February 23, 2022

When the Attorney General Comes Knocking

Current Trends in
State Attorneys General Civil Litigation

PANELISTS

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Civil litigation brought by aggressive state attorneys general (AGs) can have a significant impact on business. In our presentation, we provide a brief overview of several key types of cases frequently brought by AGs. We highlight a few major issues that should be initial areas of attention for defense counsel in these cases. We then turn from the law to the real world – how these cases come about, how they are financed in many instances and key aspects of defending them. Our focus is on large-scale cases – litigation that either targets an entire economic sector or purports to have as its aim protecting a large, or especially vulnerable, segment of a state's population or resources. This accompanying paper sets the table for the panel presentation.

The Legal Landscape

Issues related to the environment and claims against the pharmaceutical industry are key areas of focus for AGs today. While there are obviously many differences, there are important elements common to these types of cases.

Types of Cases

Environmental Litigation

Large scope environmental litigation brought by state AGs has become increasingly common. These cases differ significantly from more routine environmental enforcement cases brought by state regulatory agencies, although in such cases the AG's office may be acting as counsel for the regulator.

Typically, the complaints in those cases allege permit violations or exceedances of regulatory requirements. The plaintiff agencies generally seek statutory penalties and injunctive relief that would require facilities to come into compliance. If a release of chemicals or other hazardous substances has contaminated soil or groundwater, the complaint will typically also seek remediation to a limit set by state or federal regulation.

In the AG cases, in contrast, the named plaintiff is either the state itself, or a state official or agency designated by law as the trustee of the state's natural resources. The claims can be significantly different as well. Rather than being focused on violations of specific items in permits or regulations, such as emissions or discharge limits, the AG complaints can contain a broad range of counts. In addition to claims alleging violations of environmental laws, these complaints may include the following types of claims:

- strict product liability due to product defect
- strict product liability due to failure to warn
- strict liability for abnormally dangerous activity
- negligence
- public nuisance
- trespass
- unjust enrichment
- claims alleging violations of state consumer protections laws

Currently, much attention is focused on litigation related to certain perfluorinated compounds (PFAS). A number of state AGs have now filed large-scale cases against manufacturers of these compounds. In 2010, Minnesota sued 3M for allegedly negligent discharges of PFAS into sources of drinking water. The suit settled in 2018 for $815 million. Other AGs have since filed cases against manufacturers of PFAS. For example, Michigan has filed a case against multiple companies alleging negligence, trespass, public nuisance, unjust enrichment and statutory violations.

The PFAS cases have followed on the heels of the long running MTBE litigation against petroleum refiners. In that context, numerous states have sued virtually all refiners who operate in states in which the Clean Air Act mandates the use of reformulated gasoline. Under that statute, refiners must blend an oxygenate into the product. For many years, they used MTBE in coastal areas because there was no realistic alternative available for supply and logistics reasons. Over time, sampling results showed MTBE in numerous public and private wells. While levels were generally quite low, and the use of MTBE was phased out, litigation was inevitable. Ultimately, state AGs became very active players in MTBE litigation.

State of New Hampshire v. Hess Corp., 161 N.H. 426, 20 A.3d 212, 2011 N.H. Lexis 9 (2011), offers a good illustration of the issues and risks presented in state AG environmental litigation. The State's various complaints named as defendants thirty different corporations in the refining industry. (Three other defendants were identified only as manufacturers of MTBE.) All the refiner defendants were alleged to have placed gasoline containing MTBE into the stream of commerce that somehow made its way into the State of New Hampshire. Standing was largely premised on a parens patriae theory. The State also pointed to the public trust doctrine and argued that it is the trustee of all resources within its borders.

The State alleged that because of the manner in which the industry operates, all gasoline is comingled, making it impossible to determine which refiner's MTBE was present in any water sample. The State alleged further that MTBE contamination was pervasive in the State's groundwater so that every drinking water well in the state that was not presently contaminated was at risk of contamination. The Complaint contained all of the claims listed above except unjust enrichment. The Complaint alleged that the refiners essentially conspired to downplay the risks of MTBE to the State and its citizens. New Hampshire argued that because MTBE contamination was pervasive, a statewide program to test every public and private well was necessary so the cost of such a program would be an appropriate remedy. Because it alleged that the defendants' products were comingled, the State argued that it could use market share to apportion any liability. The court permitted this approach.

All defendants but one settled either before or during the trial. ExxonMobil took the case to verdict. The jury returned a verdict in the State's favor. The jury found that the State's total damages were $816 million, with ExxonMobil's share being $236 million. The State's total recovery from all defendants was $372 million.

One noteworthy point about the New Hampshire MTBE litigation is that the State did not pursue natural resource damages (NRD) at trial. NRD are a form of relief available only to the sovereign, through the statutorily designated trustee for natural resources. NRD has two

elements: the cost of restoring the resource (groundwater in this case) to its pre contamination condition plus compensation for the theoretical loss in the economic value of the resource during the period prior to its restoration to that pre contamination condition. These values are established through a battle of experts, principally economists. The economists retained by State AGs typically present valuations for NRD claims that are extraordinarily large and justified using a variety of different methodologies. A key aspect of these cases is the battle over such expert testimony. New Hampshire's counsel elected to drop its NRD claim before trial to simplify the case for the jury. Tactically, this clearly was a sound decision. Nevertheless, it is noteworthy that if the NRD claim had remained in the case, the State's claim at trial would have been multiples of what was presented to the jury. At this point, such claims do remain in all of the pending MTBE cases brought by other State AGs.

One final point about the New Hampshire MTBE case is worthy of note. The trial court dismissed the State's public nuisance claim before trial. It did so because under New Hampshire law, a public nuisance claim can be asserted only against one who owns or occupies the land on which the nuisance occurs. Because the defendants were sued as the manufacturers of the product, the public nuisance claim necessarily failed. In addition, because the manufacturers relinquished control over the product – gasoline with MTBE – at some point when it was in the stream of commerce, and were not alleged to have had control when it was released into the groundwater, that alone meant they were not legally responsible on a public nuisance theory.

Pharmaceutical Litigation

The opioid addiction crisis has led to thousands of cases across the country, including suits by all state AGs. The basic argument in all of the cases is that the defendants marketed and distributed opioid products in a manner that overstated the benefits of the products and downplayed their risks, and otherwise marketed the products in a manner that led to their use in ways that was not medically necessary or appropriate, resulting in abuse, addiction and harm. The cases filed by the state AGs vary in scope and with respect to the legal theories asserted.

The Complaint filed by New York's Attorney General is comprehensive and illustrative of the scope of the allegations spread throughout the docket. It includes the following causes of action:

- public nuisance
- common law fraud
- gross negligence
- unjust enrichment
- claims alleging violations of multiple New York statutes

On the common law claims, the complaint seeks direct, consequential and punitive damages plus equitable disgorgement of profits. New York is one of many states that has announced its intent to participate in a pending comprehensive settlement of many of the opioid cases.

The Oklahoma Attorney General took a different approach. In *State of Oklahoma v. Johnson & Johnson*, the Attorney General asserted only a public nuisance theory against the

defendants. After a bench trial, the district court awarded the State $465 million from Johnson & Johnson on a public nuisance theory. Johnson & Johnson appealed arguing that Oklahoma's public nuisance law does not support the claim. The State cross-appealed arguing that the district erred in making its award, which should have been $9.3 billion.

On November 21, 2021, the Oklahoma Supreme Court reversed the trial court's verdict. It found that under Oklahoma law, public nuisance claims are limited to situations involving the use of land by the one creating the nuisance. As a result, the Oklahoma Supreme Court held that the State's nuisance statute does not apply to the sale of lawful products in the state. The court noted that the focus of the State's complaint was that Johnson & Johnson had failed to warn of the dangers associated with abuse of opioids when marketing the products and that this was a classic articulation of a claim sounding in product-related liability.

Although the context is different, the Oklahoma Supreme Court's decision in the opioid case is consistent with the New Hampshire court's ruling dismissing the public nuisance claims against the MTBE defendants. In both cases, the State Attorney Generals were attempting to push the boundaries of public nuisance theory beyond their historic ties to land. In both cases, the courts rejected the attempt. Other courts have also done so in other contexts.

Consumer Protection Litigation

Numerous AGs have also relied on their states' consumer protection statutes or common law theories to pursue claims alleging various deceptive trade practices. Such claims can arise from defendants' alleged failure to warn of product defects, allegedly deceptive marketing schemes downplaying known hazards of defendants' products, allegedly deceptive sales, lending, and other financing practices, alleged privacy and data security breaches, alleged health fraud, and alleged conspiracies to artificially manipulate prices through agreements to fix prices or curtail production. Although AGs may also pursue relief under certain federal consumer protection statutes, they typically expressly disclaim reliance on those statutes to avoid removal to federal court. Examples of such litigation may be found on the National Association of Attorneys General website, at https://www.consumerresources.org/consumer-topics/lawsuits-and-settlements/.

Only a few states have adopted the Model Consumer Protection Act proposed in 1970. The claim elements, defenses, and recovery calculations and limitations for AG actions brought in those states that have enacted their own consumer protection statutes will therefore vary greatly by state. A state-by-state comparison may be found on the National Consumer Law Center's website at https://www.nclc.org/images/pdf/udap/udap-appC.pdf.

STATE OF MINNESOTA
COUNTY OF HENNEPIN

DISTRICT COURT
FOURTH JUDICIAL DISTRICT

State of Minnesota, by its Attorney General, Lori Swanson, its Commissioner of Pollution Control, John Linc Stine, and its Commissioner of Natural Resources, Tom Landwehr,

Plaintiff,

vs.

3M Company,

Defendant.

Case Type: Other Civil
Judge Kevin S. Burke
Court File No. 27-CV-10-28862

AGREEMENT AND ORDER

The State of Minnesota, by its Attorney General and its Commissioners of Pollution Control and Natural Resources, and 3M Company voluntarily enter into this Agreement, which fully and finally resolves the above-entitled matter.

I. DEFINITIONS

Whenever the terms listed below are used in this Agreement, the following definitions shall apply:

1. "3M" shall mean 3M Company, a corporation incorporated in the State of Delaware with its principal place of business in Maplewood, Minnesota.

2. "3M Grant for Water Quality and Sustainability Fund" shall mean a separate account established in the State's Remediation Fund pursuant to Minn. Stat. §§ 115B.17 subd. 7 and 116.155, subd. 3(3).

3. "Attorney General" shall mean the Attorney General of the State of Minnesota (or her authorized designee) and her successors, and the Minnesota Attorney General's Office.

4. "DNR" shall mean the Minnesota Department of Natural Resources, a statutory agency of the State of Minnesota responsible for administering and enforcing Minnesota statutes

and rules relating to the preservation, conservation, management and regulation of natural resources of the State. *See* Minn. Stat. Chs. 84, 85, 94 and 103G. Reference to the DNR shall include its Commissioner, Tom Landwehr (or his authorized designee(s)), and his successors.

5. "Effective Date" shall mean the date the Court issues its Order approving this Agreement.

6. "Grant" shall mean the grant described in paragraph 13.

7. "MPCA" shall mean the Minnesota Pollution Control Agency, a statutory agency of the State of Minnesota responsible for administering and enforcing Minnesota statutes and rules relating to water, land and air pollution. *See* Minn. Stat. Chs. 115, 115B and 116. Reference to the MPCA shall include its current Commissioner, John Linc Stine (or his authorized designee(s)), and his predecessor and successors.

8. "Parties" shall mean collectively 3M and the State.

9. "PFCs" shall mean per- and poly-fluorinated chemicals.

10. "SACO" shall mean the 2007 Settlement Agreement and Consent Order entered by and between the MPCA and 3M on May 22, 2007.

11. "State" shall mean the Attorney General, the MPCA, and the DNR.

12. "Working Group" shall mean a working group established by the MPCA and the DNR, consisting of representatives of the MPCA, the DNR, East Metropolitan Area municipalities, and 3M. The composition of the Working Group may vary depending on the project(s) at issue set forth in paragraphs 14.A.-.C.

II. PAYMENT

13. 3M will make a Grant in the amount of $850 million to the State which shall be held in the 3M Grant for Water Quality and Sustainability Fund, within fifteen (15) days from the Effective Date of this Agreement.

14. The MPCA and/or the DNR shall use the Grant (net of costs, fees, and expenses), and any interest earned or any other appreciation in value, for projects that are reasonable and necessary to achieve the purposes of this Agreement:

A. As the first and highest priority, the MPCA and/or the DNR shall utilize the Grant referenced in paragraph 13 above to enhance the quality, quantity and sustainability of the drinking water in the East Metropolitan Area, which shall include, but is not necessarily limited to, the cities of Woodbury, Oakdale, Lake Elmo, Cottage Grove, St. Paul Park, Afton, and Newport and the townships of West Lakeland and Grey Cloud Island. The goal of this highest priority work is to ensure clean drinking water in sufficient supply to residents and businesses in the East Metropolitan Area to meet their current and future water needs. Examples of projects in this first priority may include, but are not limited to, the development of alternative drinking water sources for municipalities and individual households (including but not limited to creation or relocation of municipal wells), the treatment of existing water supplies, water conservation and efficiency, open space acquisition, and groundwater recharge (including projects that encourage, enhance, and assist groundwater recharge). For individual households, projects may include, but are not limited to, connecting those residences to municipal water supplies, providing individual treatment systems, or constructing new wells. The MPCA shall conduct a source assessment and feasibility study regarding the role of the Valley Branch Water District's project known as Project 1007 in the conveyance of PFCs in the environment. In

selecting and performing activities pursuant to this paragraph, the State shall prioritize water supplies where health based values, health risk limits, and/or health risk indices for PFCs are exceeded.

B. As the second highest priority, and after the MPCA and/or the DNR have reasonably achieved the goal set forth above in paragraph 14.A., the MPCA and/or the DNR shall utilize the Grant on projects that restore and enhance aquatic resources, wildlife, habitat, fishing, resource improvement, and outdoor recreational opportunities in the East Metropolitan Area and in downstream areas of the Mississippi and St. Croix Rivers. These projects may include, but are not limited to: (i) aquatic habitat and water resource protection and restoration; (ii) terrestrial and water trails; (iii) boat ramps and/or fishing piers along the Mississippi River, Lake Elmo, or other waterbodies in or downstream of the East Metropolitan Area; (iv) the restoration of wildlife habitat; and (v) implementation of other terrestrial conservation and recreational improvements in the same geographic area. While implementing the goal set forth above in paragraph 14.A., the MPCA and/or the DNR shall have immediate access of up to $20 million of Grant funds to undertake the goals set forth in this paragraph 14.B.

C. As the third highest priority, and if any portion of the Grant remains (other than the amounts set forth in paragraphs 15-16 below) after the MPCA and/or the DNR have reasonably achieved the goals set forth above in paragraph 14.A.-.B., the MPCA and/or the DNR shall utilize the Grant to fund residual, statewide water resources, habitat restoration, open space preservation, recreation improvements, and other sustainability projects.

15. The Grant includes reimbursement to the Remediation Fund for all costs of the MPCA under the SACO, except as provided in paragraph 19. Notwithstanding paragraph 14.A.-

.C. above, the MPCA shall have immediate access to the amount referenced in this paragraph for any lawful purpose as set forth in Minn. Stat. §§ 115B.20, subd. 2 and 116.155, subd. 2.

16. The Grant also includes reimbursement to the Remediation Fund in the amount of $300,441.95 for the reasonable costs incurred by the MPCA and/or the DNR for assessing damages to natural resources, pursuant to Minn. Stat. § 115B.04, subd. 1(3). Notwithstanding paragraph 14.A.-.C. above, the MPCA and/or the DNR shall have immediate access to the amount referenced in this paragraph for any lawful purpose as set forth in Minn. Stat. §§ 115B.20, subd. 2 and 116.155, subd. 2.

17. The MPCA and/or the DNR shall form a Working Group to identify and recommend projects referenced in paragraphs 14A.-C. above. Pursuant to Minn. Stat. §§ 116.155 and 115B.20, the MPCA and/or the DNR shall have the ultimate responsibility, in their discretion, to determine the projects to be implemented under this Agreement (provided that the MPCA and/or the DNR will adhere to the spending prioritizations described above). The MPCA and/or the DNR will also consult with municipalities and the Metropolitan Council as necessary and appropriate on implementation of projects under paragraph 14.A. above and may use Grant monies to reimburse those entities for projects undertaken that meet the goals set forth in paragraph 14.A. above. The MPCA and/or the DNR may use Grant monies to retain technical experts to assist the Working Group.

III. RELEASE OF CLAIMS AND DISMISSAL

18. In consideration of the stipulated relief, the sufficiency of which is acknowledged, including 3M's payments specified herein, the State fully and completely releases and waives against 3M and its affiliates, subsidiaries, parent corporations and companies, predecessors, successors, and current or former employees, directors, attorneys, shareholders, agents,

representatives, insurers, and the like ("Released Parties"), any and all claims or causes of action known or unknown through the Effective Date of this Agreement, related to claims alleged in the State's Amended Complaint or that could have been alleged by the State in its Amended Complaint for natural resource damages, including under the Minnesota Environmental Response and Liability Act, the Minnesota Water Pollution Control Act, any statute or common law theory, arising out of or relating to 3M's manufacture, distribution, disposal or other environmental management of PFCs or the release of 3M PFCs into the environment. The MPCA also fully and completely releases and waives any and all claims against 3M relating to the MPCA's costs incurred in 2017 under the SACO. 3M fully and completely releases and waives any and all claims against the State relating to the Amended Complaint, including any claim for contribution and/or indemnity, and attorney fees and costs and expenses. 3M further fully and completely releases and waives any and all claims against the State relating to reimbursement of MPCA costs incurred in 2017 under the SACO.

19. The SACO shall remain in place, and 3M shall continue to be bound by the terms of the SACO, including the continuation of reimbursement of the MPCA's costs and 3M's ongoing implementation of the remedy approved by the MPCA for 3M's Cottage Grove, Woodbury, and Oakdale Sites. In addition, for a period of five (5) years after the Effective Date of this Agreement, 3M agrees to pay up to $40 million to fund the projects and/or activities set forth in paragraph VIII.B. of the SACO for temporary purposes, which shall include but are not limited to individual home water treatment systems that can be cost effectively connected within such five (5) year period to municipal systems, provision of bottled water, temporary municipal water treatment systems and the operation and maintenance of the temporary safe drinking water projects and activities. Otherwise, except for temporary measures referenced in the preceding

sentence, the Grant shall fund future projects that would have been payable under the SACO. If the Grant is depleted, the provisions of the SACO shall once again become operative. The Parties will annually review the continuing need for the SACO in light of the implementation of the projects outlined above, including projects related to the Washington County Landfill.

20. Within five (5) days from the Effective Date of this Agreement, the State and 3M will file a Stipulation of Dismissal with Prejudice, dismissing the Amended Complaint with prejudice and without attorneys' fees, expenses, and costs to either Party.

IV. GENERAL TERMS

21. The Parties are executing this Agreement for the sole purpose of settling and fully resolving the State's claims against 3M, which are disputed. Nothing about the Agreement shall constitute any admission by either Party of fault, responsibility, wrongdoing, or liability on the part of the Released Parties, nor does it constitute evidence of liability or wrongful conduct on the part of either Party, or any admission by either Party regarding the validity of any statutory or regulatory action by the State. Nothing in this Agreement shall be construed as an admission that 3M has legal responsibility for any contamination or other injury associated with the Washington County Landfill. This Agreement shall not be admissible in any future administrative or judicial proceeding as evidence of fault or liability in any investigation, claim, action, suit, or proceeding, or federal or state court or arbitration proceeding. Nothing in this Agreement shall relieve either Party of its obligation to comply with all applicable Minnesota and federal laws and regulations.

22. Nothing in this Agreement shall limit the Attorney General, the MPCA, and/or the DNR's ability to bring claims against any person or entity not covered by this Agreement.

23. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same Agreement. This Agreement may be executed by facsimile or electronic copy in any image format.

24. The person signing this Agreement for 3M warrants that he or she is authorized to execute this Agreement, that 3M has been fully advised by its counsel before entering into the Agreement, and that he or she executes this Agreement in an official capacity that binds 3M. The persons signing this Agreement for the Attorney General, the MPCA, and the DNR warrant that they have been authorized to do so by the Attorney General, the MPCA, and the DNR, respectively, and they do so in their official capacities. This Agreement constitutes the full and complete terms of the agreement entered into by the Parties.

25. The Parties agree that the Hennepin County District Court shall retain jurisdiction over this matter for purposes of enforcing the Agreement, including any dispute between the Parties regarding selection and/or implementation of the priority projects as described in paragraph 14.A.-.C. above. The Parties request that, upon his retirement, the Honorable Kevin Burke shall be appointed by the Court as a Consensual Special Magistrate, pursuant to Minn. R. Gen. Prac. 114.02, to carry out the duties in the preceding sentence, with his reasonable fees and expenses to be paid with Grant monies. The Court shall also retain jurisdiction of this matter for purposes of enforcing the Order for Judgment. 3M and the State may each retain one expert to provide technical assistance in evaluating any issues that arise under this paragraph. The Parties agree that, before filing any motion under this paragraph, they shall meet and confer in an attempt to resolve any dispute and shall further mediate such dispute with Judge Burke prior to filing any motion with the Court in a further attempt to resolve any outstanding issues. If Judge

Burke is unavailable, or if the Parties otherwise mutually agree, the Parties will select a mutually agreeable substitute to serve as a Consensual Special Magistrate.

26. The failure of 3M, the Attorney General, the MPCA, and/or the DNR to exercise any rights under this Agreement shall not be deemed a waiver of any right or any future rights.

27. If any part of this Agreement shall be found or held to be invalid or unenforceable by any court of competent jurisdiction, such invalidity or unenforceability shall not affect the remainder of this Agreement.

28. The Agreement shall be binding and enforceable against 3M, including any acquirer of 3M or its business.

29. This Agreement may be amended only by written agreement between the Parties and subject to approval by the Court.

30. This Agreement, including any issues relating to interpretation or enforcement, shall be governed by the laws of the State of Minnesota.

31. Each of the Parties is represented by counsel, participated in the drafting of this Agreement, and agrees that the Agreement's terms may not be construed against or in favor of any of the Parties by virtue of draftsmanship. The Parties agree to perform such further acts and to execute and deliver such further documents as may reasonably be necessary to carry out this Agreement.

THE PARTIES ENTER INTO AND APPROVE THIS AGREEMENT AND SUBMIT IT TO THE COURT SO THAT IT MAY BE APPROVED AND ENTERED AS AN ORDER.

Filed in Fourth Judicial District Court
2/20/2018 3:34 PM
Hennepin County, MN

FOR THE STATE OF MINNESOTA

LORI SWANSON

Attorney General
State of Minnesota

Date: 2/20/18

Alan I. Gilbert (No. 0034678)
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FOR THE MINNESOTA POLLUTION CONTROL AGENCY

Date: 2/20/2018

JOHN LINC STINE
Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road
St. Paul, MN 55155

FOR THE MINNESOTA DEPARTMENT OF NATURAL RESOURCES

Date: Feb. 20, 2018

TOM LANDWEHR
Commissioner
Minnesota Department of Natural Resources
500 Lafayette Road
St. Paul, MN 55155

FOR 3M COMPANY

Date: 2/20/18

JOHN BANOVETZ
Senior Vice President, Research and Development and Chief Technology Officer
3M Company
3M Center
St. Paul, MN 55144

Filed in Fourth Judicial District Court
2/20/2018 3:34 PM
Hennepin County, MN

ORDER

Based upon the foregoing Agreement, it is SO ORDERED.

Feb 20, 2018
Date

Kevin S Burke
THE HONORABLE KEVIN S. BURKE
JUDGE OF THE DISTRICT COURT

Josh Kaul
Wisconsin Attorney General

P.O. Box 7857
Madison, WI 53707-7857

NEWS FOR IMMEDIATE RELEASE

August 25, 2021

AG Kaul, Gov Evers Announce Outside Counsel for Potential PFAS Claims

MADISON, Wis. – Attorney General Josh Kaul and Governor Tony Evers today announced the selection of the law firm, Sher Edling LLP, to assist the state in its investigation and litigation of potential claims arising from PFAS contamination.

The selection follows a competitive bid process overseen by the Department of Administration (DOA) in accordance with Wis. Stat. section 20.9305. In January of this year, DOA issued an open solicitation for law firms to submit qualifications to act as outside PFAS litigation counsel to the state. DOA received 11 proposals. An evaluation panel comprised of professional civil service staff from the Departments of Justice, Natural Resources, and Administration scored the submissions and identified the finalist proposers who then submitted bids. Sher Edling LLP submitted the lowest bid among the finalists and was awarded the contract.

"Every Wisconsinite—whether they live in the Driftless, the Central Sands, the Northwoods, or in the heart of our urban areas—should be able to trust the water from their tap. Period," said Governor Evers. "But for far too many Wisconsin households that is not the case, and I am glad we are moving forward to hold polluters accountable so we can clean up our water and protect the health and safety of our communities."

"Clean water is essential to our health and well-being and to a thriving economy. We must protect it from PFAS and other contaminants that put people's health at risk," said Attorney General Kaul. "The addition of outside counsel will enhance our ability to get accountability from those who are responsible for the severe harms that PFAS contamination has caused in Wisconsin."

DOJ Communications Office DOJCommunications@doj.state.wi.us (608) 266-1220

The selected firm, Sher Edling LLP, represents state and local governments and other public agencies in significant environmental cases across the country. The firm currently represents public entities in multiple PFAS contamination matters and serves on the Plaintiffs' Executive Committee of the Aqueous Film-Forming Foams Product Liability Litigation.

PFAS, per- and polyfluoroalkyl substances, are a group of human-made chemicals manufactured and used for decades in numerous industrial processes and consumer products, which have made their way into the environment and are known to bioaccumulate in fish, wildlife, and humans, posing risk to human health. Wisconsin currently monitors nearly 50 sites across the state for PFAS contamination.

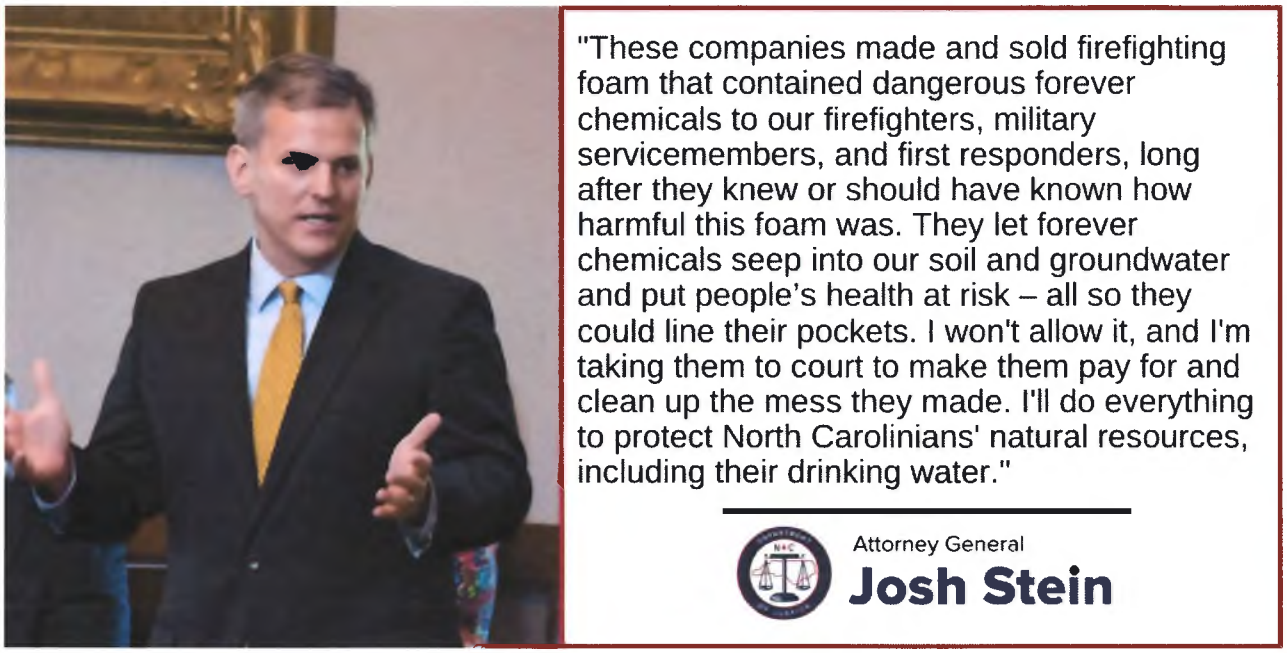
Other states, such as Michigan, Ohio, New Hampshire, and Vermont, have already pursued litigation against corporate actors responsible for PFAS contamination and have leveraged the funds derived from the litigation to support the communities most impacted.

DOJ Communications Office DOJCommunications@doj.state.wi.us (608) 266-1220

Attorney General
Josh Stein

Robocall Hotline:(844)-8-NO-ROBO
All Other Complaints:(877)-5-NO-SCAM
Outside NC:919-716-6000

Attorney General Josh Stein Files Four Lawsuits Against 14 Companies Over Toxic Firefighting Foam



For Immediate Release:
Thursday, November 4, 2021

Contact:
Nazneen Ahmed (919) 716-0060

(RALEIGH) Attorney General Josh Stein filed four lawsuits against 14 manufacturers of Aqueous Film Forming Foam (AFFF), a fire suppressant used widely by firefighters, members of the military, and other first responders. AFFF contains PFAS, or forever chemical compounds that are manmade, are toxic, persist in the environment, accumulate in people, and have serious health risks. Attorney General Stein is alleging that the manufacturers of AFFF and the PFAS used in its production – including 3M, Corteva, and DuPont – caused a public nuisance, created a design defect, failed to warn their customers, and fraudulently transferred corporate assets to shield their profits. Attorney General Stein is asking the court to require these manufacturers to pay for investigation into how widespread the damage is, to clean it up, to replace water treatment systems and wells, to restore damaged natural resources, and to monitor water quality into the future.

"These companies made and sold firefighting foam with dangerous forever chemicals to our firefighters, military servicemembers, and first responders, long after they knew or should have known how harmful this foam was," said Attorney General Josh Stein. "As a result, forever chemicals have seeped into our soil and groundwater and put people's health at risk – all so these chemical companies could line their pockets. It's wrong. So I'm taking them to court to make them clean up the mess they made. I'll do everything to protect North Carolinians' natural resources, including their drinking water."

"Every day, we learn more about this toxic class of chemicals," said Charlotte International Association of Fire Fighters Local 660 President Tom Brewer. "The research and data are clear – these deadly chemicals must be removed from the firefighters' environment. That's why I am so pleased to work with Attorney General Stein to address toxic firefighting foams present across our great state."

AFFF is designed to be mixed with water and sprayed liberally, which leads to it contaminating the soil, groundwater, and natural resources. In these lawsuits, Attorney General Stein alleges that AFFF manufacturers knew or should have known about the toxic nature of PFAS chemicals and how they harmed people, wildlife, and the environment, but they continued to manufacture, market, and sell their products in North Carolina and elsewhere while concealing the risks.

The four cases Attorney General Stein is filing are in connection to the following contaminated sites:

1. Charlotte-Douglas International Airport, where the Air Force tested at the Air National Guard Base and found PFAS in the groundwater at levels thousands of times in excess of the Environmental Protection Agency's (EPA) health advisory level.
2. Charlotte Police and Fire Training Academy, where N.C. Department of Environmental Quality (DEQ) directed-testing by the City of Charlotte found PFAS compounds at 17 different on-site groundwater wells with levels up to 1,800 times beyond EPA's health advisory level.
3. Seymour-Johnson Air Force Base, where the Air Force has conducted testing that showed PFAS concentrations in the groundwater at levels thousands of times beyond EPA's health advisory level.
4. Stanly County Airport, which also has an Air National Guard Base and where testing has revealed excessive PFAS in the soil, sediment, and groundwater.

Health problems associated with PFAS include increased risks of cancer, high blood pressure, damage to immune systems, and harm to fetal development. These lawsuits are part of Attorney General Stein's ongoing investigation into manufacturers responsible for PFAS contamination in North Carolina. The investigation may result in additional legal action.

A copy of the Charlotte-Douglas International Airport complaint is available **here**.

A copy of the Charlotte Police and Fire Training Academy complaint is available **here**.

A copy of the Seymour-Johnson Air Force Base complaint is available **here**.

A copy of the Stanly County Airport base is available **here**.

More on Attorney General Stein's work to protect North Carolinians from PFAS pollution:

- **Attorney General Josh Stein Calls for Stronger Monitoring of Forever Chemicals**
- **Attorney General Josh Stein Takes Legal Action Against DuPont Over PFAS Pollution**
- **Attorney General Josh Stein Announces Formal Investigation into PFAS**
- **Attorney General Josh Stein to EPA: Protect Our Water from Toxic Forever Chemicals**
- **Attorney General Stein Statement on Chemours Consent Order**

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Attorney General Josh Stein Announces More Than $850,000 in 2021 Environmental Grants in Eastern NC »

No. 2010-082
Supreme Court of New Hampshire. Merrimack

State v. Hess Corp.

161 N.H. 426 (N.H. 2011) · 20 A.3d 212
Decided Jan 28, 2011

No. 2010-082.

Argued: November 10, 2010.

Opinion Issued: January 28, 2011.

1. Environment and Natural Resources — Environmental Rights and Actions — Right to Relief

The State is not precluded from recovering damages related to methyl tertiary butyl ether contamination in a privately owned well.

