrate the goal to order and sell more prescription opioids. The sizes of the orders increased and CVS continued to fill those orders, without regard for their size or the ever-growing opioid crisis.

b. CVS's Leverage and Agreements with Other Defendants

1179. At all times material, CVS leveraged its corporate size and breadth of business it could offer to controlled drug distributors such as McKesson, Cardinal Health and Amerisource Bergen Drug Corporation to gain larger supplies of opioids and lenient threshold monitoring of those supplies so the end result was oversupplying CVS pharmacies with opioids that were in turn sold to consumers, including consumers who paid for those drugs with Medicaid benefits.

1180. At all times material, CVS leveraged its corporate size and breadth of business it could offer to controlled drug distributors resulting in supply contracts and agreements that allowed for larger supplies of opioids and lenient threshold monitoring of those supplies so the end result was oversupplying CVS pharmacies with opioids that were in turn sold to consumers, including consumers who paid for those drugs with Medicaid benefits.

1181. ARCOS data shows that from 2006 and 2014 CVS arranged to supply its Nevada CVS pharmacies through outside vendors with over 100 million doses of Oxycodone opioids, much of which was an oversupply of opioids that were sold at retail in Nevada CVS pharmacies and paid for with Medicaid benefits.

1182. ARCOS data shows that from 2006 and 2014 CVS arranged to supply its Nevada CVS pharmacies with over 175 million doses of Hydrocodone or Hydrocodone Combination Product opioids, much of which was an oversupply of opioids that were sold at retail in Nevada CVS pharmacies and paid for with Medicaid benefits.

1183. CVS and its outside vendor "Big Three" distributor suppliers, McKesson, Cardinal and Amerisource Bergen, have been dues paying members of controlled drug distributor trade organizations such as HDMA now known as HDA.

1184. HDA exerted concerted efforts on behalf of the distributors to thwart the enforcement efforts of the DEA in relation to distribution of opioids and increase quotas of opioids supplied to chain pharmacies including CVS. Those efforts included but are not limited to distributor meetings, including meetings at distributors' lawyers offices in Washington DC to strategize about how to thwart the DEA's enforcement efforts, launching public relations campaigns to falsely convince the public that distributors were compliant with the law and to paint a more friendly public image of the distributors and chain pharmacies in relation to their connection to opioid distribution, monitoring and sales, lobbying lawmakers to pass laws that are lenient towards distributors and chain pharmacies and thwart the DEA's enforcement efforts against distributors and chain pharmacies, filing Amicus briefs in DEA enforcement actions supporting the distributor defendants in those actions, creating a "Crisis Playbook" for distributors to deal with crisis communications and media relations recommending stock positive public image answers to tough questions concerning the opioid crisis, exerting public relations efforts to prevent the spread of legitimate litigation by states' attorney generals against the distributors of opioids which fueled and further spread the opioid epidemic and sale of opioids used for illegitimate purposes and paid for by Medicaid benefits.

1185. CVS made misrepresentations to the DEA and Nevada's agencies by continuing to register and confirm that it was in compliance with all regulations and requirements that it monitor orders of the controlled substances it distributed and sold.

1186. By marketing, distributing, ordering, and selling prescription opioids at high volume and filling orders that should have never been filled, CVS contributed to the influx of Medicaid claims for such medication that would not have been written or filled absent CVS's wrongdoing.

4. Walgreens

a. Walgreens Failed to Implement a SOM System

1187. The requirement that distributors of controlled substances design and operate a system to disclose suspicious orders has been in place since the 1970s.

1188. As a DEA registrant and distributer and seller of controlled substances, Walgreens should have been aware of its obligations to maintain a system to track suspicious orders of controlled substances and to conduct due diligence reviews of any such orders from the time it entered into the business of distributing and selling controlled substances.

1189. Upon information and belief, Walgreens received correspondence the Department of Justice sent to the DEA regarding the requirement that all companies registered to sell and distribute controlled substances, including Walgreens, must maintain a SOM system in order to track the distribution of such substances. Despite this information, Walgreens never implemented a sufficient SOM System, and abandoned the distribution of opioids after paying an $80 million settlement as a result of a 2012 DEA investigation into Walgreens' regulatory failures.

