IN THE SUPREME COURT OF THE STATE OF NEVADA

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

Petitioners,

v.

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

Respondents,

and

CITY OF RENO,

Real Party in Interest.

Supreme Court Case No.

District Court Case No. CV18-01895

PETITIONERS' APPENDIX
VOLUME XIV

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CHRONOLOGICAL INDEX TO PETITIONERS' APPENDIX

DATE	DOCUMENT	VOLUME	PAGE RANGE	
12/7/2017	Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00001	PA00050
5/15/2018	First Amended Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00051	PA00109
9/18/2018	Complaint (Case No. CV18-01895)	II	PA00110	PA00167
12/03/2018	First Amended Complaint (Case No. CV18-01895)	II	PA00168	PA00226
3/4/2019	Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint	III	PA00227	PA00264
3/5/2019	Distributors' Joint Motion to Dismiss First Amended Complaint	III	PA00265	PA00386
4/26/2019	City of Reno's Opposition to Manufacturer Defendants' Joint Motion to Dismiss and All Joinders Thereto	IV-V	PA00387	PA00709
4/26/2019	City of Reno's Opposition to Distributor Defendants' Joint Motion to Dismiss and All Joinders	VI-VII	PA00710	PA00958
5/28/2019	Reply in Support of Manufacturer Defendants' Joint Motion to Dismiss First Amended Complaint	VIII-IX	PA00959	PA01214
5/28/2019	Distributors' Joint Reply in Support of Motion to Dismiss First Amended Complaint	X	PA01215	PA01285

DATE	DOCUMENT	VOLUME	PAGE RANGE	
6/17/2019	Complaint (Case No. A-19-796755-B)	XI-XII	PA01286	PA01535
6/27/2019	First Amended Complaint (Case No. A-19-796755-B)	XIII-XV	PA01536	PA02049
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8/22/2019	Complaint (Case No. A-19-800695-B)	XVI	PA02053	PA02144
8/22/2019	Complaint (Case No. A-19-800697-B)	XVI	PA02145	PA02235
8/22/2019	Complaint (Case No. A-19-800699-B)	XVII	PA02236	PA02326
9/12/2019	Third Amended Complaint and Demand for Jury Trial (Case No. A-17-76828-C)	XVII	PA02327	PA02423
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10/4/2019	Manufacturer Defendants' Response to Plaintiff's Supplemental Briefing re Motions to Dismiss	XVIII	PA02567	PA02587
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DATE	DOCUMENT	VOLUME	PAGE RANGE	
1/4/2020	City of Reno's Supplemental Briefing in Support of Oppositions to Distributors' Joint Motion to Dismiss	XVIII	PA02592	PA02602
1/7/2020	Transcript of Proceedings	XIX-XX	PA02603	PA02871
1/8/2020	Transcript of Proceedings	XXI	PA02872	PA03034
2/14/2020	Omnibus Order Granting In Part and Denying in Part Defendants' Motions to Dismiss; and Granting Leave to Amend	XXI	PA03035	PA03052

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4/26/2019	City of Reno's Opposition to Distributor Defendants' Joint Motion to Dismiss and All Joinders	VI-VII	PA00710	PA00958
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12/7/2017	Complaint and Demand for Jury Trial (Case No. A-17-765828-C)	I	PA00001	PA00050
3/5/2019	Distributors' Joint Motion to Dismiss First Amended Complaint	III	PA00265	PA00386
5/28/2019	Distributors' Joint Reply in Support of Motion to Dismiss First Amended Complaint	X	PA01215	PA01285
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1/8/2020	Transcript of Proceedings	XXI	PA02872	PA03034

AFFIRMATION

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

Dated this 1st day of May, 2020.

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By: */s/Pat Lundvall*

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CERTIFICATE OF SERVICE

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

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

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

report suspicious orders of prescription opiates originating from Nevada.

620. 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.

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

622. 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.

623. 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.

624. 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.

625. 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.

626. 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.

627. 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."

628. 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."

629. 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."

630. 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.[199]

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."

631. 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.

[199] 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.

632. 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 . . . ."

633. Other Manufacturer Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[200]

634. 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.

635. 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 . . . ."[201] 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."[202] And, responding to criticism of Purdue's failure to report suspicious

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[200] 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/.

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

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

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."[203]

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

637. 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.

638. 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.

639. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription

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[203] 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.

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.

640. 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.

641. 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.

642. 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

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

644. 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.

645. 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.

646. 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.

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

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

649. 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.

650. 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

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

652. 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.

653. 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.

654. 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.

655. 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.

656. 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.

657. 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.

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

obligations under the law with regard to controlled substances.

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

659. 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

660. 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.

661. 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.

662. 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.[204]

[204] *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.

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

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

664. 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.

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

ii. Walgreens

666. 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.

667. 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.[205]

668. 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.

669. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[206]

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

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

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

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

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

637. When authorities in states such as Ohio and Kentucky cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of Nevada

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

[206] *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.

and other states would simply fly or drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

638. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price.[207] In Columbus, Ohio, in 2011, 16 individuals were prosecuted for being involved in the "oxycodone pipeline between Ohio and Florida."[208] 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."[209]

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

640. In yet another case, defendants who operated a pill mill in south Florida within Broward County were tried in eastern Kentucky based on evidence that large numbers of

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[207] 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.

[208] *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.

[209] *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.

customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward's] customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts."[210] The court further noted that the pill mill "gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents."[211]

641. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.[212] 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.[213] 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.[214] 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."[215]

642. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.[216]

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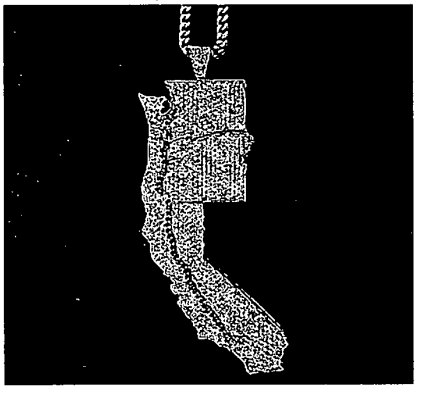
[210] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).
[211] *Id.* at 861.
[212] John Temple, *American Pain* 171 (2016).
[213] *Id.* at 172
[214] *Id.* at 171.
[215] *Id.*; *see also* Welsh-Huggins, *supra*. Note that Interstate 75 was also called as the Oxy Express; for example, the Peabody Award-winning documentary named *The OxyContin Express* focuses on the transport of prescription opioids along I-75. https://www.youtube.com/watch?v=wGZEvXNqzkM.
[216] *The OxyContin Express.* YouTube (Feb. 26, 2014), http://www.youtube.com/watch?v=wGZEvXNqzkM.

643. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California.[217] Another similar pipeline developed in Michigan. According to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.[218]

644. Along the West Coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.[219] Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.[220] 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.[221]



G. Nevada's Opioid Epidemic

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

[218] 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.

[219] 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/.

[220] *Id.*

[221] *Id.*

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

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

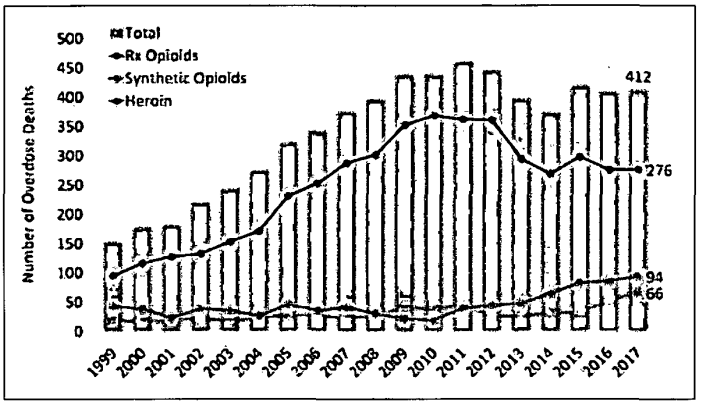


Figure 1. Number of overdose deaths involving opioids in Nevada, by opioid category. Drug categories presented are not mutually exclusive, and deaths might have involved more than one substance. Source: CDC WONDER.

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.

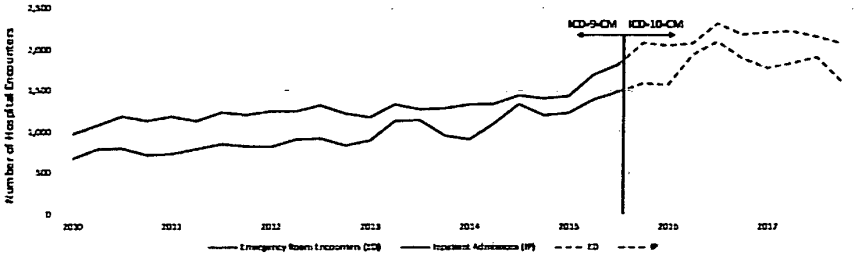
Opioid-Related Hospital Data, Nevada Residents, 2010-2017

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.

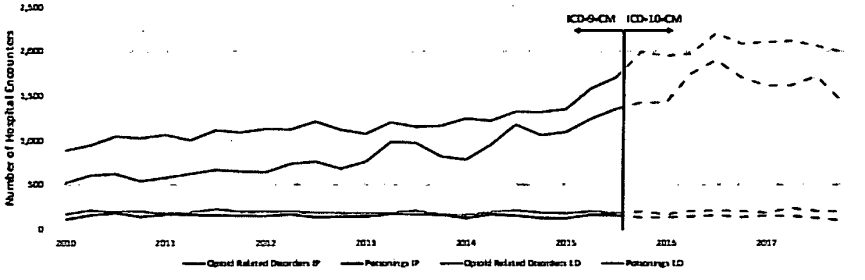
Year	Emergency Room Encounters (ED)	Emergency Room Crude Rates	Percent Change	Inpatient Admissions (IP)	Inpatient Crude Rates	Percent Change
2010	2,963	109.5		4,362	161.2	
2011	3,188	117.1	7%	4,755	174.7	8%
2012	3,473	126.3	8%	5,042	183.3	5%
2013	4,122	147.2	17%	5,057	180.9	-1%
2014	4,543	159.8	9%	5,517	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	955	3,209	2,916	721	312	169	309
2017	1,104	3,357	2,725	705	322	182	266

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

number increased to 7,035 in 2015.

648. Nevada's death rate from drug overdose grew dramatically in lockstep with Defendants' increasing sale and distribution of opioid drugs. The State went from an age-adjusted drug overdose death rate of 11.5 in 1999 to 21.7 in 2016.[222] Nevada has the fourth highest drug overdose mortality rate in the United States. Between 2010 and 2015, approximately 2,800 deaths in Nevada were attributed to opioid-related overdose. It is estimated that 55% of those deaths were caused by natural and semi-synthetic opioids.

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

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

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

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

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

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

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

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

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

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

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

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

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[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*.

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

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

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

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

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

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

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

665. 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

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

[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.

conduct has inflicted upon the State of Nevada.

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

1. Conspiracy Among Manufacturer Defendants.

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

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

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

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

670. 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.

671. 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.

672. 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.

673. 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.

674. 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.

675. 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.

676. 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.

677. 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.

678. 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...

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

2. Conspiracy Among All Defendants.

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

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

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

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

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

684. 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.

685. 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.

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

686. 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

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

688. 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

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

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

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

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

[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.

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

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

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

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

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.

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

3. Intentional Concealment

695. 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.

696. 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.

697. 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.

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

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

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

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

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

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

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

704. 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.

705. 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.

K. Facts Pertaining to Civil Penalties and Punitive Damages

706. 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.

707. 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.

708. 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.

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

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

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

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

that period.

713. 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.

714. 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."

715. 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.

716. McKesson's conscious and deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[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]

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

[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.*

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.

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

719. 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

[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.*

controlled substances from certain facilities would be partially suspended.[237]

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

721. 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]

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[237] *Id.* at 6.

[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/.

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

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

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

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

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

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

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

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."

725. 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.

726. 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.

727. 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.

728. 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.

729. 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).

730. 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.

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

732. 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.

733. 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 and Distributor Defendants)

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

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

736. 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.

737. 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.

738. 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.

738. The health and safety of the citizens 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.

739. 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.

740. 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.

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

742. 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.

743. 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.