2. Environment and Natural Resources — Environmental Rights and Actions — Right to Relief

The public trust doctrine, from which the State's authority as trustee stems, and the *parens patriae* doctrine are both available to states seeking to remedy environmental harm. The public trust doctrine provides that the government holds public lands, waters and other natural resources in trust for the benefit of its citizens. As trustee, the government must act as a fiduciary in its management of the resources which constitute the corpus of the trust. The doctrine allows a state attorney general, as trustee, to bring a cause of action for damages to natural resources held in trust by the State. To bring a successful claim, the State must prove an unreasonable interference with the use and enjoyment of trust rights. While some states allow recovery for damages to any natural resources, others allow recovery only for natural resources actually owned or held in trust by the State.

3. Environment and Natural Resources — Environmental Rights and Actions — Standing

While the public trust doctrine is its own cause of action, *parens patriae* is a concept of standing, which allows the State to protect certain "quasi-sovereign" interests. These interests include the health, comfort and welfare of a state's citizens, interstate water rights, and the general economy of the state. *Parens patriae* does not provide a cause of action, but may provide a state with standing to bring suit to protect a broader range of natural resources than the public trust doctrine because it does not require state ownership of such resources.

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4. Environment and Natural Resources — Environmental Rights and Actions — Standing

As trustee, the State must preserve the State's waters for the trust's beneficiaries, and the State can bring suit to protect the waters over which it is trustee from contamination.

5. Environment and Natural Resources — Environmental Rights and Actions — Standing

While the State has a responsibility to protect its citizens from toxins in their drinking water, the State's role as trustee does not automatically confer *parens patriae* standing to recover all damages associated with privately owned wells because a natural resources trustee still may not recover damages belonging to private citizens.

6. Parties — Generally — Standing

There are two requirements for a State to have *parens patriae* standing. As the United States Supreme Court delineated, the State must first assert an injury to a "quasi-sovereign" interest, an interest apart from the interests of particular private parties. Second, the State must allege injury to a substantial segment of its population.

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7. Parties — Generally — Standing

Parens patriae standing does not extend to the vindication of the private interests of third parties.

8. Parties — Generally — Standing

A state may act as the representative of its citizens where the injury alleged affects the general population of a state in a substantial way.

9. Environment and Natural Resources — Environmental Rights and Actions — Standing

The United States Supreme Court has consistently held that states have a right to appear as *parens patriae* regardless of the rights of individual and private users of the water in question. While acknowledging that the complained-of conduct may affect private citizens or privately owned land, these cases also provide the states with wide latitude to protect their natural resources because the interests of the state are indissolubly linked with the rights of the private appropriators or users.

10. Environment and Natural Resources — Environmental Rights and Actions — Particular Matters

Not all potential damages related to methyl tertiary butyl ether (MTBE) contamination in New Hampshire waters can properly be recovered by the State in its capacity as *parens patriae*. In fact, claims for diminution in value of private property, lost business expenditures and other business and economic losses resulting from MTBE contamination properly belong to private parties. Nonetheless, the fact that MTBE is detected in a privately owned well does not necessarily preclude the State from pursuing damages for the costs of investigating, monitoring, treating, remediating, replacing, or otherwise restoring such wells.

11. Environment and Natural Resources — Environmental Protection — Water Pollution

Groundwater is a unique and irreplaceable government resource.

Michael A. Delaney, attorney general (*Mary Makmey*, assistant attorney general, on the brief), *Sher Leff, LLP*, of San Francisco, California (*Victor M. Sher* on the brief), *Law Offices of Matthew F Pawa, P.C.*, of Newton Centre, Massachusetts (*Matthew F. Pawa* and *Benjamin A. Krass* on the brief, and *Mr. Pawa* orally), for the plaintiff.

Beveridge Diamond, PC, of Washington, D.C. (*John S. Guttmann* and *Nessa E. Horewitch* on the brief, and *Mr. Guttmann* orally), and *Devine, Millimet Branch, P.A.*, of Concord (*Peter G. Beeson* on the brief), for the defendants.

DUGGAN, J.

This case comes before us on an interlocutory transfer without ruling from the Superior Court. *See* SUP. CT. R. 9. We accept the facts as presented in the interlocutory transfer. *See In re Kotey M.*, 158 N.H. 358, 359 (2009).

In 1991, New Hampshire applied to the United States Environmental Protection Agency's (EPA) reformulated gasoline (RFG) program. The RFG program, which set specifications for formulating gasoline sold in metropolitan areas with high summertime ozone levels, was established by a 1990 amendment to the Clean Air Act and was
428 intended to reduce *428 vehicle-related air pollution. The program did not require gasoline manufacturers to utilize any specific oxygenate in reformulating their products. Instead, that decision was left to individual manufacturers.

Although not required to participate in the RFG program, New Hampshire decided to "opt-in." The EPA accepted New Hampshire's application — effective January 1, 1995 — for Rockingham, Hillsborough, Merrimack and Strafford Counties. Thereafter, between 1995 and 2006, gasoline containing methyl tertiary butyl ether (MTBE), which is a chemical compound that has been used as a gasoline additive to increase octane levels of fuel, was sold throughout the state. During this time, the State alleges that MTBE, which it asserts is a known animal carcinogen and probable human carcinogen, escaped into, and contaminated, the ground-water. In 2001, the State petitioned the E PA to opt-out of the RFG program on an expedited basis because of MTBE contamination, and then banned MTBE as a gasoline additive effective January 1, 2007.

The State exercises significant regulatory control over the State's groundwater and drinking water through the New Hampshire Department of Environmental Services (DES) and pursuant to the New Hampshire Safe Drinking Water Act (SDWA). The Commissioner of DES must adopt "primary drinking water standards" for contaminants in drinking water that "may have an adverse effect on the health of persons." RSA 485:3,1(a) (2001). These standards include a maximum contaminant level (MCL), which establishes the maximum amount of a given contaminant that may be present in water for human consumption. RSA 485:3, 1(b)(1) (2001).

For groundwater, DES must also adopt ambient groundwater quality standards (AGQS) for contaminants that "adversely affect human health or the environment," RSA 485-C:6, I (2001), which must meet drinking water standards, RSA 485-C:1, I (2001). In addition to these standards applicable to all contaminants, the legislature added a section to the SDWA in 1999, which specifically mandates DES to adopt such standards for MTBE. RSA 485:16-a, I (2001).

In 2000, DES, in consultation with the New Hampshire Department of Health and Human Services, established a primary MCL and an equivalent AGQS for MTBE of thirteen parts per billion "based on positive carcinogenic effects observed in experimental animals" reported in the publicly available literature at the time. Additionally, New Hampshire law provides that " [a]ny public water system delivering water with greater than 5 parts per billion of MTBE shall notify each customer of the MTBE content." RSA 485:16-a, II (2001). However, both the MCL for MTBE and the notification requirement apply only to public water systems. RSA 485:3, I, :16-a. The SDWA defines a "public water system" as a "system for the provision to the public of piped water for human consumption, if such system has
429 at least 15 *429 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year." RSA 485:1-a, XV (2001). All other wells, whether privately or publicly owned, that serve more than one individual home but do not qualify as a "public water system" are non-public water systems.

In 2003, New Hampshire and several other states filed suit in their respective state courts against several gasoline suppliers, refiners and chemical manufacturers (MTBE defendants) seeking damages for ground-water contamination allegedly caused by MTBE. The MTBE defendants initially removed New Hampshire's case to federal court, and it was subsequently transferred by the Judicial Panel on Multidistrict Litigation to the Southern District of New York and consolidated with numerous other MTBE lawsuits from around the country. Following the denial of its motion to remand, the State filed an interlocutory appeal with the United States Court of Appeals for the Second Circuit, which reversed and vacated the district court's order in May 2007. *See In re Methyl Tertiary Butyl Ether ("MTBE")*, 488 F.3d 112 (2d Cir. 2007). Thus, this case was remanded to Merrimack County Superior Court for trial.

In the meantime, the cities of Dover and Portsmouth brought their own suits against the MTBE defendants. We affirmed the dismissal of these suits in January 2006. *See State v City of Dover*, 153 N.H. 181 (2006). In that decision, we determined that the State, rather than the two cities, was the proper party to bring suit against the MTBE defendants because it "has a quasi-sovereign interest in protecting the health and well-being, both physical and economic, of its residents with respect to the statewide water supply." *Id.* at 186. We also noted that "MTBE contamination has directly affected a substantial portion" of the State's population. *Id.* at 187. Accordingly, we held that the State had *parens patriae* standing to bring suit against the MTBE defendants on behalf of the residents of New Hampshire. *Id.* at 187-88.

In August 2009, the MTBE defendants in this case filed a motion for partial summary judgment, seeking to prevent the State from recovering damages

> incurred by private individuals or private water supplies, including, but not limited to: (1) damages related to private property; (2) costs of alternative water supplies incurred by private parties; (3) business losses for any private entity; (4) costs of private treatment systems borne by private well owners and private water authorities; (5) increased operating expenses for private water authorities; (6) costs associated with testing/monitoring for MTBE by private parties; (7) costs
> 430 associated with MTBE *430 remediation at private wells or utilities that were incurred directly by private parties; and (8) any other similar purely private damages.

Additionally, in response to a request from the superior court, the State provided a "general explanation of the categories of damages" it seeks in this case. The State divided its requests into two categories: (1) "Damages Claims for MTBE Contamination at Any Level"; and (2) "Damages Claims for MTBE Contamination At or Above the AGQS/MCL." With regard to the first category, the State seeks

> 1. *Present and future public water system costs.* All present and future costs associated with the presence of MTBE at any level in public water systems, including the full costs of treatment and removal of MTBE at any level.
>
> 2. *Present and future private well and non-public water system costs.* All present and future costs of implementing and maintaining a comprehensive, statewide investigation, monitoring and treatment program for private wells and other unregulated . . . water systems, including the full costs of treatment and removal of MTBE at any level.

With regard to the second category, the State seeks

> 3. *Past public and private well costs.* All past public and private well costs associated with MTBE reimbursed through State reimbursement funds . . . . Because State fund expenditures are linked to the MCL for MTBE, the State is not seeking past public and private well costs associated with the presence of MTBE below the MCL.
>
> 4. *Site remediation costs.* All past, present and future costs paid by the State reimbursement funds . . . attributable to the presence of MTBE at contaminated sites.

The Superior Court held a hearing on the defendants' motion and proposed an interlocutory transfer. Pursuant to Supreme Court Rule 9, the Superior Court (*Fauver*, J.) transferred the following questions:

> 1. If the State is the trustee of the waters of New Hampshire, do all costs of investigating, monitoring, treating, remediating, replacing or otherwise restoring state water contaminated by MTBE, regardless of whether the MTBE is
> 431 detected in a *431 privately or publicly owned well, constitute damages the State is entitled to recover on its own behalf?
>
> 2. Did *City of Dover* hold that recovery of private damages to the State is permissible, or specifically authorized, in a *parens patriae* action?

Based upon the record available to us at this time, we hold, as explained below, that the State is not precluded from recovering damages related to MTBE contamination in a privately owned well. We remand to the Superior Court to determine the exact scope of damages available to the State within the limits explained below. Based upon our answer to the first question, we deem it unnecessary to reach the second question.

The MTBE defendants conceded at oral argument that the State may recover damages to test and treat statutorily defined public water systems. Thus, the crux of the current dispute is whether the State can recover damages with regard to non-public wells.

The State asserts two theories as to why we should answer the first question in the affirmative. It argues that it has the right and duty to protect its citizens from MTBE contamination in the State's water supply both in its *parens patriae* capacity and as trustee of the State's water supply. The MTBE defendants respond that the State's authority to recover damages for MTBE contamination as trustee of the water supply is "one and the same" as its authority as *parens patriae.*

The public trust doctrine, from which the State's authority as trustee stems, and the *parens patriae* doctrine are both available to states seeking to remedy environmental harm. *See generally* Kanner, *The Public Trust Doctrine, Parens Patriae, and the Attorney General as the Guardian of the State's Natural Resources*, 16 DUKE ENVTL. L. POL'Y F. 57, 59 (2005). The public trust doctrine provides that the government holds public lands, waters and other natural resources in trust for the benefit of its citizens. *Id.* at 62. As trustee, the government "must act as a fiduciary in its management of the resources which constitute the corpus of the trust." *Id.* at 76 (quotation omitted). The doctrine allows a state attorney general, as trustee, to bring a cause of action for damages to natural resources held in trust by the State. *Id.* at 59. To bring a successful claim, the State must prove an unreasonable interference with the use and enjoyment of trust rights. *Id.* While some states allow recovery for damages to any natural resources, others allow recovery only for natural resources actually owned or held in trust by the State. *Id.*

While the public trust doctrine is its own cause of action, *parens patriae* is a "concept of standing," 432 which allows the state to protect certain *432 "quasi-sovereign" interests. *City of Dover*, 153 N.H. at 185 (quotations omitted). These interests include the health, comfort and welfare of a state's citizens, interstate water rights, and the general economy of the state. *Id.* at 185-86. *Parens patriae* does not provide a cause of action, but may provide a state with standing to bring suit to protect a broader range of natural resources than the public trust doctrine because it does not require state ownership of such resources. *New Mexico v. General Elec. Co.*, 467 F.3d 1223, 1243 n. 30 (10th Cir. 2006).

Here, however, the State does not explicitly rely upon the public trust doctrine as a separate cause of action, and instead asserts that it must act in the citizens' interest as the trustee of the statewide water supply. Indeed, the General Court has declared that the State is the trustee over all of the State's water. RSA 481:1 (2001) provides that

> an adequate supply of water is indispensable to the health, welfare and safety of the people of the state and is essential to the balance of the natural environment of the state. Further, the water resources of the state are subject to an ever-increasing demand for new and competing uses. The general court declares and determines that the water of New Hampshire whether located above or below ground constitutes a limited and, therefore, precious and invaluable public resource which should be protected, conserved and managed in the interest of present and future generations. The state as *trustee of this resource for the public benefit* declares that it has the authority and responsibility to provide careful stewardship over *all the waters* lying within its boundaries. The maximum public benefit shall be sought. . . . All levels of government within the state . . . and all other entities, *public or private*, having authority over the use, disposition or diversion of water resources, or over the use of the land overlying, or adjacent to, the water resources of the state, shall comply with this policy and with the state's comprehensive plan and program for water resources management and protection.

(Emphases added.) As trustee, the State must preserve the State's waters for the trust's beneficiaries, and the State can bring suit to protect the waters over which it is trustee from contamination. *See Illinois Central Railroad v. Illinois*, 146 U.S. 387, 455-56 (1892); *State of Maryland, Dept. of N. Res. v. Amerada Hess Corp.*, 350 F. Supp. 1060, 1067 (D. Md. 1972).

While we recognize the State's responsibility to protect its citizens from toxins in their drinking water, the State's role as trustee does not automatically confer *parens patriae* standing to
433 recover all damages *433 associated with privately owned wells because a natural resources trustee still may not recover damages belonging to private citizens. *Quapaw Tribe of Oklahoma v Blue Tee Corp.*, 653 F. Supp. 2d 1166, 1181 (N.D. Okla. 2009). Accordingly, we next turn to the requirements for standing as *parens patriae.*

In *City of Dover*, we set forth the two requirements for a state to have *parens patriae* standing. As the United States Supreme Court delineated in *Alfred L. Snapp Son, Inc. v Puerto Rico*, 458 U.S. 592 (1982), the state must first assert "an injury to a `quasi sovereign' interest, an interest apart from the interests of particular private parties. Second, the state must allege injury to a `substantial segment' of its population." *City of Dover*, 153 N.H. at 186 (quotation omitted). We determined that the State met the first criteria because it "has a quasi-sovereign interest in protecting the health and well-being, both physical and economic, of its residents with respect to the statewide water supply." *Id.* We also determined that the State met the second criteria because the State alleged that MTBE was present in hundreds of public water systems and approximately 40, 000 private water supplies. *Id.* at 187.

Our holding in *City of Dover* does not mean that the State can recover all MTBE-related damages from the defendants. *See People of State of N.Y. v Operation Rescue Nat*, 80 F.3d 64, 71 (2d Cir.) (*parens patriae* standing "does not extend to the vindication of the private interests of third parties"), *cert denied*, 519 U.S. 825 (1996). However, a state may act as the representative of its citizens "where the injury alleged affects the general population of a State in a substantial way." *Maryland v. Louisiana*, 451 U.S. 725, 737 (1981). Accordingly, our inquiry now focuses upon the scope of the State's standing and whether the specific types of damages that the State requests are sufficiently "apart from the interests of particular private parties." *Massachusetts v. Bull HN Information Systems*, 16 F. Supp. 2d 90, 96 (D. Mass. 1998).

The doctrine of *parens patriae* originated in English common law, and was first recognized in American law in a series of United States Supreme Court cases at the beginning of the twentieth century. *See, e.g., Missouri v Illinois Chicago District*, 180 U.S. 208 (1901); *Georgia v. Tennessee Copper Co.*, 206 U.S. 230 (1907); *Kansas v. Colorado*, 206 U.S. 46 (1907); *New York v. New Jersey*, 256 U.S. 296 (1921); *Wyoming v Colorado*, 259 U.S. 419 (1922). Many of these cases concerned disputes regarding water and the Supreme Court consistently held that states have a right to appear as *parens patriae* regardless of the rights of individual and private users of the water. *See People of the State of*
434 *California v United States*, *434 180 F.2d 596, 601 (9th Cir.) (collecting United States Supreme Court cases discussing *parens patriae* standing in cases involving water), *cert denied*, 340 U.S. 826 (1950). While acknowledging that the complained of conduct may affect private citizens or privately owned land, these cases also provide the states with wide latitude to protect their natural resources because "the interests of the State are indissolubly linked with the rights of the [private] appropriators" or users. *Wyoming v. Colorado*, 259 U.S. at 468.

In the first of these cases, *Missouri v Illinois*, Missouri sought to enjoin Illinois from discharging sewage into Missouri's portion of the Mississippi River. *Missouri v. Illinois*, 180 U.S. at 209-10. The Court recognized that the case did not involve a boundary dispute or property rights directly belonging to one of the states. *Id.* at 241. Nonetheless, the Court concluded that "if the health and comfort of the inhabitants of a State are threatened, the State is the proper party to represent and defend them." *Id.* Further-more, the Court reasoned that the pollution did not affect just those living along the banks of the river because any diseases resulting from the pollution could spread throughout the entire state. *Id.* Additionally, the Court feared that individual suits for personal injuries would provide "wholly inadequate and disproportionate remedies." *Id.*

The Court followed similar reasoning in *Tennessee Copper Co.*, in which Georgia sought to prevent the corporate defendant from discharging noxious gases across the border from its plant in Tennessee. *Tennessee Copper Co.*, 206 U.S. at 236. Although Georgia actually owned only a small portion of the affected territory, it still had standing to bring suit in its quasi-sovereign capacity because of its interest "independent of and behind the titles of its citizens, in all the earth and air within its domain. It has the last word as to whether its mountains shall be stripped of their forests and its inhabitants shall breathe pure air." *Id.* at 237.

The Court later extended the doctrine to allow a state to protect the economic and commercial interests of its citizens. *See, e.g., Penna. v West Virginia*, 262 U.S. 553, 592 (1923) (holding that two states had standing to sue West `Virginia for mandating that gas producers first serve the needs of local customers because the withdrawal of gas from interstate commerce was "a matter of grave public concern," which "seriously jeopardized" the health, comfort and welfare of a substantial portion of the states' population); *Maryland v Louisiana*, 451 U.S. at 739 (determining that several states could challenge a tax on certain uses of natural gas imported into Louisiana because of the states' "interest in protecting [their] citizens from substantial economic injury").

Alfred L. Snapp further expanded and explained the modern requirements for *parens patriae* standing. There, the Court considered whether Puerto Rico could properly bring suit against
435 Virginian apple growers for *435 an alleged violation of federal law. *Alfred L. Snapp*, 458 U.S. at 594. Puerto Rico claimed that the apple growers violated federal laws and regulations that required employers to seek domestic workers for any job opening before employing temporary foreign

laborers and prevented employers from discriminating against domestic workers or adversely affecting their working conditions. *Id.* at 597-98. The dispute arose when Puerto Rico sent 420 workers to "Virginia, but fewer than thirty were actually employed by the apple growers. *Id.* at 597. Puerto Rico alleged that the discrimination deprived it of its right to benefit from United States laws and caused irreparable injury to its efforts to promote employment for Puerto Rican workers and reduce unemployment in Puerto Rico. *Id.* at 598.

In concluding that Puerto Rico had standing, the Court stated that "[j]ust as we have long recognized that a State's interests in the health and well-being of its residents extend beyond mere physical interests to economic and commercial interests, we recognize a similar state interest in securing residents from the harmful effects of discrimination." *Id.* at 609. The Court also agreed with the Court of Appeals that "deliberate efforts to stigmatize the labor force as inferior carry a universal sting." *Id.* (quotation and brackets omitted). Alternatively, the Court determined that Puerto Rico had a quasi-sovereign interest in ensuring its citizens' full participation in the federal employment service scheme because high unemployment among Puerto Ricans was a legitimate state concern. *Id.*

To counter this line of cases expanding *parens patriae* standing, the MTBE defendants rely upon a series of cases denying *parens patriae* standing. *See, e.g., Oklahoma v Cook*, 304 U.S. 387 (1938); *Oklahoma v. A., T. Santa Fe Ry.*, 220 U.S. 277 (1911); *N.H. u Louisiana: N.Y. v. Louisiana*, 108 U.S. 76 (1883). However, these cases all stand for the proposition that money damages are unavailable to the State in a *parens patriae* case where the State seeks to recover solely for the benefit of private individuals. *See Operation Rescue Nat.*, 80 F.3d at 71-72. We find these cases unpersuasive where the State has alleged a statewide injury affecting the health and well-being of a substantial portion of its citizens. *But see People of State of N.Y. by Abrams v. Seneci*, 817 F.2d 1015, 1017-18 (2d Cir. 1987) (denying standing where damages for a fraudulent business opportunities scheme were designed to directly provide restitution to only seventy-nine consumers rather than compensate the State for injury to the integrity of its marketplace).

While these *parens patriae* cases illustrate the broad scope of the doctrine, they do not directly address the specific types of damages available to a state in its *parens patriae* capacity. More recently, two courts have addressed this question. In *Satsky v. Paramount Communications, Inc. (Satsky II)*, 7 F.3d 1464 (10th Cir. 1993), the court
436 determined that an *436 earlier consent decree between Colorado and a mine owner barred some claims of private property owners against the mine. *Id.* at 1470. The private property owners sought damages for hazardous waste produced by mining activities in the area surrounding the Eagle Mine and Eagle River. *Id.* at 1466. The court explained that the prior consent decree barred only those claims "for injuries to interests which all citizens hold in common," and that the plaintiffs could pursue those claims that "involve[d] injuries to purely private interests." *Id.* at 1470. The court remanded the case to the district court "to determine which claims . . . are truly private, and which claims are based on common public rights." *Id.*

On remand, the district court considered whether the consent decree barred three categories of damages. *Satsky u Paramount Communications, Inc. (Satsky III)*, No. CivA 90-S-1561, 1996 WL 1062376 (D. Colo. March 13, 1996). First, the plaintiffs sought damages to pay for medical monitoring and health studies in the affected areas. *Id.* at *4. The court reasoned that while an individualized medical monitoring claim might be private, the "request for broad medical monitoring and surveillance studies [was] not a `truly private' claim, but rather a public health study," and thus barred by the consent decree. *Id.* at *6. Second, the plaintiffs requested damages for impaired

water quality and the `Increased costs of personal protection" because of contaminated water. *Id.* (quotation omitted). The court barred recovery for any claims relating to natural resources held by Colorado, such as common rights to use river water for irrigation, but allowed any claims for damages relating to private adjudicated water rights. *Id.* at *7. Third, the court allowed claims for direct loss of income, loss of asset value and increased operating expenses because they were "arguably private claims based on direct injury to the Plaintiffs' private property." *Id.*

In the second case, *Quapaw Tribe of Oklahoma*, the court differentiated between claims for which the Quapaw Tribe could recover and those that were private claims of tribal members. *Quapaw Tribe of Oklahoma*, 653 F. Supp. 2d at 1179. The Tribe had filed suit on behalf of its members against several mining companies for damages relating to the companies' use of tribal land. The court first determined that the Tribe was the proper party to bring a claim for damages to Tribal land because private landowners could not recover those damages. *Id.* at 1181. However, the court denied the Tribe standing for damages for "lost use" of land owned by tribal members because economic gain from beneficial use of the land flowed directly to the landholder. *Id.* at 1183. Second, the Court denied the mining companies' motion for summary judgment with regard to the Tribe's standing to pursue damages for subsidence (*i.e.*, "the rapid sinking of the surface caused by lack of support underneath the surface of the land," *id.* at 1184 *437 (quotation omitted)) or the risk of subsidence to tribal land. *Id.* at 1186. While individual Tribal members owned all of the affected land, the court reasoned that "[subsidence or the risk of subsidence affects all who use certain land, and the impact of subsidence may go beyond harm to the individual landowners." *Id.*

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The MTBE defendants rely on these cases to argue that the damages the State seeks to recover are not based on public rights held in common by citizens of New Hampshire. They assert a distinction between injury to a public resource for which a state can recover and damages stemming from injury to the same resource that can only be recovered by private individuals. Accordingly, they contend that simply because water is a public resource does not mean that there can be no "private damages" associated with that resource.

We agree with the defendants that not all potential damages related to MTBE contamination in New Hampshire waters can properly be recovered by the State in its capacity as *parvus patriae.* In fact, the State conceded at oral argument, and we agree, that claims for diminution in value of private property, lost business expenditures and other business and economic losses resulting from MTBE contamination properly belong to private parties. Nonetheless, the fact that MTBE is detected in a privately owned well does not necessarily preclude the State from pursuing damages for the costs of investigating, monitoring, treating, remediating, replacing, or otherwise restoring such wells.

The MTBE defendants point out that the damages related to privately owned wells are purely private in nature because remedying MTBE contamination in a private well only benefits that individual well owner. However, the State has alleged widespread MTBE contamination in privately owned wells throughout the state. In *City of Dover*, we noted that in 2002, the State alleged that MTBE was present in 13.2% of the statewide water supplies, including approximately 40, 000 private water supplies. *City of Dover*, 153 N.H. at 187. Additionally, the State's Second Amended Complaint alleges that in 2005 and 2006 testing, MTBE was present in 9.1% of private wells statewide and in 17% of private wells in the counties that participated in the RFG program. Despite these allegations, the MTBE defendants claim that the State has failed to collect and provide comprehensive testing data regarding private wells. Additionally, a 2007 U.S. Geological Survey study of MTBE contamination in New Hampshire's groundwater found that only

one of 264 private wells tested had an MTBE contamination that exceeded the state action level for notification of *438 adjacent well owners, which is a MCL of five parts per billion. None of the private wells exceeded the State's primary MCL of thirteen parts per billion.

The State also argues that private well contamination affects its entire citizenry because while some wells only serve a single family or business, these wells ultimately draw their water from the groundwater over which the State is trustee. *See* RSA 485-C:1, II (2001) (the State "has general responsibility for groundwater management in the public trust and interest"); *see also Coakley v Maine Bonding Cas. Co.*, 136 N.H. 402, 413 (1992) (groundwater is a "unique and irreplaceable government resource"). Furthermore, the State asserts that private well owners have only a usufructuary interest in their groundwater that is subject to the State's interest as trustee, *see Appeal of Town of Nottingham*, 153 N.H. 539, 548 (2006), but the MTBE defendants contend that the State loses its interest in the water once it enters a privately owned well.

These are all factual issues for the trial court on remand and for the finder of fact at trial. Nonetheless, based upon the record available to us at this time, the alleged impact of private well contamination may go beyond harm to an individual well owner. However, as both the *Satsky* and *Quapaw Tribe* cases demonstrate, the State's damages in this case are not unlimited and are subject to at least some limiting principles. We base our answer to the Superior Court's question on the limited record available to us at this stage of the proceedings, and note that this question comes to us on a motion for partial summary judgment.

We first note that because this case comes to us on the defendants' motion for partial summary judgment, the defendants, as the moving party, have the burden to demonstrate that there is no genuine issue as to any material fact. *Sabinson v Trustees of Dartmouth College*, 160 N.H. 452, 460 (2010). Should the case go to trial, the burden will rest with the State to prove that it meets all of the requirements for *parens patriae* standing. *City of Dover*, 153 N.H. at 186. However, at this stage, the defendants have the burden of proving that the uncontested facts establish that the State is not entitled to *parens patriae* standing with regard to all of the damages that it seeks.

Accordingly, on remand, and in ruling on the MTBE defendants' motion for summary judgment, the trial court should determine whether the uncontested facts establish that the defendants have met their burden to prove that the State has not alleged injury, either direct or indirect, to a sufficiently substantial segment of privately owned wells. *See Quapaw Tribe of Oklahoma*, 653 F. Supp. 2d at 1179; *Alfred L. Snapp*, 458 U.S. at 607; *City of Dover*, 153 N.H. at 186-87. In doing so, the court should *439 consider both private well contamination throughout the entire state and specifically in the four most-affected counties.

Second, the trial court should determine whether the defendants can meet their burden of proving that the State's allegations of injury to private wells are speculative in nature. *See Quapaw Tribe of Oklahoma*, 653 F. Supp. 2d at 1179. By this, we mean that the defendants must put forth evidence that shows that MTBE contamination is unlikely in the private water supply in a given area or region. To refute any such evidence, the State could point to the presence of gas stations in a given area that sold gasoline containing MTBE, or rely upon the 2007 U.S. Geological Survey, which indicated areas in the State with high incidences of MTBE contamination. We intend this requirement to prevent the State from being given a blank check to investigate and test for alleged MTBE contamination in areas of New Hampshire where the State has provided little evidence of an actual risk of contamination.

In this regard, the trial court should give especially close scrutiny to the State's request for "[present and future private well and non-public water system costs" at any level. Pursuant to this request, the State seeks "[a]ll present and future costs of implementing and maintaining a comprehensive, statewide investigation, monitoring and treatment program for private wells." We recognize the State's concern that a large percentage of the State's population relies on private wells for drinking water. However, the State has set an MCL/AGQS level, above which it deems MTBE to be a risk to the public's health and well-being. Although the State may be able to prove at trial that MTBE contamination below the MCL/AGQS level poses a threat to the public's health and well-being, the trial court should consider the evidence on the summary judgment record to determine whether the defendants can meet their burden of proof at this stage and show that the State's request for all costs at any MCL/AGQS level is too speculative and oversteps its authority as *parens patriae.*

Based on these factors, the court must determine whether "there may [be] a community-wide risk presented by the alleged [contamination] that goes beyond harm to the individual [well owners]." *Quapaw Tribe of Oklahoma*, 653 F. Supp. 2d at 1187; *see also Penna. v West Virginia*, 262 U.S. at 592 (determining that when the health, comfort and welfare of a substantial number of private consumers are seriously jeopardized, it is a matter of "grave public concern").

Additionally, as part of the standing inquiry, some courts have considered the difficulty of individuals bringing their own suits for damages. *See Maryland v. Louisiana*, 451 U.S. at 739 (observing that individual consumers were unlikely to litigate the validity of a tax when the amounts paid to each consumer are likely to be relatively small); 440 *Missouri v. Illinois*, *440 180 U.S. at 241 ("That suits brought by individuals, each for personal injuries, threatened or received, would be wholly inadequate and disproportionate remedies, requires no argument."). The State argues that individual plaintiffs would have to litigate against many of the largest gasoline companies in the world because many courts have refused to certify MTBE class actions by private property owners. *See, e.g., In re Methyl Tertiary Butyl Ether Prods. Litig.*, 209 F.R.D. 323, 337 (S.D.N.Y. 2002); *Millett v Atlantic Richfield Co.*, 760 A.2d 250 (Me. 2000). At this point, there is a factual dispute regarding whether a class action or individual suits against the MTBE defendants are possible and we leave it to the trial court to determine the weight to be given to this factor.

Finally, the MTBE defendants assert that the State may recover damages to test and treat privately owned wells only to have some well owners refuse to allow the State to treat their wells. First, the State has a right to appear as *parens patriae* regardless of the rights of individual private appropriators or users of water. *People of the State of California v United States*, 180 F.2d at 601; *see also Hudson Water Co. v McCarter*, 209 U.S. 349, 355 (1908). Additionally, there is no evidence in the record at this time that private well owners would actually object to state testing and treatment of their wells. The defendants' concern relates more to the exact dollar amount of damages recoverable by the State and is more appropriate to be resolved after trial than on the pleadings. *See State of Maine v. M/V Tamano*, 357 F. Supp. 1097, 1102 (D. Me. 1973). At that stage, any monetary damages claimed by citizens individually may be excluded from the State's recovery. *See id.* *Remanded.*

HICKS, J., concurred; HORTON, J., retired, specially assigned under RSA 490:3, concurred.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation

Master File No. 00-Civ. 1898
MDL No 1358 (SAS)

This Document Relates To:

STATE OF NEW HAMPSHIRE,

Plaintiff,

vs.