1190. In May 2006, the DEA told Walgreens that the formulation Walgreens was utilizing for reporting suspicious orders of controlled substances was insufficient. The system in place at the time placed Walgreens pharmacies with similar prescription volume into groups of 25, and identified as suspicious any orders above 3 times the average order for each group. DEA advised that the 3 times factor was arbitrary and inappropriate, and that per the regulations, a SOM system should be based on at least the size, pattern, and frequency of orders.

1191. In response, Walgreens transitioned to a SOM system that utilized a national average instead of an average for 25 similar pharmacies, but otherwise maintained the characteristics of the SOM system the DEA had described as insufficient, including the arbitrary 3 times factor. Under this new system Walgreens identified orders deemed suspicious on a monthly basis, as opposed to when the suspicious orders were actually discovered. Walgreens also reported orders deemed suspicious only after they had already shipped to the pharmacy, and without any documentation of any investigation or due diligence to justify the order that was deemed suspicious. Walgreens maintained this insufficient SOM system until the DEA investigation that was initiated in 2012.

1192. An internal Walgreens audit conducted in December 2008 at one of Walgreens' controlled substance distribution centers found inadequacies with Walgreens' suspicious order processing and reporting and that Walgreens lacked formalized controlled substance policies and procedures. Despite being told over 2 years earlier by DEA that their SOM system was insufficient, Walgreens continued to use an inadequate system, continued to report orders identified using an arbitrary 3 times factor, and continued to identify orders after they had shipped and without any documentation of due diligence to justify any reported orders.

1193. Walgreens' reaction to the findings of the December 2008 internal audit findings was to set a meeting for May 2009 to continue discussions on reporting suspicious orders.

1194. Perhaps understanding that the SOM system they were using was insufficient, Walgreens designed a second SOM system that began to be implemented in 2009. This system – designed by Wayne Bancroft and therefore referred to as the Bancroft system – identified orders as suspicious based on store-specific historical sales patterns. The system evolved over time as changes or improvements were made to the Bancroft system through 2012.

1195. Despite Walgreens' knowledge that it was required to report to DEA suspicious orders of opioids upon discovery, Walgreens never reported any orders to DEA that were flagged by the Bancroft system. Instead, the Bancroft system was designed to automatically reduce orders to an amount below where they would flag the system. DEA was therefore prevented

from investigating or otherwise reacting to suspicious orders being placed by Walgreens' pharmacies.

1196. In 2011, as a result of a DEA investigation into a Walgreens pharmacy, Walgreens agreed "to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act and applicable DEA regulations." Despite this agreement, Walgreens continued to operate an insufficient SOM system.

1197. In September 2012 DEA served Walgreens with an Order to Show Cause and Immediate Suspension of Registration regarding one of Walgreens controlled substance distribution centers. DEA again faulted Walgreens nationwide SOMs and suspicious order reporting system for utilizing the 3 times factor to identify and report suspicious orders. DEA also faulted Walgreens for only reporting suspicious orders after they had been shipped as opposed to when they orders were discovered, and for failing to clear flagged orders by performing a due diligence investigation before the order is shipped. As a result of the investigation Walgreens acknowledged that their suspicious order reporting regarding distribution to some pharmacies did not meet standards specifically identified by DEA as far back as 2006. To settle the allegations, in June of 2013 Walgreens paid an $80 million settlement to DEA and agreed to appropriately inform DEA of suspicious orders, among other requirements.

1198. In 2014 Walgreens ceased all distribution of opioids and transitioned to having their pharmacies supplied by third party distributors, primarily AmerisourceBergen.

1199. Walgreens' lack of a SOM system led to an influx of excessively large orders into the State of Nevada, which resulted in numerous prescriptions being filled and billed to the State Medicaid system that would not have been filled had Walgreens properly monitored, flagged, and reviewed opioid orders.

1200. Moreover, as a DEA registrant, Walgreens made representations that it was in compliance with all DEA regulations and the controlled substances act, which was an intentional misrepresentation because Walgreens' SOM system was not in compliance with any regulations.

b. Walgreens Entered into Contracts and Agreements with Other Defendants to Increase Opioid Sales

1201. Walgreens has a history of entering into contracts and agreements with opioid Manufacturers and Distributors.

1202. Through 2013, in addition to supplying its own pharmacies with Schedule II and III controlled substances from its own distribution centers, Walgreens also had distribution agreements with Cardinal Health and Anda for them to supply controlled substances as needed.