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

745. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECOND CAUSE OF ACTION
VIOLATION OF NEVADA DECEPTIVE TRADE PRACTICES ACT (NRS §§ 598.0903 to 598.0999)
(Against Manufacturer and Distributor Defendants)

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

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

766. 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).

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

768. 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").

769. 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.

770. 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).

771. 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).

772. 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)

773. 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).

774. 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)

775. 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).

776. 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).

777. 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.

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

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

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

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

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

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

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

g. Providing significant financial support to pro-opioid KOL doctors who made

deceptive statements, available to doctors and patients in Nevada, concerning the use of opioids to treat chronic non-cancer pain;

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

i. Assisting in the distribution of guidelines nationally and within Nevada, that 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.

779. 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.

780. 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.

781. 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.

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

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

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

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

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

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

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

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

790. Plaintiff, State of Nevada, seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement, reimbursement of all monies paid for prescription opioids by the State of Nevada via its Medicaid program, damages as allowed by law, all recoverable penalties under all sections of the Deceptive Trade Practices Act including

all civil penalties per each violation per each Defendant named in this Count, attorney fees and costs, and pre- and post-judgment interest

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

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

793. The State, both as a "person" who has sustained injury ***and*** on behalf of Nevada citizens 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, 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.

794. 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."

795. 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).

796. 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.

797. 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.

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

799. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their duty under Nevada law to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt

[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).

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.

800. 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 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.

801. Alternatively, the Racketeering Defendants were members of a legal entity enterprise within the meaning of NRS § 207.380 through which the Racketeering

[240] 21 USC § 823(a)(1), (b)(1); 21 CFR § 1301.74(b)-(c).

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.

802. 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.

803. 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.

804. 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

805. 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

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

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.

806. 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 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

[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).
[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).

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.

807. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[250] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the United States Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[251]

808. Under the CSA, as incorporated into Nevada law, it is unlawful for a registrant to

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[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).

[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).

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]

809. At all relevant times, the Racketeering Defendants operated as an enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their duty under Nevada law to identify, investigate, halt or report suspicious orders of opioids and diversion of their drugs into the illicit market, *see generally* **IV.E.1** *supra*, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The Racketeering Defendants conducted their pattern of racketeering activity in Nevada and throughout the United States through this enterprise.

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

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

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

813. The opioid epidemic has its origins in the mid-1990s when, between 1997 and

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[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.").

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]

814. 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 citizens.

815. 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.

816. The Opioid Diversion Enterprise functioned by selling prescription opioids.

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[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.

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 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.

817. 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.

818. 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.

819. 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.

820. 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.

821. 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]

822. 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), Purdue, 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.

823. 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

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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.*

meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

824. 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.

825. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the Racketeering Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis, Purdue, and Mallinckrodt, were members of the HDA.[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.

826. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[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

[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.

Distributors.

827. 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]

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

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

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction

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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.*

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]

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

830. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives,

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

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]

831. 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.

832. 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 information regarding their prescription opioid sales, including purchase orders,

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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.*

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.

833. 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.

834. 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.

835. 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 Distributors for "more than a decade."[280] From 2006 to 2016 the Distributors and

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[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).

[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-

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]

836. 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]

837. 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

838. 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.

839. 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

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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.*

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.

840. 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.

841. 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.

842. 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.

843. 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).

844. 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.

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

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

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

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

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[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*.

849. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the Racketeering Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[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.

850. 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 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]

851. 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

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[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.

[287] *Id.*

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.

852. 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;

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;

[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/.

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.

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

C. PATTERN OF RACKETEERING ACTIVITY

854. The Racketeering Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in NRS § 207.390, by at least two crimes related to racketeering (NRS § 207.360), trafficking in controlled substances (NRS §§ 207.360(22); 453.3395), 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.

855. The Racketeering Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of NRS §§ 207.360), within a five-year period. The multiple acts of racketeering

activity that the Racketeering Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Racketeering Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise.

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

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

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

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

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

861. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the State of Nevada.

Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Nevada, Nevada consumers, or other Nevada citizens. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Racketeering Defendants were also aware that the State and the citizens of this jurisdiction rely on the Racketeering Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

862. 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.

863. 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.

864. 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.

865. 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.

866. 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.

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

868. 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.

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

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

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

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

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.

872. 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.

873. 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).

874. 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.

875. 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.

876. Among other infractions, the Racketeering Defendants did not comply with

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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.

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

878. For example, the DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA

[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.

registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[290]

879. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of their duty to report suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA.[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 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]

880. 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]

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[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/.

[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.*

881. 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;

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";

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[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.

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.

882. 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.

883. 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

884. The Racketeering Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the State of Nevada and its citizens 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.

885. The State's injuries, and those of its citizens, 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.

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

887. 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.

888. 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)

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

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

891. 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.

892. 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.

893. 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.

894. 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).

895. 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).

896. By engaging in the wrongful conduct described herein, Defendants conspired to defraud the State by obtaining approval or payment on false or fraudulent claims.

897. As a result of the Manufacturer Defendants' fraudulent marketing of opioids, and the Distributor 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.

898. 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.

899. 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.

900. 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.

901. 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.

902. 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
NEVADA COMMON LAW
(Against Manufacturer and Distributor Defendants)

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

904. Each Defendant had a duty to exercise reasonable care in manufacturing and distributing highly dangerous opioid drugs in the State of Nevada.

905. 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.

906. 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.

907. 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.

908. 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.

909. 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.

910. 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.

911. 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.

912. 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.

913. 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
NEVADA COMMON LAW
(Against Manufacturer and Distributor Defendants)

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

915. 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).

916. NRS 453.005 to 453.730 and NAC §§ 453.010 to 453.740 are public safety laws that define a standard of conduct. As such, these laws were intended to protect the public welfare and safety, and the State is the proper Plaintiff to enforce these laws. Each Defendant had a duty under *inter alia* these laws to prevent diversion of prescription opioids for non-medical and non-scientific purposes and to guard against, prevent, and report suspicious orders of opioids.

916. Nevada's minimum requirement for controlled substance manufacture and

wholesale drug distribution is that they must comply with applicable laws and regulations.

917. Nevada laws and regulations require Defendants to act as gatekeepers guarding against the diversion of the highly addictive, dangerous opioid drugs.

918. Defendants have violated their duties under the Nevada Controlled Substances Act and the Nevada Administrative Code.

919. Defendants' violations of these public safety laws are prima facie evidence of negligence per se. Each Defendant had a duty under, *inter alia*, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants' violations of the law constitute negligence per se. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

920. The State is within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

921. It was foreseeable that the breach of duty described herein would result in the damages sustained by the State.

922. Defendants' conduct was willful, wanton, malicious, reckless, and/or oppressive, as described above.

923. 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.

924. 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.

925. Defendants' violations of the Nevada statutes and public safety regulations cited herein were and are substantial factors in the injuries and damages sustained.

926. It was foreseeable that Defendants' breaches of statutory and regulatory duties described herein would result in the damages sustained.

927. 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
VIOLATIONS OF 2007 CONSENT JUDGMENT
(Against Purdue Defendants)

928. The State re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

929. The 2007 Consent Judgement, as referenced above, prohibited Defendant Purdue from engaging in certain conduct and required certain affirmative measures by Purdue with respect to the marketing, promotion, and sale of the branded opioid OxyContin.

930. Purdue, by making written and/or oral claims that are false, misleading, or deceptive, has violated, continues to violate, and failed to cure, Section II(2) of the 2007 Consent Judgement, which provides that "Purdue shall not make any written or oral claim that is false, misleading or deceptive."

931. Purdue, by failing, after identifying suspicious prescribers, prescribing patterns, orders, distributions or distribution patterns, to provide notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities, has violated, continues to violate, and failed to cure, section II(13) of the 2007 Consent Judgement, which requires Purdue to sufficiently "establish, implement, and follow an OxyContin Abuse and Diversion Detection Program." Specifically, in failing to report suspicious prescribers to

Nevada law enforcement or regulatory authorities, Purdue failed to carry out its obligation to "take such further steps as may be appropriate [to combat opioid abuse and unlawful diversion] based on the facts and circumstances" and information learned through the OxyContin Abuse and Diversion Detection Program, including "providing notice of such potential abuse or diversion to appropriate medical, regulatory, or law enforcement authorities."

932. Purdue, under the guise of education, by sending deceptive materials directly to health care professionals, violated and failed to cure section II(15) of the 2007 Consent Judgement, which requires Purdue to provide to health care professionals "written, non-branded educational information related to detecting and preventing abuse and diversion of opioid analgesics." Specifically, Purdue violated and failed to cure section II(15) by (1) sending Nevada health care providers the first, second, and third editions of *Providing Relief, Preventing Abuse* and (2) creating and marinating the website www.inthefaceofpain.com, both of which disseminated information to Nevada health care providers, misrepresenting the signs of opioid abuse.

933. Purdue, by making misrepresentations with respect to OxyContin's potential for 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.

934. 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.

935. 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.

936. 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. PUNITIVE DAMAGES

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

938. The acts, conduct and omissions of Defendants, as alleged throughout this complaint, were willful, malicious, oppressive and/or were done with conscious disregard of the rights and safety of Plaintiff and for the primary purpose of increasing Defendants' profits from the sale and distribution of the subject drug.

939. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against each Defendant in an amount appropriate to punish and make an example of each Defendant.

940. 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 made efforts to abate the nuisance, but, the wrongdoing has not ceased and, thus, the public nuisance remains unabated.

941. 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 legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over patients, and the safety of the community, and an award of punitive damages is appropriate, as punishment and a deterrence

942. Defendants' conduct was despicable, and so contemptible that it would be looked down upon and despised by ordinary, decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

943. 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.

944. Plaintiff is entitled to punitive damages, for the sake of example and by way of punishing Defendants in an amount in excess of $15,000.00.

945. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

VII. RELIEF

WHEREFORE, the State of Nevada, by and through its Attorney General, respectfully prays that this Court grant the following relief:

1. Entering Judgment in favor of the State in a final order against each of the Defendants;

2. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in deceptive practices in violation of Nevada law and ordering temporary, preliminary or permanent injunction;

3. Order that Defendants compensate the State for its future costs to abate the ongoing public nuisance caused by the opioid epidemic;

4. Declaring that each act and omission of each of the Defendants described in this Complaint constitute multiple, separate violations of the Deceptive Trade Practices Act;

5. Imposing actual damages as well as civil penalties of up to $5,000, per Defendant, for each repeated and willful violation of the Deceptive Trade Practices Act;

6. Awarding actual damages, treble damages, and civil penalties of not less than $5,500 and up to $11,000 for each violation of the False Claims Act;

7. Awarding the State its past and future damages caused by the opioid epidemic, including money wrongfully paid for opioids through government-funded insurance;

8. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

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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.

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DISTRICT COURT

CLARK COUNTY, NEVADA

STATE OF NEVADA,

Plaintiff,

vs.

MCKESSON CORPORATION; CARDINAL HEALTH INC.; CARDINAL HEALTH 105, INC.; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 200, LLC; CARDINAL HEALTH 414, LLC; CARDINAL HEALTH PHARMACY SERVICES, LLC; AMERISOURCEBERGEN DRUG CORPORATION; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.; WALGREEN EASTERN CO., INC.; WALMART INC.; CVS HEALTH CORPORATION; CVS PHARAMCEY, INC.; TEVA PHARMACEUTICALS USA,;TEVA PHARMACEUTICAL INDUSTRIES, LTD.; ACTAVIS PHARMA, INC.; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; PURDUE HOLDINGS, L.P.; THE PURDUE FREDERICK COMPANY, INC.; INC.; P.F. LABORATORIES, INC.; RICHARD S. SACKLER; JONATHAN D. SACKLER, MORTIMER D.A. SACKLER; KATHE A. SACKLER; ILENE SACKLER LEFCOURT; DAVID A. SACKLER; BEVERLY SACKLER; THERESA SACKLER; PLP ASSOCIATES HOLDINGS L.P.; ROSEBAY MEDICAL COMPANY L.P.; BEACON COMPANY; DOE ENTITIES 1-10; MALLINCKRODT PLC; MALLINCKRODT LLC; SPECGX LLC; INSYS THERAPEUTICS, INC.JOHN KAPOOR; RICHARD M. SIMON; SUNRISE LEE; JOSEPH A. ROWAN; MICHAEL J. GURRY; MICHAEL BABICH; ALEC BURLAKOFF;

Defendants.