AMERADA HESS CORPORATION; BP PRODUCTS NORTH AMERICA, INC.; CHEVRONTEXACO CORPORATION; CHEVRON U.S.A., INC.; CITGO PETROLEUM CORPORATION; CITGO REFINING AND CHEMICAL COMPANY, LP; CONOCOPHILLIPS COMPANY; EL PASO MERCHANT ENERGY-PETROLEUM COMPANY; EQUISTAR CHEMICALS, LP; EXXONMOBIL CORPORATION, EXXONMOBIL OIL CORPORATION; FLINT HILLS RESOURCES, LP; GIANT YORKTOWN, INC.; GULF OIL LIMITED PARTNERSHIP; IRVING OIL CORPORATION; IRVING OIL LIMITED; LYONDELL-CITGO REFINING, LP; LYONDELL CHEMICAL COMPANY; LYONDELL PETROCHEMICAL GP, INC.; MOTIVA ENTERPRISES, LLC; NORTH ATLANTIC REFINERY, LTD.; SHELL OIL COMPANY; SUNOCO, INC. (R&M); TEXACO REFINING AND MARKETING, INC.; ULTRAMAR ENERGY, INC.; ULTRAMAR LIMITED; UNOCAL CORPORATION; VALERO MARKETING AND SUPPLY COMPANY; VALERO REFINING – TEXAS, L.P.; VALERO REFINING COMPANY – NEW JERSEY; VALERO REFINING COMPANY – LOUISIANA; VALERO ENERGY CORPORATION; VITOL S.A.,

Defendants.

Case No. 04 Civ. 4976 (SAS)

Transferred from:
United States District Court for the District of New Hampshire,
Case No. 03-CV-486

United States District Court for the District of Rhode Island,
Case No. CIVS 03-0529L

Removed from:
Merrimack County Superior Court,
Case No. 03-C-550

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Without waiving its sovereign immunity or otherwise consenting to the jurisdiction of this Court or any other federal court, the State of New Hampshire, by and through the New Hampshire Attorney General, 33 Capitol Street, Concord, New Hampshire, complains against Amerada Hess Corporation, 1185 Avenue of the Americas, New York, New York; BP Products North America, Inc., 200 East Randolph Drive, Chicago, Illinois; ChevronTexaco Corporation, 6001 Bollinger Road, San Ramon, California; Chevron U.S.A., Inc., 6001 Bollinger Road, San Ramon, California; CITGO Petroleum Corporation, 6100 South Yale Avenue, Tulsa, Oklahoma; CITGO Refining and Chemical Company, LP, 6100 South Yale Avenue, Tulsa, Oklahoma; ConocoPhillips Company, 600 North Dairy Ashford, Houston, Texas; El Paso Merchant Energy-Petroleum Company, 1001 Louisiana Street, Houston, Texas; Equistar Chemicals, LP, 1221 McKinney Street, Houston, Texas; ExxonMobil Corporation, 5959 Las Colinas Boulevard, Irving, Texas; ExxonMobil Oil Corporation, 5959 Las Colinas Boulevard, Irving, Texas; Flint Hills Resources, LP, 4111 E. 37th Street North, Wichita, Kansas; Giant Yorktown, Inc., 23733 North Scottsdale Road, Scottsdale, Arizona; Gulf Oil Limited Partnership, 90 Everett Avenue, Chelsea, Massachusetts; Irving Oil Corporation, 190 Commerce Way, Portsmouth, New Hampshire; Irving Oil Limited, 210 Crown Street/10 Sydney Street, Saint John, New Brunswick, Canada; Lyondell-Citgo Refining, LP, 12000 Lawndale, Houston, Texas; Lyondell Chemical Company, 1221 McKinney Street, Suite 700, Houston, Texas; Lyondell Petrochemical GP, Inc., 1221 McKinney Street, Houston, Texas; Motiva Enterprises, LLC, 1100 Louisiana, Suite 1000, Houston, Texas; North Atlantic Refinery, Ltd., 29 Pippy Place, St John's, Newfoundland, Canada;

Shell Oil Company, One Shell Plaza, 910 Louisiana, Houston, Texas; Sunoco, Inc. (R&M), 1801 Market Street, Philadelphia, Pennsylvania; Texaco Refining and Marketing, Inc., One Shell Plaza, 910 Louisiana, Houston, Texas; Ultramar Energy, Inc., One Valero Place, San Antonio, Texas; Ultramar Limited, 2200 McGill College, Montreal, Quebec, Canada; Unocal Corporation, 2141 Rosencrans Avenue, Suite 4000, El Segundo, California; Valero Marketing and Supply Company, One Valero Place, San Antonio, Texas; Valero Refining - Texas, L.P., 1301 Loop 197 S., Texas City, Texas; Valero Refining Company - New Jersey, 800 Billingsport Road, Paulsboro, New Jersey; Valero Refining Company – Louisiana, Hwy 105 South, Krotz Springs, Louisiana; Valero Energy Corporation, One Valero Place, San Antonio, Texas; and Vitol S.A., 1100 Louisiana, Houston, Texas (hereinafter collectively, "defendants") and, based on information and belief and investigation of counsel, alleges as follows:

I. SUMMARY OF THE CASE

1. The State of New Hampshire, by and through the Attorney General, (hereinafter the "State"), brings this action at law in order to protect and to remedy important state interests affected by widespread contamination of the waters of the State with methyl tertiary butyl ether ("MTBE"), a chemical used in some gasoline.

2. The waters of the State, whether located above or below ground, constitute limited, precious and invaluable public resources that are held in trust for the public benefit and for which the State has the authority and responsibility to protect, conserve and manage in the interest of present and future generations.

3. Defendants' use of MTBE in gasoline has created an unprecedented threat to both the surface and groundwaters of the State (hereinafter "waters of the State"),

including many public and private drinking water supplies. Unlike other gasoline constituents, MTBE contaminates and spreads in water resources quickly, and hides and resists removal and treatment, thereby presenting a serious threat to waters throughout the State. MTBE has already contaminated numerous drinking water sources in the State and threatens to contaminate many more, as a result of normal and foreseen storage, purchase and use of gasoline by its residents.

4. MTBE can cause significant adverse health effects, and, even at very low concentrations, can render drinking water foul, putrid and unfit for human consumption.

5. The defendants in this action are major oil and chemical companies that manufacture MTBE and supply gasoline containing MTBE to the State. The defendants include MTBE manufacturers and refiners and major-brand marketers of gasoline containing MTBE, which was entered and continues to be entered into the stream of the State's commerce and which has damaged and continues to damage the waters of the State.

6. In addition to producing and/or supplying MTBE or gasoline containing MTBE for importation into and sale within the State, defendants knowingly and willfully promoted, marketed and sold MTBE and gasoline and other petroleum products (hereinafter collectively, "gasoline") containing MTBE, when they knew or reasonably should have known that MTBE would be released into the environment and pollute the waters of the State in violation of New Hampshire law, would interfere with the State's interest in protecting and preserving surface and groundwaters and threaten public health and welfare and the environment, as has occurred and is continuing to occur within the State.

7. The State alleges that under New Hampshire law defendants are: strictly liable for manufacturing and supplying a defective product and failing to provide adequate warnings in connection therewith; liable for creating a public nuisance; strictly liable for directly or indirectly causing or suffering the discharge of MTBE into the waters of the State; liable for trespass upon the waters of the State; liable for negligently causing damage to the waters of the State; liable for unfair and deceptive business acts; and liable for all resulting damages, including all costs to investigate, monitor, prevent, abate, contain and remove any contamination or threatened contamination from MTBE and to restore and protect State waters. The State also alleges that certain defendants are liable for enhanced damages to reflect the aggravating circumstances caused by such defendants' wanton, malicious and oppressive conduct. Finally, the State alleges that defendants are liable for civil penalties under State environmental and consumer protection laws.

II. PLAINTIFF

8. Plaintiff is the State of New Hampshire (the "State"), as represented by and through the Attorney General of the State of New Hampshire, with principal offices at 33 Capitol Street, Concord, New Hampshire. The State bring this action as a trustee of the waters within New Hampshire and pursuant to its police power, which includes, but is not limited to, its power to prevent pollution of the surface and groundwaters of the State, to prevent nuisances and to prevent potential hazards to public health, welfare and the environment.

9. The State also has a significant property interest in the waters of the State and a quasi-sovereign interest in protecting the quality of such waters. The

contamination of waters of the State by MTBE constitutes injury to the environment and to property held in public trust by the State for which the State seeks damages in its capacity as *parens patriae*.

10. The Attorney General is expressly authorized to enforce statutes pertaining to environmental protection, control and preservation, to exercise common law powers to protect the environment, and to bring public nuisance and other actions in Superior Court in the name of the State when the activity complained of may have a substantial impact upon the environment of the State. RSA 21-M:10, II.

11. The Attorney General is expressly authorized to institute such legal or equitable action as he deems necessary to recover or obtain judgment for the costs of containment, cleanup, removal, corrective measures or civil penalties related to the discharge or spillage of oil, which includes petroleum products and their by-products of any kind, into the waters of the State. RSA 146-A:9; RSA 146-G:3. The Attorney General is also expressly authorized to bring an action under RSA 358-A:4 in the name of the State to prevent, remedy and penalize violations of the Consumer Protection Act.

III. DEFENDANTS

12. The defendants in this action are petroleum-related companies doing business in New Hampshire. The two categories of defendants are: (1) the refiners and major-brand marketers of gasoline containing MTBE; and (2) the manufacturers and promoters of MTBE that contaminates and threatens the waters of the State.

A. Refiner/Marketer Defendants

13. The following defendants, at all times relevant to this action, refined, marketed and/or otherwise supplied (directly or indirectly) gasoline containing MTBE

that each such defendant knew or should have known would be delivered into the State (or areas affecting the waters of the State):

(a) Amerada Hess Corporation ("Hess") is a Delaware corporation with its principal place of business at 1185 Avenue of the Americas, New York, New York, doing business and registered to transact business in New Hampshire.

(b) BP Products North America, Inc. ("BP") is a Maryland corporation with its principal place of business in 200 East Randolph Drive, Chicago, Illinois, doing business in and registered to transact business in New Hampshire. On information and belief, the State alleges that BP is the successor corporation to Amoco Oil Company and BP Exploration and Oil Inc..

(c) ChevronTexaco Corporation ("ChevronTexaco") is a Delaware corporation with its principal place of business at 6001 Bollinger Road, San Ramon, California, doing business in New Hampshire. On information and belief, the State alleges that ChevronTexaco was formed as a result of a merger in 2001 of Chevron Corporation and Texaco, Inc. On information and belief, the State further alleges that ChevronTexaco is the successor corporation to Chevron Corporation and Texaco, Inc. On information and belief, the State further alleges that ChevronTexaco owns and/or controls defendant Chevron U.S.A., Inc.

(d) Chevron U.S.A., Inc., individually and formerly known as Gulf Oil

Corporation and doing business as Chevron Products Company and Chevron Chemical Company, ("Chevron U.S.A.") is a Pennsylvania corporation with its principal place of business at 6001 Bollinger Road, San Ramon, California, doing business and registered to transact business in New Hampshire. The term "Chevron" as used in this First Amended Complaint refers to ChevronTexaco and/or Chevron U.S.A.

(e) CITGO Petroleum Corporation ("CITGO Petroleum") is a Delaware corporation with its principal place of business at 6100 South Yale Avenue, Tulsa, Oklahoma, doing business and registered to transact business in New Hampshire.

(f) CITGO Refining and Chemical Company, LP ("CITGO Refining") is a Oklahoma limited partnership with its principal place of business at 6100 South Yale Avenue, Tulsa, Oklahoma, doing business in New Hampshire. The term "CITGO" as used in this First Amended Complaint refers to CITGO Petroleum and/or CITGO Refining.

(g) ConocoPhillips Company, individually and formerly known as Phillips Petroleum Company, ("ConocoPhillips") is a Delaware corporation with its principal place of business at 600 North Dairy Ashford, Houston, Texas, doing business and registered to transact business in New Hampshire. The State is informed and believed that ConocoPhillips is the successor corporation to Tosco

Corporation.

(h) El Paso Merchant Energy-Petroleum Company, individually and formerly known as Coastal Refining and Marketing Inc. and Coastal States Trading Inc., ("El Paso") is a Delaware corporation with its principal place of business at 1001 Louisiana Street, Houston, Texas, doing business and registered to transact business in New Hampshire. On information and belief, the State alleges that El Paso is the successor corporation to Coastal Refining and Marketing, Inc.

(i) ExxonMobil Corporation, individually and formerly known as Exxon Corporation and doing business as ExxonMobil Refining and Supply Company, Exxon Chemical U.S.A., and ExxonMobil Chemical Corporation, ("ExxonMobil Corp.") is a New Jersey corporation with its principal place of business at 5959 Las Colinas Boulevard, Irving, Texas, doing business and registered to transact business in New Hampshire. On information and belief, the State alleges that ExxonMobil Corp. was formed as a result of a merger in 1999 of Mobil Corporation and Exxon Corporation. On information and belief, the State alleges that ExxonMobil Corp. is the successor corporation to Exxon Corporation.

(j) ExxonMobil Oil Corporation, individually and formerly known as Mobil Oil Corporation, ("ExxonMobil Oil") is a New York corporation with its principal place of business at 5959 Las Colinas

Boulevard, Irving, Texas, doing business and registered to transact business in New Hampshire. The term "ExxonMobil" as used in this First Amended Complaint refers to ExxonMobil Corp. and/or ExxonMobil Oil.

(k) Flint Hills Resources, LP, individually and formerly known as Koch Petroleum Group, LP, is a Delaware limited partnership with its principal place of business at 4111 E. 37th Street North, Wichita, Kansas, doing business in New Hampshire.

(l) Giant Yorktown, Inc. ("Giant") is a Delaware corporation with its principal place of business at 23733 North Scottsdale Road, Scottsdale, Arizona, doing business and registered to transact business in New Hampshire.

(m) Gulf Oil Limited Partnership ("Gulf") is a Delaware limited partnership with its principal place of business at 90 Everett Avenue, Chelsea, Massachusetts, doing business and registered to transact business in New Hampshire.

(n) Irving Oil Corporation ("Irving Oil Corp.") is a Maine corporation with its principal place of business at 190 Commerce Way, Portsmouth, New Hampshire, doing business and registered to transact business in New Hampshire.

(o) Irving Oil Limited ("Irving Oil") is a Canadian corporation with its principal place of business at 210 Crown Street/10 Sydney Street, Saint John, New Brunswick, Canada, doing business in New

Hampshire. The term "Irving" as used in this First Amended Complaint refers to Irving Oil Corp. and/or Irving Oil.

(p) Lyondell-Citgo Refining, LP ("Lyondell-Citgo") is a Delaware limited partnership with its principal place of business at 12000 Lawndale, Houston, Texas, doing business in New Hampshire.

(q) Motiva Enterprises, LLC, individually and formerly known as Star Enterprises LLC, ("Motiva") is a Delaware limited liability company with its principal place of business at 1100 Louisiana, Suite 1000, Houston, Texas, doing business and registered to transact business in New Hampshire. On information and belief, the State alleges that Motiva is a successor in interest to certain entities related to defendant Shell Oil Company and defendant Texaco Refining and Marketing, Inc., and is owned and/or controlled by defendant Shell Oil Company.

(r) North Atlantic Refinery, Ltd. ("North Atlantic") is a Canadian corporation with its principal place of business at 29 Pippy Place St John's, Newfoundland, Canada, doing business in New Hampshire. On information and belief, the State alleges that North Atlantic is owned and/or controlled by defendant Vitol S.A.

(s) Shell Oil Company ("Shell Oil") is a Delaware corporation with its principal place of business at One Shell Plaza, 910 Louisiana, Houston, Texas, doing business and registered to transact business in New Hampshire. The term "Shell" as used herein refers to

Motiva and/or Shell Oil.

(t) Sunoco, Inc. (R&M) ("Sunoco") is a Pennsylvania corporation with its principal place of business at 1801 Market Street, Philadelphia, Pennsylvania, doing business and registered to transact business in New Hampshire.

(u) Texaco Refining & Marketing, Inc., now also known as TMR Company, ("Texaco") is a Delaware corporation with its principal place of business at One Shell Plaza, 910 Louisiana, Houston, Texas, doing business and registered to transact business in New Hampshire. On information and belief, the State alleges that Texaco is owned and/or controlled by defendant Shell Oil.

(v) Ultramar Energy, Inc. ("Ultramar Energy") is a Delaware corporation with its principal place of business at One Valero Place, San Antonio, Texas, doing business and registered to transact business in New Hampshire.

(w) Ultramar Limited ("Ultramar") is a Canadian corporation with its principal place of business at 2200 McGill College, Montreal, Quebec, Canada, doing business in New Hampshire.

(x) Unocal Corporation, individually and formerly known as Union Oil Company of California, ("Unocal") is a Delaware corporation with its principal place of business at 2141 Rosencrans Avenue, Suite 4000, El Segundo, California, doing business and registered to transact business in New Hampshire.

(y) Valero Marketing and Supply Company ("Valero Marketing") is a Delaware corporation with its principal place of business at One Valero Place, San Antonio, Texas, doing business and registered to transact business in New Hampshire.

(z) Valero Refining - Texas, L.P. ("Valero Texas"), a wholly-owned subsidiary of Valero Energy, is a Texas limited partnership with its principal place of business at 1301 Loop 197 S., Texas City, Texas, doing business in New Hampshire.

(aa) Valero Refining Company - New Jersey ("Valero New Jersey") is a Delaware corporation with its principal place of business at 800 Billingsport Road, Paulsboro, New Jersey, doing business in New Hampshire.

(bb) Valero Refining Company – Louisiana ("Valero Louisiana") is a Delaware corporation with its principal place of business at Hwy 105 South, Krotz Springs, Louisiana, doing business in New Hampshire.

(cc) Valero Energy Corporation ("Valero Energy") is a Delaware corporation with its principal place of business at One Valero Place, San Antonio, Texas, doing business in New Hampshire. On information and belief, the State alleges that Valero merged with Ultramar Diamond Shamrock Corporation in 2001, and that, as a consequence of such merger, Valero owns and/or controls certain entities related to Ultramar Diamond Shamrock Corporation,

including defendants Ultramar Energy and Ultramar. On information and belief, the State further alleges that Valero Energy owns and/or controls Valero Marketing, Valero Texas, Valero New Jersey and Valero Louisiana. The term "Valero" as used in this First Amended Complaint refers to Valero Energy, Valero Marketing, Valero Texas, Valero New Jersey and Valero Louisiana, Ultramar and/or Ultramar Energy.

(dd) Vitol S.A. ("Vitol") is a Swiss corporation with its principal place of business at 1100 Louisiana, Houston, Texas, doing business and registered to transact business in New Hampshire. On information and belief, the State alleges that Vitol owns and/or controls defendant North Atlantic.

14. The defendants identified in paragraphs 13(a) through 13(dd) above will be collectively referred to as the "refiner/marketer defendants." The refiner/marketer defendants, and each of them, among other things: (a) designed, manufactured, formulated, refined, set specifications for, exchanged, promoted, marketed and/or otherwise supplied (directly or indirectly) gasoline containing MTBE that was delivered into the State (or areas affecting the waters of the State), such that releases of MTBE contaminate and threaten the waters of the State; (b) were legally responsible for and committed each of the multiple tortious and ongoing wrongful acts alleged in this First Amended Complaint; (c) participated in one or more enterprises to promote MTBE and/or gasoline containing MTBE, despite the availability of reasonable alternatives and their actual or constructive knowledge that the pollution alleged herein would be the

inevitable result of their conduct; and (d) in doing the tortious and wrongful acts alleged in this First Amended Complaint, acted in the capacity of joint-venturer, partner, agent, principal, successor-in-interest, surviving corporation, fraudulent transferee, fraudulent transferor, controller, alter-ego, co-conspirator, licensee, licensor, patent holder and/or indemnitor of each of the named defendants.

B. Manufacturer Defendants

15. Lyondell Chemical Company, individually and formerly known as ARCO Chemical Company ("Lyondell Chemical"), is a Delaware corporation with its principal place of business at 1221 McKinney Street, Houston, Texas, doing business and registered to transact business in New Hampshire. On information and belief, the State alleges that Lyondell is a successor in interest to ARCO Chemical Company, which Lyondell acquired in 1998.

16. Equistar Chemicals, LP ("Equistar") is a Delaware limited partnership with its principal place of business at 1221 McKinney Street, Houston, Texas, doing business and registered to transact business in New Hampshire

17. Lyondell Petrochemical GP, Inc., individually and as a general partner of Equistar ("Lyondell Petrochemical"), is a Delaware limited partnership with its principal place of business at 1221 McKinney Street, Houston, Texas, doing business in New Hampshire. The term "Lyondell" as used in this First Amended Complaint refers to Lyondell Chemical, Equistar, and Lyondell Petrochemical.

18. Defendants Hess, BP, Chevron U.S.A., CITGO, ConocoPhillips, ExxonMobil, Motiva, Shell Oil, Sunoco, and Valero also manufacture MTBE and/or TBA for use in gasoline.

19. The defendants identified in paragraphs 15 through 18, and each of them, manufactured, promoted and sold MTBE to gasoline refiners with actual or constructive knowledge that: (a) the refiners would blend such MTBE into gasoline; and (b) such gasoline would, in turn, be delivered into the State (or areas affecting the waters of the State).

20. The defendants identified in paragraphs 15 through 18 will be referred to as the "manufacturer defendants." The manufacturer defendants, among other things: (a) designed, manufactured, formulated, promoted, marketed, distributed, exchanged and/or sold MTBE that contaminates and threatens the waters of the State; (b) are legally responsible for and committed each of the multiple tortious and ongoing wrongful acts alleged in this First Amended Complaint; (c) participated in one or more enterprises to promote MTBE and/or gasoline containing MTBE, despite the availability of reasonable alternatives and its actual or constructive knowledge that the pollution alleged herein would be the inevitable result of its conduct; and (d) in doing the tortious and wrongful acts alleged in this First Amended Complaint, acted in the capacity of joint-venturer, partner, agent, principal, successor-in-interest, surviving corporation, fraudulent transferee, fraudulent transferor, controller, alter-ego, co-conspirator, licensee, licensor, patent holder and/or indemnitor of each of the named defendants.

21. The refiner/marketer defendants and manufacturer defendants are referred to collectively herein as "defendants."

22. Among other things, the defendants knew, or reasonably should have known, that: (a) the gasoline distribution and retail system throughout the State contained leaking gasoline storage and delivery systems; (b) MTBE is more readily released from

gasoline storage and delivery systems than the constituents of conventional gasoline; and (c) releases of MTBE into the environment would be an inevitable consequence of placing MTBE into the stream of commerce in the absence of precautionary measures to prevent or mitigate such releases – measures that the defendants failed to take.

23. The defendants also knew, or reasonably should have known, that, unlike the constituents of conventional gasoline, MTBE, when released into the environment, would move great distances, mix easily with groundwater, resist biodegradation, render drinking water unsafe and/or non-potable, and require significant expenses to find and remove from public and private drinking water supplies.

24. The defendants further knew, or reasonably should have known, that various consumer and commercial activities, such as use of snowmobiles, motorized watercraft and lawnmowers and operation of junkyards and vehicle maintenance and repair facilities, would result in releases of MTBE into waters of the State.

25. Despite knowing the devastating risk of drinking water contamination posed by MTBE, and despite the availability of reasonable alternatives, the defendants failed to warn customers, retailers, regulators or public officials, including the State of New Hampshire, and failed to take any other precautionary measures to prevent or mitigate such contamination. Instead, defendants promoted MTBE, and gasoline containing MTBE, as environmentally sound products appropriate for widespread use. Moreover, certain defendants engaged in separate and joint activities to suppress, conceal and/or discredit studies and other information regarding the hazards of MTBE. Defendants' wrongful conduct, among other things, encouraged the State to participate in the federal reformulated gasoline program without a full understanding of the risks to the

State's water resources, which resulted in: (a) a dramatic increase in the use and presence of gasoline containing MTBE in the State; (b) the consequent injuries to the waters of the State; and (c) the substantial damages incurred by the State in response thereto.

26. To the extent any act or omission of any of the defendants is alleged in this First Amended Complaint, the officers, directors, agents, employees or representatives of each such defendant committed or authorized each such act or omission, or failed to adequately supervise or properly control or direct their employees while engaged in the management, direction, operation or control of the affairs of such defendants, and did so while acting within the scope of their duties, employment or agency.

IV. JURISDICTION AND VENUE

27. Jurisdiction is vested in the New Hampshire Superior Court, where this action was originally filed, pursuant to: (a) RSA 491:7, which grants that court subject matter jurisdiction over all civil actions according to the course of the common law, except certain actions not applicable herein; (b) RSA 491:14 which grants that court subject matter jurisdiction over suits in equity; (c) RSA 491:22 which grants that court subject matter jurisdiction over claims for declaratory relief; (d) RSA 21-M:10, which authorizes that court to hear public nuisance and other actions brought by the Attorney General in the name of the State; (e) RSA 146-A:9 and 146-G:3, which authorize that court to hear legal and/or equitable actions instituted by the Attorney General to recover or obtain judgment for the costs of containment, cleanup, removal, corrective measures and/or civil penalties; and (f) RSA 358-A:4, which authorizes the Attorney General to

bring an action in the name of the State in New Hampshire Superior Court for temporary or permanent injunction, restitution and civil penalties.

28. Venue is proper in Merrimack County, where this action was originally filed, pursuant to RSA 507:9. This is a transitory action brought by the State in the county in which the capital is located.

29. This action was removed to the United States District Court for the District of New Hampshire by certain defendants, and transferred to this Court pursuant to 28 U.S.C. § 1407 over the objection of the State. By filing this First Amended Complaint, the State preserves all objections to federal court jurisdiction over this action, including any and all objections based on the State's sovereign immunity, and neither waives any such objections nor in any way consents to the jurisdiction of this or any other federal Court.

V. FACTUAL ALLEGATIONS

A. The Contaminant MTBE.

30. MTBE is a chemical compound produced from methanol and isobutylene. It is used by some refiners in some gasoline. As used in this First Amended Complaint, MTBE consists not only of methyl tertiary butyl ether, but also the degradation byproducts of and contaminants in commercial grade MTBE, including but not limited to tertiary butyl alcohol.

31. One way that MTBE contaminates the environment is through releases, leaks, overfills, and spills from gasoline delivery facilities, including, but not limited to, gasoline stations, gasoline storage, transfer, delivery, and dispensing systems ("gasoline delivery systems").

32. Another way that MTBE contaminates the environment is through releases, leaks, overfills, and spills of gasoline associated with or incident to certain consumer activities, including but not limited to the use of lawnmowers, snowmobiles, and motorized watercraft, and certain commercial activities, including but not limited to the operation of junkyards and vehicle repair and maintenance facilities.

33. As a result of its physical characteristics, MTBE finds unique pathways for release into the environment from gasoline delivery systems and is more readily released from such systems than conventional gasoline components.

34. Once released to the environment, MTBE's unique characteristics cause extensive environmental contamination and a corresponding threat to the public health and welfare beyond that caused by gasoline that does not contain MTBE. In particular, the fate and transport of MTBE in the subsurface differs significantly from that of gasoline constituents that have historically been of environmental and/or toxicological concern, specifically the "BTEX compounds" (benzene, toluene, ethylbenzene, and xylene).

35. When released into the environment, MTBE separates from other gasoline constituents in the presence of moisture. In contrast to the BTEX compounds, MTBE has a strong affinity for water, is easily dissolved and does not readily adhere to soil particles, making it more mobile and able to penetrate great distances from the source of the release.

36. In groundwater, MTBE moves freely at approximately the rate of the water's movement, unlike BTEX compounds, which tend to adhere to soil and float on

the surface of water. This makes it more difficult to find and more difficult to remove or treat than BTEX compounds.

37. MTBE is also more persistent than BTEX compounds because it does not readily biodegrade in groundwater. As a result, MTBE is relatively more difficult and expensive to remove from groundwater.

38. In sum, when MTBE is released into the environment, it migrates farther and faster through soil and groundwater, penetrates deeply into aquifers, resists biodegradation and results in persistent contamination that is more costly to address. As a result of these properties, MTBE has contaminated, and continues to contaminate and threaten, the groundwaters of the State.

39. MTBE also contaminates surface waters through releases, leaks, overfills and spills of gasoline associated with or incident to certain consumer and commercial activities, including but not limited to the use of snowmobiles and motorized watercraft.

40. Not all of the MTBE contamination of water resources in the State can be traced to a specific source.

41. Contamination of the State's waters with MTBE has damaged and continues to damage and threaten these precious resources, and threatens the health, safety and welfare of the citizens of the State.

42. Federal and other studies link MTBE to a variety of adverse health effects.

43. The State has established a health-based Primary Maximum Contaminant Level ("MCL") for MTBE of 13 parts per billion ("ppb"). This is one of the most stringent standards in the nation.

44. The establishment of the health-based MCL for MTBE triggers certain state regulatory requirements if that level is exceeded in drinking water supplies. Such state requirements include, but are not limited to, required investigatory and remedial action to protect public health and the environment and remedial actions by public water suppliers.

45. In addition to the health and environmental risks posed by MTBE in drinking water supplies, MTBE can render water supplies undrinkable by changing the taste and odor of water in such a manner that it becomes a foul smelling liquid with a turpentine odor and a chemical taste unfit for human consumption. Many individuals can smell and/or taste MTBE in drinking water at levels well below the health-based MCL of 13 ppb.

B. History of MTBE in the State.

46. Oil companies began blending MTBE into gasoline in the late 1970's. Initially used as an octane enhancer, MTBE was used throughout the 1980's at low concentrations in some gasoline by some refiners, primarily in high-octane grades.

47. In or about the late 1970's, the U.S. Environmental Protection Agency ("EPA") registered MTBE as a fuel additive that does not cause or contribute to the failure of any emission control device or system, pursuant to section 211 of the Clean Air Act, 42 U.S.C. § 7545. Such registration did not and does not constitute endorsement, certification, or approval of MTBE as a fuel additive by any agency of the United States.

48. Refiners, including defendants, significantly increased their use of MTBE in gasoline after 1990. In 1990, Congress established the Reformulated Gasoline Program ("RFG Program") in section 211(k) of the Clean Air Act , 42 U.S.C. § 7545(k).

The RFG Program requires the use of reformulated gasoline in certain metropolitan areas with the most severe summertime ozone ("smog") levels, none of which is located in New Hampshire. The RFG Program also allows states with other, less serious, ozone non-attainment areas to opt into the program as a means to address their nonattainment.

49. Unlike conventional gasoline, reformulated gasoline under the RFG Program must contain a specified chemical oxygen content. The RFG Program requires that reformulated gasoline sold in areas subject to the RFG Program consist of approximately 2.0% oxygen by weight.

50. The RFG Program is both fuel neutral and oxygenate neutral, in that it does not mandate the use of MTBE or any particular oxygenate. Rather, it leaves the decision on how to meet the oxygen requirements to individual refiners, including defendants. Alternative oxygenates other than MTBE have, at all relevant times, been available to defendants.

51. New Hampshire sought to "opt in" four of its counties to the federal RFG Program as a means to address air quality problems in those counties. In particular, on October 22, 1991, the State submitted an application to EPA seeking to opt in to the RFG Program the four southern counties of Merrimack, Hillsborough, Rockingham and Strafford, effective January 1, 1995. EPA approved the State's application on December 23, 1991.

52. At the time that New Hampshire opted into the federal RFG program, it had no control over which oxygenate would be added to gasoline supplied to New Hampshire.

53. At the time that New Hampshire chose to opt into the RFG Program, the defendants had not provided the State with all of the information available to them concerning the unique characteristics and hazards associated with use of MTBE as an oxygenate in gasoline.

54. Defendants made MTBE their oxygenate of choice for reformulated gasoline manufactured for and supplied to New Hampshire. From the date of approval of New Hampshire's opt-in of the four southern counties until the present, defendants' gasoline sold in New Hampshire has contained much greater concentrations of MTBE than before the opt-in as a result of defendants' choice to meet the RFG requirements through use of MTBE.

55. Gasoline containing low levels of MTBE was sold at various times, in various quantities and in various locations in New Hampshire before 1995. Reformulated gasoline containing significantly higher quantities of MTBE has been sold on a virtually universal basis in the four southern counties of Merrimack, Hillsborough, Rockingham and Strafford since 1995. Gasoline containing MTBE at various concentrations also has been and is sold in other locations throughout the State.

56. On May 30, 2001, the State submitted a petition to EPA requesting to withdraw, or "opt out" of the RFG Program on an expedited basis, citing the significant contamination threat that MTBE poses to New Hampshire's surface and groundwater. The State's petition is still pending before EPA. The State has also adopted rules eliminating any requirement for a minimum oxygenate content in fuel supplied to the State.

C. State Regulation of MTBE

57. The State regulates MTBE as an "oil" under oil discharge statutes, including RSA 146-A and RSA 146-C, as well as under other statutes and rules designed to protect the State's waters.

58. MTBE contamination is associated with all transportation, storage and use of gasoline containing MTBE.

59. The State provides funding for investigation, remediation, individual third-party damages and other activities related to MTBE contamination in the State through State-administered petroleum reimbursement funds, the Oil Discharge Cleanup Fund under RSA 146-A, and through general funding.

60. The State has incurred and will continue to incur significant costs and expenses in addressing releases of MTBE into the environment and into waters of the State.

D. Defendants' Promotion of MTBE and TBA.

61. Defendants, all of whom have promoted the use of gasoline containing MTBE for its purported environmental benefits, knew or should have known of the grave harm and threat to public health, safety and welfare and the environment represented by the proliferating use of MTBE, including (among other things): widespread pollution of groundwater with MTBE, contamination of public and private drinking water supplies by this harmful and noxious compound, the rendering of drinking water supplies unfit and unusable for consumption, and increased costs to the State in addressing MTBE contamination of drinking water supplies and other waters of the State.