1203. In 2013, when Walgreens made the decision to stop distributing controlled substances and transition to solely using third party suppliers, Cardinal Health "red flagged" hundreds of Walgreens stores and refused to ship Schedule II drugs to them because it considered orders from those stores to be suspicious. Walgreens then terminated its relationship with Cardinal Heath and entered into a distribution agreement with AmerisourceBergen Drug Corporation.

1204. In 2016, Walgreens was AmerisourceBergen's largest customer and accounted for 30% of their revenue.

1205. As of May 31, 2019, Walgreens owned over 56 million shares of AmerisourceBergen's common shares of stock, representing approximately 27% of the outstanding AmerisourceBergen common stock.

1206. Walgreens is and historically has been a member of the National Association of Chain Drug Stores (NACDS). NACDS is a trade association which counts as members defendants Albertsons, CVS, Kroger, and Walmart, in addition to Walgreens. NACDS has a stated mission of advancing the interests and objectives of chain community pharmacy industry. This mission has led NACDS to take positions on behalf of its membership on issues that include

the regulatory responsibilities of pharmaceutical distributors as it did by submitting an amicus brief in *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

1207. In 2005 Walgreens entered into an amended contract with Endo which provided that Walgreens would receive rebates on all strengths of Endo Oxycodone HCl for units purchased through Cardinal Health, and that Walgreens would receive a free bottle of each strength of Endo Oxycodone HCl for each new store that Walgreens opened.

1208. In 2008 Walgreens entered into an agreement with Mallinckrodt that provided Walgreens the opportunity to earn volume incentive rebates of up to 5% on $22 million in purchases of Mallinckrodt generics, which include oxycodone products.

1209. In 2009 Walgreens entered into an agreement with Actavis that provided Walgreens the opportunity to earn volume growth rebates of up to 2.5% on $37.55 million in purchases of Actavis generic productions, which include oxycodone products.

1210. In 2011 Walgreens entered into a contract with Watson Pharma, Inc. that provided rebates up to 9% for certain products based on volume, including hydrocodone and oxycodone products.

1211. Walgreens failed to implement a SOM system despite knowing of its legal obligations to do so. Its internal communications and external communications with Manufacturer and Distributor Defendants demonstrate the goal to order and sell more prescription opioids. The sizes of the orders increased and Walgreens continued to fill those orders, without regard for their size or the ever-growing opioid crisis.

1212. Walgreens made misrepresentations to the DEA and Nevada's agencies by continuing to register and confirm that it was in compliance with all regulations and requirements that it monitor orders of the controlled substances it distributed and sold.

1213. Walgreens engaged in marketing actions with Manufacturers thereby adopting and furthering Manufacturers' misleading marketing, deliberately concealing the dangers associated with prescription opioids and selling them for long-term use despite those dangers.

1214. By marketing, distributing, ordering, and selling prescription opioids at high volume and filling orders that should have never been filled, Walgreens contributed to the influx of Medicaid claims for such medication that would not have been written or filled but for Walgreens' wrongdoing.

5. Walmart

a. Walmart Failed to Implement a SOM System

1215. As a DEA registrant and distributer and seller of controlled substances, Walmart should have been aware of its obligations to maintain a system to track suspicious orders of controlled substances and to conduct due diligence reviews of any such orders from the time it entered into the business of distributing and selling controlled substances in 2002.

1216. Upon information and belief, Walmart was aware of the requirement to implement a SOM system in 2007, at the latest, when it received correspondence the Department of Justice sent to the DEA regarding the requirement that all companies registered to sell and distribute controlled substances, including Walmart, must maintain a SOM system in order to track the distribution of such substances. Despite this information, Walmart failed to implement a SOM system until 2015.

1217. Internal Walmart communications demonstrate that, in preparation for a 2007 visit from the DEA, Walmart were personnel were aware that they were not in possession of the opioid related data that they were required to provide to the DEA.