Case No.:

Dept. No.:

COMPLAINT

REQUEST FOR BUSINESS COURT

EXEMPT FROM ARBITRATION

EGLET ADAMS

EGLET ADAMS

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Plaintiff, the State of Nevada, by and through the undersigned attorneys, files this Complaint against Plaintiff, the State of Nevada, by Aaron D. Ford, Attorney General (the "State"), brings this Complaint against Defendants McKesson Corporation; Cardinal Health, Inc.; Cardinal Health 105, Inc.; Cardinal Health 108, LLC; Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health 414, LLC; Cardinal Health Pharmacy Services, LLC; AmerisourceBergen Drug Corporation; Walgreens Boots Alliance, Inc.; Walgreen Co.; Walgreen Eastern Co., Inc.; Walmart Inc.; CVS Health Corporation; CVS Pharmacy, Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; Actavis Pharma, Inc.; Purdue Pharma L.P.; Purdue Pharma Inc.; Purdue Holdings L.P.; The Purdue Frederick Company, Inc.; P.F. Laboratories, Inc.; Richard S. Sackler; Jonathan D. Sackler; Mortimer D.A. Sackler; Kathe A. Sackler; Ilene Sackler Lefcourt; David A. Sackler; Beverly Sackler; Theresa Sackler; PLP Associates Holdings L.P.; Rosebay Medical Company L.P.; Beacon Company; Doe Entities 1-10; Mallinckrodt plc; Mallinckrodt LLC; SpecGx LLC; Insys Therapeutics, Inc.; John Kapoor; Richard M. Simon; Sunrise Lee; Joseph A. Rowan; Michael J. Gurry; Michael Babich; Alec Burlakoff; (collectively "Defendants") and alleges, upon information and belief, as follows:

I. INTRODUCTION

1. The State of Nevada, by and through Aaron Ford, Attorney General for the State of Nevada, and Ernest Figueroa, Consumer Advocate, files this Complaint on behalf of the State to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance in this State, and to recover civil fines arising out of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids (hereinafter "opioids").[1] Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

2. The State asserts two categories of claims: (1) claims against the pharmaceutical manufacturers of prescription opioid drugs that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share and (2) claims against entities in the supply chain that reaped enormous financial rewards by refusing to monitor and restrict the improper distribution of those drugs.

3. 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.[2]

4. The Centers for Disease Control ("CDC") recently estimated that prescription opioid misuse costs the United States $78.5 billion per year, taking into account healthcare expenses, lost productivity, addiction treatment, and criminal justice involvement.[3] In 2015, over 33,000 Americans died as a result of opioid overdose, while an estimated 2 million people in the United States suffered from substance abuse disorders relating to prescription opioids.[4]

5. This case arises from the worst man-made epidemic in modern medical history— the misuse, abuse, diversion, and over-prescription of opioids. Nevada has been greatly impacted by this opioid crisis. By 2016, Defendants had flooded the State with enough opioid prescriptions for 87 out of every 100 Nevadans and Nevadan overdoses well exceeded the national average for opioid deaths.[5] The impact of Defendants' scheme to misinform and deceptively promote the use of opioids is evident in the numerous instances of overprescribing in Nevada communities; for example, Dr. Robert Rand, Reno's notorious "Pill Mill" case, Dr. Steven Holper in Clark County who has been indicted for prescribing excess quantities of Insys product, Subsys, to his patients, one of whom died from a Subsys overdose, and Lam's Pharmacy, the Las Vegas top five seller of OxyContin in the nation.

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[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

[3] *See* Curtis S. Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013, 54 Medical Care 901 (2016).

[4] *See* Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016); Substance Abuse and Mental Health Servs. Admin., U.S. Dep't of Health and Human Servs., *National Survey on Drug Use and Health, 2015 Detailed Tables* (2016).

[5] Nev. Div. of Pub. and Behavioral Health, *The Scope of Opioid Use in Nevada*, 2016, NEV. DIV. OF PUB. AND BEHAVIORAL HEALTH (DPBH), 1 (Oct. 18, 2017), http://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Resources/opioids/Opioid%20Infographic.pdf.

6. The opioid crisis is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[6]

7. Opioids are regulated as Schedule II controlled substances under both Nevada and federal law. *See* NAC § 435.520(a).[7] Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. *See* NAC, §§ 435.510 to 435.550. The Nevada Controlled Substances Act imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally are categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

8. ***Hydrocodone*** is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other licit or illicit opioid. Its street names include Hydro, Norco, and Vikes. It is an orally active agent most frequently prescribed for the treatment of moderate to moderately severe pain. There are numerous brand and generic hydrocodone products marketed in the United States. The most frequently prescribed combination is hydrocodone and acetaminophen (for example, Vicodin®, Lorcet®, and Lortab®). Other examples of combination products include those containing aspirin (Lortab ASA®), ibuprofen (Vicoprofen®) and antihistamines (Hycomine®). Most often these drugs are abused by oral rather than intravenous administration.[8]

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[6] *See* Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

[7] The Nevada Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations. NAC 435.100, 435.140, 435.150, 639.426, 639.266, 639.295. References made to the federal Controlled Substances Act, 21 USC § 801 et seq. ("CSA") are for reference only and to state the duty owed under Nevada tort law, *not* to allege an independent federal cause of action and *not* to allege any substantial federal question. *See* Section III, *infra*.

[8] *See* Drug Enf't Admin., *Drug Fact Sheet: Hydrocodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Hydrocodone.pdf.

9. ***Oxycodone*** is a semi-synthetic narcotic analgesic and historically has been a popular drug of abuse among the narcotic abusing population. Its street names include Hillbilly Heroin, Kicker, OC, Ox, Oxy, Perc, and Roxy. Oxycodone is marketed alone as OxyContin® in 10, 20, 40 and 80 mg controlled-release tablets and other immediate-release capsules like 5 mg OxyIR®. It is also marketed in combination products with aspirin such as Percodan® or acetaminophen such as Roxicet®. Oxycodone is abused orally or intravenously. The tablets are crushed and sniffed or dissolved in water and injected. Others heat a tablet that has been placed on a piece of foil then inhale the vapors.[9]

10. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. But few realize that this crisis arose from the opioid manufacturers' deliberately deceptive marketing strategy to expand opioid use, together with the distributors' equally deliberate efforts to evade restrictions on opioid distribution. Manufacturers and distributors alike acted without regard for the lives that would be trammeled in pursuit of profit.

11. From 1999 through 2016, overdoses killed more than 350,000 Americans.[10] Over 200,000 of them, more than were killed in the Vietnam War, died from opioids prescribed by doctors to treat pain.[11] These opioids include brand-name prescription medications such as OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

12. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely than people not

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[9] *See* Drug Enf't Admin., *Drug Fact Sheet: Oxycodone* (n.d.), https://www.dea.gov/druginfo/drug_data_sheets/Oxycodone.pdf.

[10] *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).

[11] *Prescription Opioid Overdose Data*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/overdose.html (last updated Aug. 1, 2017).

addicted to prescription opioids to become addicted to heroin, and the Centers for Disease Control and Prevention ("CDC") identified addiction to prescription opioids as the strongest risk factor for heroin addiction.[12]

13. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

14. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion.

15. The State brings this suit against the manufacturers of these highly addictive drugs. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

16. The State also brings this suit against the wholesale distributors of these highly addictive drugs, which breached their legal duties under *inter alia* the Nevada Controlled Substances Act, Nev. Rev. Stat., §§ 453.005 to 453.730 and the Nevada Administrative Code, Nev. Admin. Code, §§ 639.010 to 639.978, to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses,

[12] *Today's Heroin Epidemic*, "Overdose Prevention" tab, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/opioids/heroin.html (last updated Aug. 29, 2017); *see also Today's Heroin Epidemic*, Ctrs. for Disease Control and Prevention https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

17. Defendants' conduct has exacted, and foreseeably so, a financial burden on the State of Nevada. Categories of damages sustained by the State include, but are not limited to Medicaid funds paid out as a result of Defendants' wrongful conduct within the State of Nevada; the prospective damages associated with abating the nuisance created by the Defendants; as well as fines attributable to the thousands, if not millions, of incidents of wrongful conduct by Defendants within the State.

18. The State brings this action exclusively under the law of the State of Nevada. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim for relief arising under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

19. In addition, notwithstanding anything to the contrary, under no circumstance is the State bringing this action against, or bringing an action or claim of any kind directed to, any federal officer or person acting under any officer of the United States for or relating to any act under color of such office; nothing in this Complaint raises such an action, and to the extent that anything in the Complaint could be interpreted as potentially bringing an action against or directed to any federal officer or person acting under any officer of the United States for or relating to any act under color of such office, then all such claims, actions, or liability, in law or in equity, are denied and disavowed in their entirety. Specifically and without limitation, nothing in the State's Complaint seeks to bind the McKesson Corporation, or any other Defendant, in law or in equity, or to otherwise impose any liability or injunction, related to any United States government contract, including without limitation any Pharmaceutical Prime Vendor (PPV) contract that the McKesson Corporation (or any affiliated entity) or any other Defendant has or had with the United States Veterans Administration. Specifically, and without limitation, nothing in this Complaint challenges in any way, in law or in equity or otherwise, actions of McKesson pursuant to a contract it has or ever had with the United States Veterans Administration.

20. Nor does the State bring this action on behalf of a class or any group of persons that can be construed as a class. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual users of opioids may have against Defendants.

II. PARTIES

A. Plaintiff

21. The State of Nevada is a body politic created by the Constitution and laws of the State; as such, it is not a citizen of any state. This action is brought by the State in its sovereign capacity in order to protect the interests of the State of Nevada and its citizens as *parens patriae*, by and through Aaron D. Ford, the Attorney General of the State of Nevada. Attorney General Ford is acting pursuant to his authority under, *inter alia*, NRS 228.310, 338.380, 228.390, and 598.0963(3).

B. Defendants

22. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times, each Defendant has occupied agency, employment, joint venture, or other relationships with each of the other named Defendants; that at all times herein mentioned each Defendant has acted within the course and scope of said agency, employment, joint venture, and/or other relationship; that each other Defendant has ratified, consented to, and approved the acts of its agents, employees, joint venturers, and representatives; and that each has actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

23. At all relevant times Defendants, together and independently, have engaged in the business of, or were successors in interest to, entities engaged in the business of researching, licensing, designing, formulating, developing, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing, and/or selling the prescription opioid drugs to individuals and entities in the State of Nevada.

24. At all relevant times, Defendants have sold and supplied opioid prescription drugs to individuals and entities located within every county of the State of Nevada.

1. Manufacturer Defendants

25. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs.

a. Teva Entities

26. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation regularly engaged in business in the United States of America and the state of Nevada.

27. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do business with the Nevada Secretary of State as a Delaware corporation with its principal place of business in Parsippany-Troy Hills, New Jersey. Actavis Pharma, Inc. was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

28. Teva USA, Teva Ltd. and Actavis Pharma, Inc., together with their DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "Teva"), work together to manufacture, promote, distribute and sell brand name and generic versions (including Kadian, Duragesic, and Opana) of opioids nationally, and in Nevada, including the following:

Product Name	Chemical Name
Actiq	Fentanyl citrate

Fentora	Fentanyl buccal
Kadian	Morphine sulfate, extended release
Norco	Hydrocodone bitartrate and acetaminophen

29. From 2000 forward, Teva, directly and through its named and unnamed subsidiaries and/or agents, has made thousands of payments to physicians nationwide, many of whom were not oncologists and did not treat cancer pain, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

b. Purdue Entities and the Sackler Defendants

30. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut and is registered with the Nevada Secretary of State to do business in Nevada.

31. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

32. Defendant Purdue Holdings L.P. ("PHL") is a Delaware limited partnership and wholly owns the limited partnership interest in Purdue Pharma L.P.

33. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

34. Defendant P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business in Totowa, New Jersey.

35. PPL, PPI, PHL, PFC, and PF Labs, together with their Drug Enforcement Administration ("DEA") and Nevada registrant and licensee subsidiaries and affiliates (collectively, "Purdue"), are engaged in the manufacture, promotion, distribution, and sale of opioids nationally, and in Nevada, including the following:

Product	Chemical Name
OxyContin	Oxycodone hydrochloride, extended release
MS Contin	Morphine sulfate, extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride

36. Purdue made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

37. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

38. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay a $635 million fine – at the time, one of the largest settlements with a drug company for marketing misconduct. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long-term use, even after being caught, by using unbranded marketing methods to circumvent the system. On May 8, 2007, as part of these settlements, Purdue entered into a consent judgment with the State of Nevada, in which it agreed to a number of terms intended to prevent any further misleading marketing in the State of Nevada. In short, Purdue paid the fine when caught and then continued business as usual, deceptively marketing and selling billions of dollars of opioids

each year.

39. At all relevant times, Purdue, which is a collection of private companies, has been controlled by members of the extended Sackler family, who are the ultimate intended beneficiaries of virtually all of Purdue's profit distributions. The individual Defendants named in this action are the remaining living Sackler family members who served on the board of Purdue Pharma, Inc. (the "Purdue board"), which functioned as the nexus of decision-making for all of Purdue.

40. Defendant Richard S. Sackler became a member of the Purdue board in 1990 and became its co-chair in 2003, which he remained until he left the board in 2018. He was also Purdue's head of research and development from at least 1990 through 1999, and its president from 1999 through 2003. He resides in New York, Florida, and Texas. He currently holds an active license to practice medicine issued by the New York State Education Department. He is a trustee of the Sackler School of Medicine, a director and the vice president of the Raymond and Beverly Sackler Foundation, and a director and the president and treasurer of the Richard and Beth Sackler Foundation, Inc., all three of which are New York Not-for-Profit Corporations.

41. Defendant Jonathan D. Sackler was a member of Purdue's board from 1990 through 2018. He resides in Connecticut. He is a trustee of the Sackler School of Medicine, the president and CEO of the Raymond and Beverly Sackler Foundation, and the vice president of the Richard and Beth Sackler Foundation Inc., all three of which are New York Not-for-Profit Corporations.

42. Defendant Mortimer D.A. Sackler has been a member of Purdue's Board since 1993. He resides in New York. Mortimer is a director and the president of the Mortimer and Jacqueline Sackler Foundation, and a director and the vice president and treasurer of the Mortimer D. Sackler Foundation, Inc., both of which are New York Not-for-Profit Corporations.

43. Defendant Kathe A. Sackler was a member of Purdue's board from 1990

through 2018. She resides in New York and Connecticut. Kathe is a director and president of the Shack Sackler Foundation, a director and vice president and secretary of the Mortimer D. Sackler Foundation Inc. and is a governor of the New York Academy of Sciences, all three of which are New York Not-for-Profit Corporations.

44. Defendant Ilene Sackler Lefcourt was a member of Purdue's board between 1990 and 2018. She resides in New York. She is a director of Columbia University and is the president of the Sackler Lefcourt Center for Child Development Inc., both of which are New York Not-for-Profit Corporations.

45. Defendant David A. Sackler was a member of Purdue's board from 2012 through 2018. He resides in New York.

46. Defendant Beverly Sackler was a member of Purdue's board from 1993 through 2017. She resides in Connecticut. Beverly Sackler serves as a Director and the Secretary and Treasurer of the Raymond and Beverly Sackler Foundation, a New York Not-for-Profit Corporation.

47. Defendant Theresa Sackler was a member of Purdue's board from 1993 through 2018. She resides in New York and the United Kingdom.

48. These individual Defendants used a number of known and unknown entities named as Defendants herein as vehicles to transfer funds from Purdue directly or indirectly to themselves. These include the following:

49. Defendant PLP Associates Holdings L.P., which is a Delaware limited partnership and a limited partner of Purdue Holdings L.P. Its partners are PLP Associates Holdings Inc. and BR Holdings Associates L.P.

50. Defendant Rosebay Medical Company L.P., which is a Delaware limited partnership ultimately owned by trusts for the benefit of one or more of the individual Defendants. Its general partner is Rosebay Medical Company, Inc., a citizen of Delaware and Connecticut. The Board of Directors of Rosebay medical Company, Inc. includes board members Richard S. Sackler and Jonathan D. Sackler.

51. Defendant Beacon Company, which is a Delaware general partnership ultimately owned by trusts for the benefit of members of one or more of the individual Defendants.

52. Defendant Doe Entities 1-10, which are unknown trusts, partnerships, companies, and/or other legal entities, which are ultimately owned and/or controlled by, and the identities of which are particularly within the knowledge of, one or more of the individual Defendants.

53. The foregoing individual Defendants are referred to collectively as "the Sacklers." The foregoing entities they used as vehicles to transfer funds from Purdue directly or indirectly to themselves are referred to as "the Sackler Entities." Together, the Sacklers and the Sackler Entities are referred to collectively as "the Sackler Defendants."

c. SpecGX and Mallinckrodt Entities

54. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 with the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

55. Defendant Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware.

56. Defendant SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is registered with the Nevada Secretary of State to do business in Nevada.

57. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC, together with their DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "Mallinckrodt"), manufacture, market, sell, and distribute pharmaceutical drugs throughout the United States, and in Nevada. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among

the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

58. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. Exalgo was approved for the treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

59. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt also estimated, based on IMS Health data for 2015, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[13]

60. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers with mail-order pharmacies, and hospital buying groups.

61. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Product Name	**Chemical Name**
Exalgo	Hydromorphone hydrochloride, extended release

[13] Mallinckrodt plc 2016, Annual Report (Form 10-K), at 5 (Nov. 29, 2016), https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/0001567892-16- 000098-index.htm.

Roxicodone	Oxycodone hydrochloride
Xartemis XR	Oxycodone hydrochloride and acetaminophen
Methadose	Methadone hydrochloride
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Generic	Oxycodone and acetaminophen
Generic	Hydrocodone bitartrate and acetaminophen
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release

Product Name	**Chemical Name**
Generic	Naltrexone hydrochloride
Generic	Oxymorphone hydrochloride
Generic	Methadone hydrochloride
Generic	Oxycodone hydrochloride
Generic	Buprenorphine and naloxone

62. Mallinckrodt made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

d. Insys Therapeutics and Insys Executives

63. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures, promotes, sells, and distributes the opioid fentanyl also known as Subsys, in the United States, including in Nevada.

Subsys is Insys's principal product and source of revenue:

Product Name	Chemical Name
Subsys	Fentanyl

64. Insys made thousands of payments to physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. In fact, these payments were made to deceptively promote and maximize the use of opioids.

65. Subsys is a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under-the-tongue administration. Subsys was approved by the FDA solely for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[14]

66. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, and in Nevada. Subsys was Insys's only marketed product from March 2012 until July 2017. Insys is a pharmaceutical company, wholesaler, and distributor in the State of Nevada.

67. Subsys is notorious in Nevada as the drug prescribed by Dr. Steven Holper to the late Henderson Municipal Court Judge Diana Hampton, which was determined to be the cause of her fatal overdose. [15]

68. Defendant John Kapoor, the founder of Insys Therapeutics, Inc. and former Executive Chairman, was a member of Insys's board between 1990 and 2017. He resides in Phoenix, Arizona.

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[14] *Highlights of Prescribing Information, SUBSYS® (fentanyl sublingual spray), CII* (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202788s016lbl.pdf.

[15] *See* Scott Hampton, as Heir, Executor and Personal Representative of the Estate of Diana Hampton v. Steven A. Holper, Insys Therapeutics, et al., Case No. A-18-770455-C (Clark Co., Nev.).

69. Defendant Richard M. Simon was a former National Director of Sales for Insys during the time relevant to the allegations of this action. He resides in Seal Beach, California.

70. Defendant Sunrise Lee was a former Regional Sales Director of Insys. He resides in Bryant City, Michigan.

71. Defendant Joseph A. Rowan was a former Regional Sales Director of Insys during the time relevant to the allegations of this action. He resides in Panama City, Florida.

72. Defendant Michael J. Gurry was a former Vice President of Managed Markets for Insys during the time relevant to the allegations of this action. He resides in Scottsdale, Arizona.

73. Defendant Michael Babich was the former president and CEO of Insys during the time relevant to the allegations of this action. He resides in Scottsdale, Arizona.

74. Defendant Alec Burlakoff was the former vice president of sales for Insys during the time relevant to the allegations of this action. He resides in Charlotte, North Carolina.

75. The foregoing individual Defendants are referred to collectively as "the Insys Executives."

76. Insys's founder and owner, John Kapoor, was recently convicted of criminal racketeering in a case brought by the Massachusetts Department of Justice. Insys executives, Richard M. Simon, Sunrise Lee, Joseph A. Rowan, and Michael J. Gurry, were all convicted in the same case. Michael L. Babich, former Insys chief executive, pleaded guilty to conspiracy and mail fraud charges. Alec Burlakoff pled guilty to one count of racketeering conspiracy.

2. Distributor Defendants

77. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription drug opioids, without fulfilling their fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The State alleges that the unlawful conduct by the Distributor Defendants is a substantial cause

for the volume of prescription opioids plaguing the State and that the negligence of those Distributor Defendants caused catastrophic harm to the state of Nevada and its citizens.[16]

a. McKesson Corporation

78. Defendant McKesson Corporation is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson Corporation, together with and through its DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "McKesson"), is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Nevada. McKesson operated as a licensed pharmacy wholesaler in the State of Nevada and is and was at all relevant times registered with the Nevada Secretary of State as a Delaware corporation with its principal office located in San Francisco, California.

79. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

b. Cardinal Health Entities

80. Defendant Cardinal Health, Inc. and its subsidiaries Cardinal Health 105, Inc.; Cardinal Health 108, LLC; Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health 414, LLC; and Cardinal Health Pharmacy Services, LLC operated as licensed pharmacy wholesalers in the State of Nevada and will be referred to collectively herein as "Cardinal Health."

81. Defendant Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal Health, Inc. describes itself as a "global, integrated health

[16] Although addressed in Section 1(e), Defendant Mallinckrodt LLC and related entities are direct distributors of drugs relevant to this action in the state of Nevada and should be considered both a manufacturer defendant as well as distributor defendant.

care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Based on Defendant Cardinal Health's own estimates, one out of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

82. Defendant Cardinal Health 105, Inc. d/b/a Xiromed, LLC is an Ohio corporation with its principal place of business in Dublin, Ohio.

83. Defendant Cardinal Health 108, LLC f/k/a Cardinal Health 108, Inc. is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Tennessee.

84. Defendant Cardinal Health 110, LLC d/b/a ParMed Pharmaceuticals is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Dublin, Ohio.

85. Defendant Cardinal Health 200, LLC is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Waukegan, Illinois.

86. Defendant Cardinal Health 414, LLC is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Dublin, Ohio.

87. Defendant Cardinal Health Pharmacy Services, LLC is and was at all relevant times registered to do business with the Nevada Secretary of State as a Delaware limited liability company with its principal place of business in Houston, Texas.

c. AmerisourceBergen Drug Corporation

88. Defendant AmerisourceBergen Drug Corporation, together with and through its DEA and Nevada registrant and licensee subsidiaries and affiliates (collectively, "AmerisourceBergen"), is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country, including in Nevada. AmerisourceBergen, at all relevant times, operated as a licensed pharmacy wholesaler in the State of Nevada and is and was registered to

do business with the Nevada Secretary of State as a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016.

d. Walgreens Entities

89. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois.

90. Defendant Walgreen Co. is and was registered to do business with the Nevada Secretary of State as an Illinois with its principal place of business in Deerfield, Illinois. Walgreen Co. is a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens.

91. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois.

92. Defendants Walgreens Boots Alliance, Inc., Walgreen Eastern Co., and Walgreen Co. are collectively referred to as "Walgreens". Walgreens, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in Nevada. At all relevant times, this Defendant operated as a licensed pharmacy wholesaler in the State of Nevada.

e. Walmart Entities

93. Defendant Walmart Inc., ("Walmart") formerly known as Wal-Mart Stores, Inc., is and was registered to do business with the Nevada Secretary of State as a Delaware corporation with its principal place of business in Arkansas. Walmart, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor under named business entities including Wal-Mart Warehouse #6045 a/k/a Wal-Mart Warehouse #45. At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in Nevada. At all relevant times, this Defendant operated as a licensed pharmacy wholesaler in the State of Nevada.

f. CVS Entities

94. Defendant CVS Health Corporation ("CVS HC") is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. CVS HC conducts business as a licensed wholesale distributor under the following named business entities, among others: CVS Orlando FL Distribution L.L.C. and CVS Pharmacy, Inc. (collectively "CVS"). At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Nevada.

95. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy is a subsidiary of CVS HC. At all times relevant to this Complaint, CVS Pharmacy operated as a licensed pharmacy wholesaler, distributor and controlled substance facility in Nevada.

96. Defendants CVS HC, and CVS Pharmacy are collectively referred to as "CVS." CVS conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Nevada.

C. Agency and Authority

97. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

III. JURISDICTION & VENUE

98. Subject matter jurisdiction for this case is conferred upon this Court pursuant to, inter alia, Article 6, Section 6 of the Nevada Constitution.

99. This Court has personal jurisdiction over Defendants because Defendants do

business in Nevada and/or have the requisite minimum contacts with Nevada necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also within the contemplation of the Nevada "long arm" statute, NRS § 14.065.

100. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 USC § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdiction of the Class Action Fairness Act of 2005. Likewise, federal question subject matter jurisdiction pursuant to 28 USC § 1331 is not invoked by the Complaint, as it sets forth herein exclusively viable state law claims against Defendants. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. No federal issue is important to the federal system as a whole under the criteria set by the Supreme Court in *Gunn v. Minton*, 568 U.S. 251 (2013) (*e.g.*, federal tax collection seizures, federal government bonds). Specifically, the causes of action asserted, and the remedies sought herein, are founded upon the positive statutory, common, and decisional laws of Nevada. Further, the assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Accordingly, any exercise of federal jurisdiction is without basis in law or fact.

101. In this complaint, Plaintiff cites federal statutes and regulations. Plaintiff does so to state the duty owed under Nevada tort law, *not* to allege an independent federal cause of action and *not* to allege any substantial federal question under *Gunn v. Minton.* "A claim for negligence in Nevada requires that the plaintiff satisfy four elements: (1) an existing duty of care, (2) breach, (3) legal causation, and (4) damages." *Turner v. Mandalay Sports Entertainment, LLC*, 124 Nev. 213, 180 P.3d 1172 (Nev. 2008). The element of duty is to be determined as a matter of law based on foreseeability of the injury. Estate of Smith ex rel. Smith v. Mahoney's Silver Nugget, Inc., 127 Nev. 855, 265 P.3d 688, 689 (Nev. 2011). To be clear, Plaintiff cites federal statutes and federal regulations for the sole purpose of stating the duty owed under Nevada law to the citizens of Nevada. Thus, any attempted removal of this

complaint based on a federal cause of action or substantial federal question is without merit.

102. Venue is proper in this Court pursuant to NRS § 598.0989(3) because Defendants' conduct alleged herein took place in Clark County, Nevada.

IV. FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS[17]

A. Opioids and Their Effects

103. Opioids are a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to temporarily relieve pain, opioids block pain signals but do not treat the source of the pain. Opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

104. The medicinal properties of opioids have been recognized for millennia—as has their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

105. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to temporarily relieve the pain of the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing

[17] The allegations in this Complaint are made upon facts, as well as upon information and belief. The State reserves the right to seek leave to amend or correct this Complaint based upon analysis of DEA data or other discovery, including, upon analysis of the ARCOS, IMS Health, and other date and upon further investigation and discovery.

extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[18]

106. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

107. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

108. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

109. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

110. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets

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[18] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in- the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

delivered sixteen times that.

111. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

112. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

113. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total amount of MME in circulation, even though it currently claims to have a small percentage of the market share in terms of pills or prescriptions.

114. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Manufacturer Defendants' promotion, with particularly lethal consequences.

115. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients

with end-stage cancer. The Manufacturer Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

116. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

117. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

118. As a leading pain specialist doctor put it, the widespread, long-term use of opioids "was a *de facto* experiment on the population of the United States. It wasn't randomized, it wasn't controlled, and no data was collected until they started gathering death statistics."

B. <u>The Resurgence of Opioid Use in the United States</u>

1. The Sackler Family Integrated Advertising and Medicine.

119. Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Manufacturer Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

120. As it turned out, Purdue Pharma was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with a net worth of $13 billion

as of 2016. All of the company's profits go to Sackler family trusts and entities.[19] Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

121. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company in 1952. It was Arthur Sackler who created the pharmaceutical advertising industry as we know it, laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

122. Arthur Sackler was both a psychiatrist and a marketing executive. He pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He also understood the persuasive power of recommendations from fellow physicians and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.[20]

123. It was Arthur Sackler who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So, Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution.[21] The campaign, for which Arthur was compensated based on volume of pills sold,[22] was a remarkable success.

124. Arthur Sackler created not only the advertising for his clients but also the vehicle

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[19] David Armstrong, *The Man at the Center of the Secret OxyContin Files*, STAT News (May 12, 2016), https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/.

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

[21] *Id.* at 202; see also, One Family Reaped Billions From Opioids, *WBUR On Point (Oct. 23, 2017), http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids.*

[22] Meier, *supra,* at 201-203.

to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which was distributed for free to doctors nationwide. Arthur also conceived a company called IMS Health Holdings Inc. (now called IQVIA), which monitors prescribing practices of every doctor in the
U.S and sells this valuable data to pharmaceutical companies like Manufacturer Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

2. Purdue Developed and Aggressively Promoted OxyContin.

125. After the Sackler brothers acquired the Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue, which would have been a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

126. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin, and it quickly became Purdue's bestseller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard had grand ambitions for the company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[23] Richard believed Purdue should develop another use for its "Contin" timed-release system.

127. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely

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

because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodeine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[24]

128. For Purdue and OxyContin to be "I mean *really* big,"[25] Purdue needed to both distance its new product from the traditional view of narcotic addiction risk and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

129. To achieve its marketing goals and avoid the "stigma" attached to less potent opioids, Purdue persuaded the FDA examiner, over internal objections within the FDA, to approve a label stating: "Delayed absorption as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."

130. The basis for this reduced abuse liability claim was entirely theoretical and not based on any actual research, data, or empirical scientific support, and the FDA ultimately pulled this language from OxyContin's label in 2001.

131. Nonetheless, as set forth in detail below, Purdue made reduced risk of addiction

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[24] *Id.*
[25] *Id.*

and abuse the cornerstone of its marketing efforts.

132. At the OxyContin launch party, Richard Sackler asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said, "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white...."

133. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non- acute, everyday aches and pains. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[26]

134. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin:[27]

135. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

136. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

137. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin

[26] Meier, *supra*, at 269.

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

abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

138. Facing increasing domestic scrutiny from the public and increasing awareness of the harm their drugs cause, Purdue and Richard Sackler now have their eyes on even greater profits. Under the name of Mundipharma International, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

139. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
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> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin

> internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.[28]

140. With the opioid epidemic in the United States now a national public health emergency, Purdue announced on February 9, 2018, that it had reduced its sales force and would no longer promote opioids directly to prescribers. Under this new policy, sales representatives will no longer visit doctors' offices to discuss opioid products. Despite its new policy, however, Purdue continues to use the same aggressive sales tactics to push opioids in other countries. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

3. Other Manufacturer Defendants Leapt at the Opioid Opportunity.

141. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Manufacturer Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in greater detail below.

142. Actavis also pursued a broader chronic pain market. Its predecessor, Watson Pharmaceuticals, Inc., obtained approval for Norco (hydrocodone and acetaminophen) and launched the product in 1997. Actavis also developed Kadian (morphine sulfate) and was the

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

contract manufacturer for Kadian starting in 2005. Actavis then acquired Kadian in December 2008.[29] Kadian sales grew 50 percent from 2007 to 2011 to approximately $275 million for the year ending September 30, 2011 and Actavis then introduced a generic version of the drug.[30] As described with more particularity below, Actavis deceptively promoted Kadian to its highest prescribers in order to increase sales and stated that Kadian was less likely to be abused when it had no evidence of this.

143. Mallinckrodt also pursued a broader chronic pain market - marketing its branded and generic drugs by misrepresenting their addictive nature and falsely claiming that the drugs could be taken in higher doses but without disclosing the greater risks of addiction. From 2009 to 2014, Mallinckrodt expanded its branded opioid portfolio while also maintaining its role as leading manufacturer of generic opioids. As described with more particularity below, Mallinckrodt, through its website, sales force, and unbranded communications, promoted its opioids by consistently mischaracterizing the risk of addiction. Specifically, Mallinckrodt promoted both Exalgo (hydromorphone hydrochloride) and Xartemis XR (oxycodone hydrochloride and acetaminophen) as formulated to reduce abuse when it had no evidence of this. In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it.

144. As described with more particularity below, Insys Executives also deceptively promoted their product Subsys (fentanyl) as safe and appropriate for uses such as neck and back pain, without disclosing that the drug had not been approved for such uses. Subsys was approved in 2012 only for management of "breakthrough" pain in adult cancer patients who were already receiving and were tolerant to opioid therapy for underlying persistent cancer pain. Insys was only allowed to market Subsys for this use.

145. Since its launch in 2012, Insys Executives aggressively worked to grow their

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[29] *Actavis Acquires Kadian; Extends Specialty Drug Portfolio in U.S.,* Business Wire (December 30, 2008) https://www.businesswire.com/news/home/20081230005227/en/Actavis-Acquires- Kadian-Extends-Specialty-Drug-Portfolio.

[30] *Actavis Launches Generic KADIAN® Capsules in the U.S.*, PR Newswire, (Nov. 11, 2011), https://www.prnewswire.com/news-releases/actavis-launches-generic-kadian-capsules-in-the-us- 133689873.html.

profits through deceptive, illegal, and misleading tactics, including its reimbursement-related scheme. Through sales representatives and other marketing efforts, Insys Executives implemented a kickback scheme wherein they paid prescribers for fake speakers' programs in exchange for prescribing Subsys. All of these deceptive and misleading schemes had the effect of pushing Insys's dangerous opioid onto patients who did not need it.

146. By adding opioid products or expanding the use of their existing opioid products, the other Manufacturer Defendants took advantage of the market created by Purdue's aggressive promotion of OxyContin and reaped enormous profits. For example, Insys made approximately $330 million in net revenue from Subsys in 2015.

C. Defendants' Conduct Created an Abatable Public Nuisance.

147. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

148. The public nuisance—*i.e.*, the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing effective, long-term addiction treatment to patients who are already addicted to opioids; (c) making naloxone and other overdose reversal drugs widely available so that overdoses are less frequently fatal; and (d) ensuring that state regulators have the information they need to investigate compliance.

149. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well-positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's marketing and promotion. And, all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to

appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet state consumer protection laws and regulations, as well as the obligations under the Nevada Controlled Substances Act and the Nevada Administrative Code. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

D. The Manufacturer Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception to Increase Demand for Opioids

150. In order to accomplish the fundamental shift in perception that was key to successfully marketing their opioids, the Manufacturer Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Manufacturer Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

151. The Manufacturer Defendants promoted, and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of these risks. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients were and are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

152. The deceptive marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Manufacturer Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled, "Front Groups," so-called industry "Key Opinion Leaders," and Continuing Medical Education ("CME") programs discussed subsequently below.

1. The Manufacturer Defendants Promoted Multiple Falsehoods About Opioids.

153. The Manufacturer Defendants' misrepresentations fall into the following nine categories:

a. False or misleading claims that the risk of addiction from chronic opioid therapy is low.

b. False or misleading claims that to the extent there is a risk of addiction, it can be easily identified and managed.

c. False or misleading claims that signs of addictive behavior are actually signs of "pseudoaddiction," requiring more opioids.

d. False or misleading claims that opioid withdrawal can be avoided by tapering.

e. False or misleading claims that there are no risks associated with taking increased doses of opioids.

f. False or misleading claims that long-term opioid use improves functioning.

g. False or misleading claims that alternative forms of pain relief pose greater risks than opioids.

h. False or misleading claims that certain opioids, including, but not limited to OxyContin, provide twelve hours of pain relief.

i. False or misleading claims that new formulations of certain opioids successfully deter abuse.