62. Despite knowing that pollution by MTBE was an inevitable consequence of their conduct, and despite the availability of reasonable alternatives (including, but not limited to, adequate warnings), defendants failed to warn customers, retailers, regulators or public officials, including the State, regarding the hazards of MTBE. As production and sales of MTBE and gasoline containing MTBE increased, defendants failed to take any reasonable, appropriate, and special precautions to ensure that gasoline containing MTBE was stored safely. Despite knowing the risk of harm posed by MTBE, defendants also failed to warn purchasers, the public, regulators, and/or the State that without such precautions, increasing amounts of MTBE would be released into the environment and cause, among other significant adverse effects, long-term groundwater contamination, contamination of water supplies, and threats to public health, safety and welfare.

63. At all relevant times, the defendants have represented to purchasers of MTBE and/or gasoline containing MTBE, as well as to the public and government agencies, that such products were environmentally sound and appropriate for widespread production, distribution, sale and use. Indeed, defendants represented that gasoline containing MTBE could be handled in the same fashion as conventional gasoline, and required no special measures to protect against, respond to, or mitigate suspected releases to the subsurface.

64. Defendants knew, or reasonably should have known, that, throughout the State, the gasoline distribution and retail system contained leaking gasoline delivery systems, and that the nature of such systems involved frequent spillage, leaks and overfills that allowed gasoline to enter soils and waters of the State.

65. Defendants knew, or reasonably should have known, that: (a) MTBE would escape from gasoline delivery systems more readily than the constituents of conventional gasoline; (b) gasoline storage facilities in the State were not designed to prevent any and all leakage of gasoline containing MTBE; and (c) the operators and users of these facilities either (i) were unaware of the special hazards posed by MTBE and the steps necessary to eliminate or mitigate those hazards or (ii) would fail to take such steps.

66. Before introducing MTBE into gasoline delivery systems, the defendants knew, or reasonably should have known, among other things, that, once released into the environment, MTBE would mix easily with groundwater, move great distances, resist biodegradation, render drinking water unsafe and/or non-potable, cause significant expenses to remove from public and private drinking water supplies and other waters of the State, and otherwise damage and threaten public health, safety and welfare and the environment.

67. Defendants further exacerbated the situation by continued unreasonable and negligent acts, including providing gasoline containing MTBE to gasoline stations without either providing appropriate warnings or taking other precautions adequate to prevent or mitigate releases of MTBE to the subsurface. Defendants did so despite the fact that they knew, or reasonably should have known, that releases of MTBE were substantially certain to occur, because a substantial percentage of those gasoline stations would and, in fact, did: (a) place the gasoline into inadequate and leaking gasoline delivery systems; (b) suffer the routine spillage of appreciable quantities of gasoline containing MTBE in connection with the filling of storage tanks and the use of gasoline dispensing systems; (c) fail to take adequate measures to monitor, detect, and respond to

releases of MTBE to soil, surface water and/or groundwater; and (d) fail to take adequate precautions to investigate, contain and clean up releases of MTBE.

68. The widespread problems of gasoline spillage and leaking gasoline delivery systems were well known to the defendants prior to the introduction of MTBE into the State. At least as early as the mid-1960's, defendants knew, or reasonably should have known, that gasoline delivery systems generally suffer significant and widespread leaks and failures, and release gasoline products into the environment, including into groundwater.

69. Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, El Paso, ExxonMobil, Gulf, Irving, Shell, Sunoco, Texaco, Unocal, Valero, and Vitol not only knew or reasonably should have known about the widespread problems of leaking gasoline delivery systems generally, but, at all times relevant to this action, had first-hand knowledge and experience regarding leaking gasoline delivery systems and releases of MTBE to groundwater therefrom. These defendants obtained such first-hand knowledge and experience because each of them owned and operated individual gasoline stations with leaking gasoline delivery systems, including gasoline stations in the State, and/or exercised control over such gasoline stations through a variety of means, including but not limited to written agreements, inspection rights, prescribing certain procedures and operating practices, prescribing specifications for products, conditions on sale of branded goods, agreements obligating such stations to acquire, store and sell gasoline containing MTBE, and training. Despite their first-hand knowledge that contamination of waters of the State with MTBE was the inevitable result of their conduct, these defendants continued to refine, market, promote, and supply gasoline containing MTBE.

70. The manufacturers, refiners and suppliers of MTBE and gasoline containing MTBE had a duty and breached their duty to evaluate and test MTBE adequately and thoroughly to determine its environmental fate and transport characteristics and potential human health and environmental impacts before they produced and sold MTBE and gasoline containing MTBE. They also had a duty and breached their duty to minimize the environmental harm caused by MTBE and/or gasoline containing MTBE. Furthermore, they had a duty and breached their duty to take precautions, including warnings, necessary to ensure that gasoline containing MTBE was properly stored and that all necessary measures to promptly detect, contain, abate and respond to spills and leaks were instituted. Nonetheless, defendants, and each of them, failed to adequately evaluate, test, store, warn, mitigate or otherwise ensure that gasoline containing MTBE would not contaminate waters of the State. As a direct, indirect and proximate result of these failures, MTBE was released, and continues to be released, into the environment, causing and threatening to cause widespread contamination of the waters of the State.

71. In addition to the negligent and/or reckless conduct alleged herein, Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero also intentionally failed to warn downstream handlers, the public and government officials, including the State, as to the threat caused by MTBE and, by agreement and tacit understanding among them, each knowingly pursued or took an active part in a common plan, design and conspiracy to market and promote a product they knew to be dangerous to the environment. In particular, the defendants identified in this paragraph formed and participated in joint task-forces,

committees and trade associations for the specific purpose of suppressing, concealing and minimizing information regarding MTBE hazards. These defendants also engaged in separate and joint activity to mislead government agencies, including the State, as well as the public regarding these same dangers. Such defendants' common plan, design and conspiracy, and the acts taken in furtherance of such common plan, design and conspiracy, are a direct, indirect and proximate cause of the MTBE contamination of the waters of the State.

E. Impact of MTBE on Waters of the State

72. MTBE has been found in drinking water supplies throughout the State in varying amounts and at varying times. As of 2002, MTBE was present in 13.2% of public water supplies that were tested statewide, more than 23% of public water supplies that were tested in Rockingham County, more than 33% of public water supplies tested in Strafford County and more than 18% of public water supplies tested in Hillsborough and Merrimack Counties.

73. As of 2003, preliminary results from a study of Rockingham County public water supplies indicate that MTBE is present at some level in more than 41% of the public drinking water supplies that were tested.

74. Based upon studies conducted by other states, the State estimates that MTBE is present at some level in roughly 40,000 private drinking water wells. The State has also estimated from other states' studies that MTBE is present at levels exceeding the health-based MCL of 13 ppb in roughly 3,100 of the 40,000 private drinking water wells estimated to be impacted by MTBE.

75. A 2003 State study of Paugus Bay in Lake Winnepesaukee indicates that MTBE is also present in surface waters that are used as drinking water sources by residents of the State.

76. At all times relevant to this action:

(a) The manufacturer defendants manufactured, promoted and supplied MTBE to refiners, including certain refiner/marketer defendants, for use as a component of gasoline.

(b) The refiner/marketer defendants, and each of them, refined, marketed and/or otherwise supplied (directly or indirectly) gasoline containing MTBE that was delivered to commercial and consumer users such as retail gasoline stations and other gasoline delivery systems in the State (and areas affecting waters of the State). Such supplies and deliveries of gasoline containing MTBE to such users in the State occurred over time and continue to occur.

(c) Gasoline containing MTBE was released and continues to be released to the subsurface from retail gasoline facilities, from other commercial and consumer uses, and from other sources at locations throughout the State and/or in areas affecting waters of the State. Such releases of gasoline containing MTBE have occurred over time and are still occurring, all in varying amounts at different locations.

(d) MTBE, which takes time to migrate from release points through the subsurface to locations where it may be detected in

groundwater, has migrated from dispersed release points at or near the surface at retail gasoline facilities and other sources and facilities within or near the State's boundaries, causing and threatening to cause pollution, contamination, and substantial and continuing damage to the waters of the State, including drinking water, causing damage to the State at such times and in amounts within the jurisdictional limits of this Court.

(e) Gasoline containing MTBE was released and continues to be released to surface waters of the State through normal consumer usage, including use of motorized watercraft, snowmobiles and other sources at dispersed locations throughout the State. Such releases of gasoline containing MTBE have occurred over time and are still occurring, all in varying amounts at different locations, causing and threatening to cause contamination and substantial and continuing damage to the waters of the State, including drinking water, causing damage to the State at such times and in amounts within the jurisdictional limits of this Court.

77. At all times relevant to this action, the refiner/marketer defendants together controlled virtually the entire market for gasoline containing MTBE in New Hampshire.

78. MTBE is a fungible product. Once released into the environment, MTBE lacks characteristics or a chemical signature that would enable identification of the refinery or company that manufactured the product. Even when a source of a plume of

MTBE – such as a leaking underground storage tank – is identified, the identity of the manufacturer of the MTBE and refiner of the offending gasoline frequently cannot be determined due to the refiner/marketer defendants' practice of trading, bartering, or otherwise exchanging their product with each other, as well as the chemical characteristics of MTBE.

79. Defendants, and each of them, are jointly and severally liable for the costs and damages alleged herein.

80. The injuries to the waters of the State caused and/or threatened by defendants' conduct as alleged herein constitute an unreasonable interference with natural resources that the State holds in trust for the benefit of the public. Such injuries also constitute damages to limited, precious and invaluable public resources in which the State has a significant property and quasi-sovereign interest. The State's unique interest in protecting the quality of its Waters constitutes a reason personal to the State for seeking damages for restoration of such waters.

COUNT I

(Strict Product Liability Based On Defective Design Against All Defendants)

81. The State realleges paragraphs 1 through 80 above, and by this reference incorporates them as though set forth in full.

82. The manufacturer defendants designed, manufactured, formulated, promoted, marketed, distributed, exchanged and/or sold MTBE to refiners, including certain refiner/marketer defendants, for use as a component of gasoline.

83. The refiner/marketer defendants, and each of them, designed, manufactured, formulated, refined, set specifications for, exchanged, promoted, marketed

and/or otherwise supplied (directly or indirectly) gasoline containing MTBE that was delivered into the State (or areas affecting the waters of the State).

84. Defendants, and each of them, represented, asserted, claimed and warranted that gasoline containing MTBE could be used in the same manner as gasoline not containing MTBE, and/or otherwise did not require any different or special handling or precautions.

85. Defendants, and each of them, knew or reasonably should have known that MTBE and/or gasoline containing MTBE were to be purchased and used without inspection for defects.

86. MTBE and/or gasoline containing MTBE are defective and unreasonably dangerous products because, among other things:

(a) MTBE escapes more readily from gasoline delivery systems than the constituents of conventional gasoline.

(b) MTBE causes extensive groundwater contamination, as well as surface water contamination, when used in its foreseeable and intended manner.

(c) Even at extremely low levels, MTBE renders drinking water putrid, foul, and unfit for purveying as drinking water to the public.

(d) MTBE poses significant threats to the public health and welfare and the environment.

(e) Defendants failed to conduct reasonable, appropriate or adequate scientific studies to evaluate the environmental fate and transport and potential human health effects of MTBE.

(f) At all times relevant to this action, feasible alternatives to MTBE that would have eliminated the unreasonable danger posed by gasoline containing MTBE, without excessive costs or loss of product efficiency, were available to defendants.

(g) Commercial grade MTBE is defectively manufactured when it contains and/or degrades into unnecessary but environmental harmful impurities such as tertiary butyl alcohol.

87. At all times relevant to this action, MTBE and/or gasoline containing MTBE were dangerous to an extent beyond that which would be contemplated by the ordinary consumer, and/or the risk of harm to public health and welfare and the environment posed by MTBE and/or gasoline containing MTBE outweighed the cost to defendants of reducing or eliminating such risk.

88. At all time relevant to this action, MTBE and gasoline containing MTBE were used in a manner in which they were foreseeably intended to be used and without substantial change in their condition, and as a proximate result of the defects previously described, MTBE proximately caused the State to sustain the injuries and damages set forth in this First Amended Complaint.

89. As a direct and proximate result of defendants' acts and omissions as alleged herein, the State has incurred, is incurring, and will continue to incur, investigation, remediation, cleanup, restoration, removal, treatment and monitoring costs and expenses related to contamination of the waters of the State with MTBE, in an amount within the jurisdictional limits of this Court, for which defendants are strictly, jointly and severally liable.

90. As a further direct and proximate result of the acts and omissions of the defendants alleged in this First Amended Complaint, the State has sustained and will sustain other substantial expenses and damages, in an amount within the jurisdictional limits of this Court, for which defendants are strictly, jointly and severally liable.

91. The injuries to the waters of the State caused and/or threatened by defendants' acts and omissions as alleged herein are indivisible.

92. Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero knew or reasonably should have known that it was substantially certain that their alleged acts and omissions described above would threaten public health and cause extensive contamination of the waters of the State, public and private drinking water supplies, and property damage. Nonetheless, the defendants identified in this paragraph intentionally failed to warn downstream handlers, the public and government officials, including the State, as to the threat caused by MTBE, and engaged in separate and joint activities to suppress, conceal and/or minimize information regarding MTBE hazards in order to mislead government agencies, including the State, and the public regarding such hazards. These defendants committed each of the above-described acts and omissions knowingly, willfully, and with oppression, fraud, and/or malice and with conscious disregard of the health and safety of others, and of the State's interest in protecting its natural resources.

93. The conduct alleged herein was performed to promote sales of MTBE and/or gasoline containing MTBE in conscious disregard of the known risks of injury to health, property and the environment. The defendants identified in the preceding paragraph acted with willful and conscious disregard of the probable dangerous

consequences of that conduct and its foreseeable impact upon the citizens and natural resources of the State. Therefore, the State requests an award of enhanced damages against these defendants that fairly reflects the aggravating circumstances alleged herein. After the completion of additional investigation and discovery, the State may seek leave of court to amend this First Amended Complaint to allege a claim for enhanced damages against additional defendants if warranted by the facts.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

COUNT II

(Strict Product Liability Based On Failure to Warn Against All Defendants)

94. The State realleges paragraphs 1 through 93 above, and by this reference incorporates them as though set forth in full.

95. The manufacturer defendants designed, manufactured, formulated, promoted, marketed, distributed, exchanged and/or sold MTBE to refiners, including certain refiner/marketer defendants, for use as a component of gasoline.

96. The refiner/marketer defendants, and each of them, designed, manufactured, formulated, refined, set specifications for, exchanged, promoted, marketed and/or otherwise supplied (directly or indirectly) gasoline containing MTBE that was delivered into the State (or areas affecting the waters of the State).

97. Defendants, and each of them, represented, asserted, claimed and warranted that gasoline containing MTBE could be used in the same manner as gasoline not containing MTBE, and/or otherwise did not require any different or special handling or precautions.

98. Defendants, and each of them, knew or reasonably should have known that MTBE and/or gasoline containing MTBE were to be purchased and used without inspection for defects.

99. MTBE and/or gasoline containing MTBE are defective and unreasonably dangerous products for the reasons set forth in Paragraph 82 above.

100. Defendants, and each of them, knew, or reasonably should have known, of the foreseeable risks and defects of MTBE and/or gasoline containing MTBE. Defendants nonetheless failed to provide adequate warnings of the known and foreseeable risks of MTBE and/or gasoline containing MTBE, including contamination of groundwater with MTBE.

101. MTBE and/or gasoline containing MTBE were used in a manner in which they were foreseeably intended to be used, and as a proximate result of defendants' failure to warn of the risks of MTBE and/or gasoline containing MTBE that were known to them, MTBE contaminates and threatens the waters of the State, causing the State to sustain the injuries and damages set forth in this First Amended Complaint.

102. As a direct and proximate result of defendants' acts and omissions as alleged herein, the State has incurred, is incurring, and will continue to incur, investigation, remediation, cleanup, restoration, removal, treatment and monitoring costs and expenses related to contamination of the waters of the State with MTBE, in an amount within the jurisdictional limit of this Court, for which defendants are strictly, jointly and severally liable.

103. As a further direct and proximate result of the acts and omissions of the defendants alleged in this First Amended Complaint, the State has sustained and will

sustain other substantial expenses and damages, in an amount within the jurisdictional limits of this Court, for which defendants are strictly, jointly and severally liable.

104. The injuries to the waters of the State caused and/or threatened by defendants' acts and omissions as alleged herein are indivisible.

105. For the reasons set forth and specifically alleged in paragraphs 92 through 93, the State is entitled to an award of enhanced damages against defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero that fairly reflects the aggravating circumstances alleged herein. After the completion of additional investigation and discovery, the State may seek leave of court to amend this First Amended Complaint to allege a claim for enhanced damages against additional defendants if warranted by the facts.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

COUNT III

(Public Nuisance Against All Defendants)

106. The State realleges paragraphs 1 through 105 above, and by this reference incorporates them as though set forth in full.

107. The negligent, reckless, intentional and ultrahazardous activity of defendants, and each of them, alleged herein has resulted in the contamination and pollution of the waters of the State as alleged herein, and constitutes a public nuisance.

108. The public nuisance caused, contributed to, maintained, and/or participated in by defendants, and each of them, has substantially and unreasonably interfered with, obstructed and/or threatened, among other things, the State's significant property and quasi-sovereign interests in the waters of the State, the State's ability to

protect, conserve and manage the waters of the State, which are by law precious and invaluable public resources held by the State in trust for the benefit of the public, as well as the rights of the people of the State to enjoy a water supply free from unacceptable health risk, taste, odor, pollution, and contamination.

109. Each defendant has, at all times relevant to this action, caused, maintained, participated in and/or assisted in the creation of such public nuisance. Among other things, each defendant is a substantial contributor to such public nuisance as follows:

(a) The manufacturer defendants manufactured, promoted, marketed, distributed and/or supplied MTBE to refiners when they knew, or reasonably should have known, that: (i) the refiners would in turn blend the MTBE into gasoline; (ii) such gasoline containing MTBE would then be placed into leaking gasoline delivery systems, including those in the State; (iii) MTBE would be released even more readily than the constituents of conventional gasoline from gasoline delivery systems; and (iv) when released into the subsurface, MTBE would spread farther and faster than other components of gasoline, resist biodegradation, contaminate groundwater, including drinking water supplies, and, ultimately, be difficult and costly to find and remove from the water.

(b) The refiner/marketer defendants, and each of them, refined, marketed, promoted, supplied and/or otherwise placed into the stream of commerce gasoline containing MTBE that was delivered into the State (and areas affecting the waters of the State), when

they knew, or reasonably should have known, that: (i) such gasoline would be placed into leaking gasoline delivery systems; (ii) MTBE would be released even more readily than the constituents of conventional gasoline from gasoline delivery systems; and (iii) when released into the subsurface, MTBE would spread farther and faster than other components of gasoline, resist biodegradation, contaminate groundwater, including drinking water supplies, and, ultimately, be difficult and costly to remove from the water.

(c) Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, El Paso, ExxonMobil, Irving, Shell, Sunoco, Texaco, Unocal, Valero, and Vitol had first-hand knowledge and experience regarding leaking gasoline delivery systems and releases of MTBE to groundwater therefrom. These defendants obtained such first-hand knowledge and experience because each of them owned, operated and/or controlled individual gasoline stations with leaking gasoline delivery systems, including gasoline stations in the State.

(d) Defendants, and each of them, manufactured, refined, marketed, promoted, supplied and/or otherwise placed into the stream of commerce MTBE and/or gasoline containing MTBE to downstream handlers, when they knew, or reasonably should have known, that MTBE would: (i) be released into the environment from commercial and consumer uses and sources in the State other

than gasoline delivery systems; and (ii) contaminate the waters of the State.

(e) Despite their knowledge that contamination of the waters of the State with MTBE was the inevitable consequence of their conduct as alleged herein, defendants, and each of them, failed to provide any warnings or special instructions, failed to take any other precautionary measures to prevent or mitigate such contamination, and/or affirmatively misrepresented the hazards of MTBE in their product information and/or instructions for use;

(f) Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero engaged in separate and joint activities to suppress, conceal and/or minimize information regarding the hazards of MTBE in order to mislead government agencies, including the State, and the public regarding the hazards of MTBE.

110. The public nuisance caused, contributed to, maintained, and/or participated in by defendants, and each of them, has caused and/or threatens to cause substantial injury to the waters of the State, in which the State has significant property rights and quasi-sovereign interests.

111. The contamination of the waters of the State with MTBE alleged herein has varied over time and has not yet ceased. MTBE continues to threaten, migrate into and enter the waters of the State.

112. As a direct and proximate result of defendants' acts and omissions as alleged herein, the State has incurred, is incurring, and will continue to incur, investigation, remediation, cleanup, restoration, removal, treatment and monitoring costs and expenses related to contamination of the waters of the State with MTBE, in an amount within the jurisdictional limits of this Court, for which defendants are jointly and severally liable.

113. As a further direct and proximate result of the acts and omissions of the defendants alleged in this First Amended Complaint, the State has sustained and will sustain other substantial expenses and damages, in an amount within the jurisdictional limits of this Court, for which defendants are jointly and severally liable.

114. The injuries to the waters of the State caused and/or threatened by defendants' acts and omissions as alleged herein are indivisible.

115. For the reasons set forth and specifically alleged in paragraphs 92 through 93, the State is entitled to an award of enhanced damages against defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero that fairly reflects the aggravating circumstances alleged herein. After the completion of additional investigation and discovery, the State may seek leave of court to amend this First Amended Complaint to allege a claim for enhanced damages against additional defendants if warranted by the facts.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

COUNT IV

(Strict Liability Under RSA 146-A/146-G Against All Defendants)

116. The State realleges paragraphs 1 through 115 above, and by this reference incorporates them as though set forth in full.

117. RSA 146-A:3 provides that the discharge or spillage of oil into the surface water or groundwater of this State, or in a land area where the oil will ultimately seep into surface water or groundwater is prohibited.

118. MTBE is an "oil" as defined in RSA 146-A, which includes petroleum products and their by-products of any kind, and in any form.

119. RSA 146-A:3-a provides that any person who, without regard to fault, directly or indirectly causes or suffers the discharge of oil into or onto any surface water or groundwater of this State, or in a land area where oil will ultimately seep into any surface water or groundwater of the State in violation of chapter 146-A, or rules adopted thereunder, shall be strictly liable for costs directly or indirectly resulting from the violation relating to: (a) containment of the discharged oil; (b) cleanup and restoration of the site and surrounding environment, and corrective measures as defined under RSA 146-A:11-a, III(a) and (b); and (c) removal of the oil.

120. RSA 146-A:9 and 146-G:3 expressly authorize the Attorney General, on behalf of the State, to recover or obtain judgment for the costs of containment, cleanup, removal and corrective measures.

121. Defendants, and each of them, directly or indirectly caused or suffered the discharge of oil in the form of MTBE into or onto the waters of the State and/or in a land

area where MTBE has seeped or will ultimately seep into the waters of the State, in violation of RSA 146-A and rules duly adopted by the State.

122. As a direct or indirect result of such violations, the State has incurred, is incurring, and will continue to incur substantial costs including, but not limited to, costs relating to: (a) the investigation, containment, cleanup and removal of the discharged MTBE; (b) restoration of waters of the State contaminated by such discharges; and (c) the institution of corrective measures including, but not limited to, provision of interim water supplies to residents whose water supplies have been contaminated due to such discharges, the establishment of acceptable sources of potable water to injured members of the public, and other necessary remedial actions, all at significant expense, loss, and damage in amounts within the jurisdictional limits of this Court.

123. Defendants are strictly, jointly and severally liable for any and all such costs and damages that the State has incurred and will incur as a result of defendants' actions.

124. Defendants are subject to civil penalties under RSA 146-A:14.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

COUNT V

(Trespass Against All Defendants)

125. The State realleges paragraphs 1 through 124 above, and by this reference incorporates them as though set forth in full.

126. The State is the owner and/or actual possessor of property rights and interests in the waters of the State, as alleged herein, which the State holds in trust for the benefit of the public. These property rights and interests include, but are not limited to, a

quasi-sovereign interest in protecting the quality of such waters from contamination and pollution.

127. Defendants, and each of them, intentionally manufactured, refined, marketed, and/or otherwise supplied MTBE and/or gasoline containing MTBE with the knowledge that contamination of the waters of the State with MTBE was substantially certain to result.

128. Among other things, defendants, and each of them, intentionally caused MTBE to enter, invade, intrude upon and injure the waters of the State as follows:

(a) The manufacturer defendants manufactured, promoted and supplied MTBE to refiners when they knew that it was substantially certain that: (i) the refiners would in turn blend the MTBE into gasoline; (ii) such gasoline containing MTBE would then be placed into leaking gasoline delivery systems, including those in the State; (iii) MTBE would be released even more readily than the constituents of conventional gasoline from gasoline delivery systems; and (iv) when released into the subsurface, MTBE would spread farther and faster than other components of gasoline, resist biodegradation, contaminate groundwater, including drinking water supplies, and, ultimately, be difficult and costly to find and remove from the water.

(b) The refiner/marketer defendants, and each of them, refined, marketed and/or otherwise supplied gasoline containing MTBE that was delivered into the State (or areas affecting the waters of

the State), when they that it was substantially certain that: (i) such gasoline would be placed into leaking gasoline delivery systems; (ii) MTBE would be released even more readily than the constituents of conventional gasoline from gasoline delivery systems; and (iii) when released into the subsurface, MTBE would spread farther and faster than other components of gasoline, resist biodegradation, contaminate groundwater, including drinking water supplies, and, ultimately, be difficult and costly to remove from the water.

(c) Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, El Paso, ExxonMobil, Gulf, Irving, Shell, Sunoco, Texaco, Unocal, Valero, and Vitol had first-hand knowledge and experience regarding leaking gasoline delivery systems and releases of MTBE to groundwater therefrom. These defendants obtained such first-hand knowledge and experience because each of them owned, operated and/or controlled individual gasoline stations with leaking gasoline delivery systems, including gasoline stations in the State.

(d) Defendants, and each of them, manufactured, refined, marketed, promoted, and/or otherwise supplied MTBE and/or gasoline containing MTBE to downstream handlers, when they that it was substantially certain that MTBE would: (i) be released into the environment from commercial and consumer uses and sources in

the State other than gasoline delivery systems; and (ii) contaminate the waters of the State.

(e) Despite their knowledge that groundwater contamination with MTBE was the inevitable consequence of their conduct as alleged herein, defendants, and each of them, failed to provide any warnings or special instructions, or take any other precautionary measures to prevent or mitigate such contamination.

(f) Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero engaged in separate and joint activities to suppress, conceal and/or minimize information regarding the hazards of MTBE in order to mislead government agencies, including the State, and the public regarding the hazards of MTBE.

129. The contamination of the waters of the State with MTBE alleged herein has varied over time and has not yet ceased. MTBE continues to threaten, migrate into and enter the waters of the State.

130. The State has not consented to and does not consent to the trespass alleged herein. Defendants, and each of them, knew or reasonably should have known, that the State would not consent to this trespass.

131. As a direct and proximate result of defendants' acts and omissions as alleged herein, the State has incurred, is incurring, and will continue to incur, investigation, remediation, cleanup, restoration, removal, treatment and monitoring costs and expenses related to contamination of the waters of the State with MTBE, in an

amount within the jurisdictional limits of this Court, for which defendants are jointly and severally liable.

132. As a further direct and proximate result of the acts and omissions of the defendants alleged in this First Amended Complaint, the State has sustained and will sustain other substantial expenses and damages, in an amount within the jurisdictional limits of this Court, for which defendants are jointly and severally liable.

133. The injuries to the waters of the State caused and/or threatened by defendants' acts and omissions as alleged herein are indivisible.

134. For the reasons set forth and specifically alleged in paragraphs 92 through 93, the State is entitled to an award of enhanced damages against defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero that fairly reflects the aggravating circumstances alleged herein. After the completion of additional investigation and discovery, the State may seek leave of court to amend this First Amended Complaint to allege a claim for enhanced damages against additional defendants if warranted by the facts.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

COUNT VI

(Negligence Against All Defendants)

135. The State realleges paragraphs 1 through 134 above, and by this reference incorporates them as though set forth in full.

136. Defendants had a duty to the State to exercise due care in the design, manufacture, formulation, handling, control, disposal, promotion, marketing, distribution,

sale, testing, labeling, use, provision of product information and instructions for use of MTBE and/or gasoline containing MTBE.

137. Defendants so negligently, carelessly, and recklessly designed, manufactured, formulated, handled, labeled, provided product information and/or instructions for use of, controlled (or failed to control), tested (or failed to test), marketed, promoted, sold, supplied and/or otherwise entrusted MTBE and gasoline containing MTBE that they breached their duties and directly and proximately caused MTBE to contaminate and threaten the waters of the State, resulting in the damages alleged in this First Amended Complaint.

138. Defendants, and each of them, failed to conduct reasonable, appropriate or adequate scientific studies to evaluate the environmental fate and transport characteristics of MTBE, and/or the likelihood that use of MTBE as a component of gasoline would pollute public water supplies, render drinking water unusable and unsafe, and threaten public health and welfare and the environment.

139. The manufacturer defendants, among other things, manufactured, promoted, marketed, supplied and/or otherwise placed into the stream of commerce MTBE to refiners when they knew, or reasonably should have known, that: (a) the refiners would in turn blend the MTBE into gasoline; (b) such gasoline containing MTBE would then be placed into leaking gasoline delivery systems, including those in the State; (c) MTBE would be released even more readily than the constituents of conventional gasoline from gasoline delivery systems; and (d) when released into the subsurface, MTBE would spread farther and faster than other components of gasoline, resist

biodegradation, contaminate groundwater, including drinking water supplies, and, ultimately, be difficult and costly to find and remove from the water.

140. The refiner/marketer defendants, and each of them, among other things, refined, marketed, promoted, supplied and/or otherwise placed into the stream of commerce gasoline containing MTBE that was delivered into the State and/or in areas affecting waters of the State, when they knew, or reasonably should have known, that: (a) such gasoline would be placed into leaking gasoline delivery systems; (b) MTBE would be released even more readily than the constituents of conventional gasoline from gasoline delivery systems; and (c) when released into the subsurface, MTBE would spread farther and faster than other components of gasoline, resist biodegradation, contaminate groundwater, including drinking water supplies, and, ultimately, be difficult and costly to remove from the water.

141. Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, El Paso, ExxonMobil, Gulf, Irving, Shell, Sunoco, Texaco, Unocal, Valero, and Vitol also had first-hand knowledge and experience regarding leaking gasoline delivery systems and releases of MTBE to groundwater therefrom. These defendants obtained such first-hand knowledge and experience because each of them owned, operated and/or controlled individual gasoline stations with leaking gasoline delivery systems, including gasoline stations in the State.

142. Defendants, and each of them, manufactured, refined, marketed, promoted, supplied and/or otherwise placed into the stream of commerce MTBE and/or gasoline containing MTBE to downstream handlers, when they knew, or reasonably should have known, that MTBE would: (i) be released into the environment from

commercial and consumer uses and sources in the State other than gasoline delivery systems; and (ii) contaminate the waters of the State.

143. Despite their knowledge that groundwater contamination with MTBE was the inevitable consequence of their conduct as alleged herein, defendants, and each of them, failed to provide any warnings or special instructions, failed to take any other precautionary measures to prevent or mitigate such contamination, and/or affirmatively misrepresented the hazards of MTBE in their product information and/or instructions for use.

144. In light of the facts alleged herein, defendants, and each of them, breached their duty to use due care in the design, manufacture, formulation, handling, control, marketing, promotion, distribution, sale, testing, labeling, use, provision of product information and/or instructions for use of MTBE and/or gasoline containing MTBE.

145. As a direct and proximate result of defendants' acts and omissions as alleged herein, the State has incurred, is incurring, and will continue to incur, investigation, remediation, cleanup, restoration, removal, treatment and monitoring costs and expenses related to contamination of the waters of the State with MTBE, in an amount within the jurisdictional limit of this Court, for which defendants are jointly and severally liable.

146. As a further direct and proximate result of the acts and omissions of the defendants alleged in this First Amended Complaint, the State has sustained and will sustain other substantial expenses and damages, in an amount within the jurisdictional limit of this Court, for which defendants are jointly and severally liable.

147. The injuries to the waters of the State caused and/or threatened by defendants' acts and omissions as alleged herein are indivisible.

148. For the reasons set forth and specifically alleged in paragraphs 92 through 93, the State is entitled to an award of enhanced damages against defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero that fairly reflects the aggravating circumstances alleged herein. After the completion of additional investigation and discovery, the State may seek leave of court to amend this First Amended Complaint to allege a claim for enhanced damages against additional defendants if warranted by the facts.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

COUNT VII

(Unfair or Deceptive Business Acts In Violation of RSA 358-A:2 Against All Defendants)

149. The State realleges paragraphs 1 through 149 above, and by this reference incorporates them as though set forth in full.

150. The State enforces Consumer Protection laws through the Attorney General, who is expressly authorized to seek on behalf of New Hampshire consumers redress for deceptive trade practices.

151. Defendants, and each of them, have engaged in acts and/or practices in the conduct of trade and commerce within the State that is unfair and deceptive in violation of RSA 358-A:2 in connection with their design, testing, manufacture, promotion, marketing and supply of gasoline containing MTBE. Such acts and/or practices include, but are not limited to, the following:

(a) Defendants, and each of them, represented that MTBE and/or gasoline containing MTBE were environmentally sound products appropriate for widespread production and use, when they were not environmentally sound and appropriate for widespread production and use.