1218. In September 2010, Walmart personnel exchanged internal communications in preparation for a DEA Audit, in which the DEA expected to see closer relationships between the distribution centers and customers as well as the due diligence systems in place for those distribution centers. Although Walmart was aware of the DEA's expectations and had been for several years, it had not yet implemented any system to track orders or perform due diligence.

1219. In 2011, Walmart entered into an agreement with the DEA wherein Walmart agreed to "maintain a compliance program, updated as necessary, designed to detect and prevent

diversion of controlled substances as required by the Controlled Substances Act (CSA) and applicable DEA regulations." Again, despite this agreement with the DEA, Walmart did not adopt a SOM program until 2015.

1220. Walmart's internal emails reference a "Diversion Team" that was tasked with running audits and flagging excessive purchases. However, there was no due diligence system in place to review the orders or to stop the orders before they were sent out. The emails suggest that Walmart employees were going to arbitrarily set threshold numbers that were not so high that they were never triggered, but not so low that they would trigger with every order. Walmart was aware of its legal obligations to track orders for controlled substances, but failed to take any action in that regard.

1221. In 2012, Walmart created the "Over 20" system where it would document orders for more than 20 bottles of Oxycontin. The system did not include a requirement to stop the orders, simply to identify such large orders. Jeffery Abernathy, who at the time served as the Operations Manager for Walmart's Distribution Center 6045, testified that this system only consisted of employees informing each other about the "Over 20" orders, but there was no system for documenting those orders or requirement that the pharmacies be monitored.

1222. Walmart's internal documents demonstrate that Walmart did not take steps to create a SOM system until mid-2014 and did not implement the system until the beginning of 2015. As of 2014, no one at Walmart was aware of who, if anyone, received cut order reports from distribution centers or whether anyone even knew such reports existed. At that time, the SOM system still consisted of verbal reports between employees regarding orders of Oxycontin or Hydrocodone that exceeded the arbitrary 20 bottle limit. The largest cause of delay in the implementation of a SOM system was the need to identify "Orders of Interest" and developing a system to stop those orders until they are evaluated and approved.

1223. Moreover, as a DEA registrant, Walmart made representations that it was in compliance with all DEA regulations and the controlled substances act, which was an intentional misrepresentation because Walmart's SOM system was not in compliance with any regulations.

b. Walmart's Contracts and Agreements with Other Defendants

1224. Walmart has a history of entering into contracts and agreements with opioid Manufacturers and Distributors.

1225. Upon information and belief, in 2010, Walmart entered into a marketing agreement with Humana that required individuals utilizing Humana to purchase their medications at Walmart pharmacies thus increasing Walmart's profits exponentially.

1226. Walmart had a contract with Mallinckrodt in which Walmart received rebates for the prescription opioids it ordered from Mallinckrodt. Many of the Mallinckrodt orders were distributed to Walmart by McKesson. Initially, Walmart received a 15% rebate, but was later offered a 1% additional rebate on all products purchased from Mallinckrodt if Walmart agreed to include fentanyl lozenges manufactured by Mallinckrodt in their agreement and place the lozenges in a primary position. Walmart's prior Senior Buyer testified that Walmart was aware that fentanyl lozenges were not FDA approved and were known to cause or contribute to deaths.

1227. Walmart also entered into an agreement with Qualitest (now known as Par), for the purchase of Hydrocodone. Communications between Walmart and Qualitest demonstrate that Walmart was running into shortages of Hydrocodone and asked Qualitest to "take whatever steps needed to ramp up production, for immediate supply." Walmart entered into similar agreements with Qualitest for the purchase of Oxycodone.

1228. Similarly, Walmart entered into an agreement with Actavis for orders of Oxycodone, both 15mg and 30mg. The agreement with Actavis included an agreement from Actavis to issue a credit memo to Walmart for a "marketing fee" within 45 days from the date Actavis shipped Walmart's initial Oxycodone order. Actavis offered Walmart lower prices and reimbursements for Oxycodone because Walmart purchased CII drugs directly from Actavis.