154. Each of these propositions was false. The Manufacturer Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

155. The categories of misrepresentations are offered to organize the numerous statements the Manufacturer Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Manufacturer Defendant's liability. While each Manufacturer Defendant deceptively promoted their opioids specifically, and, together with other Manufacturer Defendants, opioids generally, not every Manufacturer Defendant propagated (or needed to propagate) each misrepresentation. Each Manufacturer Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids. While this Complaint endeavors to document examples of each Manufacturer Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Manufacturer Defendant.

a. Falsehood #1: The false or misleading claims that the risk of addiction from chronic opioid therapy is low.

156. Central to the Manufacturer Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Manufacturer Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly

led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Manufacturer Defendants and substantially contributing to the opioid epidemic.

157. Each of the Manufacturer Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

158. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at recommended dose,"[31] and the risk substantially increases with more than three months of use.[32] As the CDC Guideline states, "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[33]

i. Purdue's misrepresentations regarding addiction risk

159. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

160. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of

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[31] *FDA Announces Safety Labeling Changes and Postmarket Study Requirements For Extended- Release and Long-Acting Opioid Analgesics*, MagMutual (Aug. 18, 2016), https://www.magmutual.com/learning/article/fda-announces-safety-labeling-changes-and- postmarket-study-requirements-opioids; *see also* Press Release, U.S. Food & Drug Admin., *Announces Enhanced Warnings For Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[32] Deborah Dowell, M.D. et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016,* 65(1) Morbidity & Mortality Wkly. Rep. 1, 21 (Mar. 18, 2016) (hereinafter "CDC Guideline").

[33] *Id.* at 2.

addiction "rare" for patients treated with opioids.[34] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

161. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[35]

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind V, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

162. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[36] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. Purdue was the first Manufacturer to rely upon this letter to assert that its opioids were not addictive, but the other Manufacturer Defendants eventually followed suit, citing to the letter as a basis for

[34] Jane Porter & Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.
[35] Meier, *supra*, at 174.
[36] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, *supra.*

their misrepresentations regarding the addictive nature of their products. Dr. Jick, author of the letter, later stated "that's not in any shape or form what we suggested in our letter.".

163. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%.*"[37] Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"[38]

164. Other Manufacturer Defendants relied on and disseminated the same distorted messaging. 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 crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[39]

165. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[40]

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[37] Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyel.

[38] Patrick R. Keefe, *The Family That Built an Empire of Pain,* New Yorker (Oct. 30, 2017) (hereinafter, "Keefe, *Empire of Pain*").

[39] Pamela T.M. Leung, B.Sc. Pharm., *et al., A 1980 Letter on the Risk of Opioid Addiction*, 376 New Engl. J. Med. 2194, 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150.

[40] Marilynn Marchione, Assoc. Press, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemicnejm-letter/.

166. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, "The fear of addiction is exaggerated."[41]

167. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[42]

168. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question "Aren't opioid pain medications like OxyContin Tablets 'addicting'?," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.[43]

169. Sales representatives marketed OxyContin as a product "'to start with and to

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[41] Press Release, Purdue Pharma L.P., *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

[42] *Oxycontin: Its Use and Abuse: Hearing Before the House Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (Statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG- 107hhrg75754.htm.

[43] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and a set of medical education resources distributed to prescribers by sales representatives. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

stay with.'"[44] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[45] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[46]

170. Purdue, through its unbranded website *Partners Against Pain*, stated the following: "Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids." "Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain."

171. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[47] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

172. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to

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[44] Keefe, *Empire of Pain, supra.*
[45] Meier, *supra,* at 102.
[46] *Id.*
[47] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new- yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

173. With regard to addiction, Purdue's label for OxyContin has not sufficiently disclosed the true risks to, and experiences of, its patients. Until 2014, the OxyContin label stated in a black-box warning that opioids have "abuse potential" and that the "risk of abuse is increased in patients with a personal or family history of substance abuse."

ii. As the Owners of Purdue, members of Purdue's Board and Former Officers of the Company, the Sacklers had actual knowledge of, sanctioned, and participated in Purdue's deceptive, misleading, and otherwise illegal practices

174. Purdue's deliberate actions to mislead prescribers and the public about the risks and benefits of long-term opioid treatment were orchestrated by the Sacklers from the launch of OxyContin through the present. Purdue is not a publicly traded company, but rather a family business: it is completely Sackler-owned and Sackler-led. The Sacklers were directly involved in development and sanctioning Purdue's deceptive and illegal activities, and they each participated in its decisions to mislead Nevada providers, patients, government authorities, and insurers to normalize opioid prescribing and generate a financial windfall for themselves.

175. The Sacklers control Purdue. Each of them took seats on the board of PPI and many served as officers of Purdue entities. Together, they always controlled the directorate that gave them total power over Purdue and its officers and other employees, and they frequently exercised that power in person at Purdue headquarters, some working there on a daily basis. From 1990 to 2018, the Sacklers made up a majority of the Purdue Board of Directors and, in some years, the Board consisted only of members of the Sackler family.

176. Each of the Sacklers knew and intended that the sales representatives and Purdue's other marketing employees would not disclose to Nevada providers and patients the truth about Purdue's opioids. They each intended and directed Purdue staff to reinforce these misleading messages throughout Nevada, including by sending deceptive publications to

Nevada doctors and deceptively promoting Purdue opioids at CME events in the State of Nevada. And they each knew and intended that patients, prescribers, pharmacists, and insurers in Nevada would rely on Purdue's deceptive sales campaign to request, prescribe, dispense, and reimburse claims for Purdue's opioids.

177. The Sacklers—Defendants Richard, Ilene, Jonathan, Kathe, Theresa, Beverly, and Mortimer Sackler—took seats on the Board from PPI's inception in 1990. David Sackler joined the Board in July 2012.

178. Richard Sackler played an active and central role in the management of Purdue. He is named as inventor on dozens of patents relating to oxycodone and other pain medications, including patents issued as late as 2016. Most of these patents were assigned to Purdue. He began working for Purdue as assistant to the president in the 1970s. He later served as vice president of marketing and sales. In the early 1990's he became senior vice president, which was the position he held at the time OxyContin was launched in 1996. In 1999, he became president/CEO, and he served in that position until 2003.

179. Richard Sackler resigned as President in 2003 but he continued to serve as co-chair of the Purdue board. He was actively involved in the invention, development, marketing, promotion, and sale of Purdue's opioids, including OxyContin. And he saw to it that Purdue launched OxyContin with an unprecedented marketing campaign causing OxyContin to generate a billion dollars in sales within five year of its introduction in the pain management market. For example, in 1998, Richard Sackler instructed Purdue's executives that OxyContin tablets provide more than merely "therapeutic" value and instead "enhance personal performance."

180. Defendant Jonathan Sackler served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. He resigned that officer position in or after 2003, but he continued to serve on the board of Purdue

181. Defendant Mortimer D. A. Sackler also served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. He

resigned that position in or after 2003, but he continued to serve on the board of Purdue.

182. Defendant Kathe Sackler also served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. She resigned that position in or after 2003, but continued to serve on the board of Purdue.

183. Defendant Ilene Sackler served as a vice president of Purdue during the period of development, launch, promotion, and marketing of OxyContin. Like Richard, Jonathan, Mortimer, and Kathe, Ilene resigned that position in or after 2003, but continued to serve on the board of Purdue.

184. Defendant David A. Sackler served as a member of Purdue's board between 2012 and 2018.

185. Defendant Beverly Sackler served on Purdue's board between 1993 and 2017. During the relevant time period, she also served as a trustee of one or more trusts that beneficially own and control Purdue.

186. Defendant Theresa Sackler served as a member of Purdue's board between 1993 and 2017.

187. Through their positions as the owners, directors, and officers of Purdue, the Sacklers had oversight and control over the unlawful sales and marketing described in this complaint.

188. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients about opioids' risk of abuse and addiction. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol.

189. The Sacklers who were involved in running the family business knew since at least the summer of 1999 that prescription opioids lead to addiction, and specifically that OxyContin could be, and was, abused. In summer 1999, a Purdue sales representative wrote to

the president of Purdue reporting widespread abuse of OxyContin. "We have in fact picked up references to abuse of our opioid products on the internet," Purdue Pharma's general counsel, Howard R. Udell, wrote in early 1999 to another company official.

190. In January 2001, Richard Sackler received an email from a Purdue sales representative describing a community meeting at a local high school that organized by mothers whose children overdosed on OxyContin and died. The sales representative wrote: "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."

191. In February 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Defendant Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

192. In 2007, Richard Sackler applied for a patent to treat opioid addiction. He finally received it in January 2018 and assigned it to Rhodes, a different company controlled by the Sackler family, instead of Purdue. Richard's patent application says opioids *are* addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.

193. At no point during the relevant time period did the Sacklers receive information showing that prescription opioid abuse had abated.

194. Instead, in 2010, staff gave the Sacklers a map, which showed a correlation between the location of dangerous prescribers with reports of oxycodone poisonings, burglaries and robberies.

195. In March 2013, staff reported to the Sacklers on the devastation caused by prescription opioids. Staff told the Sacklers that drug overdose deaths had more than tripled since 1990— the period during which Purdue had made OxyContin the best-selling painkiller.

They told the Sacklers that tens of thousands of deaths were only the " tip of the iceberg," and that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.

196. Just two months later, at a May 2013 board meeting, staff reported to the Sacklers that they were successfully pushing opioid savings cards through direct mail and email to get patients to "remain on therapy longer."

197. In February 2001, Richard Sackler dictated Purdue's strategy for responding to the increasing evidence of abuse of prescription opioids and addiction to Purdue's opioids: blame and stigmatize their own victims. Richard Sackler wrote in an email: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."

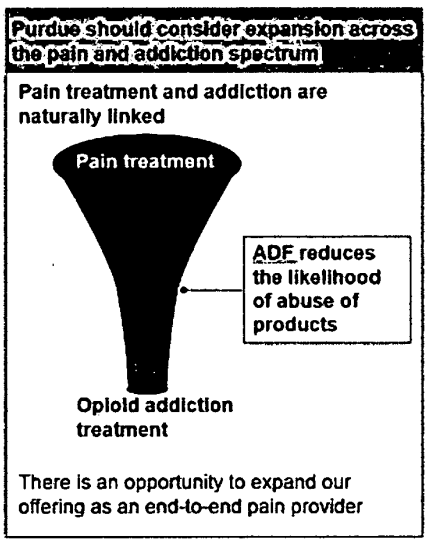
198. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time's* coverage of people who lost their lives to OxyContin was not " balanced," and the deaths were the fault of " the drug addicts," instead of Purdue.

199. The Sacklers' full understanding of opioids' abuse and addiction risk is underscored by their willingness to research, quantify and ultimately monetize opioid abuse and addiction by pursuing the development of medications to treat the addiction their own opioids caused.

200. Defendants Kathe Sackler, Richard Sackler, and Purdue's staff determined that millions of people who became addicted to opioids were the Sackler Families' next business opportunity. A PowerPoint stated: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction."

201. In September 2014, Kathe Sackler participated in a call about *Project Tango*—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their

internal documents, defendant Kathe Sackler and staff memorialized what Purdue publicly denied for decades: "Pain treatment and addiction are naturally linked." They illustrated this point, and the business opportunity it presented, with a funnel beginning with pain treatment and leading to opioid addiction treatment:



202. The same presentation also provided: "[Opioid addiction] can happen to anyone from a 50 year old woman with chronic lower back pain to a 18 year old boy with a sports injury, from the very wealthy to the very poor."

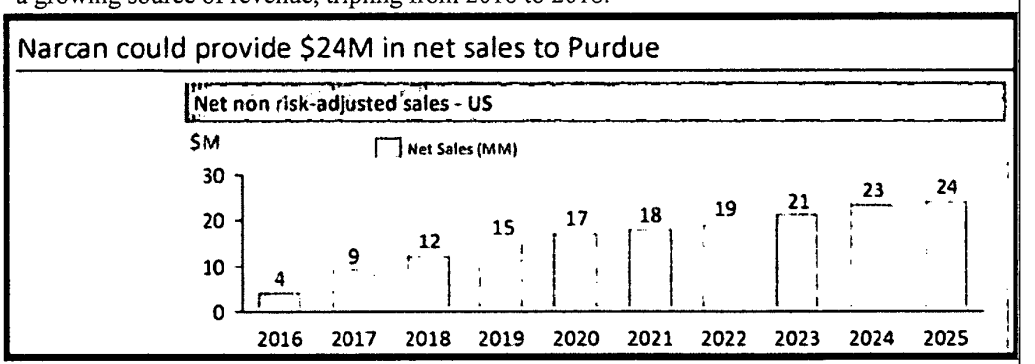
203. Defendant Kathe Sackler and Purdue's *Project Tango* team reviewed findings that the " market" of people addicted to opioids had doubled from 2009 to 2014. Kathe and the staff found that the national catastrophe they caused provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."