(b) Despite their knowledge that MTBE is more readily released from gasoline delivery systems than conventional gasoline components, and that, once released into the environment, the fate and transport of MTBE in the subsurface differs significantly from that of conventional gasoline constituents, defendants represented that gasoline containing MTBE does not require special handling, storage or other procedures to mitigate or prevent the special dangers posed by MTBE.

(c) Despite their knowledge that environmental contamination, and particularly drinking water contamination, with MTBE was the inevitable consequence of their conduct, defendants, and each of them, failed to provide any warnings or special instructions regarding the threat caused by MTBE, failed to take any other precautionary measures to prevent or mitigate such contamination, and/or affirmatively misrepresented the hazards of MTBE in their product information and/or instructions for use.

(d) Defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero

engaged in separate and joint activities to suppress, conceal and/or minimize information regarding the hazards of MTBE in order to mislead government agencies, including the State, and the public regarding such hazards.

152. By committing the acts and omissions alleged above, among others, defendants, and each of them, have used unfair or deceptive acts or practices in violation of RSA §358-A:2.

153. Pursuant to RSA 358-A:4, b, each defendant is subject to civil penalties of up to $10,000 for each violation.

154. Pursuant to RSA 358-A:6, IV, defendants are subject to an award of the State's legal costs and expenses.

155. Pursuant to RSA 358-A:5, prior notice to defendants of this action is unnecessary because the Attorney General has reason to believe that defendants would take action to the immediate and irreparable harm of the public if such notice were provided.

WHEREFORE, the State prays judgment against defendants as set forth hereafter.

PRAYER FOR RELIEF

WHEREFORE, the State of New Hampshire respectfully requests a trial of this Action before a jury, and that, upon a favorable verdict, this Honorable Court enter judgment in favor of the State and against defendants, jointly and severally, as follows:

A. Declare that defendants are jointly and severally liable for the full cost of all investigatory, remedial and other actions necessary to detect, abate, remove and remediate

MTBE in the waters of the State and to restore such waters to their original condition, and for such orders as may be necessary to provide full relief to address risks to the State.

B. Pursuant to RSA 146-A:3-a, order defendants to pay all costs related to investigation, containment, cleanup, restoration, corrective measures (as defined in RSA 146-A:11-a, III(a) and (b)) and removal directly or indirectly resulting from the contamination of waters of the State with MTBE.

C. Order defendants to pay compensatory damages in an amount at least equal to the full cost of restoring the waters of the State to their original condition prior to the contamination of such waters with MTBE, including but not limited to, the costs of:

(1) testing all public and private drinking water supplies for the presence of MTBE;

(2) treatment of all water supplies containing detectable levels of MTBE until restored to non-detectable levels and provision of alternate water supplies, where appropriate; and

(3) present and future monitoring of surface and groundwaters to detect the presence of MTBE.

D. Order defendants to pay all other damages sustained by the State as a direct and proximate result of defendant's acts and omissions alleged herein, according to proof, including but not limited to remedial, administrative, oversight and legal expenses and compensation for damage to waters of the State.

E. Order defendants Hess, BP, CITGO, Chevron, ConocoPhillips, ExxonMobil, Lyondell, Shell, Sunoco, Texaco, Unocal and Valero to pay enhanced damages that fairly reflect the aggravating circumstances alleged herein.

F. Order defendants to pay all appropriate civil penalties to the maximum extent permitted by law.

G. Grant all appropriate injunctive relief to abate or mitigate the MTBE contamination of waters of the State.

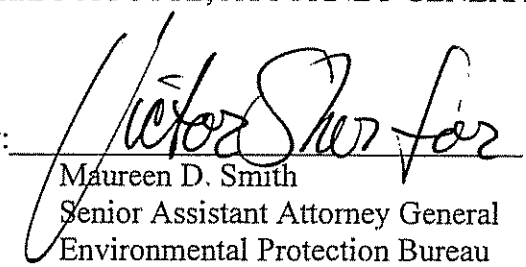
H. Order defendants to pay costs, including reasonable attorneys' fees, incurred in prosecuting this action, together with prejudgment interest, to the full extent permitted by law.

I. Grant such other further relief as this Honorable Court deems just and proper.

A JURY TRIAL IS DEMANDED ON ALL COUNTS SO TRIABLE.

THE STATE OF NEW HAMPSHIRE
KELLY AYOTTE, ATTORNEY GENERAL

DATED: October 27, 2004

By: 

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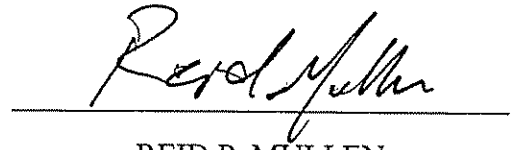
STATE OF NEW HAMPSHIRE

DECLARATION OF SERVICE

I, Reid P. Mullen, hereby declare under perjury of law that a true copy of Plaintiff State of New Hampshire's

FIRST AMENDED COMPLAINT

was served via e-mail, pursuant to Judge Shira A. Scheindlin's Case Management Order dated April 1, 2004 [Section IV] upon Peter Sacripanti, Esq. and Stanley Alpert, Esq., to serve in their capacity as liaison counsel on the 28th day of October, 2004.



REID P. MULLEN

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE PEOPLE OF THE STATE OF NEW YORK, by Letitia James, Attorney General of the State of New York,

Plaintiff,

-against-

PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., THE P.F. LABORATORIES, INC., PURDUE HOLDINGS L.P., ROSEBAY MEDICAL COMPANY L.P., THE BEACON COMPANY, PLP ASSOCIATES HOLDINGS, L.P., DOE ENTITIES 1-10, RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, DAVID A. SACKLER, BEVERLY SACKLER, THERESA SACKLER, JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN PLC, ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN DRUG CORPORATION, ROCHESTER DRUG COOPERATIVE, INC.,

Defendants.

SUPPLEMENTAL SUMMONS

Index No.: 400016/2018

TO THE ABOVE NAMED DEFENDANTS:

YOU ARE HEREBY SUMMONED to answer the attached first amended complaint in this action and to serve a copy of your answer on the Plaintiff's attorney within twenty (20) days after service of this summons, exclusive of the day of service, or within thirty (30) days after service is complete if this summons is not personally delivered to you within the State of New York. In case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint. Plaintiff designates Suffolk County as the place for trial.

New York, New York
March 28, 2019

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SEE ATTACHED DEFENDANTS RIDER

DEFENDANTS RIDER

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE PEOPLE OF THE STATE OF NEW YORK, by Letitia James, Attorney General of the State of New York,

Plaintiff,

-against-

PURDUE PHARMA L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, INC., THE P.F. LABORATORIES, INC., PURDUE HOLDINGS L.P., ROSEBAY MEDICAL COMPANY L.P., THE BEACON COMPANY, PLP ASSOCIATES HOLDINGS, L.P., DOE ENTITIES 1-10, RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, DAVID A. SACKLER, BEVERLY SACKLER, THERESA SACKLER, JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, SPECGX LLC, ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., TEVA PHARMACEUTICAL INDUSTRIES LIMITED, TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., ALLERGAN PLC, ALLERGAN FINANCE, LLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, WATSON LABORATORIES, INC., MCKESSON CORPORATION, CARDINAL HEALTH, INC., AMERISOURCEBERGEN DRUG CORPORATION, ROCHESTER DRUG COOPERATIVE, INC.,

Defendants.

FIRST AMENDED COMPLAINT

Index No.: 400016/2018

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Plaintiff, The People of the State of New York (the "State"), through its attorney, Letitia James, Attorney General of the State of New York, alleges the following, with personal knowledge of the actions of the Office of the Attorney General ("OAG") and upon information and belief as to the action of others:

INTRODUCTION

1. New York State is in the throes of an opioid[1] epidemic that has ravaged the lives of its residents and drained its public coffers for more than two decades. This statewide catastrophe happened because the Defendants in this case—the drug manufacturers and distributors entrusted under New York law with critical roles in preventing the misuse and diversion of controlled substances—deliberately betrayed those duties through a persistent course of fraudulent and illegal misconduct, in order to profiteer from the plague they knew would be unleashed. Plaintiff brings this lawsuit to compel these unrepentant culprits to abate the dangers posed by the enduring public nuisance they generated, enjoin the ongoing threats posed by their continuing misconduct, and hold them accountable in law and equity for the devastation they have inflicted on the State and its residents.

2. Each day, more than 130 people in the United States, and about nine who live in New York, die as a result of opioid-related overdoses. These people are not—and cannot become—just statistics. They are our family, our friends, our neighbors. They are our fathers and our sons, our mothers and our daughters. They have real names and their deaths have left real, jagged holes in the fabric of the communities where they used to live.

[1] As used herein, "opioid(s)" refers to the entire class of powerful narcotic painkillers derived from opium or that mimic its effects, including older, mostly non-synthetic drugs like codeine, morphine, and heroin that some sources separately classify as "opiates," as well as newer, mostly-synthetic drugs like oxycodone, hydrocodone and fentanyl that those sources may distinguish as "opioids."

3. They are real people, like Saige December Earley, of Cazenovia, New York, population 2,835. She was prescribed opioids by the dentist who extracted her wisdom teeth in spring 2017. When the prescription, but not the dependence it had left her with, had ended, she turned to the streets, and heroin—abandoning her two-year-old son to his grandparents. A year later, after committing to recovery, Saige returned home, determined to stay sober and care for her child. She rekindled her passion for dance, music, and art, and reconnected with her mother over homemade peanut butter cookies and late-night movies. But after a friend died from an overdose, she relapsed. Knowing she was in crisis, she booked herself into a treatment facility in California. She never made it. She died in a bathroom stall at the Syracuse airport terminal with a needle in her arm, and her boarding pass in her hand.

> [Saige] needed to run. But she always wanted to return, to make us laugh, to love her baby, to show us this cruel yet fascinating world through her eyes. She ran again last weekend….just a little too far this time. She left a tribe that loved her and that tribe will keep her memory and spirit alive as we care for her son.

Saige December Earley was 23 years old.[2]

4. These individual stories add up to a terrible toll. Since 1999, the scourge of opioid addiction unleashed by the Defendants in this action has taken nearly 400,000 lives:[3]

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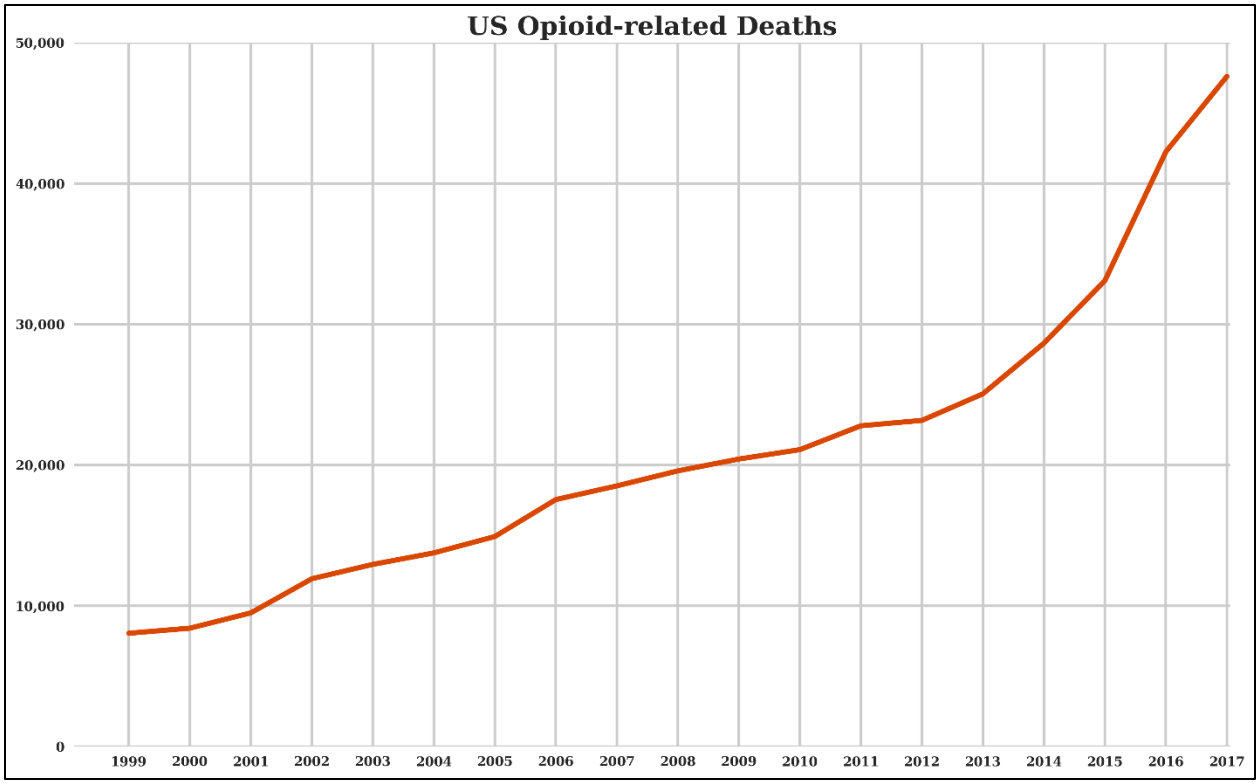
[2] *Saige December Earley Obituary*, Syracuse Post Standard, Sept. 19, 2018, *available at* http://obits.syracuse.com/obituaries/syracuse/obituary.aspx?n=saige-december-earley&pid=190265564&fhid=22206.

[3] *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention (Dec. 19, 2018), https://www.cdc.gov/drugoverdose/epidemic/index html (last visited Mar. 25, 2019).



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So deep and wide is the swath cut by these corporate wrongdoers that for the first time since the Second World War, the average life expectancy of an American has now fallen—for three consecutive years.

The Origin and Explosion of the Opioid Crisis

5. The taproot of the opioid epidemic is easy to identify: OxyContin. In 1996, Purdue launched its "revolutionary" new opioid drug with a nationwide marketing campaign that relied on deception and insider payoffs to overcome a long-established medical understanding that opioids

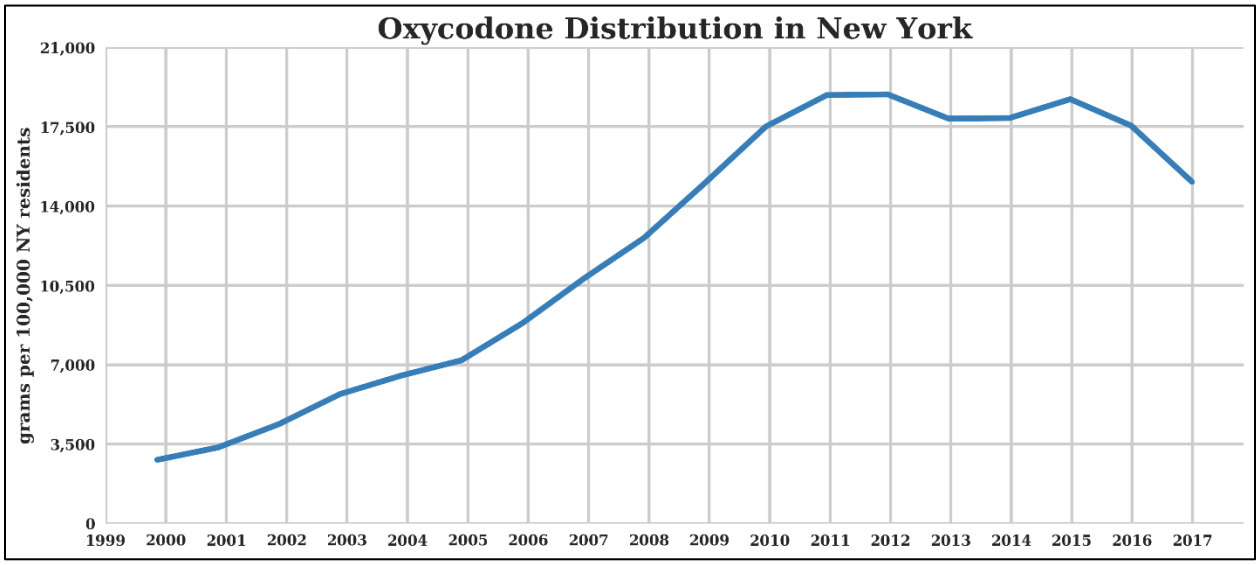
[4] *See Opioid Overdose Crisis*, Nat'l Inst. on Drug Abuse (Rev'd Jan. 2019) (Supporting Data Document, identifying 42,249 opioid related deaths in 2016, and 49,069 such deaths for 2017), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one (last visited Mar. 25, 2019).

posed a high risk of addiction and abuse, and should only be prescribed for short-term acute pain, cancer, or end-of-life care. Purdue's competitors quickly followed suit.

6. Together, these drug manufacturers (the "Manufacturer Defendants") collaborated to falsely deny the serious risks of opioid addiction generally, and high-dose opioid prescriptions specifically. At the same time, they created and promoted the concept of "pseudoaddiction"—a made-up term designed to re-cast familiar symptoms of addiction as signs that patients needed *more* opioid drugs. They falsely claimed that their opioid drugs could be counted on to improve chronic pain patients' function and quality of life, and that their extended-release opioid formulations would provide effective pain relief for 12 hours, when they knew there was no scientific support for those claims. And they misleadingly suggested that other pain relief methods were riskier than opioids, while falsely claiming that opioid dependence and withdrawal could be easily managed and effectively prevented with unproven screening tools and management techniques.

7. Each Manufacturer Defendant spent millions of dollars over the following decade to push these fraudulent messages. They pushed their own name-brand drugs by "detailing" their sales representatives to target susceptible doctors with in-person visits, flooding medical publications with deceptive advertisements, and offering consumers discount cards to entice them to request treatment with their products. And they collaborated to promote the overall expansion of the opioid market by sponsoring misleading Continuing Medical Education ("CME") seminars and manipulating seemingly independent organizations ("Front Groups") that the manufacturers funded and disguised as "unbiased" sources of cutting-edge medical research and information. Both the Front Groups and CME seminars depended on co-opted doctors—so-called "Key Opinion Leaders" ("KOLs")—that the manufacturers recruited and paid.

8. The scheme was spectacularly successful. From 2000 through 2011, the number of prescriptions for the Manufacturer Defendants' opioid drugs more than quadrupled nationwide, even though there was no scientific basis for any significant increase in opioid treatment as medically necessary or appropriate. This scheme was particularly effective in New York, where opioid prescriptions rose *ninefold* during the same time period.



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9. This first wave of the opioid epidemic could not have crested so high, however, without the fraud, willful misconduct, and/or gross negligence of the pharmaceutical distributors named as defendants in this action (the "Distributor Defendants"), who buy controlled substances in bulk from the Manufacturer Defendants and then sell them to individual pharmacies and other licensed dispensers.

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[5] *ARCOS Retail Drug Summary Reports*, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary (last visited Mar. 25, 2019); *Population and Housing Unit Estimates*, U.S. Census Bureau, https://www.census.gov/programs-surveys/popest.html (last visited Mar. 25, 2019).

10. Indeed, both the Manufacturer Defendants *and* the Distributor Defendants knew that their internal compliance systems were totally inadequate to provide the anti-diversion monitoring function that was (and is) legally required of all companies selling controlled substances in New York. And even though their customers were displaying a continuous parade of red flags indicating illegal activity, they continued to pour enormous volumes of opioid drugs into those customers' dispensaries. All the while, they lied to New York regulators, both affirmatively and by omission, about these and other violations of the New York Controlled Substance Act, N.Y. Public Health Law ("PHL") §§ 3300 *et seq.* (the "NYCSA"), in order to maintain their licenses.

11. While the Manufacturer Defendants may have invented and perpetuated the fraudulent messaging aimed at doctors and patients, the Distributor Defendants were the ones that jammed open the floodgates, saturating the State's pharmacies with the Manufacturer Defendants' opioids. This saturation enabled the "pill mill" prescribers who had been stoked by the fraudulent marketing campaign to have massive prescriptions for their addicted patients filled by the Distributor Defendants' pharmacy customers without drawing any meaningful scrutiny.

12. The second wave of the opioid crisis was triggered in August 2010 when Purdue released a purportedly "abuse deterrent" version of OxyContin, and withdrew the original formulation from the market. The release of this reformulation, covered by a new patent, allowed Purdue to keep its highly-profitable and heavily marketed drug "on brand," ensuring that it could continue to charge a premium, rather than have prices slip in the face of competition from generic versions produced by other manufacturers. Other manufacturers immediately followed Purdue's lead—again—with similar reformulations of their own opioid products. Notwithstanding the implicit concession of these reformulations that the first wave of opioid drugs were dangerously

addictive and subject to misuse, none of the Defendants changed their behavior, except for the worse.

13. The Manufacturer Defendants did not stop lying about the risks and alleged benefits of opioids, reform their anti-diversion policies and practices, or tell New York regulators the truth about their violations of the NYCSA. Instead, they simply added new falsehoods about the effectiveness of the new formulations to the fraudulent repertoire employed by their sales representatives, speaker's programs, and front groups. Meanwhile, the Manufacturer Defendants lobbied state and federal regulators to *mandate* the use of their brand-protected "abuse deterrent" formulations, despite the pills costing nearly twice as much as the original versions.[6]

14. Meanwhile, the Distributor Defendants continued to turn a blind eye to their obvious compliance deficiencies while competing with each other to take on high-risk pharmacies in New York as customers. Indeed, by this time, two of the four Distributor Defendants had weighed down their already defective compliance systems with acquisitions of smaller, regional companies with even shoddier safeguards, and whose New York customers exhibited an even higher number of unresolved warning signs than their existing customer bases.

15. As a result, prescriptions in New York for the Manufacturer Defendants' opioid drugs continued to climb, and to be easily filled by the Distributor Defendants' pharmacy customers, even as the dangers of opioid misuse became so obvious as to prompt reformulation of those drugs, and even as the pills themselves became more expensive.

16. To the extent the Manufacturer Defendants' "abuse deterrent" opioids had an impact, it was one that was dire, if predictable: driving patients to a cheaper and more available alternative

[6] *Drugmakers Promote Profitable, but Unproven, Opioid Solutions*, CBS News, Dec. 15, 2016, *available at* https://www.cbsnews.com/news/opioid-epidemic-drugmakers-promote-profitable-but-unproven-solution.

that could be counted on to deliver the fix the manufacturers had hooked them on in the first place—heroin. Indeed, as many as 80% of all heroin users first became dependent on opioids as a result of a "legitimate" prescription for the Defendants' products.[7] Over the next three years, while the Defendants all continued to gorge themselves on profits from increasing opioid sales, the more desperate of their victims, unable to "score" from their original "dealers," fueled a threefold increase in heroin-related fatalities among New Yorkers.

17. In 2013, an even more terrifying third wave of the opioid crisis, under which New Yorkers are still drowning, was set off by an extension of the heroin-substitution trap into which the Defendants should have known their victims would fall. Specifically, heroin dealers began profiteering by "cutting" their product with massive increases of inactive adulterants, and attempting to achieve the same intoxicating and addictive effects by introducing small quantities of fentanyl, a synthetic opioid that is ten times cheaper but 50 times more powerful then heroin itself.[8]

18. Opioid users began dying at an unprecedented rate as they overdosed on the unpredictable, uncontrollable, and undetectable amounts of fentanyl contained in any given batch of street heroin. This, in turn, led to a flourishing new market for counterfeit opioid pills among those seeking the relative "safety" of the Defendants' products—a cruel hoax, given that the counterfeits are themselves laced with deadly fentanyl. At the same time, more and more patients

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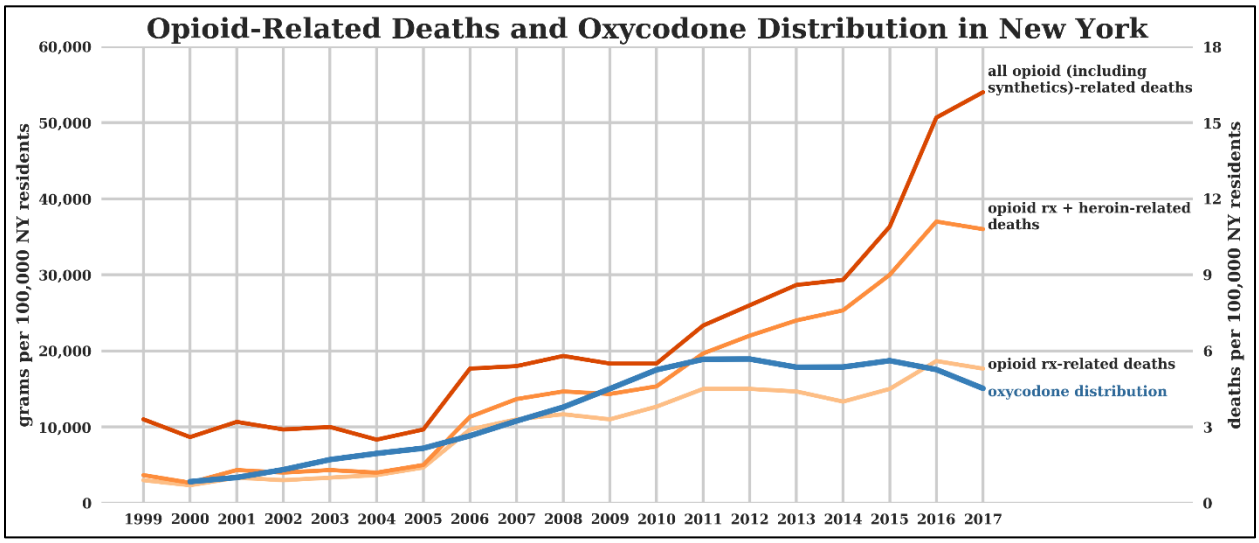
[7] Christopher M. Jones, *Heroin Use and Heroin Use Risk Behaviors Among Nonmedical Users of Prescription Opioid Pain Relievers—United States, 2002-2004 and 2008-2010*, 132 Drug Alcohol Dependence 95-100 (2013); Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Review (Aug. 2013), *available at* https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013 htm.

[8] *Synthetic Opioid Overdose Data*, Ctrs. For Disease Control and Prevention (Dec. 19. 2018), https://www.cdc.gov/drugoverdose/data/fentanyl.html, (last visited Mar. 25, 2019).

were pushed into this death trap by the Manufacturer Defendants, who increased the prices for their branded opioid drugs by more than 50% between 2013 and 2016.[9]

19. This latest surge of the opioid crisis has been the deadliest and most intractable: opioid-related overdose fatalities in the State have more than doubled since 2013—with a *30-fold* increase in fentanyl-related deaths in New York City[10]—even though opioid prescriptions in New York have been decreasing since that same year, when the state began implementing a Prescription Drug Monitoring Program ("PDMP") that requires prescribers to check a database recording all of their patients' other prescriptions for controlled substances:



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[9] U.S. Food and Drug Admin., *FDA Analysis of Long-Term Trends in Prescription Opioid Analgesic Products: Quantity, Sales, and Price Trends* (Mar. 1, 2018), *available at* https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM598899.pdf.

[10] Cody Colon-Berezin et al., *Overdose Deaths Involving Fentanyl and Fentanyl Analogs — New York City, 2000–2017*, 68 Morbidity & Mortality Wkly. Rep. 37–40 (Jan. 18, 2019), *available at* https://www.cdc.gov/mmwr/volumes/68/wr/mm6802a3 htm.

[11] Ctrs. for Disease Control and Prevention Wide-Ranging Online Data for Epidemiologic Research (CDC WONDER), https://wonder.cdc.gov/ (data accessed Feb. 5, 2019); *ARCOS Retail Drug Summary Reports*, Drug Enforcement Admin. Diversion Control Div., https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary (last

20. It is now clear that nobody in the State is safe from Defendants' depredations. Not the elderly, who are hospitalized more than five times as often for opioid overuse as they were when OxyContin exploded onto the market.[12] Not our State's veterans, who are twice as likely to die from an opioids overdose as those who have not served in the military.[13] Not even our families' newborns, who are now more than four times as likely to suffer from Neonatal Abstinence Syndrome—forced to endure physical withdrawal from opioids as they struggle to take their first breaths and open their eyes to the world—than they were just a decade ago.

21. As the enormity of the Defendants' misconduct has begun to be uncovered through the course of multiple governmental investigations, they have made cosmetic and inconsequential changes to their practices to settle those investigations and to deflect public outrage. Nonetheless, they remain defiant and unaccountable for the immense damage they have done, and indifferent to their corporate responsibilities moving forward. The Manufacturer Defendants may have curtailed their deceptive-marketing spree, but they have done nothing to correct the misinformation they propagated in the medical community, which sparked the crisis in the first place, and is still putting patients at risk. Likewise, the Distributor Defendants are now paying lip service to their legal duties under the NYCSA to prevent the diversion of opioids, but their compliance systems remain deeply flawed in ways that are continuing to enable and perpetuate the oversupply of these deadly and addictive drugs at pharmacies throughout the State.

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visited Mar. 25, 2019); *Population and Housing Unit Estimates*, U.S. Census Bureau, https://www.census.gov/programs-surveys/popest.html (last visited Mar. 25, 2019).

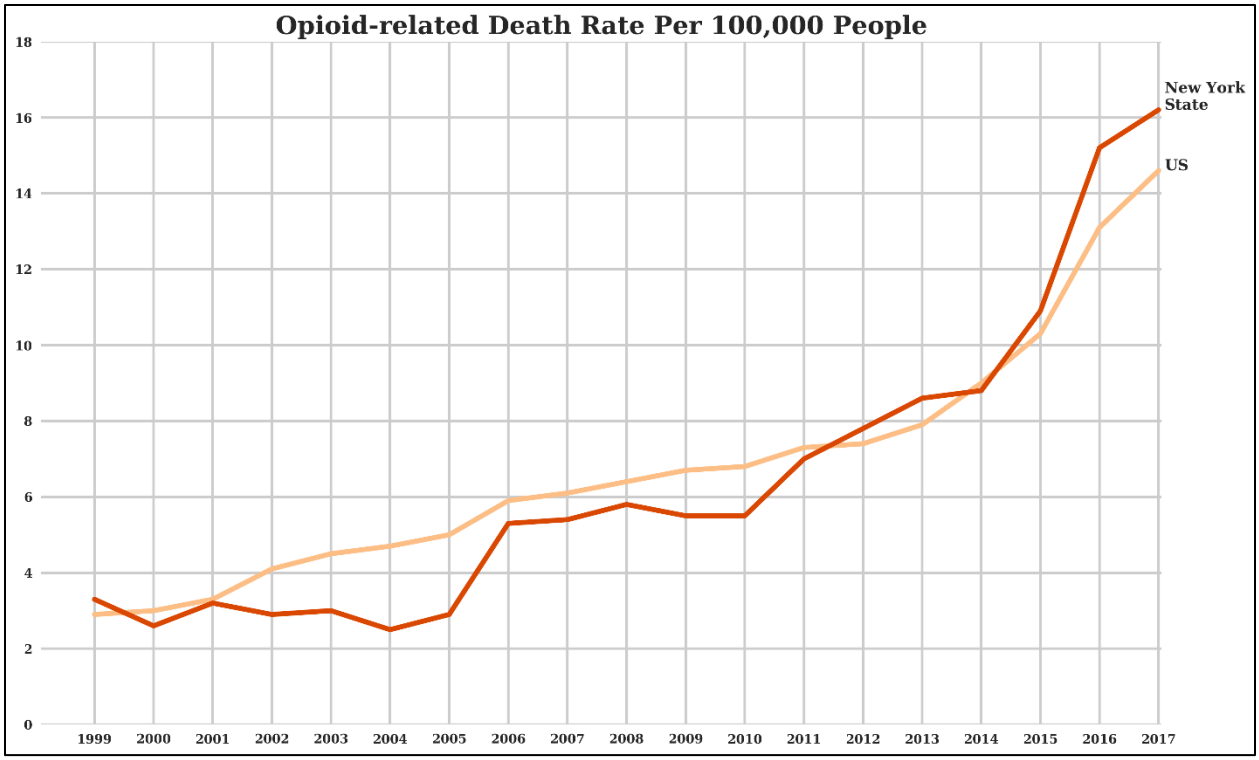
[12] Uma Suryadevara et al., *Opioid Use in the Elderly*, Psychiatric Times, Jan. 30, 2018, *available at* https://www.psychiatrictimes.com/special-reports/opioid-use-elderly.

[13] Barbara Goldberg, *Opioid Abuse Crisis Takes Heavy Toll on U.S. Veterans*, Reuters, Nov. 10, 2017, *available at* https://www.reuters.com/article/us-usa-veterans-opioids/opioid-abuse-crisis-takes-heavy-toll-on-u-s-veterans-idUSKBN1DA1B2.

The Danger Still Looming, the Damage Done, and the Remedies Required

22. First and foremost, Plaintiff seeks to protect the State and its residents from the ongoing threat posed by the public nuisance Defendants have created, and the lawless practices they are bound to continue if not restrained. The dangers posed by the Defendants' enduring impact in warping the perception and availability of opioids will remain embedded in the landscape of the State until and unless they are compelled to root it out. Indeed, New York already spends hundreds of millions annually on support, treatment, and recovery programs, residential services, 24/7 urgent access centers, community coalitions, family support navigators, and overdose-reversing naloxone kits and training. Yet despite these efforts, the State's rate of opioid-related deaths continues its steady climb:[14]

[14] *See also* N.Y. State Office of Alcoholism and Substance Abuse Services (OASAS), *New York State Epidemiological Profile: Substance Abuse and Other Mental, Emotional, and Behavioral (MEB) Disorders* (Nov. 2018) *available at* https://www.oasas.ny.gov/prevention/documents/NYS_Epidemiological_Profile_12_18.pdf (noting that opioid overdose deaths increased statewide by 192.4% from 2007–16); Office of the N.Y. State Comptroller, *Prescription Opioid Abuse and Heroin Addiction in New York State* 1–2 (June 2016), *available at* https://www.osc.state.ny.us/press/releases/june16/heroin_and_opioids.pdf.