1229. Additionally, Walmart entered into agreements with Endo and Teva for the purchase of prescription opioids.

1230. Walmart's orders from the various manufacturers it contracted with were distributed by McKesson.

1231. Walmart failed to implement a SOM system despite knowing of its legal obligations to do so. Its internal communications and external communications with Manufacturer and Distributor Defendants demonstrate the goal to order and sell more prescription opioids. The sizes of the orders increased and Walmart continued to fill those orders, without regard for their size or the ever-growing opioid crisis.

1232. Walmart engaged in marketing actions with Manufacturers thereby adopting and furthering Manufacturers' misleading marketing, deliberately concealing the dangers associated with prescription opioids and selling them for long-term use despite those dangers.

1233. Walmart made misrepresentations to the DEA and Nevada's agencies by continuing to register and confirm that it was in compliance with all regulations and requirements that it monitor orders of the controlled substances it distributed and sold.

1234. By marketing, distributing, ordering, and selling prescription opioids at high volume and filling orders that should have never been filled, Walmart contributed to the influx of Medicaid claims for such medication that would not have been written or filled but for Walmart's wrongdoing.

C. Health Care Provider Defendants' Actions that Led to False Medicaid Claims

1235. The Health Care Provider Defendants prescribed, or caused to be prescribed, opioids to patients without a legitimate medical purpose. The Health Care Provider Defendants did so knowingly and willfully in order to receive direct and indirect pecuniary benefits.

1236. Each Defendant knowingly presented, or caused to be presented, to the State false or fraudulent claims for payment or approval, in violation of NRS § 357.040(1)(a).

1237. Each Defendant knowingly made, used, or caused to be made or used, false, misleading or fraudulent statements or records to obtain or support the approval of, or the payment on, false or fraudulent claims, in violation of NRS § 357.040(1)(b).

1238. By engaging in the wrongful conduct described herein, Defendants conspired to defraud the State by obtaining approval or payment on false or fraudulent claims.

1239. As a result of the Manufacturer Defendants' fraudulent marketing of opioids, and the Distributor and Retail Pharmacy Defendants' abdication of non-delegable duties to prevent opioids from being diverted into illicit channels, the State of Nevada paid millions of dollars for opioids. As a result, Defendants were illegally enriched at the expense of the State of Nevada. Further, the State of Nevada was required and will be required to pay the costs of treatment for State of Nevada participants actively harmed by the Defendants' actions.

1240. Defendants made misrepresentations to the state agencies, the public, and physicians regarding the safety and efficacy of opioid drugs. Manufacturers made these misrepresentations, which were then forwarded by Distributors and Retail Pharmacies by and through their agreements with Manufacturers. The marketing led to increased opioid prescriptions being written, and billed to Medicaid, that would not have been written but for the misrepresentations made in marketing.

1241. Defendants made misrepresentations to the DEA and Nevada agencies confirming that they were in compliance with their obligations to maintain adequate SOM systems in order to track, report, stop, and review suspicious opioid orders. Defendants failed to implement any effective or adequate systems, leading to orders being filled for prescription opioids. The prescriptions for opioids were issued to patients and billed to the State Medicaid system. Had the orders been adequately tracked, reported, stopped, and reviewed, those prescriptions would not have been billed to Medicaid.

1242. Each claim for opioid prescriptions for improper purposes; for longer periods than appropriate; and in quantities inappropriate for approved use, presented to the State of Nevada or to a contractor, grantee or other recipient of state funds constitutes a separate violation pursuant to NRS § 357.040.

1243. Claims submitted for rehabilitation services for individuals with opioid dependency and/or addiction; claims for sustained opioid use for non-cancer and non-hospice patients; claims for treating Neonatal Abstinence Syndrome; as well as any and all claims arising out of the use of opioids in Nevada by individuals for non-cancer and non-hospice purposes, constitute separate violations pursuant to NRS § 357.040.

1244. In addition to, or in the alternative, each exposure of a state employee or contractor, Nevada health care professional or State of Nevada participant to Defendants' misleading and deceptive information, communicated in any manner by Defendants, constitutes a separate violation pursuant to NRS § 357.040.

1245. In addition to, or in the alternative, each opioid prescription written in Nevada in connection with State of Nevada programs constitutes a separate and distinct violation pursuant to NRS § 357.040.