204. Defendant Kathe Sackler ordered staffs "immediate attention, verification, and assessment" of reports of children requiring hospitalization after swallowing buprenorphine as a film that melts in your mouth, and staff assured Kathe that children were *overdosing on pills like OxyContin,* not films, " which is a positive for *Tango*."

205. In February 2015, staff presented Kathe Sackler's work on *Project Tango* to Purdue's board. The plan was for a joint venture controlled by the Sacklers to sell the addiction medication suboxone and would result in the Sacklers' acquisition of the "market lead[] in the addiction medicine space."

206. During the presentation, the *Tango* team mapped how patients could get addicted to opioids through prescription opioid analgesics such as Purdue's OxyContin or heroin, and then become consumers of the new company's suboxone. The team noted the opportunity to capture customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.

207. In June 2016, the Sacklers met to discuss a revised version of *Project Tango* and considered a scheme to sell the overdose antidote NARCAN. At this meeting, the Sacklers and the Purdue board calculated that the need for NARCAN to reverse overdoses could provide a growing source of revenue, tripling from 2016 to 2018.



208. The Sacklers identified patients on Purdue's prescription opioids as the target market for NARCAN. The plan called for studying "long-term script users" to "better understand target end-patients" for NARCAN. The Sacklers planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers" and determined that Purdue could profit from government efforts to use NARCAN to save lives.

209. In December 2016, Richard, Jonathan and Mortimer Sackler had a call with staff regarding yet another version of *Project Tango* to discuss acquiring a company that treated

opioid addiction with implantable drug pumps. The business was a "strategic fit," because Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence."

210. Despite having full knowledge of opioids' risk of addiction, abuse, and diversion,

the Sacklers, as the owners of Purdue involved with each and every material decision relating to the development and sale of Purdue's opioids, were actively involved in marketing Purdue's opioids in a way that deceptively minimized those risks and overstated the benefits."

211. For example, the Sacklers oversaw:

- Purdue's research, including research that contradicted its marketing. Purdue's board received reports about studies of Purdue opioids in "opioid-naïve" patients and patients with osteoarthritis, down to the details of the strategy behind the studies and the enrollment of the first patients.

- Purdue's improper response to signs of abuse and diversion by high-prescribing doctors.

- Purdue's strategy to pay high prescribers to promote Purdue's opioids. A report for the Purdue board listed the exact number of conferences and dinner meetings, with attendance figures and the board was told the amounts paid to certain doctors, and they received detailed reports on the Return on Investment that Purdue gained from paying doctors to promote its drugs.

- Purdue's strategy to push patients to higher doses of opioids which are more dangerous, more addictive, and more profitable. The Board routinely received reports on Purdue's efforts to push patients to higher doses and to use higher doses of opioids to keep patients on drugs for longer periods of time. These internal communications only increased as Purdue's market share for its opioids declined.

- Purdue's push to steer patients away from safer alternatives. They tracked the company's effort to emphasize "the true risk and cost consequence of acetaminophen-related liver toxicity."

212. The Sacklers focused their attention on the sales force, directing both the messaging and their tactics and closely monitoring compliance with their directives and the results. The Sacklers tracked the exact number of sales representatives and the exact number

of visits they made to urge doctors to prescribe Purdue opioids. They knew which drugs were promoted; how many visits sales representatives averaged per workday; how much each visit cost Purdue. They knew the company's plan for sales visits in each upcoming quarter and approved specific plans to hire new sales representatives, hire and promote new District and Regional managers, and create sales "territories" in which representatives would target doctors. The Sacklers knew how many visits sales representatives averaged per workday and required their sales representatives to average 7.5 prescribers per day. As with the daily visits per representative, the Sacklers tracked the total number of sales visits per quarter until at least 2014.

213. The Sacklers made key decisions relating to Purdue's sales representatives. For example, they considered and approved hiring more sales representatives. They decided to approve sales representatives' compensation, and they even voted to gift sales representatives with laptops.

214. The Sacklers oversaw the tactics that sales representatives used to push their opioids. For example, a Purdue board report analyzed a Purdue initiative to use iPads during sales visits, which increased the average length of the sales meeting with the doctor.

215. The Sacklers even monitored sales representatives' emails. Purdue held thousands of face-to-face sales meetings with doctors, but the company prohibited its sales representatives from writing emails to doctors, which could create evidence of Purdue's misconduct. When Purdue found that some sales representatives had emailed doctors, the company conducted an "investigation" and reported to the board that sales representatives had been disciplined and that their emails would be discussed at the board meeting.

216. Even after Purdue's 2007 guilty plea and the Corporate Integrity Agreement binding Purdue's directors, the Sacklers maintained their control over Purdue's deceptive sales campaign. Richard Sackler even went into the field to supervise representatives face to face.

217. The Sacklers directed Purdue to hire hundreds of sales representatives to carry out their deceptive sales campaign subsequent to the 2007 guilty plea. Complying with those orders, Purdue staff reported to the Sacklers in January 2011 that a key initiative in Q4 2010

had been the expansion of the sales force.

218. In November 2012, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at $312,563,000.

219. Further demonstrating how intimately involved the Sackler Defendants were in decisions concerning the sales force: in February 2012, during a lengthy exchange between some Sackler individual Defendants and Purdue's officers, Defendant Mortimer Sackler suggested that Purdue reschedule its January annual sales meeting to February so that sales representatives "get back to work for January and back in front of doctors who enter the new year refreshed...". Mortimer also suggested that representatives take " three full weeks" to " visit all their doctors while they are still fresh from the winter break." Mortimer posed these questions *despite* Purdue's robust sales during that time period. In response to this exchange defendant Richard Sackler suggested the annual meeting be canceled altogether.

220. In October 2013, Mortimer Sackler pressed for more information on dosing and "the breakdown of OxyContin market share by strength." Staff told the Sacklers that "the high dose prescriptions are declining," and " there are fewer patients titrating to the higher strengths from the lower ones." In response to the Sacklers' questions, staff explained that sales of the highest doses were not keeping up with the Sacklers' expectations because some pharmacies had implemented "good faith dispensing" policies to double-check prescriptions that looked illegal and some prescribers were under pressure from the Drug Enforcement Administration (" DEA"). Staff promised to increase the budget for promoting OxyContin by $50,000,000, and get sales representatives to generate more prescriptions with a new initiative to be presented to the Sacklers the following week.

221. In 2013, staff reported to the Sacklers that net sales for 2013 had been $377 million less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. Staff told the Sacklers that a "Key Initiative" was to get patients to "stay on therapy longer." The Sacklers agreed.

222. In July and again in August, September, and October 2014, staff warned the

Sacklers that two of the greatest risks to Purdue's business were "[continued pressure against higher doses of opioids," and "[c]ontinued pressure against long term use of opioids." Staff told the Sacklers that Purdue's best opportunity to resist that pressure was by sending sales representatives to visit prescribers; and, specifically, by targeting the most susceptible doctors, who could be convinced to be prolific prescribers, and visiting them many times.

223. The Sacklers knew that Purdue's marketing had an immense effect in driving opioid prescriptions. According to Purdue's analysis in February 2014, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013.

224. Purdue and the Sacklers disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional Front Groups and KOLs. They purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

225. Purdue and the Sacklers generated and approved the deceptive content used by the KOLs and professional Front Groups.

226. In 2013, Purdue abolished the detailed Quarterly Reports that had created a paper trail of targets for sales visits and been emailed among the Board and staff. For 2014, Purdue decided to limit many of its official board reports to numbers and graphs, and relay other information orally. The Sacklers continued to demand information about sales tactics, and their control of Purdue's deceptive marketing did not change.

227. While Purdue was under investigation by the U.S. Attorney's Office for its opioid marketing practices, the Sacklers formed a new company to enter the generic opioid business: Rhodes. According to a former senior manager at Purdue, "Rhodes was set up as a 'landing pad' for the Sackler family in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin."

228. Rhodes Pharmaceuticals L.P. is a Delaware limited partnership, and Rhodes Technologies is a Delaware general partnership, and each are 100% owned by Coventry Technologies L.P., a Delaware limited partnership, which is ultimately owned by the same

various trusts for the benefit of members of the Sacklers. The general partner of Rhodes Pharma is Rhodes Pharmaceuticals Inc., and the managing general partner of Rhodes Tech is Rhodes Technologies Inc. Together, these entities are referred to as "Rhodes." In 2009, Rhodes began selling generic opioids and further enriched the Sacklers.

229. Purdue and the Sacklers oversaw and approved all Rhodes-related activity. The Sacklers received the agendas for Rhodes Pharma and Rhodes Tech board of directors' meetings in addition to Rhodes' financial statements and financial results. Some of the individual Sackler Defendants served on Rhodes' committees. For example, in 2015, Theresa Sackler (Chairperson), Kathe Sackler, and Jonathan Sackler served on Rhodes' Governance committee. And in 2017, Rhodes' Business Development Committee included individual Sackler Defendants Kathe Sackler, Jonathan Sackler, Mortimer Sackler, and David Sackler. In 2018, defendant Richard Sackler was listed on Rhodes' patent for a drug to treat opioid addiction and further profit from the opioid crisis the Sackler Families created. Rhodes relied on Purdue for compliance; for example, in 2018, Rhodes' Compliance Committee discussed the suspicious ordering system and statistics for 2018 as provided by Purdue. Rhodes also made distributions to defendants Rosebay Medical L.P. and the Beacon Company in the millions, for the benefit of the Sackler Families.

230. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[48] Purdue has often argued that it is a relatively small producer of opioids in the United States, but those claims regarding market share completely omit Rhodes, which when combined with Purdue, the Sacklers control up to six percent of the United States opioid market. By 2018, the two companies owned by the Sacklers, Rhodes and Purdue, ranked seventh in terms of market share for opioids when combined.[49]

231. Whereas the Sacklers have reduced Purdue's operations and size, Rhodes

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[48] David Crow, *How Purdue's 'One-Two' Punch Fueled the Market for Opioids,* Financial Times, Sept. 9, 2018, *available at* https://www.ft.com/content/8e64ec9c-bl33-l Ie8-8dl4-6f049d06439c.

[49] Amy Baxter, *Billionaire Drugmaker Granted Patent for Opioid Addiction*, Health Exec, Sept. 10, 2018, *available at* https://www.healthexec.com/topics/healthcare-economics/billionaire-drugmaker-granted-patent-addiction.

continues to grow and sell opioids for the benefit of the Sackler families.

232. The Sacklers caused Purdue and other associated companies that they beneficially owned and controlled to distribute to the Sackler Families billions of dollars in connection with the sale of Purdue's opioids.

233. From the 2007 convictions to 2018, the Sacklers voted to pay their families hundreds of millions of dollars each year, reflecting both the Sacklers' personal incentives to sell as many opioids as possible, as well as the extent of their control over the Purdue board and Purdue.

234. By 2014, the Sacklers knew that state attorneys general were investigating Purdue, commencing actions against the company, and that settlements and/or judgments against Purdue would become a cost of doing business for Purdue. Despite this knowledge, the Sackler Defendants continued to vote to have Purdue pay the Sackler Families significant distributions and send money to offshore companies. And Purdue continued to forecast hundreds of millions of distributions of Purdue's profits to the Sackler Families.

235. Despite knowing that Purdue faces certain liabilities to the states, including the State of Nevada, Purdue—at the Sackler Defendants' direction—continued to pay the Sackler Defendants hundreds of millions of dollars each year in distributions during the relevant time period for no consideration and in bad faith. As a result of Defendants' unlawful distributions to the Sackler Defendants, assets are no longer available to satisfy Purdue's future creditor, the State of Nevada.