23. However, prospective remedies alone will not suffice to work justice here. The State and its residents have already suffered a staggering toll as a result of the Defendants' misconduct: thousands of lives lost, thousands more families destroyed, and communities broken in every part of the State.

24. From some of these injuries certain measures of economic loss can be distilled, including, for example: sums spent by the State on fraudulently-induced reimbursements of improper opioid prescriptions; lost productivity among state workers impacted by the opioid crisis; and increased public health and public safety expenditures.

25. Other injuries inflicted by the Defendants, though, can only addressed, however imprecisely, through the imposition of strict liability for the *per se* statutory penalties the Defendants knowingly courted by violating their legal duties, or by resorting to the flexibility of the equitable remedies available to Plaintiff and the Court.

26. Accordingly, the State of New York brings this action to protect its residents, families, and communities, end this continuing tragedy playing out across the State, and bring accountability to those responsible for causing this crisis.

27. Specifically, Plaintiff seeks an order: (i) requiring Defendants to endow an abatement fund with sufficient capital to eliminate the public nuisance they have created; (ii) enjoining Defendants from marketing or distributing opioids in New York unless they comply with heightened and independently-monitored safeguards against the recurrence of their fraudulent and illegal practices; (iii) compelling Defendants to correct their false and misleading public statements and omissions concerning those practices; (iv) awarding Plaintiff monetary damages for the full range of economic injuries Defendants' misconduct has inflicted on New York State; (v) awarding Plaintiff statutory penalties for each and every violation of New York's controlled-substance and consumer-protection laws by Defendants; (vi) declaring the Defendants' licenses to manufacture and/or distribute controlled substances *void ab initio* on the grounds that those licenses were improperly procured; (vii) fashioning appropriate equitable remedies, including, without limitation, disgorgement of all ill-gotten gains and restitution where and when it can practicably be made; (viii) awarding Plaintiff punitive damages due to the egregious nature of defendants' fraud, willful misconduct, and/or gross negligence; and (ix) granting such other relief as the Court may deem just.

JURISDICTION AND VENUE

28. This Court has jurisdiction pursuant to New York Constitution, Article VI, § 7(a), and Judiciary Law § 140-b. No claim or substantial question of federal law is alleged.

29. This Court has personal jurisdiction over each defendant pursuant to Civil Practice Law and Rules §§ 301 and 302. Each Defendant transacts substantial business within the State and has committed and continues to commit tortious acts within the State; and several own, use, or possess real property situated within the State.

30. Venue in this district is proper pursuant to Civil Practice Law and Rules § 505, and the New York Litigation Coordinating Panel's Decision and Order, issued July 17, 2017 (NYSCEF Doc. No. 1, filed July 31, 2017).

PARTIES

Plaintiff

31. Plaintiff, The People of the State of New York, brings this action through its Attorney General, Letitia James, in its sovereign capacity to protect the interests of the State and its citizens. This action is brought pursuant to the Attorney General's common law and statutory authority including, *inter alia*, Executive Law § 63 and General Business Law Article 22-A.

Defendants

32. The Defendants in this action are the opioid manufacturers and distributors that largely fueled the State's opioid crisis.

A. The Manufacturer Defendants

33. The Manufacturer Defendants are the entities and individuals responsible for manufacturing and marketing the opioids that fueled the opioid epidemic within the State.

1. Purdue and the Sackler Defendants

34. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Its principal place of business is Stamford, Connecticut.

35. Defendant Purdue Pharma Inc. is a New York corporation and is the general partner of, and ultimately controls, Purdue Pharma L.P. Its principal place of business is Stamford, Connecticut.

36. Defendant Purdue Holdings L.P. is a Delaware limited partnership and wholly owns the limited partnership interest in Purdue Pharma L.P.

37. Defendant The Purdue Frederick Company, Inc. is a New York corporation. Its principal place of business is Stamford, Connecticut.

38. Defendant The P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation. Its principal place of business is Totowa, New Jersey.

39. The above-identified Defendants and their DEA registrant subsidiaries and affiliates are collectively are referred to as "Purdue."

40. 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. [redacted]

41. 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. In September 2017, through a trust he ultimately controls for the benefit of his children and grandchildren, and with proceeds from his interests in Purdue, he purchased a condominium on Manhattan's East Side for

$3.225 million.

42. 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.

43. 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.

44. Defendant Kathe A. Sackler was a member of Purdue's board from 1990 through 2018. She resides in New York and Connecticut, and owns an estate in Suffolk County valued at approximately $5 million. Kathe is a director and president of the Shack Sackler Foundation, a director and the 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.

45. 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.

46. Defendant David A. Sackler was a member of Purdue's board from 2012 through 2018. He resides in New York. In 2012, he purchased a $6 million apartment on Manhattan's East Side with the proceeds from his interests in Purdue.

47. 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.

48. Defendant Theresa Sackler was a member of Purdue's board from 1993 through 2018. She resides in New York and the United Kingdom. In 2011, she purchased a multimillion-dollar apartment on Manhattan's Fifth Avenue with the proceeds from her interests in Purdue.

49. 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:

50. 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.

51. 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.

52. 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.

53. 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.

54. 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."

2. Janssen

55. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

56. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals is a wholly owned subsidiary of J&J. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

57. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with a principal place of business in Titusville, New Jersey.

58. Defendant Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

59. The above-identified defendants and their DEA registrant subsidiaries and affiliates are referred to collectively as "Janssen."

3. Mallinckrodt

60. Defendant Mallinckrodt plc is an Irish public limited company, with headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Within the United States, Mallinckrodt plc operates under the name Mallinckrodt Pharmaceuticals, and maintains its U.S. headquarters in Hazelwood, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of

holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year.

61. Shares of Mallinckrodt plc are traded on the New York Stock Exchange (symbol: MNK). In its most recent Form 10-K filed with the United States Securities and Exchange Commission ("SEC"), Mallinckrodt plc stated that its products compete primarily in the U.S. market, which accounted for almost 90% of the company's $3.2 billion in net sales during the fiscal year ended December 28, 2018. Mallinckrodt plc regularly conducts business in New York.

62. Defendant Mallinckrodt LLC is a Delaware corporation with a principal place of business in Hazelwood, Missouri. Since June 28, 2013, Mallinckrodt LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly owned subsidiary of Covidien pllc.

63. Defendant SpecGx LLC is a Delaware limited liability company with a principal place of business in Clayton, Missouri. SpecGx was formed on November 14, 2016 as a wholly owned subsidiary of Mallinckrodt LLC.

64. Mallinckrodt LLC and SpecGx LLC operate an opioids manufacturing facility in Hobart, New York.

65. The above-identified defendants and their DEA registrant subsidiaries and affiliates are referred to collectively as "Mallinckrodt."

4. Endo

66. Defendant Endo International plc is an Irish public limited company, with global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. Endo International plc operates in the U.S. as Endo Pharmaceuticals.

67. Shares of Endo International plc are traded on NASDAQ (symbol: ENDP). In its most recent Form 10-K filed with the SEC, Endo International plc stated that its sales and marketing

activities are primarily based in the U.S., and that its U.S. business segments accounted for more than 95% of the company's $2.9 billion in total net revenue during the year ended December 31, 2018. Endo International plc regularly conducts business in New York.

68. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. EHS is a wholly owned subsidiary of Endo International plc.

69. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

70. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.

71. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively "Par Pharmaceutical."

72. Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc.

73. The above-identified defendants and their DEA registrant subsidiaries and affiliates are referred to collectively as "Endo."

5. Teva

74. Defendant Teva Pharmaceutical Industries, Limited ("Teva Ltd.") is a global pharmaceutical company with headquarters in Petah Tikva, Israel. Shares of Teva Ltd. are traded on the New York Stock Exchange (symbol: TEVA). In its most recent Form 10-K filed with the SEC, Teva Ltd. stated that it does business in the United States through its North America Segment,

which accounted for approximately 50% of the company's $18.9 billion in net revenue during the year ended December 31, 2018. Teva Ltd. regularly conducts business in New York.

75. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Ltd.

76. In August 2016, Teva Ltd. bought Actavis Pharma, Inc. and Actavis LLC from Allergan plc. Thus, since August 2016, Teva Ltd. has owned the generic opioids business that was formerly owned by the Allergan entities.

77. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

78. The above-identified defendants and their DEA registrant subsidiaries and affiliates are referred to collectively as "Teva."

6. Allergan

79. Defendant Allergan plc (f/k/a Actavis plc) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in June 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013 and then to Actavis plc in October 2013.

80. Shares of Allergan plc are traded on the New York Stock Exchange (symbol: AGN). In its most recent Form 10-K filed with the SEC, Allergan plc stated that it does business in the U.S. through its US Specialized Therapeutics and US General Medicine segments, which generated nearly 80 percent of the company's $15.8 billion in net revenue during the year ended December 31, 2018. Allergan plc regularly conducts business in New York.

81. Defendant Allergan Finance, LLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.) is a Nevada limited liability company that exists for the purpose of holding shares of other companies that manufacture and distribute prescription pharmaceuticals. Its sole member is Allergan W.C. Holding Inc. f/k/a Actavis W.C. Holding Inc., a Delaware corporation with its principal place of business in Madison, New Jersey.

82. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California.

83. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey.

84. Defendant Actavis LLC (f/k/a Actavis Inc.) is a Delaware limited liability company with its principal place of business in New Jersey.

85. Until August 2016 when they were sold to Teva, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC were owned by Allergan plc.

86. During the time period described herein and until they were sold to Teva Pharmaceutical Industries Ltd. in August 2016, Watson Laboratories, Inc., Actavis Pharma, Inc., and Actavis LLC were part of the same corporate family as Allergan Finance, LLC and sold and marketed opioids as part of a coordinated strategy to sell and market the branded and generic opioids of Allergen Finance, LLC, Actavis Pharma, Inc., and Actavis LLC.

87. The above-identified Defendants and their DEA registrant subsidiaries and affiliates are referred to collectively as "Allergan," except that references to Allergan do not encompass Actavis Pharma, Inc. and Actavis LLC after the time of their sale to Teva.

B. The Distributor Defendants

88. The opioid distributors are entities that unlawfully distributed opioids within New York State, thereby fueling the State's opioid epidemic.

1. McKesson

89. Defendant McKesson Corporation ("McKesson") is a Delaware corporation. Its principal place of business is San Francisco, California. McKesson distributes pharmaceutical drugs, including opioids, throughout the United States, including the State of New York.

90. Last year, McKesson reported over $198 billion in annual revenue and was ranked as the sixth largest company in the United States.

2. Amerisource

91. Defendant AmerisourceBergen Drug Corporation is a Delaware corporation. Its principal place of business is in Chesterbrook, Pennsylvania. Bellco Health Corp. ("Bellco") is a pharmaceutical and healthcare distribution company. Bellco is based in North Amityville, New York, and since October 2007, has operated as a wholly owned subsidiary of AmerisourceBergen Drug Corporation.

92. AmerisourceBergen Drug Corporation and Bellco, and their DEA registrant subsidiaries and affiliates (collectively, "Amerisource"), distribute opioids throughout the United States, including the State of New York.

93. Last year, Amerisource reported over $153 billion in annual revenue and was ranked as the 12th largest company in the United States.

3. Cardinal

94. Defendant Cardinal Health, Inc. is an Ohio corporation. Its principal place of business is in Dublin, Ohio. Kinray Inc. ("Kinray") is a wholesale distributor of branded and generic pharmaceutical drugs, including opioids. Kinray is based in Whitestone, New York, and since December 2010, has operated as a wholly owned subsidiary of Cardinal Health Inc.

95. Cardinal Health Inc. and Kinray, and their DEA registrant subsidiaries and affiliates (collectively "Cardinal"), distribute opioids throughout the United States, including the State of New York.

96. Last year, Cardinal reported nearly $130 billion in annual revenue and was ranked as the fourteenth largest company in the United States.

4. Rochester Drug

97. Rochester Drug Cooperative, Inc. ("Rochester Drug") is a New York corporation. Its principal place of business is Rochester, New York.

98. Rochester Drug distributed prescription opioids throughout the United States, including the State of New York.

99. Rochester Drug is among the ten largest drug wholesalers in the United States, with an estimated annual revenue of $2 billion.

C. Defendants' Agents, Successors, and Parent-Subsidiary Relationships

100. Each action described herein is part of, and in furtherance of, the unlawful conduct alleged herein, and was authorized, ordered, and agreed to by each Defendant's officers, agents, employees, or other representatives who were actively engaged in the management of said Defendant's affairs within the course and scope of their duties and employment and with said Defendant's actual, apparent, and ostensible authority.

101. With respect to each parent company Defendant identified above, each parent-owner:

- Knew of and/or participated in the fraudulent and/or otherwise illegal conduct of its subsidiaries;
- Exercised complete domination over the acquired-subsidiary company, and such domination and control over finances, policy, and business practices

was used to commit the unlawful acts complained of herein, which resulted in the State's injury;

- Expressly or impliedly assumed the predecessor's liabilities for the unlawful acts complained of herein, which resulted in the State's injury;

- Essentially merged itself in substance, if not in form, with the acquired-subsidiary company;

- Is a mere continuation of the acquired-subsidiary company; and/or

- Entered into such transaction to fraudulently escape such obligations.

FACTS

I. Defendants' Collective Pattern of Misconduct that Sparked, Spread, and Sustained the Opioid Epidemic in New York

102. Defendants caused this disaster together. One of the Manufacturing Defendants—Purdue—undoubtedly tipped the first domino. The others quickly went in on the scheme to expand the opioids market through a predatory campaign of lies, payoffs, and high-pressure sales tactics. The Distributor Defendants, who were supposed to provide the public with a safeguard against just such a danger, instead turned a collective blind eye as orders for opioids in New York skyrocketed up their sales charts. Both groups of Defendants systematically disregarded their duties under State law to maintain effective compliance functions to prevent the diversion of opioids. Indeed, the feeding frenzy that characterized Defendants' race to sell the most opioids was paralleled only by their seeming competition to see who could accumulate the most violations of the NYCSA by instituting the weakest compliance policies and the shoddiest practices for enforcing them.

103. To be sure, each Defendant played a unique role in this tragedy, and those specifics are set forth below in detail in Parts II and III. But to understand the nature and impact of each of those individual misdeeds, it is necessary to take in the entire picture—how drugs long known to be dangerous came to be dispensed like candy, and how two related, highly-regulated industries chose dollars over duties to make that happen.

A. The Original Consensus: Opioids are Powerful Drugs with Narrow Medical Uses That Pose Dangerously High Risks of Abuse and Dependence

104. From well before the establishment of modern medicine, common-sense experience had established a widespread understanding that while opioid drugs could serve a useful and important role, they were also dangerous and highly addictive. The Roman physician Galen prescribed an opium drink to ease the pain of the frail and sickly Marcus Aurelius, but soon came

to recognize that the emperor had become "habituated" to the drug.[15] The Yongzheng Emperor of China banned the import and sale of opium for non-medicinal use in 1729 after receiving reports that people "become corrupted by smoking it until their lives collapse, their families; livelihood vanishes, and nothing is left but trouble."[16] His grandson, the Qianlong Emperor, banned opium outright in 1799, and their successors fought two costly and unsuccessful wars against the British Empire just to keep the drug out of China.

105. In this country, the dangers of opiate drugs were apparent enough by 1908 for President Theodore Roosevelt to appoint an Opium Commissioner of the United States, who stated that opium was "the most pernicious drug known to humanity."[17] In 1914, Congress banned the non-medicinal use of opium, and in 1924 it banned heroin entirely. When national drug laws were modernized in the Controlled Substances Act of 1970, a five-tier system of Schedules to rank the dangerousness of pharmaceuticals was established. Schedule I drugs were banned entirely. Opiate drugs were placed in Schedule II, indicating a "high potential for abuse" that could "lead to severe psychological or physical dependence."

106. By that time, nearly 50 years ago, the specific chemical processes that create the risks inherent in opioid use had been discovered by researchers. Since then, there has been no dispute that opioids have a unique ability to attach to special receptors in the brain and spine that trigger a temporary state of euphoria. When the effect wears off, the desire to bring it back—by taking the drug again—inevitably sets in. But repeated use of opioids leads to tolerance: the need to take ever higher doses to achieve the same euphoric effect, as the body defensively produces

[15] Africa, T., *The Opium Addiction of Marcus Aurelius*, 22 J. Hist. Ideas 97-102 (1961).
[16] Frank Dikötter et al., *Narcotic Culture: A History of Drugs in China* 33-36 (2004).
[17] Edward Marshall, *Uncle Sam is the Worst Drug Fiend in the World*, N.Y. Times, Mar. 12, 1911.

more and more of a stimulating chemical called noradrenaline to counteract the sedating effects of the opioids. Once tolerance sets in, physical withdrawal and dependence come with it, because when the opioids leave the body, the excess noradrenaline remains, causing jitters, anxiety, muscle cramps, and diarrhea.[18]

107. As a result of this powerful combination of physical and psychoactive reactions, anyone who uses opioids, even for a short time, may develop opioid use disorder, commonly known as addiction.[19] Opioid use disorder is a condition in which the brain literally changes—prefrontal regulatory circuits are impaired, and normal reward and emotional response mechanisms skewed—making it extraordinarily difficult for the people it affects to voluntarily reduce their drug-taking behavior, despite knowing the potentially catastrophic consequences.[20]

108. Until the mid-1990's, awareness of these proven risks of opioid use among the established medical and scientific communities kept the prescription of opioids tightly restricted to a relatively narrow population of patients for whom the benefits were deemed to outweigh the dangers, such as people battling cancer or advanced HIV, or in end-of-life care. But that was about to change, when the company that made the gold-standard drug for these niche uses faced the expiration of its patent, with grim consequences for New Yorkers and the nation.

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[18] *See* Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, Science & Practice Perspectives 13-20 (July 2002), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/.

[19] *How Opioid Addiction Occurs*, Mayo Clinic (Feb. 16, 2018), https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/how-opioid-addiction-occurs/art-20360372 (last visited Mar. 25, 2019); Nora D. Volkow & Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 New Engl. J. Med. 1253 (2016), *available at* https://www nejm.org/doi/full/10.1056/NEJMra1507771 (chart 1).

[20] N. D. Volkow et al., *Neurobiologic Advances from the Brain Disease Model of Addiction*, 374 New Eng. J. Med. 363 (2016), *available at* https://www ncbi.nlm nih.gov/pmc/articles/PMC6135257.

B. Lighting the Fire of an Epidemic: A Small Drug Manufacturer Bets on Expanding the Market for Opioids to Save its Corporate Future

109. Over most of its history, Purdue was a successful but relatively small player in the pharmaceutical industry, focusing mainly on over-the-counter products. In the 1980's, though, the company was able to break into the prescription market with its release of MS Contin. This controlled-release formulation of morphine quickly became the default option for cancer patients eligible for opioid treatments. For over a decade thereafter, MS Contin was the engine that drove unprecedented growth for Purdue and a financial windfall for its owners, the Sacklers. But by the late 1980's, Purdue faced what seemed to be a cliff-edge for their fortunes—the MS Contin patent was set to expire—and so a plan was hatched to save the company's future.

110. Purdue knew that once its much larger multinational competitors could sell generic versions of MS Contin, it would lose most of its space in the market for treating cancer patients. One way to deal with that was "going laterally with MS Contin to non-cancer pain indications": convincing doctors to prescribe the drug for patients for whom opioids were traditionally thought of as inappropriate, a sign of things to come.[21] But by mid-1990, Purdue's chief scientist was warning its then head of research and development, and future president, Richard Sackler, that "MS Contin may eventually face such serious generic competition," even if the market could be expanded, that to avoid "crushing all of the analgesic eggs," "other controlled-release opioids must be considered."[22]

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[21] Harriet Ryan et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, Los Angeles Times, May 5, 2016, *available at* http://www.latimes.com/projects/oxycontin-part1 (linking to Purdue memo *at* http://documents.latimes.com/purdues-need-new-painkiller-1990).
[22] *Id.*

111. The solution Purdue and the Sacklers settled on was to develop a controlled-release formulation of the synthetic opioid oxycodone, despite the fact that "relatively little [was] known about the clinical pharmacology" of that drug.[23] Once the company patented this new "OxyContin" formulation, the branded drug could be "positioned against numerous analgesics in non-cancer painful indications including chronic non-malignant pain" and thereby avoid the consequences when generic competition arrived "to (as previously discussed) crush all of the MS Contin eggs."[24]

112. But developing and patenting OxyContin would be the easy part. Purdue still faced the challenge of reversing hundreds of years of common-sense experience, and decades of established scientific research, professional ethics, and government regulation, which by that point was more or less safely containing the dangers posed by the over-prescription of opioids.

C. Through the Looking Glass: The Manufacturer Defendants' Campaign to Reverse the Perception of Opioids

113. Leading up to the release of OxyContin in 1996, Purdue began surreptitiously backing an emerging movement among some palliative-care doctors to de-stigmatize the use of opioids in a wider variety of treatment settings. When the drug became an instant blockbuster, the other Manufacturer Defendants, who were racing to develop their own branded reformulations of opioids, eagerly jumped on board. Together, they quickly developed a massive bandwagon of fraudulent marketing and promotion aimed at convincing doctors and other health-care providers authorized to write prescriptions ("HCPs") that up was down—that opioids were actually safe, effective, and non-addictive enough to prescribe in virtually any situation to virtually any patient in any kind of pain.

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[23] *Id.*
[24] *Id.*

114. To make HCPs feel comfortable prescribing dangerously high dosages of opioids, the Manufacturer Defendants repeatedly invoked an overarching myth of an "epidemic" of untreated pain in America in which as many as 100 million adults were allegedly suffering silently. The truth is that individuals with severe chronic pain—who deserve the safe and effective treatment that can be accomplished in most cases without opioids—are far fewer in number[25] and represent principally a profit center for the opioid industry. But this lie was just the tip of the iceberg in the complex web of deceit that was to come.

115. Over the following two decades, the Manufacturer Defendants developed a three-part playbook for their fraudulent scheme: (i) conjure up no fewer than ten separate categories of deceptive statements about the use of opioids; (ii) use those lies in high-frequency "detailing" sales calls to susceptible HCPs, advertisements, and discount card programs to promote their branded opioid formulations; and (iii) spread those lies throughout the health-care community by using co-opted, paid-off doctors (the KOLs) to secretly sponsor phony CMEs and Front Groups that broadly targeted unwitting HCP's and even the most vulnerable patient populations.

116. The Manufacturer Defendants have collectively spent billions of dollars on this fraudulent marketing campaign over the last two decades. In 2000, the Manufacturer Defendants' combined annual spending on opioids marketing was $91 million. By 2011, that figure had climbed to almost $300 million annually, including $142 million by Janssen and $110 million by Purdue. Included in these figures were payments directly to individual prescribers in New York: from August 2013 through December 2015 alone, they collectively paid more than $3.5 million to almost

[25] Cindy Steinberg, Nat'l Dir. of Policy & Advocacy, U.S. Pain Found., Prepared Testimony for Senate HELP Committee Hearing on "Managing Pain During the Opioid Crisis" (Feb. 12, 2019) *available at* https://www.help.senate.gov/imo/media/doc/Steinberg.pdf (citing 50 million people).

3,400 New York HCPs.[26] Among the Manufacturer Defendants, Purdue was the top payer, with payments to almost 2,000 providers totaling over $600,000, followed by Teva with payments to more than 400 providers totaling over $335,000, and Janssen with payments to almost 500 providers totaling more than $200,000.[27]

D. The Manufacturer Defendants' Catalog of Deception

117. The theme of the Manufacturer Defendants' false and misleading statements was simple and consistent: downplaying the well-established risks of opioids, in particular addiction and overdose death, while overstating, beyond the limits of any scientific support, their supposed benefits. None of the these claims were credible, and the Manufacturer Defendants knew it. But they each promoted (and never retracted) some or all of the following false and misleading claims to New York HCP's for nearly twenty years.

1. Misrepresentation #1: The Risk of Addiction from Chronic Opioid Therapy is Low

118. According to the 2016 Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (the "CDC Guideline"), which simply confirmed earlier scientific findings, up to 26% of people who are prescribed opioids become addicted.[28] The rate is even worse—up to 40%—among chronic pain patients treated with the drugs.

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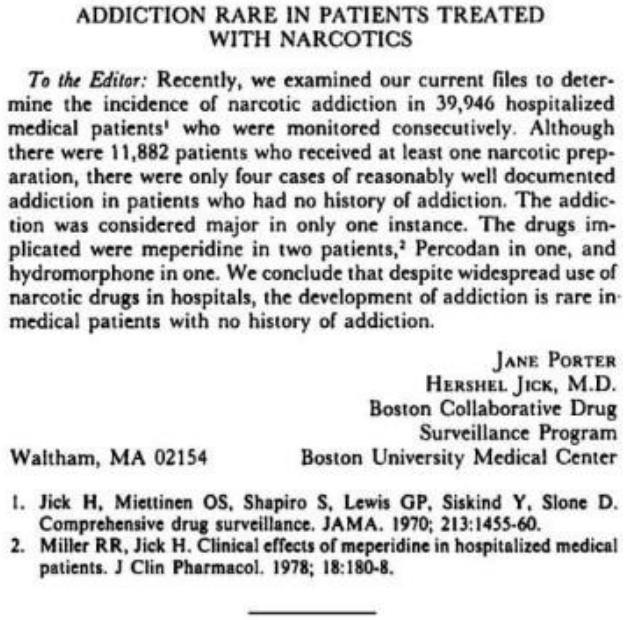
[26] Ctrs. for Medicare & Medicaid Services, Open Payments Data, https://openpaymentsdata.cms.gov (last visited Mar. 25, 2019); New York State Health Foundation, *Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State* (June 2018), *available at* https://nyshealthfoundation.org/wp-content/uploads/2018/06/following-the-money-pharmaceutical-payments-opioid-prescribing-june-2018.pdf.

[27] *Id.*; Ctrs. for Medicare & Medicaid Services, Open Payments Data, https://openpaymentsdata.cms.gov (last visited Mar. 25, 2019).

[28] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 Morbidity & Mortality Wkly. Rep. at 10 (Mar. 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf (hereinafter "CDC Guideline"); Caleb Banta-Green et al., *Opioid Use Behaviors, Mental Health and Pain—Development of a Typology of Chronic Pain Patients*, 104 Drug Alcohol Dependence 34-42 (Sept. 2009); Joseph Boscarino et al., *Risk Factors for Drug Dependence Among Out-Patients on Opioid Therapy in a Large US Health-Care System*, 105 Addiction 1776–82 (Oct. 2010); Bhushan Bhamb

119. To upend this hard reality, the Manufacturer Defendants turned to a one-paragraph letter to the editor from Dr. Hershel Jick and Jane Porter published in the *New England Journal of Medicine* ("NEJM") in 1980 (the "Porter/Jick letter"), which concluded that "the development of addiction is rare in medical patients with no history of addiction."[29]



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.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, 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.

The letter—which was not peer reviewed—drew this conclusion from a review of the records of patients who were given small, short-term doses of opioids to treat acute pain in the controlled setting of an academic hospital.[30] Dr. Jick later noted that he wrote a letter because the data were not robust enough to be published as a study.[31]

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et al., *Substance Use Disorders in a Primary Care Sample Receiving Daily Opioid Therapy*, J. Pain 573–82 (July 2007).

[29] Jane Porter & Herschel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med. 123 (1980); Pamela Leung, *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Eng. J. Med. 2194 (2017), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[30] Harrison Jacobs, *This One-Paragraph Letter may have Launched the Opioid Epidemic*, Business Insider, May 26, 2016, *available at* https://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5.

[31] Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic* 174 (2d Ed. 2018).

120. The Manufacturer Defendants nevertheless extensively relied on this letter in promotional and educational materials to support the lie that opioids posed a low risk of addiction.[32] "But that's not in any shape or form what we suggested," Dr. Jick later lamented.[33]

121. The enormous impact of how the Defendants "grossly misrepresented" the Porter/Jick letter was documented in another letter to NEJM:

> [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 . . .[34]

"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."[35]

2. Misrepresentation #2: Signs of Addictive Behavior are "Pseudoaddiction," Potentially Requiring More Opioids

122. The Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, and that the appropriate response was to prescribe even more opioids. Dr. David Haddox, who later became a senior medical director for Purdue, published a study in 1989 inventing the term "pseudoaddiction," which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate

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[32] Porter & Jick, *supra* note 29.
[33] Taylor Haney & Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers*, NPR, June 16, 2017, *available at* https://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi.
[34] Meier, *supra* note 31, at 174.
[35] Porter & Jick, *supra* note 29.

pain management."[36] In other words, patients 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 undertreatment of their pain.

123. According to this hypothesis, which has never been scientifically validated, drug-seeking behaviors consistent with addiction in many cases represent "legitimate" efforts to obtain more opioids for adequate treatment of pain—thus the term "pseudoaddiction." Opioid manufacturers, in disseminating the pseudoaddiction myth, told providers that patients may exhibit drug-seeking behaviors because "opioids are frequently prescribed in doses that are inadequate."

124. The concept of "pseudoaddiction" shows how research performed by the seemingly-independent KOLs was misused. A 2015 investigative review found that while pseudoaddiction was discussed in 224 medical-journal articles in prior years, only 18 of those articles discussed its validity, including four articles supporting this fictitious diagnosis that were funded by pharmaceutical companies.[37] The remaining 200+ articles stand as a testament to the effectiveness of this particular lie, in that they all cited the concept of "pseudoaddiction" "as a matter of routine acceptance" *despite no empirical evidence supporting the theory*.[38]

125. The CDC Guideline has never recommended giving more opioids to patients showing signs of addiction. Even Dr. Lynn Webster, a KOL discussed below, admitted that

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

[37] Marion S. Green & R. Andrew Chambers, *Pseudoaddiction: Fact or Fiction? An Investigation of the Medical Literature*, Current Addiction Reps. 310-317 (2015).

[38] *Id.*; Of the 22 articles in the combined group that disclosed funding from drugmakers, the authors identified Purdue as a sponsor in nine.

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."[39]

3. Misrepresentation #3: The Risk of Addiction Can Be Easily Identified and Managed

126. While continuing to maintain that most patients are at low risk for addiction, the Manufacturer Defendants asserted that for the susceptible few, HCPs could effectively identify and manage the risk. They promoted screening tools, like questionnaires, that try to identify patients with addiction risks (such as personal or family histories of substance use, mental illness, or trauma) to make HCPs feel like they knew which small number of patients they had to closely monitor, thereby making them more comfortable prescribing them to everyone else.

127. One prominent KOL who received millions of dollars from the Manufacturer Defendants, Dr. Lynn Webster,[40] developed the Opioid Risk Tool ("ORT") screening test, a five-question *self-reported* patient questionnaire that the Manufacturer Defendants deceptively represented could accurately predict the risk of addiction.[41]

128. But there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. There is also no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. And there is no reliable scientific evidence

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[39] John Fauber, *Chronic Pain Fuels Boom in Opioids*, MedPage Today, Feb. 19, 2012, *available at* https://www.medpagetoday.com/neurology/painmanagement/31254.
[40] Open Payments Data, *supra* note 26.
[41] L. Webster & R. Webster, *Predicting Aberrant Behaviors in Opioid-Treated Patients: Preliminary Validation of the Opioid Risk Tool*, Pain Medicine 432–442 (Nov. 2005), *available at* https://academic.oup.com/painmedicine/article/6/6/432/1853982.

that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.[42]

4. Misrepresentation #4: Opioid Withdrawal Can Be Avoided by Tapering

129. In an effort to downplay the risk and impact of addiction, the Manufacturer Defendants claimed that physical dependence is totally separate from addiction, and that the symptoms of opioid withdrawal can be easily addressed by gradually tapering patients' doses as they are taken off the drugs.[43] But there was no scientific support for this claim, and tapering (essentially "cutting down," but still using the same drug) has never been recommended or recognized by any legitimate medical or addiction professionals as a responsible or effective way to help those who have developed an opiate use disorder overcome the physical consequences of withdrawal.

5. Misrepresentation #5: Opioid Doses Can Be Increased without Limits or Greater Risks

130. The Manufacturer Defendants instructed HCPs that they could safely increase patients' opioid doses without risk in order to achieve pain relief, deceptively omitting warnings of known, increased adverse effects that occur at higher doses, and the spiral of problems caused by tolerance to the drugs.

131. For example, a 2011 study reported that dosages of opioids (expressed in morphine milligram equivalents, or "MMEs") of 100 MME or more were associated with dramatic increases

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[42] *See* Agency for Healthcare Research and Quality, *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain* 1, 21 (Sept. 2014), *available at* https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-opioid-treatment_research.pdf.