1246. Plaintiff, State of Nevada seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, civil penalties of not less than $5,500 and up to $11,000 for each violation, attorney fees and all costs and expenses of suit, and pre- and post-judgment interest.

FIFTH CAUSE OF ACTION
Negligence
(Against Manufacturer and Distributor Defendants)

1247. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

1248. Each Defendant had a duty to exercise reasonable care in manufacturing and distributing highly dangerous opioid drugs in the State of Nevada.

1249. Each Defendant owed a duty to the State, and to the public health and safety in Nevada, because the injury was foreseeable, and in fact foreseen, by the Defendants.

1250. Reasonably prudent wholesale drug distributors would have anticipated that the scourge of opioid addiction would wreak havoc on communities. As explained above, the

system whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies exists ***for the purpose*** of controlling dangerous substances such as opioids. Moreover, Defendants were repeatedly warned by law enforcement.

1251. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

1252. The escalating amounts of addictive drugs flowing through Defendants' business, and the sheer volume of these pills, further alerted all of the Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

1253. As described above in language expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

1254. As described above in language expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain. The causal connection between Defendants' breach of duties and ensuing harm was entirely foreseeable.

1255. As described above in language expressly incorporated herein, Defendants' breach of duty caused, bears a causal connection with, and/or proximately resulted in, harm and damages to the State.

1256. Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent. Here, Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. NAC § 435.520(a). Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels.

1257. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

SIXTH CAUSE OF ACTION
Negligence Per Se
(Against Manufacturer and Distributor Defendants)

1258. The State re-alleges all prior paragraphs of this Complaint as if set forth fully herein.

1259. Nevada recognizes the doctrine of negligence per se. Negligence per se consists of four elements: (1) A duty to exercise due care with respect to a plaintiff as defined by a statue or administrative regulation; 2) plaintiff is in the class of persons the statute or regulation was designed to protect; (3) defendant breached the duty by violating the statute or regulation, constituting negligence as a matter of law; and (4) causation and damages. *Atkinson v. MGM Grand Hotel, Inc.*, 98 P.3d 678, 680 (Nev. 2004).

1260. NRS 453.005 to 453.730 and NAC §§ 453.010 to 453.740 are public safety laws that define a standard of conduct. As such, these laws were intended to protect the public welfare and safety, and the State is the proper Plaintiff to enforce these laws. Each Defendant had a duty under *inter alia* these laws to prevent diversion of prescription opioids for non-medical and non-scientific purposes and to guard against, prevent, and report suspicious orders of opioids.

1261. Nevada's minimum requirement for controlled substance manufacture and wholesale drug distribution is that they must comply with applicable laws and regulations.

1262. Nevada laws and regulations require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs.

1263. Defendants have violated their duties under the Nevada Controlled Substances Act and the Nevada Administrative Code.

1264. Defendants' violations of these public safety laws are prima facie evidence of negligence per se. Each Defendant had a duty under, *inter alia*, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

1265. The State is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

1266. It was foreseeable that the breach of duty described herein would result in the damages sustained by the State.

1267. Defendants' conduct was willful, wanton, malicious, reckless, and/or oppressive, as described above.

1268. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

1269. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and proximately resulted in, harm and damages to the State.

The harm at issue is the type of harm that the legislature sought to prevent in promulgating the public safety statutes at issue.

1270. Defendants' violations of the Nevada statutes and public safety regulations cited herein were and are substantial factors in the injuries and damages sustained.

1271. It was foreseeable that Defendants' breaches of statutory and regulatory duties described herein would result in the damages sustained.

1272. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

SEVENTH CAUSE OF ACTION
Negligence
(Against J&J)

1273. The State re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

1274. J&J had a duty to exercise reasonable care in the creation of the APIs created for use in prescription opioid.

1275. J&J owned the two (2) subsidiaries – Tasmanian Alkaloids and Noramco – responsible for cultivating and processing the opium poppy plants used to manufacture narcotic raw materials, which were imported into the U.S. to be processed and made into APIs necessary to manufacture prescription opioids.

1276. J&J's subsidiaries supplied the following opioid APIs to drug manufacturers in the U.S.: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.

1277. J&J's subsidiaries were in the business of producing and selling natural opium, semisynthetics, and J&J's own branded synthetics.