236. According to publicly available information, annual revenue at Purdue averaged about $3 billion, mostly due to OxyContin sales, and Purdue had made more than $35 billion since releasing OxyContin in 1995.[50] According to publicly available information, Purdue, at the direction of the Sackler-controlled board, paid the Sackler Defendants $4 billion in profits stemming from the sale of Purdue's opioids. In June 2010, Purdue's staff gave the Sacklers an updated 10-year plan for growing Purdue's opioid sales in which the Sacklers stood to receive

[50] Ella Nilsen, *AG locked in prolonged battle with drug companies*, Concord Monitor, July 14 2016, *available at* https://www.concordmonitor.com/NH-attorney-general-battle-with-drug-companies-3424021.

at least $700 million each year from 2010 through 2020. In December 2014, Purdue's staff told the Sacklers that Purdue would pay their family $163 million in 2014 and projected $350 million in 2015. At board meeting after board meeting, the Sacklers voted to have Purdue pay their families hundreds of millions in Purdue profits from the sale of OxyContin, among other drugs.

237. Purdue has been involved in two decades of litigation for its misconduct vis-à-vis the sale and marketing of OxyContin. Purdue and the Sackler Defendants thus always understood, and were aware of, the catastrophic effect of investigations and lawsuits relating to the opioid litigation. But Purdue's and the Sacklers' business as usual approach means—by Purdue's own recent admission—that Purdue cannot pay what it owes to plaintiffs including the State of Nevada because distributions to Purdue's owners (the Sackler Defendants) continued unabated during the relevant time period.

238. Purdue, at the direction of the Sackler Defendants, inappropriately and illegally conveyed hundreds of millions of dollars of Purdue's profits from opioids to the Sackler Defendants each year during the relevant time period despite Purdue's and the Sacklers' knowledge that they face certain, and significant, liabilities because of the multitude of litigations against Purdue by state attorneys general, including Nevada's Attorney General.

239. No regard was given to Purdue's ability to pay creditors like Nevada, or even negotiate a settlement in good faith, given that hundreds of millions of dollars each year were squandered by distributing those funds to members of the Sackler family.

240. Now, when faced with reality that Purdue—and the Sacklers—will finally be held accountable commensurate to their misconduct, Purdue has publicly admitted that it cannot pay these liabilities and is threatening to commence bankruptcy proceedings on the eve of a landmark jury trial and in the middle of discovery with dozens of state attorneys general, including Nevada.

241. Ultimately, the Sacklers used their ill-gotten wealth to cover up their misconduct with a philanthropic campaign intending to whitewash their decades-long success in profiting at Nevadans' expense.

iii. Actavis's misrepresentations regarding addiction risk

242. Through its "Learn More About Customized Pain Control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

243. Training for Actavis sales representatives deceptively minimizes the risk of addiction by: (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described elsewhere, dismisses evidence of addiction as the under-treatment of pain, and dangerously, counsels doctors to respond to its signs with more opioids.

244. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The study revealed that doctors reported a strong recollection of the sales representatives' discussion of Kadian's supposed low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential were considered an important factor to doctors, and were likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that Kadian sales representatives used during the visits, and Actavis noted that doctors who reviewed those visual aids associated Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

245. A guide for prescribers, published under Actavis's copyright, deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) KADIAN may be less likely to be abused by health care providers and illicit

users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma. These statements convey both that (1) Kadian does not cause euphoria and therefore is less addictive and that (2) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

246. In March 2010, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated."[51]

iv. Mallinckrodt's misrepresentations regarding addiction risk

247. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through the "C.A.R.E.S. Alliance" it created and led.

248. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

249. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book

[51] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth, LLC (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

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

251. Manufacturer Defendants' suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing

scheme, but those suggestions are at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who "doctor-shop"—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing (and unconstrained distribution) of the drugs, not problem patients.

b. Falsehood #2: The false or misleading claims that to the extent there is a risk of addiction, it can be easily identified and managed.

252. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturer Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients. These false and misleading claims were made by all Manufacturer Defendants, examples of which are in the following paragraphs.

253. Purdue shared its *Partners Against Pain* "Pain Management Kit," which contains several screening tools and catalogues of Purdue materials, which included these tools, with prescribers. The website, which directly provides screening tools to prescribers for risk assessments, includes a "[f]our question screener" to purportedly help physicians identify and address possible opioid misuse.[52]

254. Purdue and another manufacturer, Cephalon, sponsored the APF's *Treatment*

[52] *Risk Assessment Resources,* Prescribe Responsibly, http://www.prescriberesponsibly.com/risk- assessment-resources (last modified July 2, 2015).

Options: A Guide for People Living with Pain (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed."

255. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, a so-called "key opinion leader" (KOL) discussed below, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."

256. Purdue sponsored a 2011 CME program titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

257. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

258. There are three fundamental flaws in the Manufacturer Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

c. Falsehood #3: The false or misleading claims that signs of addictive behavior are "pseudoaddiction," requiring more opioids.

259. The Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. Dr. David Haddox, who later became a Senior Medical Director for Purdue, published a study in 1989 coining the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[53] In other words, people on prescription opioids who exhibited classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain.

260. In the materials and outreach they produced, sponsored, or controlled, Manufacturer Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

261. Purdue, Endo, and Cephalon, sponsored the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing* (2007), written by Dr. Scott Fishman and discussed in more detail below, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of "pseudoaddiction." Nevada doctors could obtain CME credit by reading it.

262. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, *www.PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but "pseudoaddiction" caused by untreated pain.

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[53] David E. Weissman & J. David Haddox, *Opioid Pseudoaddiction – An Iatrogenic Syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565. ("Iatrogenic" describes a condition induced by medical treatment.).

263. According to documents provided by a former Purdue detailer, sales representatives were regularly trained and tested on the meaning of pseudoaddiction, implying that sales representatives were directed to, and did, describe pseudoaddiction to prescribers. Purdue's *Pain Management Kit* is another example of publication used by Purdue's sales force that endorses pseudoaddiction by claiming that "pain-relief seeking behavior can be mistaken for drug-seeking behavior." Upon information and belief, the kit was in use from 2011 through June 2016, or later.

264. The CDC Guideline does not and, upon information and belief, never did recommend attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Webster admitted that pseudoaddiction "is already something we are debunking as a concept" and became "too much of an excuse to give patients more medication. It led us down a path that caused harm."[54]

d. Falsehood #4: The false or misleading claims that opioid withdrawal can be avoided by tapering.

265. In an effort to underplay the risk and impact of addiction, the Manufacturer Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients' dose to avoid withdrawal. Manufacturer Defendants failed to disclose the extremely difficult and painful effects that patients can experience upon ceasing opioid treatment – adverse effects that also make it less likely that patients will be able to stop using the drugs. Manufacturer Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for prolonged periods.

266. For example, Purdue sponsored the APF's *A Policymaker's Guide to*

[54] John Fauber, "Chronic Pain Fuels Boom in Opioids," *Medpage Today*, (Feb. 19, 2012). https://www.medpagetoday.com/neurology/painmanagement/31254.

Understanding Pain & Its Management, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

267. To this day, the Manufacturer Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

e. Falsehood #5: The false or misleading claims that opioid doses can be increased without limit or greater risks.

268. In materials they produced, sponsored or controlled, Manufacturer Defendants instructed prescribers that they could safely increase a patient's dose to achieve pain relief. Each of the Manufacturer Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

269. These misrepresentations were integral to the Manufacturer Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

270. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is "no[] upward limit" for dosing and ask, "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[55]

271. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor,

[55] Letter from Windell Fisher, Purdue Regional Manager, to B. Gergely, Purdue Employee (Nov. 7, 1996), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/ (last updated May 5, 2016) (hereinafter "Letter from Fisher").

> if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."
>
> The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

272. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

273. By way of example, in its 2010 Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[56]

274. Purdue, along with another manufacturer, sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and therefore are safer than taking acetaminophen or other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen.

275. Manufacturer Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged "that the available data do suggest a relationship

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[56] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

between increasing opioid dose and risk of certain adverse events" and that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." For example, a study of patient data from the Veterans Health Administration published in 2011 found that higher maximum prescribed daily opioid doses were directly associated with a higher risk of opioid overdose deaths.[57]

f. Falsehood #6: The false or misleading claims that long-term opioid use improves functioning.

276. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturer Defendants consistently promoted opioids as capable of improving patients' function and quality of life because they viewed these claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

277. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . .We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[58]

278. Despite its acknowledgment that "[w]e do not have such data to support OxyContin promotion," Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, "There Can Be Life With Relief," and showing a man

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[57] Amy S. B. Bohnert, Ph.D. et al., *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths*, 305(13) J. of Am. Med. Assoc. 1315, 1315-1321 (Apr. 6, 2011), https://jamanetwork.com/journals/jama/fullarticle/896182.

[58] Meier, *supra* at 281.

happily fly- fishing alongside his grandson, implying that OxyContin would help users' function. This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[59]

279. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this in fact stated the contrary, noting the absence of long-term studies and concluding, "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."

280. A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months— that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

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

282. Mallinckrodt's website, in a section on responsible use of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[60]

283. The Manufacturer Defendants' claims that long-term use of opioids improves

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[59] Chris Adams, *FDA Orders Purdue Pharma to Pull Its OxyContin Ads*, Wall St. J. (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

[60] Mallinckrodt Pharmaceuticals, *Responsible Use*, http://www.mallinckrodt.com/corporate-responsibility/responsible-use.

patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[61] Based upon a review of the existing scientific evidence, the CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use."[62]

284. Consistent with the CDC's findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid use had "consistently poor results," and "several studies have showed that opioids for chronic pain may actually worsen pain and functioning . . ."[63] along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

285. The available evidence indicates opioids may worsen patients' health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long- term

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[61] The FDA has warned other drugmakers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities... has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[62] CDC Guideline *supra* at 20.

[63] Thomas R. Frieden and Debra Houry, *Reducing the Risks of Relief – The CDC Opioid- Prescribing Guideline*, New Eng. J. Med., at 1503 (Apr. 21, 2016).

opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[64] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[65]

286. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[66] In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[67] Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all.[68] Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was recently published on March 6, 2018, in the Journal of the American Medical Association. The study reported that "[t]here was no significant difference in pain-related function between the 2 groups" – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and NSAIDs like ibuprofen. Accordingly, the study concluded: "Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."

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[64] CDC Guideline, *supra* at 2, 18.
[65] Frieden & Houry, *supra,* at 1503.
[66] Andrea Rubinstein, M.D. *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma- medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.
[67] Jeffrey Dersh, et al., *Prescription Opioid Dependence Is Associated With Poorer Outcomes In Disabling Spinal Disorders*, 33(20) Spine 2219-27 (Sept. 15, 2008).
[68] Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: The Disability Risk Identification Study Cohort*, 33 Spine 199, 201-202.

g. Falsehood #7: The false or misleading claims that alternative forms of pain relief pose greater risks than opioids.

287. In materials they produced, sponsored or controlled, the Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would favor opioids over other therapies such as over- the-counter acetaminophen or over-the-counter or prescription NSAIDs.

288. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturer Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time,"[69] hormonal dysfunction,[70] decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly,[71] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or with benzodiazepines, which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain.[72]

289. The APF's *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdoses, when the figure is closer to 3,200.[73]

290. Additionally, Purdue and Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available

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[69] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[70] H.W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3(5) J. Pain 377-84 (2001).
[71] *See* Bernhard M. Kuschel, *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – a Swedish Case-Control Study*, Eur. J. Pub. H. 527, 527-32 (July 31, 2014).
[72] Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940-47 (2012).
[73] Robert E. Tarone, et al., *Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies*, 11 Am. J. of Therapeutics 17-25 (2004).

for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

291. As a result of the Manufacturer Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.[74]

h. Falsehood #8: The false or misleading claims that OxyContin provides twelve hours of pain relief.

292. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

293. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials:[75]

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[74] M. Daubresse, et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. *See also* J. Mafi, et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

[75] Jim Edwards, "*How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power,*" CBS News, September 28, 2011, https://www.cbsnews.com/news/how-purdue-used-misleading- charts-to-hide-oxycontins-addictive-power/; *see also* Jim Edwards, "*Who Signed Off on Purdue's Misleading OxyContin Chart? Judge May Want Answers,*" CBS News, January 7, 2010, https://www.cbsnews.com/news/who-signed-off-on-purdues-misleading-oxycontin-chart-judge- may-want-answers/.