[43] *Is There a Difference Between Physical Dependence and Addiction?*, Nat'l Institute on Drug Abuse (Jan. 2018), https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/there-difference-between-physical-dependence (last visited Mar. 25, 2019).

in overdose rates.[44] A study of veterans from 2004 to 2009 found the rate of overdose deaths is directly related to maximum daily dose of opioids, with a mean fatal dose of 98 MME.[45] Other studies show that among patients who receive an initial ten-day opioid prescription, one in five will still be on opioids after one year.[46] Almost half of those who receive an initial 30-day supply of opioids will still be on them after a year.[47]

132. The CDC Guideline states that due to lack of evidence of benefits of opioids for chronic non-cancer pain beyond three months[48] and the "increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent,"[49] HCPs should limit opioid prescribing to three months (unless benefits outweigh harms) and "avoid increasing doses" above 90 MME.[50]

6. Misrepresentation #6: Long-Term Opioid Use Improves Functioning

133. Despite substantial evidence showing that opioids do not improve functioning and worsen health, the Manufacturer Defendants consistently and misleadingly promoted opioids as capable of improving patients' ability to function at home and work and overall quality of life, because they viewed these claims as a critical part of their marketing strategies. To recalibrate the

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[44] Amy S. Bohnert et al., *Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths*, 305 J. Am. Med. Ass'n 1315–21 (2011).
[45] Amy S. Bohnert et al., *A Detailed Exploration Into the Association of Prescribed Opioid Dosage and Overdose Deaths Among Patients with Chronic Pain*, 54 Med. Care 435 (May 2016), *available at* http://journals.lww.com/lww-medicalcare/Abstract/publishahead/A_Detailed_Exploration_Into_the_Association_of.98952.aspx (In a national sample of Veterans Health Administration patients with chronic pain who were prescribed opioids, mean prescribed opioid dosage among patients who died from opioid overdose was 98 MME (median 60 MME) compared with mean prescribed opioid dosage of 48 MME (median 25 MME) among patients not experiencing fatal overdose).
[46] Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*, 65 Morbidity & Mortality Wkly. Rep. 265 (Mar. 2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1 htm (Figure 1).
[47] *Id.*
[48] CDC Guideline, *supra* note 28, at 2.
[49] *Id.* at 19.
[50] *Id.* at 16.

risk-benefit analysis for opioids, the Manufacturer Defendants falsely touted nonexistent benefits of opioid treatment in order to overcome its known dangers.

134. A 2006 study-of-studies found that opioids did not produce 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 . . ."[51] 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.

135. A 2008 study published in the journal *Spine* showed that patients prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work.[52] 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.[53]

136. A 2012 study published in the *Journal of Pain*, which followed 68,000 women over three years, found that patients who received opioid treatment were less likely to have improvement in pain, and had worsened function.

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[51] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid- Prescribing Guideline*, 374 New Eng. J. Med. 1501, 1503 (2016).
[52] Jeffrey Dersh et al., *Prescription Opioid Dependence is Associated with Poorer Outcomes in Disabling Spinal Disorders*, 33 Spine 2219-27 (2008).
[53] Gary Franklin et al., *Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: the Disability Risk Identification Study Cohort*, 33 Spine 199, 201-02 (2008).

137. In 2014, the U.S. Agency for Healthcare Research and Quality concluded that "[e]vidence on long-term opioid therapy for chronic pain is very limited but suggests an increased risk of serious harms that appears to be dose-dependent."[54]

138. In 2016, the CDC concluded that "there is no good evidence that opioids improve pain or function with long-term use,"[55] and that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[56] 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]."[57]

139. The CDC also stated that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration)," while "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)."[58]

140. The Food and Drug Administration ("FDA") has rejected as false and misleading claims that opioids improve patients' function and quality of life if they are not supported by substantial evidence or clinical experience. For example, in 2008, the FDA warned King Pharmaceuticals that its statements about Avinza (morphine sulfate ER) were false and misleading because its claims that "patients who are treated with the drug experience an improvement in their

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[54] Agency for Healthcare Research and Quality, *supra* note 41, at ix.
[55] CDC Guideline, *supra* note 28, at 20.
[56] *Id.* at 2, 18.
[57] Frieden & Houry, *supra* note 51, at 1503.
[58] CDC Guideline, *supra* note 28, at 15.

overall function, social function, and ability to perform daily activities" were not demonstrated by substantial evidence or substantial clinical experience.[59]

141. In 2010, the FDA warned Allergan that its claims that its opioid Kadian (morphine ER) improved functioning were false and misleading:

> [W]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience (such as the common adverse events of drowsiness, dizziness, constipation and nausea), results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life. In addition, we are not aware of any studies demonstrating that the level of pain reduction experienced by patients on Kadian therapy corresponds with a positive impact on the outcomes claimed.[60]

7. Misrepresentation #7: Alternative Forms of Pain Relief Pose Greater Risks than Opioids

142. In their marketing, the Manufacturer Defendants consistently 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 acetaminophen or nonsteroidal anti-inflammatory drugs ("NSAIDs").

143. 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

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[59] Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Marketing, Advertising, and Comm'n, Dep't of Health & Human Servs., to Brian A. Markison, Chairman, President, and Chief Exec. Officer, King Pharmaceuticals, Inc. (Mar. 24, 2008), *available at* http://wayback.archive-it.org/7993/20170112064025/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054134.pdf.

[60] Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Marketing, Advertising, and Comm'n, Dep't of Health & Human Servs., to Doug Boothe, Chief Exec. Officer, Actavis U.S. (Feb. 18 2010), *available at* http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240 htm.

"known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[61] hormonal dysfunction;[62] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[63] neonatal abstinence syndrome; 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.[64]

144. 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.[65]

145. A 2018 study designed to make head-to-head comparisons between opioids and other kinds of pain medications showed 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. The study

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[61] 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).
[62] Harry W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3 J. Pain 377-84 (2001).
[63] *See* Bernhard M. Kuschel et al., *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – a Swedish Case-Control Study*, 25 Eur. J. Pub. H. 527 (July 2014).
[64] Karen H. Seal et al., *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307 J. Am. Med. Ass'n 940-47 (2012).
[65] M. Daubresse et al., *Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,* 51 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* John Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173 J. Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

concluded that "[t]reatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."[66]

8. Misrepresentation #8: Extended-Release Drugs Provide Twelve or More Hours of Pain Relief

146. The Manufacturer Defendants misled doctors and patients about the original selling point of their "revolutionary" extended-release ("ER") opioids, making the knowingly false claim that such drugs would provide 12 or more hours of pain relief for most patients. This claim provided the basis for the Manufacturer Defendants' patents and their efforts to differentiate themselves from competitors, and facilitated their false claims that ER drugs have a more even, stable release mechanism that avoids peaks and valleys, and therefore the rush that fosters misuse and addiction.

147. The active ingredient in the Manufacturer Defendants' ER opioids does not enter the body at a linear rate. OxyContin, for example, works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief. As a result, in many patients, OxyContin does not last for the twelve hours promised.

148. An ER pill releases an initial rush of nearly half of the opioid dosage, which triggers a powerful psychological response—like an immediate release opioid. Consequently, there is less of the drug at the end of the 12 hours, which precipitates withdrawal symptoms, a phenomenon known as "end of dose" failure.

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[66] Erin E. Krebs et al., *Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial*, 319 J. Am. Med. Ass'n. 872-82 (2018), *available at* https://jamanetwork.com/journals/jama/fullarticle/2673971.

149. End-of-dose failure can render ER opioids even more dangerous than IR opioids because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for more ER opioids. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[67] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

150. The Manufacturer Defendants' refusal to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of their ER drugs in a manner that preserved their competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

9. Misrepresentation #9: Newly-Developed but More Expensive Formulations of Opioids Successfully Deter Abuse

151. In 2010, the FDA approved a reformulated version of OxyContin, which was the first opioid that was allowed to make claims that it was designed to help discourage misuse.[68] The FDA noted that the new version was "intended to prevent the opioid medication from being cut, broken, chewed, crushed or dissolved to release more medication," but that "it still can be abused or misused by simply ingesting larger doses than are recommended."[69]

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[67] Harriet Ryan, *supra* note 21.
[68] Press Release, U.S. Food & Drug Administration, FDA Approves New Formulation for OxyContin (Apr. 5, 2010), *available at* https://wayback.archive-it.org/7993/20170112130258/http:/www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm207480.htm.
[69] *Id*.

152. The CDC Guideline, however, confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[70] CDC staff could not find "any evidence showing the updated opioids [abuse deterrent opioids] actually reduce rates of addiction, overdoses, or death."[71]

153. The Manufacturer Defendants marketed "abuse-deterrent formulation" ("ADF") opioids—whether or not they had FDA approval to do so—as safer to prescribe than traditional opioids. Their false and misleading marketing of the benefits of ADF opioids falsely reassured prescribers that prescribing such opioids was not risky, thereby exacerbating the opioid epidemic.

10. Misrepresentation #10: The Manufacturer Defendants Worked Diligently to Detect and Prevent Diversion of Opioids

154. After the diversion of opioids increased dramatically in the 2000's, each of the Manufacturer Defendants extensively advertised their efforts to monitor and report abuse and diversion of their products, to convey that they were socially responsible companies. These communications, designed to create a false sense of security, were misleading, because, as explained below, none of the Manufacturer Defendants had an effective suspicious order monitoring program, as required by law.

E. The Manufacturer Defendants' Deceptive Marketing Directly Supported Sales of their Branded Formulations

155. The Manufacturer Defendants' branded marketing efforts relied on three primary channels for promoting their false and deceptive claims concerning opioids: (a) "detailing" visits

[70] CDC Guideline, *supra* note 28, at 22 (emphasis added).
[71] Matthew Perrone et al., *Drugmakers Push Profitable, but Unproven, Opioid Solution,* Public Integrity, Dec. 15, 2016, *available at* https://publicintegrity.org/state-politics/drugmakers-push-profitable-but-unproven-opioid-solution/.

to HCPs by each manufacturer's sales representatives; (b) advertisements placed in medical journals aimed at prescribers; and (c) discount cards aimed at consumers. And while these efforts were explicitly in support of the Manufacturer Defendants' branded drugs, they inevitably impacted perceptions of the generic versions of those drugs they knew HCPs would frequently prescribe in their place.

1. Detailing

156. Each Manufacturer Defendant aggressively detailed New York HCPs, typically promoting their branded opioids but often touting the benefits of opioids generally. Between 2000 and 2014, their combined detailing expenditures more than doubled to $168 million.

157. The Manufacturer Defendants trained their sales representatives to disseminate to HCPs the false and misleading claims described above. Each manufacturer analyzed prescription drug sales data (e.g., from IMS Health Holdings, Inc., today known as IQVIA), which contained details regarding the drugs prescribed by HCPs and the pharmacies that dispensed those drugs,[72] to track the prescribing practices of individual HCPs in order to select them for detailing. Manufacturers could have—but did not—use this data to identify inappropriate prescribing and potential diversion.

158. From 2008 through present, the Manufacturer Defendants' sales representatives have visited New York HCPs more than one million times. While Purdue implemented the most pervasive opioids detailing program, the other Manufacturer Defendants were not far behind, collectively making nearly 600,000 opioid-related sales visits to New York HCPs from 2008

[72] Jeremy A. Greene, *Pharmaceutical Marketing Research and the Prescribing Physician*, 146 Annals of Internal Med. 742 (2007), *available at* https://annals.org/aim/fullarticle/734723/pharmaceutical-marketing-research-prescribing-physician.

through the present. Janssen led the pack with [redacted] visits promoting Nucynta, followed by Endo with nearly 165,000 visits promoting Opana, Mallinckrodt with more than [redacted] visits promoting Exalgo and Xartemis, Teva with [redacted] visits promoting Fentora, and Allergan with nearly 3,000 visits promoting Kadian. Each Manufacturer Defendant has paid bonuses to its sales representatives based on prescriptions written by those HCPs, and has made extensive payments to those HCPs in the form of speakers' fees, lunches, and dinners.

159. A study published in the Journal of the American Medical Association in 2018 concluded that even small payments of $10 from opioid manufacturers can influence HCPs to prescribe opioids, and that "receipt of any opioid-related payments from industry in 2014 was associated with 9.3% … more opioid claims in 2015 compared with physicians who received no such payments []."[73] Another 2018 study that focused on New York HCPs concluded that "[o]pioid-related payments may lead to an increase in opioid prescribing, based on comparisons with a matched group of similar physicians who did not receive any opioid-related payments."[74]

160. Detailing can have deadly results. A study published in January 2019 in *JAMA Network Open* concluded that "across US counties, marketing of opioid products to physicians was associated with increased opioid prescribing and, subsequently, with elevated mortality from overdoses."[75]

2. Advertisements

161. To promote the purported benefits of its branded opioids, each Manufacturer Defendant placed advertisements in medical journals and popular magazines promoting the use of

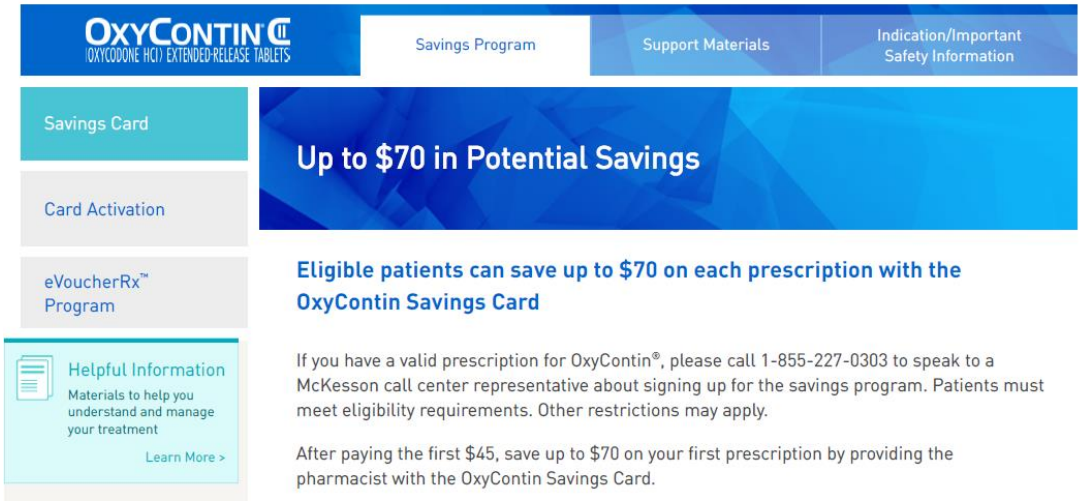
[73] Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing*, 178 J. Am. Med. Ass'n Internal Med. 861, 862 (June 2018), *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2681059.
[74] NYS Health Foundation, *supra* note 26, at 2.
[75] Scott E. Hadland, *supra* note 73, at 861.

opioids. Such advertisements, among other things, deceptively omitted or downplayed the risk of addiction and overstated the benefits of opioids for chronic pain.

162. The manufacturers aggressively promoted their opioids through such branded advertising, such that by 2011, the manufacturers' collective spend on such advertising reached $14 million—an amount triple the size of their collective advertising ten years earlier in 2001.

3. Discount Cards

163. The Manufacturer Defendants recognized that one of the largest obstacles to consumers starting and remaining on their branded opioids, including by switching from a competitor's drug, was out-of-pocket cost. To overcome this barrier, they each advertised to consumers and distributed widely—including on their public websites—co-pay discount cards, which often enabled consumers to receive a "starter" dose of addictive narcotics at low cost or *for free*. For example, in 2012, Janssen planned to distribute 1.5 million in savings cards worth $25 each. Disregarding the consequences of the opioids epidemic they created, the Manufacturer Defendants continue to advertise opioids discount cards directly to consumers, sometimes working with distributors. For example, Purdue's savings program for OxyContin is currently administered by McKesson:



F. The Manufacturer Defendants' Surreptitious Campaign to Infect the Wider Community of HCPs and Patients with their Lies

164. Each Manufacturer Defendant also spent hundreds of millions of dollars on unbranded advertising in order to create the appearance that unbiased and impartial medical information supported the widespread prescription of opioids, as a cover for their fraudulent misrepresentations aimed at both HCPs and patients. This unbranded advertising took the form of:

- Continuing Medical Education (CME), aimed at unwary HCPs;
- Key Opinion Leaders (KOLs), who were recruited and trained to: deliver skewed CMEs and other deceptive scripted talks; author misleading studies; and serve on the boards and committees of the Front Groups; and
- Front Groups designed to appear as neutral and credible professional societies and patient advocacy groups that developed educational materials and treatment guidelines supporting the use of opioids for long-term treatment of chronic pain.

165. The Manufacturer Defendants also co-opted reputable health care organizations to promote opioid prescribing and aimed their deceptive marketing at vulnerable populations, including the elderly and veterans. All of these efforts were designed to present a misleading view of how and when opioids could be safely and effectively used.

1. Continuing Medical Education Programs

166. The Manufacturer Defendants aggressively distributed their false and deceptive messaging through in-person and online CMEs, which should represent the "body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public."[76]

[76] American Med. Ass'n & Accreditation Council for Continuing Med. Education, *Glossary of Terms and Definitions*, "Continuing Medical Education (CME)" (April 2017), *available at*: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/physicians/cme/ama-accme-glossary-terms.pdf.

167. Instead, the Manufacturer Defendants sponsored thousands of CMEs that they manipulated to promote their false and deceptive claims downplaying the risks and touting unproven benefits of their opioid drugs. As with all of their promotional efforts, the Manufacturer Defendants continually measured the effect of CMEs on HCPs' views on opioids, and the absorption of specific messages, providing direct evidence of the effectiveness of their scheme in misleading the HCPs who attended.

2. Key Opinion Leaders

168. The Manufacturer Defendants extensively cultivated and paid a select circle of KOLs, including Drs. Russell Portenoy, Lynn Webster, and Perry Fine, to advocate for the widespread prescription of opioids.

169. The Manufacturer Defendants directed these KOLs to write, consult on, edit, and lend their names to books and articles, and to give speeches and CMEs supportive of opioid therapy. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids, and on boards of pro-opioid advocacy groups and professional societies that developed and presented deceptive CMEs.

170. As the KOLs began publishing seemingly independent and "scientific" papers supporting the Manufacturer Defendants' false and misleading claims, the companies then poured enormous funds and resources into their marketing machines, which widely cited and promoted the KOLs' work to drive prescriptions of opioids.

a) Dr. Russell Portenoy

171. Dr. Russell Portenoy was a top KOL and spokesperson for several Manufacturer Defendants, including Purdue, Teva, Endo, and Janssen.

172. Dr. Portenoy sat as a director on the board of two Front Groups, the American Pain Foundation ("APF"), and was also president of the American Pain Society ("APS"). Dr. Portenoy

was also a chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, and co-authored roughly 100 articles on pain and related issues.

173. Dr. Portenoy was a key figure in destigmatizing opioid use, touting their purported benefits and minimizing their risks in all marketing channels, from medical literature to an appearance on *Good Morning America*, falsely claiming that less than 1% of patients would become addicted to opioids.

174. Starting in 1997, Dr. Portenoy received research support, consulting fees, and honoraria from several manufacturers. In 2009, for example, Purdue contributed [redacted] to [redacted] in New York for the [redacted] In turn, Dr. Portenoy played a critical role in amplifying Purdue's fraudulent claims about the risks and benefits of long-term opioid use for managing chronic pain.

175. Dr. Portenoy also frequently appeared in the media to promote opioids by dramatically understating the risk of addiction. In 2010, for example, he appeared on the nationally televised *Good Morning America* show, to discuss the long-term use of opioids to treat chronic pain and to falsely claim the following: [77]

> Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance misuse, and does not have a history in the family of substance misuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.

176. Dr. Portenoy also repeatedly emphasized to physicians and the public that opioids posed a low risk of addiction, relying exclusively on the 1980 Porter/Jick letter discussed above. In his own words:

[77] *Good Morning America* (ABC News television broadcast Aug. 30, 2010).

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence, this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*[78]

177. Dr. Portenoy later admitted that he had misrepresented the risks and benefits of opioid treatment, noting that he "gave innumerable lectures in the late 1980s and 90s about addiction that weren't true," and that "[d]ata about the effectiveness of opioids does not exist."[79] He further admitted: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, … I guess I did." Dr. Portenoy also later rescinded his promotion of opioids as "pseudoscience."

b) Dr. Lynn Webster

178. Another important KOL was Dr. Lynn Webster, who received millions of dollars from the Manufacturer Defendants[80] and authored numerous CMEs sponsored by Teva, Endo, and Purdue.

179. Among his other pro-opioid activities, Dr. Webster is a member of the board and past president of the Front Group the American Academy of Pain Medicine ("AAPM") and is senior editor of *Pain Medicine*, a journal that published Endo's special advertising supplements touting Opana ER.

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[78] Interview of Russell Portenoy by Physicians for Responsible Opioid Prescribing, 2:07-2:51, (YouTube Oct. 30, 2011), *available at* https://www.youtube.com/watch?time_continue=2&v=DgyuBWN9D4w (last visited Mar. 25, 2019) (emphasis added).
[79] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.
[80] Open Payments Data, *supra* note 26.

180. Dr. Webster has been the leading national proponent of "pseudoaddiction." As described in his co-authored book, *Avoiding Opioid Abuse While Managing Pain* (2007), a doctor's "first response" when facing signs of "aberrant" behavior should "in most cases" to increase the amount of opioids prescribed.

181. In 2010, the DEA raided Dr. Webster's Salt Lake City pain clinic following an investigation for overprescribing opioids after 20 patients had overdosed and died.

c) Dr. Perry Fine

182. The Manufacturer Defendants also relied extensively on Dr. Perry Fine, whose KOL activities have included serving on Purdue's advisory board, providing medical consulting for Janssen, participating in CME activities for Endo, and authoring seemingly "independent" publications for Teva. Dr. Fine also co-chaired the AAPM/APS Guideline Panel, served as the AAPM's treasurer (2007–10) and president (2011–13), and on APF's Board of Directors.

183. Dr. Fine has campaigned extensively against legislation restricting high-dose opioid prescriptions for non-cancer patients. One of the many examples of the dangerous and deceptive statements by KOLs is in *A Clinical Guide to Opioid Analgesia*, co-written by Drs. Fine and Portenoy, which downplays risks of opioid treatment such as respiratory depression and addiction: "At clinically appropriate doses . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk."[81]

[81] Perry G. Fine & Russell K. Portenoy, *A Clinical Guide to Opioid Analgesia* 20, 34 (2004), *available at* http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

184. Pro-opioid KOLs often failed to disclose their financial ties to the Manufacturer Defendants. For example, in 2011, after Dr. Fine and fellow KOL Dr. Scott Fishman published a letter in the *Journal of the American Medical Association* ("JAMA") called "Reducing Opioid Abuse and Diversion," which emphasized the importance of maintaining patient access to opioids,[82] the editors of *JAMA* found that both had provided incomplete financial disclosures and required them to submit corrections listing all of their ties to the opioids industry.[83]

3. Front Groups

185. In addition to relying on CMEs and KOLs, the Manufacturer Defendants used, funded, and directed numerous Front Groups, which often had directors who were undisclosed KOLs, to promote their false and misleading claims.[84] Under the guise of neutrality, the Front Groups deepened the Manufacturer Defendants' ability to convey to HCPs, patients, and policymakers that pro-opioid messaging was independent and patient-centered rather than driven by profits, as was the case.[85]

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[82] Perry G. Fine & Scott M. Fishman, *Reducing Opioid Abuse and Diversion*, 306 J. Am. Med. Ass'n 381 (July 2011), *available at*: https://jamanetwork.com/journals/jama/articleabstract/1104144?redirect=true.

[83] Perry G. Fine, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 J. Am. Med. Ass'n 1445 (Sept. 2011), *available at* https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true; Scott M. Fishman, *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 J. Am. Med. Ass'n 1446 (Oct. 2011), *available at*: https://jamanetwork.com/journals/jama/fullarticle/1104453.

[84] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* 3 (February 12, 2018), https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*").

[85] The extensive bond between opioid manufacturers and Front Groups was revealed in the U.S. Senate 2017 report *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, which was "the first comprehensive snapshot of the financial connections between opioid manufacturers and advocacy groups and professional societies operating in the area of opioids policy." The report found that the opioid manufacturers, including Manufacturer Defendants Purdue and Janssen, contributed millions of dollars to various Front Groups and individuals associated therewith; these groups "'play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public.'" As the Senate report found, the Front Groups "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC

186. The groups described below are among those that the Manufacturer Defendants deployed to fuel the epidemic within New York State:

a) American Pain Foundation

187. One of the most prominent Front Groups, the American Pain Foundation ("APF"), held itself out as an independent patient advocacy organization, but from its founding in 1997 to its abrupt demise in 2012, APF was a shill for the opioids industry. In 2010, 90 percent of its funding came from the industry, including from each of the Manufacturer Defendants; during its last five years, APF received more than $10 million in funding from opioid manufacturers alone.

188. APF was controlled by the Manufacturer Defendants, as demonstrated by:

a. Stocking its board of directors with doctors who were on opioid manufacturers' payrolls either as consultants or as speakers at medical events;

b. Submitting grant proposals for projects that had been suggested by the manufacturers—for example, in 2001, Purdue told APF that the basis of a grant to the organization was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests";

c. Distributing opioid manufacturers' publications, which were rife with misrepresentations regarding the risks, benefits, and superiority of opioids;

d. Engaging in a multimedia campaign to "educate" patients about their "right" to opioid pain treatment; and

e. Developing the National Initiative on Pain Control ("NIPC"), which operated a facially unaffiliated website, www.painknowledge.com. NIPC promoted itself as an education initiative led by purported experts in the pain management field and published unaccredited prescriber education programs. Manufacturers such as Endo, however, substantially controlled NIPC by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials.

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guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."

189. APF's materials and programs were available nationally and reached many New Yorkers, as intended. For example, APF distributed 17,200 copies of a guide for consumers sponsored by Purdue and Teva, entitled *Treatment Options: A Guide for People Living with Pain* ("*Treatment Options*"). This guide, which is still available online, misleadingly downplays the risk of addiction from opioids, stating that physical dependence, which is a symptom of addiction, "does NOT mean you are addicted," and suggests that only persons who already have "addictive disease" have misused opioids. The guide also deceptively states that "[d]espite the great benefits of opioids, they are often under-used."

190. *Treatment Options* falsely stated that some opioids have "no ceiling dose as there is with the NSAIDs" and therefore are more appropriate for treatment of pain, and attributed 10,000 to 20,000 annual deaths to NSAID overdose, even though the actual figure is closer to 3,200 per year.[86] The guide also misleadingly suggested that "opioid agreements" between patients and prescribers would "ensure that [the patient] take[s] the opioid as prescribed."

191. Among its other industry-funded projects, APF published *Exit Wounds*, a 2009 book written by Derek McGinnis, a disabled veteran employed by APF, with "assistance" from APF staff. The book made numerous misrepresentations about the risk of addiction associated with opioids, describing the drugs as "underused" and the "gold standard of pain medications." It misleadingly downplayed physical tolerance as "simply a psychological process that doesn't occur for all people or with all medications," and implied that only those who abuse opioids or use them recreationally become addicted. Even more egregiously, *Exit Wounds* claimed that

[86] 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. Therapeutics 17, 21 (2004).

"[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

192. *Exit Wounds* also failed to disclose the risks of fatal interactions between opioids and anti-anxiety medicines known as benzodiazepines, which are commonly prescribed to veterans with posttraumatic stress disorder. According to a VA Office of Inspector General Report, 96.4% of veterans who were prescribed opioid drugs long-term were also prescribed benzodiazepines, despite the increased danger of respiratory depression when the two drugs are taken together.[87]

193. *Exit Wounds* also exaggerated the side effects of NSAIDs, such as stomach ulcers and gastrointestinal bleeding, while understating the significantly more serious side effects associated with opioids, which include nausea, vomiting, constipation, mental clouding, and, of course addiction, overdose, and death.

194. APF also published *A Policymaker's Guide to Understanding Pain & Its Management*, which among other misleading statements, characterized as a "myth" the idea that "[c]hildren can easily become addicted to pain medications," because "[l]ess than 1 percent of children treated with opioids become addicted." This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

195. In May 2012, the U.S. Senate Finance Committee began investigating APF's ties to opioid manufacturers. Immediately thereafter, the manufacturers cut off funding for APF, which shortly thereafter folded, it claimed, "due to irreparable economic circumstances."

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[87] Dep't of Veterans Affairs Office of Inspector General, *Review of Pain Management Services in Veterans Health Administration Facilities* at iv (Sept. 27, 2018), *available at* https://www.va.gov/oig/pubs/VAOIG-16-00538-282.pdf.

b) American Academy of Pain Medicine and the American Pain Society

196. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies that received substantial funding from the Manufacturer Defendants, in particular from 2009 to 2013, which allowed the manufacturers to control the groups' projects and messaging. For example:

a. In 1997, AAPM issued a "consensus" statement (which is still accessible today) that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. In fact, however, the "consensus" was stacked with undisclosed KOLs, including the statement committee's chair, Dr. J. David Haddox, who was at the time a paid speaker for Purdue (and later became a Purdue executive), and the committee's sole consultant, Dr. Russell Portenoy, was also a spokesperson for Purdue;

b. AAPM's past presidents, including Dr. Haddox (1998), Dr. Scott Fishman, (2005), Dr. Perry G. Fine (2011) and Dr. Lynn R. Webster (2013), each had deep connections to the Manufacturer Defendants. Dr. Fishman, for example, also served as a KOL for several manufacturers, and stated that he would place the group "at the forefront" of teaching that "the risks of addiction are ... small and can be managed";

c. At one AAPM conference, 37 of the roughly 40 sessions related to opioids; and

d. AAPM, which received more than $2.2 million in funding from opioid manufacturers, maintained a corporate relations council, whose members—including each of the Manufacturer Defendants—paid $25,000 per year (on top of other funding) to participate in private meetings.

197. In 2009, with the prompting, assistance, involvement, and funding of the manufacturers, the AAPM and APS jointly issued guidelines for chronic opioid therapy (the "2009 AAPM/APS Guidelines").

198. The 2009 AAPM/APS Guidelines are supposed to serve the noble purpose of educating physicians about "best practices," especially for practitioners who are not already knowledgeable about pain management. But, in fact, the Guidelines promote the Manufacturer Defendants' deceptive messages by distorting the risks and benefits of using opioids to treat

chronic pain, despite acknowledging that "[r]eliable evidence on methods to accurately assess the potential benefits of [chronic opioid therapy] is limited."

199. When the 2009 AAPM/APS Guidelines were released, 14 of the 21 panel members who drafted the guidelines received financial support from the Manufacturer Defendants. Other panel members further suggested that the guidelines might be biased in many important respects, including the high presumptive maximum dose of opioids, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

200. Despite these red flags, the 2009 AAPM/APS Guidelines have been a particularly effective tool of deception for the Manufacturer Defendants, influencing not only treating physicians, but also the scientific literature on opioids. The Manufacturer Defendants' sales representatives have discussed the Guidelines with HCPs during sales calls; the CDC has recognized that treatment guidelines can "change prescribing practices." The Guidelines have been cited hundreds of times in academic literature and reprinted in the *Journal of Pain*, in addition to being posted online. In addition, the Manufacturer Defendants, in particular Endo, widely promoted the Guidelines in New York without disclosing the companies' involvement in the development of the Guidelines or their financial backing of the authors.

c) Academy of Integrative Pain Management

201. The Academy of Integrative Pain Management ("AIPM" and formerly known as the American Academy of Pain Management) was a highly influential pro-opioid group. Between 2012 and 2017, Manufacturer Defendants Purdue and Janssen gave more than $1.2 million to the AIPM. In 2016, seven of AIPM's nine corporate council members listed on its website were opioid makers.

202. AIPM's leaders provided Manufacturer Defendant-friendly testimony on opioid-related issues, issued action alerts to its network, and gave presentations to HCPs, regulators,

legislators, patient advocacy organizations, and consumers. In 2008, AIPM's executive director urged the FDA to consider the risk of under-treating pain as far more urgent and serious than the calamity of increasing opioid diversion, abuse, and addiction.

203. AIPM led the Pain Action Alliance to Implement a National Strategy ("PAINS") program, which published a state policy report card that downgraded a state for regulating overprescribing of opioids and a brief denying its role in creating the opioid epidemic.

204. Purdue, Janssen and Endo funded a medical education guide, *Opioid Prescribing: Clinical Tools and Risk Management Strategies* ("*Opioid Prescribing*"), which was authored by three members of the board of directors of AIPM, one of whom served as a paid consultant to Janssen. The guide, which was made available to members of AIPM at no charge, was intended to reach primary care physicians and other health care professionals, and large portions of the guide remain available online.

205. *Opioid Prescribing* minimizes risks associated with opioid addiction, teaching prescribers, for example, that "fear of addiction and abuse prevents physicians from properly prescribing opioids, particularly for those with a substance abuse history who could benefit from opioids[.]" The guide deceptively instructs HCPs to give patients who present symptoms of "pseudoaddiction" more pain treatment—in other words, higher or more frequent dosages of opioids—because "[w]hen pain is treated appropriately, aggressive drug-seeking behavior ceases." *Opioid Prescribing* tells HCPs that patients who use opioids to "cope with stress [or] relieve anxiety," or even patients who "use opioids to get high, but ... not in a compulsive way," are not exhibiting signs of addiction, but rather are displaying "other forms of aberrant drug use." *Opioid Prescribing* further provides that even "behaviors that suggest abuse," such as "unscheduled visits, multiple telephone calls to the clinic, unsanctioned dose escalations,

obtaining opioids from more than one source, selling prescription drugs, and forging prescriptions," may not be signs of addiction, but rather "may only reflect ... having pain that is undertreated."