1278. J&J, Tasmanian Alkaloids, and Noramco knew that Schedule II opioids have high abuse potential and that Schedule II pills and patches can lead to death if very small doses.

1279. The United States has strict regulations regarding the percentage of narcotic raw materials that may be sourced from non-traditional supplier countries, which includes Australia, where Tasmanian Alkaloids is based and, from which, Noramco imports narcotic raw material for processing into APIs for ultimate sale to drug manufacturers.

1280. These regulation and calculations are only based on the amount of morphine alkaloid contained in the narcotic raw material, but not the thebaine alkaloid content of the materials.

1281. Though thebaine is not used in therapy on its own, it is an important raw material in the manufacture of several opioids, including oxycodone.

1282. J&J subsidiary, Tasmanian Alkaloids, developed a high thebaine poppy – the Norman Poppy - to meet an anticipated increase in demand for oxycodone.

1283. Tasmanian Alkaloids supplied the raw materials – the Norman Poppy – to Noramco, who then processed the Poppy into the APIs, which it then supplied to various drug manufacturers for use in their branded prescription opioids.

1284. Noramco entered into several long-term supply agreements with drug manufacturers for the supply and sale of the opioid APIs.

1285. J&J, and its subsidiaries, made misrepresentations to the medical community and patients regarding the safety, efficacy, and appropriate use of its opioid products.

1286. J&J, and its subsidiaries, developed the Norman Poppy in order to bypass strict regulations on the import of narcotic raw materials and to continue the growth of the opioid epidemic in the State of Nevada.

1287. Defendant J&J had a duty to exercise reasonable care in the creation of the raw materials utilized in manufacturing prescription opioids, promoting and marketing the raw materials for use by other prescription drug manufacturers, and the sale of raw materials utilized in the manufacturing of prescription opioids.

1288. Defendant J&J breached this duty in the course and furtherance of Defendant J&J's business in the State of Nevada, by creating a stronger product for use as raw materials in prescription opioids that was not limited or regulated by government import regulations, and was subsequently used in the manufacture of prescription opioids that have been used and abused in the State of Nevada.

1289. Defendant J&J had a duty to exercise reasonable care in the manufacture, marketing, promotion, and/or sale of opioids.

1290. In the course and furtherance of Defendant J&J's business in the State of Nevada, they breached their duty by manufacturing, marketing, promoting, and/or selling opioids in an improper manner.

1291. As a direct and proximate result of Defendant J&J's negligence, the State 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 State resources in relation to opioid use and abuse.

1292. Defendant J&J was active in the creation of the addictive raw ingredients utilized in prescription opioids as well as the marketing done to increase sales of prescription opioids, whether J&J branded medications or other prescription opioids manufactured by other drug companies that were prescribed and taken throughout the State of Nevada.

1293. The State is without fault and the injuries to the State would not have occurred in the ordinary course of events had J&J used due care commensurate to the dangers involved in the manufacture, sale, and use of opioids.

1294. The continued tortious conduct by J&J 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.

1295. Therefore, the State's claims are subject to equitable tolling, stemming from J&J's wrongful concealment and from the State's inability to obtain vital information underlying its claims.

1296. That the State has been required to prosecute this action and is entitled to attorneys' fees and costs as provided by Nevada statute.

1297. The State's general, special, and punitive damages are in amounts in excess of $15,000.00.

EIGHTH CAUSE OF ACTION
Violations of 2007 Consent Judgment
(Against Purdue Defendants)

1298. The State re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

1299. The 2007 Consent Judgement, as referenced above, prohibited Defendant Purdue from engaging in certain conduct and required certain affirmative measures by Purdue with respect to the marketing, promotion, and sale of the branded opioid OxyContin.

1300. Purdue, by making written and/or oral claims that are false, misleading, or deceptive, has violated, continues to violate, and failed to cure, Section II(2) of the 2007 Consent Judgement, which provides that "Purdue shall not make any written or oral claim that is false, misleading or deceptive."

1301. Purdue, by failing, after identifying suspicious prescribers, prescribing patterns, orders, distributions or distribution patterns, to provide notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities, has violated, continues to violate, and failed to cure, section II(13) of the 2007 Consent Judgement, which requires Purdue to sufficiently "establish, implement, and follow an OxyContin Abuse and Diversion Detection Program." Specifically, in failing to report suspicious prescribers to Nevada law enforcement or regulatory authorities, Purdue failed to carry out its obligation to

"take such further steps as may be appropriate [to combat opioid abuse and unlawful diversion] based on the facts and circumstances" and information learned through the OxyContin Abuse and Diversion Detection Program, including "providing notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities."

1302. Purdue, under the guise of education, by sending deceptive materials directly to health care professionals, violated and failed to cure section II(15) of the 2007 Consent Judgement, which requires Purdue to provide to health care professionals "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics." Specifically, Purdue violated and failed to cure section II(15) by (1) sending Nevada health care providers the first, second, and third editions of *Providing Relief, Preventing Abuse* and (2) creating and marinating the website www.inthefaceofpain.com, both of which disseminated information to Nevada health care providers, misrepresenting the signs of opioid abuse.

1303. Purdue, by making misrepresentations with respect to OxyContin's potential for addiction, and by claiming that abuse-deterrent formulations of OxyContin are not subject to abuse, despite knowing that the abuse-deterrent features of reformulated OxyContin have not been effective to prevent abuse, has violated, continues to violate, and failed to cure, section II(20) of the 2007 Consent Judgement, which provides that:

> All material used in promoting OxyContin, regardless of format (audio, internet, video, print) and whether directed primarily to patients or Health Care Professionals, shall, not be inconsistent with the Package Insert, contain only information that is truthful, balanced, accurately communicated, and not minimize the risk of abuse, addiction or physical dependence associated with the use of OxyContin.

1304. Purdue's violations of the 2007 Consent Judgement affected and continue to affect the public interest, caused and continue to cause injury to numerous Nevada consumers, political subdivisions, and the State, and contributed to a public health crisis, which has cost consumers, political subdivisions, and the State substantial financial and social harm.

1305. Purdue's violations of the 2007 Consent Judgement, on information and belief

were, in some cases, also directed toward elderly persons or persons with a disability.

1306. Plaintiff, the State of Nevada, seeks all legal and equitable relief as allowed by law, including *inter alia* all relief and damages set forth in the 2007 Consent Judgment. Plaintiff specifically incorporates the 2007 Consent Judgment as if restated fully herein and avails itself of each and every remedy contained therein, in addition to the remedies available by statute, common law, an equity.

VI. RELIEF

WHEREFORE, the State of Nevada, by and through its Attorney General, respectfully prays that this Court grant the following relief:

1. Entering Judgment in favor of the State in a final order against each of the Defendants;

2. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in deceptive practices in violation of Nevada law and ordering temporary, preliminary or permanent injunction;

3. Order that Defendants compensate the State for its future costs to abate the ongoing public nuisance caused by the opioid epidemic;

4. Declaring that each act and omission of each of the Defendants described in this Complaint constitute multiple, separate violations of the Deceptive Trade Practices Act;

5. Imposing actual damages as well as civil penalties of up to $5,000, per Defendant, for each repeated and willful violation of the Deceptive Trade Practices Act;

6. Awarding actual damages, treble damages, and civil penalties of not less than $5,500 and up to $11,000 for each violation of the False Claims Act;

7. Awarding the State its past and future damages caused by the opioid epidemic, including money wrongfully paid for opioids through government-funded insurance;

8. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

9. Granting the State:

a. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

b. Pre-judgment and post-judgment interest; and,

c. All other relief as provided by law and/or as the Court deems appropriate and just.

d. Plaintiff asserts claims herein in excess of the minimum jurisdictional requirements of this Court.

DATED this 9th day of March, 2021.

Submitted By:

/s/ Robert T. Eglet

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CERTIFICATE OF SERVICE

Pursuant to NRCP 5(b), I certify that I am an employee of EGLET ADAMS, and that on the 9th day of March, 2021, I caused the foregoing **SECOND AMENDED COMPLAINT** to be served upon those persons designated by the parties in the E-Service Master List for the above-referenced matter in the Eighth 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.

/s/ Makaela Otto
An Employee of EGLET ADAMS