206. AIPM abruptly ceased operations in January 2019.

d) The Alliance for Patient Access

207. The Manufacturer Defendants have also communicated their misleading messaging through the Alliance for Patient Access ("AfPA"). Founded in 2006, AfPA claims to be a "patient advocacy" organization that is "dedicated to ensuring patient access to approved therapies," but in fact is the creation of a Washington, D.C. lobbying firm that does the bidding of drug companies.

208. The Manufacturer Defendants fund AfPA – and its board members – promoting, among other things, the distribution of an issue brief titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse," which features Mallinckrodt KOL Dr. Srinivas Nalamachu and criticizes prescription drug monitoring programs and regulation of pill mills because these measures may restrict access to opioids.

e) The U.S. Pain Foundation

209. The U.S. Pain Foundation ("USPF') is another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. As one of the largest recipients of contributions from the Manufacturer Defendants, it collected nearly $3 million in payments between 2012 and 2015 alone. USPF has been a critical component of the Manufacturer Defendants' lobbying efforts to block limits on overprescribing.

210. USPF has made numerous misleading statements regarding opioids. For example, USPF overstated the ability of opioids to allow patients to function normally, and suggested—in a website page devoted to veterans, and available to all New Yorkers—that

prescribing limits are problematic, and that because unrelieved chronic pain is a risk factor for suicide, "cautioning initiation of opioid therapy for those with suicide ideation may do more harm than good."

211. Manifesting the same types of fiscal improprieties as other Front Groups, in 2018, USPF, which claimed to be the leading advocacy group representing chronic pain patients, terminated its CEO due to misuse of funds and other "financial irregularities."

f) American Geriatrics Society

212. The Manufacturer Defendants also used Front Groups—in particular the American Geriatrics Society ("AGS"), to which they provided substantial financial support—to target their deceptive marketing at the vulnerable elderly. Members of the AGS Board of Directors were on the Manufacturer Defendants' payrolls as either consultants or speakers at medical events. Representatives of the Manufacturer Defendants suggested activities, lobbying efforts, and publications to AGS, which then submitted grant proposals seeking to fund these activities and publications, knowing that they would receive support.

213. AGS contracted with Purdue, Janssen, and Endo to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*) and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines").

214. The 2009 AGS Guidelines misleadingly recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy," and that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." These recommendations are not supported by reliable scientific evidence.

g) The Pain Care Forum

215. The PCF is a coalition of opioid manufacturers (including all of the Manufacturer Defendants), distributors, and trade groups, as well as Front Groups, which lobbies on issues that might impact the opioid industry's bottom line. It was co-founded in 2005 by a lobbyist for Purdue and an individual who served as president, executive director, and CEO of the APF between 2003 and 2011.

216. Through the PCF, the Manufacturer Defendants have deployed extensive resources to resist efforts by New York and other states to adopt measures that would have mitigated the opioid epidemic, such as common-sense restrictions on opioid prescribing and related practices.[88] As part of these efforts, the Manufacturer Defendants spent over $880 million on lobbying and campaign contributions targeting federal and state officials, including in New York, during the period 2006 to 2015 alone.[89]

217. PCF members were actively involved in crafting a 2011 Institute of Medicine report that misleadingly estimated that 100 million Americans (roughly 40 percent of adults) suffer from chronic pain. To this day, the figure supports the Manufacturer Defendants' rallying cry that the U.S. faces an epidemic of untreated pain.

h) The American Chronic Pain Association

218. The Manufacturer Defendants also fund and control the American Chronic Pain Association ("ACPA"), yet another self-proclaimed "patient advocacy" organization to which

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[88] Geoff Mulvihill, et al., *Drugmakers fought state opioid limits amid crisis*, Associated Press, Sept. 18, 2016, *available at* https://apnews.com/86e948d183d14091a80f5c3bfb429c68/drugmakers-fought-state-opioid-limits-amid-crisis. Members of the Purdue-created Pain Care Forum employed over 200 lobbyists in New York State in 2013 through 2015 – the most in any state – and made over $3.7 million in campaign contributions between 2006 and 2015 – the second-highest sum of any state—according to data obtained by the Associated Press. *See* http://data.ap.org/projects/2016/cpi_ap_opioids/indexcpiap html.

[89] *Id.*

they have given substantial funding—both to the entity and its advisory board members. The ACPA website deceptively downplays the risk of addiction, stating that physical dependence "is not at all the same" as addiction.

4. The Manufacturer Defendants Spread their Misleading Messages through Reputable Organizations

a) The Joint Commission

219. The Manufacturer Defendants have manipulated reputable organizations such as the Joint Commission on Accreditation of Healthcare Organizations (the "Joint Commission") to further advance their unlawful marketing of opioids. The Joint Commission certifies over 21,000 health care organizations and is the nation's oldest and largest health care standards-setting and accrediting body.

220. In 2000, Purdue sponsored a book through the Joint Commission that falsely asserted "there is no evidence that addiction is a significant issue when persons are given opioids for pain control." It also labeled doctors' concerns about addiction "inaccurate and exaggerated." Dr. David W. Baker, the Joint Commission's executive vice president for health care quality evaluation, has acknowledged that "[t]he Joint Commission was one of the dozens of individual authors and organizations that developed educational materials for pain management that propagated this erroneous information."

221. In 2001, due to the influence of the Manufacturer Defendants, the Joint Commission introduced standards for health care organizations to improve their care for patients with pain, designating pain as the "fifth vital sign." The standards, *Pain: Current Understanding of Assessment, Management and Treatments*, required systemic assessment of pain in all patients using quantitative measures of pain, as dictated by the Front Group APS.

222. As a result of the Manufacturer Defendants' efforts to manipulate the standard of care, many health care organizations risked loss of their Joint Commission accreditation if they did not incorporate the "fifth vital sign" standard and reduce patients' subjective experience of pain. Prescribing opioids thus went from rare to routine.

b) The Federation of State Medical Boards

223. Purdue, Endo, and Teva also worked through the Federation of State Medical Boards ("FSMB"), a national trade organization representing various state medical boards.

224. In 2007, FSMB nationally disseminated a publication called *Responsible Opioid Prescribing*, and in 2012 it published a second edition entitled *Responsible Opioid Prescribing: A Clinician's Guide*. These publications were widely distributed through legitimate channels: first to state medical boards, and then to practicing physicians.

225. These publications misleadingly recommended powerful opioids as a first choice for chronic pain, underplayed the risk of addiction from those drugs, and reiterated the misleading concept of "pseudoaddiction" as an alternative explanation for drug-seeking behaviors or abuse.

226. The publications acknowledge funding from Purdue and other organizations, but readers would have no way to know that the publications' contents were reliant on materials sponsored by Purdue, that Purdue paid a $50,000 grant to support their publication and contributed $100,000 for distribution, and that they were written by a Purdue KOL, Dr. Scott Fishman, with extensive input from Purdue's senior medical director at the time, Dr. Haddox. Indeed, Dr. Haddox was personally invested, stating in an email to Purdue's [redacted]

5. The Manufacturer Defendants Targeted Their Surreptitious Campaign at Vulnerable Populations

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

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

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

230. A study showed that veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries.[90] A 2008 survey showed that prescription drug misuse among

[90] *Iraq and Afghanistan Veterans: National Findings from VA Residential Treatment Programs*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3661276/pdf/nihms468727.pdf (last visited Mar. 25, 2019).

military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years.[91] Veterans are twice as likely as non-veterans to die from an opioid overdose.[92]

231. The Manufacturer Defendants deliberately targeted veterans with deceptive marketing. For example, as detailed above, *Exit Wounds*, sponsored by Purdue, Endo, and Janssen, was rife with misrepresentations about the risk of addiction from opioids.

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

G. The Distributors Accelerated the Damaging Flood of Opioids into New York State by Persistently Violating their Legal Duties

233. While the Manufacturer Defendants created the initial surge in demand for opioids, and maintained it with their ongoing fraudulent conduct, the explosion in opioid overuse in New York could not have been perpetuated and expanded over the past decade to such devastating effect without the misconduct of the Distributor Defendants.

234. None of them fulfilled their duties under the New York Controlled Substances Act ("NYCSA") to create effective policies to guard against the oversupply of opioids to pharmacies, thereby enabling and expanding their widespread diversion.

235. Indeed, while each Distributor Defendant nominally implemented at least some form of written anti-diversion policy, they all failed to address one or more critical weaknesses or

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[91] *Substance Abuse among the Military, Veterans, and their Families*, Nat'l Institute on Drug Abuse (April 2011), http://www.drugs.indiana.edu/repository/veterans.pdf (last visited Mar. 25, 2019).
[92] *Accidental Poisoning Mortality Among Patients in the Department of Veterans Affairs Health System*, Bohnert AS, Ilgen MA, Galea S, McCarthy JF, Blow FC (April 2011), https://www.ncbi.nlm.nih.gov/pubmed/21407033 (last visited Mar. 25, 2019).

gaps in the diversion pipeline under their supervision. Even if the policies had been strictly enforced, therefore, they could not have been effective in stopping the flow of improperly-distributed opioids.

236. For example, none of the Distributor Defendants' written policies adequately addressed the risk of using sales personnel to communicate with, and provide accurate compliance-related information from, their pharmacy customers. Indeed, their written policies sometimes actually exacerbated that problem. For example, salespeople would warn customers that they were approaching their monthly threshold limits for ordering certain categories of controlled substances, putting them in a position to assist their customers in evading compliance reviews that would have otherwise occurred by manipulating the timing and volume of their orders.

237. Likewise, none of the Distributor Defendants enacted policies that adequately safeguarded against customers receiving unjustifiable increases in their monthly threshold allowance for opioid product orders. Instead, those policies directed compliance staff to rely principally on information provided by the customers themselves in order to justify such increases, and rarely mandated independent investigation before a threshold allowance for opioids could be increased.

238. Most consequentially, none of the Distributor Defendants enacted policies that required customers to be suspended from ordering controlled substances, or terminated entirely, after those customers had displayed consistent (and even years-long) patterns of making suspicious orders that exceeded their established threshold limits.

239. This broad failure of the Distributor Defendants to fulfill their explicit statutory duties to create effective anti-diversion policies was then compounded in each case by a common

pattern of practical failures, which represented separate violations of the NYCSA's requirement that they *maintain* effective anti-diversion policies.

240. *First*, the Distributor Defendants routinely failed to staff their compliance functions with qualified personnel, and failed to provide those compliance employees and their sales representatives with appropriate training. Even front-line compliance functions, such as approving threshold increases, detecting, blocking, and reporting suspicious orders, and terminating and/or suspending customers, were often assigned to operations, sales and administrative employees who had no experience with regulatory compliance of any kind.

241. *Second,* none of the Distributor Defendants had a consistent practice of conducting appropriate due diligence of either prospective new customers or their existing customers. New customers were routinely onboarded despite the acknowledged presence of unresolved red flags, and none of the Distributor Defendants ensured that additional investigations were conducted when existing customers made suspicious orders, even when compliance staff flagged those orders as suspicious, blocked them, and reported them to the State.

242. Indeed, the Distributor Defendants routinely allowed their customers to make multiple suspicious orders within the same month, week, or even year, without conducting any additional due diligence of those customers. Even where customers had to be blocked from ordering opioids in excess of their monthly threshold allowance multiple times within that month, the Distributor Defendants would allow those customers to resume ordering opioids the next month, at the same volume levels as before, without requiring any follow up investigation.

243. And none of the Distributor Defendants conducted periodic, unexpected due-diligence audits of their customers, even among the easily identifiable and relatively small groups of pharmacies that consistently ordered the highest volumes of opioids. Instead, these pharmacies

could go for years without the Distributor Defendants updating their knowledge of those customers' prescriber base, customer traffic patterns, and other relevant store conditions. Even when those pharmacies were scrutinized, the customer was often warned in advance.

244. *Third*, the Distributor Defendants routinely failed to detect, block and report their customers' suspicious orders for opioids.

245. While the Distributor Defendants' policies nominally allowed for compliance staff to identify any order as suspicious based on factors such as the non-exhaustive criteria identified by the NYCSA, as a matter of practice, only orders that exceeded a customer's monthly threshold limit for a particular category of controlled substances would actually trigger a compliance review. As a result, untold numbers of opioid orders that should have been reviewed due to their unusual size or frequency, or their departure from the customers' normal ordering patterns, were never even checked to determine whether they were suspicious.

246. Because the Distributor Defendants routinely allowed their customers to obtain information about the monthly threshold limits governing their orders of opioid products, orders customers made within the limits after being enabled to "game" them were improperly excluded from compliance review, when they all should have been checked to see whether the customers were deliberately structuring their orders to evade scrutiny.

247. Even as to orders that exceeded customers' monthly thresholds, the Distributor Defendants, over varying time periods, routinely failed to accurately identify those orders as suspicious. Instead, they released those orders for delivery based on perfunctory and unverified information provided by the customer, or for no documented reason at all.

248. Moreover, even when the Distributor Defendants did identify orders as suspicious and did block them from delivery to customers, they routinely failed to report those suspicious

orders to the State, sometimes going months or years without reporting any at all. When they did make suspicious-order reports, the reports were routinely incomplete, for example, by failing to identify all of the relevant suspicious orders for a customer, even when they were made within the same month, week, or even day.

249. *Fourth*, the Distributor Defendants failed to act to suspend customers from ordering controlled substances, let alone terminate their accounts, even after compliance staff had blocked and reported dozens, or even hundreds, of suspicious orders from those customers. In the relatively rare instances where a customer had been terminated or suspended, the Distributor Defendants allowed them to reinstate their accounts, or open accounts under new business names, without investigating and resolving the issues that had led to the initial termination or suspension.

250. *Fifth*, none of the Defendant Distributors systematically stored, organized, and made accessible for reference information about their customers or their owners, pharmacists, and top prescribers, in order to allow for meaningful future compliance efforts.

251. The Defendant Distributors did not require compliance staff to obtain customers' prescriber information, and some actually changed their policies to *forbid* such inquiries, willfully blinding themselves to one of the most important indicators of diversion.

252. While compliance staff and/or third-party investigators retained by the Defendant Distributors would sometimes flag prescribers as suspicious in the course of conducting due diligence of a pharmacy, that information was not stored or shared in any useable format. As a result, when the same suspicious prescriber appeared among another pharmacy's top prescribers, the compliance staff handling that subsequent due diligence investigation would have no way of knowing about this risk that had already been identified, unless they had personally handled the earlier investigation, and happened to remember the prescriber's name.

253. Similarly, they made no effort to collect and compare information about pharmacies that made high-volume orders of opioids, had been flagged for making suspicious orders, or had been suspended or terminated for suspicious or illegal practices. As a result, compliance staff had no way of knowing that a pharmacy they were investigating shared ordering patterns or top prescribers with another risky, suspicious, and/or previously disciplined customer.

254. *Sixth*, the Distributor Defendants failed to promptly report compliance violations to the State. Indeed, even when they actually detected failures in their compliance systems, they made no effort to report those known incidents. More broadly, due to the combination of systematic failures riddling their compliance systems described above, none of the Distributor Defendants had the competence to effectively detect their own violations.

255. For example, if any of the relevant Distributor Defendants had conducted periodic audits of their own records of customers' orders, those customers' patterns of ordering in excess of their monthly threshold allowance for opioid products, the number of times those orders were released without justification, and the number of times those orders were blocked as suspicious without being reported to government agencies and/or triggering additional investigations, suspensions, or terminations, they would have each been obliged to report hundreds, if not thousands, of NYCSA violations at a time.

256. In short, the Distributor Defendants deliberately lied to the State, both expressly and by omission, year in and year out, about the effectiveness of their compliance systems and the incidence of NYCSA violations, so that they could fraudulently maintain their licenses to continue doing business in New York.

II. Specific Misconduct of Each of the Manufacturer Defendants

A. Purdue

257. Purdue manufactured, marketed, sold, and/or distributed in the following opioid drugs in New York:

Product Name	Chemical Name
OxyContin	Oxycodone hydrochloride, extended release
MS Contin	Morphine sulfate, extended-release
Butrans	Buprenorphine transdermal system
Hysingla ER	Hydrocodone bitartrate, extended release
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride, extended-release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride, high potency
Palladone	Hydromorphone hydrochloride, extended-release
Ryzolt	Tramadol hydrochloride, extended-release

258. The market for long-term use of opioids to manage chronic pain conditions, such as lower back pain and osteoarthritis, did not exist until Purdue worked relentlessly to change prescribing norms to generate a financial windfall through its new product, OxyContin, a timed-release formulation of oxycodone.

259. Employing a range of misleading and deceptive practices, Purdue worked towards completely transforming providers' and the public's perceptions about the safety of long-term opioid use in general and the risk profile of OxyContin in particular.

1. The Sacklers Set the Stage for Aggressive Opioid Marketing

260. The foundation for OxyContin's success was laid by the Sackler family well before OxyContin was even developed, and the Sacklers continued to play a key role in bringing it to market, promoting its commercial success, and causing its devastating effects.

a) The Sacklers and the Integration of Advertising and Medicine

261. Arthur Sackler was a psychiatrist turned "ad man": he worked both as a psychiatrist at Creedmoor State Hospital in New York and as the president of the William Douglas McAdams advertising agency. Using his unique insight into the medical profession, he became a pioneer of pharmaceutical advertising in the 1950's and 60's by understanding, and exploiting, the power of recommendations from fellow physicians.

262. In striving to make Pfizer (with its blockbuster drug, Valium) a household name among physicians, Arthur Sackler recognized that "selling new drugs requires a seduction of not just the patient but the doctor who writes the prescription."[93] This "seduction" meant disseminating pharmaceutical messaging to the masses under the guise of science and truth through such tactics as underwriting scientific studies to be published as seemingly neutral articles in medical journals, paying prominent physicians to endorse products, marketing illness as "under treated," and providing physician "education" in the form of seminars and continuing medical education courses.

263. Allen Frances, the former chair of psychiatry at Duke University School of Medicine, stated that "'[m]ost of the questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler.'"[94] And yet it is his playbook that Purdue—and, ultimately, many other opioid manufacturers—employed and perfected to market opioids to the masses.

b) The Sacklers and the Development of OxyContin

264. In 1952, the Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called the Purdue Frederick Company ("PF Co."). The company,

[93] Patrick Radden Keefe, New Yorker, *The Family that Built an Empire on Pain*, Oct. 30, 2017.
[94] *Id.*

originally formed and incorporated in New York (up until May 2004, when it was merged into PF Labs), sold a range of products. Raymond was the head executive of the family's U.S. business while Mortimer ran the U.K. side of the business.

265. Then in the 1980s, PF Co. and its associated companies entered the opioid business. The Sackler Families, through a U.K. affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. PF Co. marketed this extended-release morphine as MS Contin, which quickly became a best seller, principally for managing cancer and end-of-life pain.

266. With MS Contin's patent expiration looming, however, the Sackler Families searched for a drug to replace it. Around that time, Richard Sackler, Raymond Sackler's son, became more involved in the management of the families' businesses. Richard had grand ambitions for the family business; according to a long-time Purdue sales representative, Richard really wanted Purdue to be big—"I mean *really* big."[95] Richard believed Purdue should develop another use for its "Contin" timed-release system.

267. 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.[96] Accordingly, Purdue developed "OxyContin"—a pure oxycodone in a time-release formula similar to MS Contin, more potent than morphine, and available in doses far in excess of other prescription opioids.

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[95] Christopher Glazek, *The Secretive Family Making Billions From The Opioid Crisis*, Esquire Magazine, Oct. 16, 2017 (quoting Purdue sales representative Shelby Sherman) (emphasis in original).
[96] Harriet Ryan, *supra* note 21, Purdue memo.

268. With Richard Sackler leading the charge, Purdue launched its blockbuster drug OxyContin in 1996 with the explicit strategy of positioning it as an opioid that physicians could responsibly prescribe to address a broad spectrum of pain relief, in contrast to existing (and, paradoxically, less potent) opioids on the market, which had the "stigma" of only being appropriate for cancer and end-of-life pain.

269. This strategy was devised from Purdue's experience with MS Contin and [redacted]. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show [redacted]

270. To achieve that marketing goal and avoid the "stigma" attached to less potent opioids, Purdue persuaded the assigned 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."

271. 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.

272. Nonetheless, as set forth in detail below, Purdue made reduced risk of addiction and abuse the cornerstone of its marketing efforts.

273. 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…."

2. Purdue Deployed Multiple Marketing Tactics to Deliberately and Insidiously Distort the Risks and Benefits of Long-Term Opioid Use

274. To sell its new extended-release opioid, OxyContin, Purdue developed an aggressive marketing scheme to fundamentally change opioid prescribing norms by using seemingly independent practitioners and medical societies, as well as an army of sales representatives and unbranded "patient advocacy" websites, to distort the risks and benefits of long-term opioid use.

a) Key Opinion Leaders and Front Groups Developed and Disseminated Materials Containing Purdue's Misleading Messages

275. A critical component of Purdue's deceptive marketing scheme was using KOLs and Front Groups to infiltrate the medical community.

276. Purdue paid New York physicians significant sums to act as speakers, KOLs, and/or consultants. For example, from August through December 2013, Purdue paid a single New York physician [redacted] In 2014, Purdue paid that same physician [redacted] and another New York physician [redacted]

277. Another crucial, and complementary, marketing channel for Purdue was Front Groups over whose publications Purdue exercised editorial input and control. From 2006 to 2016, Purdue provided more than [redacted], much of which was directed to various Front Groups in exchange for seemingly independent and credible "education" efforts about opioids. This included grants of [redacted] to AAPM and over [redacted] to APS—the organizations that issued the highly beneficial guidelines on opioid prescribing.

278. Purdue particularly dominated APF, described above, with grants totaling over [redacted] APF understood that it was expected to disseminate Purdue's misleading messaging in

exchange for this funding: in 2010 APF reported to Purdue that it reached more than 38.9 million people "with key messages about pain and overcoming barriers to treatment through print, television, radio, and online placements as a part of *Purdue's local market media outreach grant*." APF's work on behalf of Purdue grew into an official consulting relationship in 2011, allowing Purdue to continue funding APF's operations in exchange for APF promoting Purdue's marketing initiatives.

279. Purdue spared no expense in getting its message to New York prescribers and the public through seemingly legitimate sources. From 2007 through 2016, Purdue paid [redacted] in New York State alone. This included [redacted]

b) Purdue Directly Disseminated these "Independent" Findings to Health Care Providers through its Army of Sales Representatives and Unbranded Websites

280. Purdue compounded the effect of the deceptive "educational" materials generated by KOLs and Front Groups by directly disseminating them through hundreds of sales representatives deployed around the country to promote Purdue's products directly to providers.

281. Sales representatives were Purdue's most effective means of communicating its misleading messaging, and Purdue relied on them heavily in New York. By 2017, Purdue had [redacted] sales representatives targeting New York prescribers and pharmacies, making a total of [redacted] sales calls to [redacted] unique providers. Purdue's sales calls steadily increased from 2007 to 2011 and then stayed at an incredible rate—from between [redacted] to [redacted] visits per year:

282. From 2006 through 2017, Purdue sales representatives visited New York prescribers and pharmacists nearly [redacted] *times*:

283. This relentless marketing included a combined total of thousands of visits to dozens of HCPs who were indicted for or convicted of illegal prescribing.

284. Purdue exerted significant control over sales representatives' communications with providers through these sales calls. For example, Purdue required its detailers to use only sales aides that were reviewed, approved, and supplied by Purdue, in addition to conducting national and regional sales trainings and routinely sending guidance memos to the entire sales force.

285. Through these detailers' in-person sales calls, armed with Purdue-approved messaging and materials, Purdue distorted the benefits and risks of ER opioids. As a sales representative told a reporter: "We were directed to lie. Why mince words about it? …."

286. Purdue strategically directed its detailers to focus their misleading messaging on two key targets: primary care providers and heavy opioid prescribers. First, Purdue targeted primary care physicians and others unfamiliar with pain management—including "physicians still in training"—to position OxyContin as the drug they could "start with and stay with" to manage their patients' pain relief, even if they did not previously manage patients' pain.

287. This strategy is reflected in Purdue sales representatives' call notes. In 2008, [redacted]

288. For its second target, Purdue analyzed vast data sets to identify the highest volume opioid prescribers so detailers could repeatedly visit them to encourage switching to Purdue's opioid products and "titrate" to higher doses.

289. This questionable detailing practice also emerges from call notes. For example, [redacted] This facility had a long history with Purdue—in 2011, the facility's clinical research director entered into a contract with Purdue to be a "consultant."

290. To ensure the success of its detailing strategy, Purdue dangled financial incentives to drive its sales force to increase opioid prescriptions, giving sales representatives the ability to earn bonuses of tens of thousands of dollars, and possibly more, depending on the volume of prescriptions they could generate. In 2001, annual bonuses for sales representatives averaged $71,500 and reached as high as nearly $240,000.

291. To take just one quarter as an example: in the third quarter of 2010, detailers could receive up to *four different bonuses* based on oxycodone and Ryzolt prescriptions in a single

quarter. This included a bonus of up to $12,500 for increased retail prescriptions of *brand or generic* oxycodone. Another bonus was based on the volume of generic or brand ER opioids prescribed *at each dosage* to incentivize driving up prescribing at all strengths.

292. Purdue knew that its detailing visits were effective at changing prescriber behavior. Its business plan emphasized that "OxyContin is promotionally sensitive, specifically with the higher doses, and recent research findings reinforce the value of sales calls."

293. Purdue also disseminated its misleading materials directly to patients and physicians through its unbranded pain management advocacy websites, www.inthefaceofpain.com and www.partnersagainstpain.com, which were aimed at raising general awareness of untreated pain.

c) Purdue Broadly Disseminated False and Deceptive Information about the Risks and Benefits of Opioids for Chronic Pain

294. Through its combination of Front Groups and KOLs to generate Purdue-approved content and its army of financially-incented detailers to bring that messaging to targeted providers, Purdue created an ecosystem for disseminating its key misrepresentations about opioids, all intended to distort prescribers' understanding of the risks and benefits of starting their patients on opioids as a long-term treatment for chronic pain.

295. At the time it made each misrepresentation, Purdue knew it was spreading information that, at best, had no factual foundation, and, at worst, was deliberately distorting or directly contrary to existing data and information. Indeed, the goal of Purdue's elaborate and expensive marketing scheme was to overcome the existing scientific consensus that opioids were highly addictive and thus were generally not appropriate for treating chronic pain.

i. Purdue's False and Deceptive "Superiority" Claims

296. Purdue deceptively highlighted the risks of high doses of acetaminophen and NSAIDs by marketing that opioids, unlike those medications, have "no ceiling dose" and are thus safer pain management options.

297. Directly and through its various Front Groups, Purdue promoted the message that NSAIDs and Tylenol have "life-threatening" side effects, while opioids are "the gold standard of pain medications." For example, Purdue sponsored a nationally-available CME, edited in part by KOL Dr. Russell Portenoy, that deceptively instructed physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

298. As late as 2016, [redacted]

299. Even while it was promoting these misrepresentations, Purdue knew its opioids were not safer alternatives. A 2011 Purdue sales training acknowledged that the company "cannot represent or suggest" that its drugs are "safer" or "more effective" or make "any other sort of comparative claim."

ii. Purdue Falsely Claimed Opioids Improved Function and Quality of Life

300. Purdue also promoted its opioid products by falsely claiming that they improve patients' function and "quality of life." Purdue's direct marketing materials and sales representatives repeatedly claimed that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

301. For example, call notes from 2006 reflect that sales representatives repeatedly [redacted] Similarly, a 2008 call note reflects the detailer's follow up topic with a provider is to [redacted]

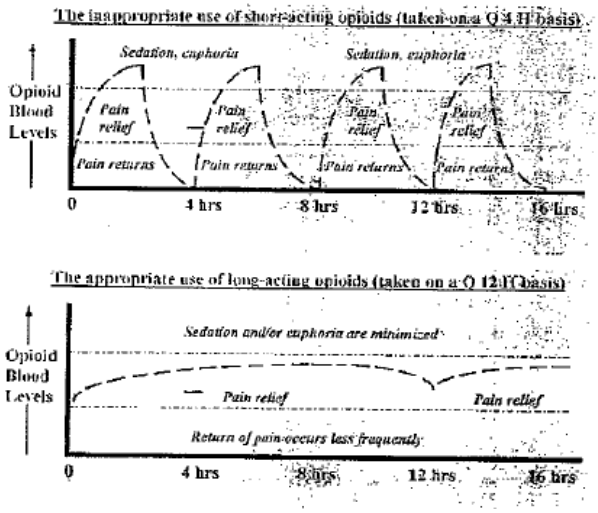
302. Not only was there no evidentiary basis for these claims, as described above, but Purdue's internal documents admit that [redacted]

iii. Purdue's Deceptive Claim that OxyContin Provided Twelve Hours of Pain Relief

303. Although OxyContin is approved by the FDA for 12 hour dosing, Purdue knew that many patients, and possibly most, did not receive a full 12 hours of continuous pain relief when taking OxyContin and that patients started experiencing not just pain, but also withdrawal symptoms, before the time for their next dose.

304. Nonetheless, Purdue made 12-hour dosing one of its core marketing messages, routinely promoting that OxyContin provided a full 12 hours of pain relief.

305. To support its claim that OxyContin provides patients with a "smoother" 12 continuous hours of pain relief, unlike its competitors that cause "peaks" of euphoria and "troughs" of insufficient pain relief, Purdue used "Peak and Trough" graphs:



306. In fact, however, extended-release oxycodone does not enter the body on a linear rate, as reflected in Purdue's marketing graphs; rather, OxyContin releases a greater proportion of oxycodone into the body upon administration, and the release gradually tapers.

307. Purdue's own research on OxyContin found a recurrence of post-surgical pain well before 12 hours, and more than of the half of the study participants given OxyContin re-medicated before 12 hours. In 2008, the FDA found that a "substantial number" of chronic pain patients taking OxyContin experience "end-of-dose failure" with little or no pain relief at the end of the dosing period.[97]

308. Purdue expressly told the FDA that 12-hour dosing "represents a significant competitive advantage of OxyContin over other products."

iv. Purdue Concealed the Link Between Long-Term Use of Opioids and Abuse and Addiction

309. One of Purdue's key hurdles when launching OxyContin was overcoming the medical community's entrenched views about opioids' significant risk of addiction.

[97] Letter from Janet Woodcock, MD., Dir., Ctr. for Drug Eval. and Research, to Connecticut Attorney General Richard Blumenthal 5 (Sept. 9, 2008), *available at* https://www.scribd.com/document/328752805/Blumenthal-Cp-Woodcock.

310. Rather than truthfully market its opioid products based on the known risks of addiction and abuse, Purdue began inundating the medical community, both directly and through its KOLs and Front Groups, with misleading information to deceptively conceal the link between long-term opioid use and addiction. Purdue recognized that physicians wanted "pain relief for these patients without addicting them to an opioid," and positioned its products accordingly.

311. For example, in its 1998 promotional video, *I Got My Life Back*, Purdue claimed the rate of addiction "is much less than 1%." Purdue mailed thousands of doctors this promotional video, where a physician asserts:

> There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects.

312. Purdue even trained its sales representatives to deceive doctors that the risk of addiction was "less than one percent."

313. Even while promoting these misrepresentations, Purdue knew that patients who used opioids as prescribed were at risk of developing an addiction. As early as 1996, Purdue's leadership began receiving anecdotal reports that the time-release mechanism used in both OxyContin and MS Contin was being subverted easily by crushing and other straightforward methods. By 1998, Purdue knew of findings reported in a medical journal concerning MS Contin abuse and street value—a 2,059 percent markup.

314. By 1999, the company and its sales staff were receiving widespread reports from the field that OxyContin was being widely diverted and abused. Purdue itself funded a study in 1999 that found 13% of patients who used OxyContin to treat headaches developed "addictive behavior."

315. A 1999 internal email to a senior executive about abuse and diversion of MS Contin and OxyContin reflects Purdue's familiarity with the issues, [redacted]

316. Prescribers in New York also reported their abuse and diversion concerns to Purdue's detailers. For example, one detailer in New York wrote in 2008: [redacted] Another sales representative was told [redacted]

v. Purdue Misrepresented the Extent to which Addiction Risk Can Be Managed

317. To downplay concerns over addiction even further, Purdue disseminated Front Group-branded addiction management "tools" that Purdue claimed could be used to manage the risk of addiction, despite lacking evidence the tools were at effective for achieving that goal.

318. For example, Purdue distributed APF's *Treatment Options* guide, which as noted above, touted "opioid agreements." Purdue's detailers also provided New York prescribers a Partners Against Pain "Pain Management Kit" that contained several "drug abuse screening tools," including the "Opioid Risk Tool." Purdue actively disseminated these materials to misleadingly give providers a false sense of security that they could safely start a course of opioids with patients and effectively manage those with a high risk of addiction.

vi. Purdue Falsely Claimed that Opioid Withdrawal Is Easily Managed

319. Purdue also sought to allay fears of opioid addiction and tolerance by claiming that patients' opioid dependence could be managed by tapering the dosage while intentionally downplaying the severe withdrawal symptoms associated with such tapering.

320. For example, [redacted] This is contrary to providers' actual experience—for example, one New York sales representative was told [redacted]

d) Purdue Misrepresented or Omitted the Greater Dangers Posed by Higher Doses of Opioids

321. Once patients started on opioids, Purdue then pushed health care providers to increase the dosages prescribed while omitting the increased risk, particularly regarding overdoses. Purdue trained its detailers to reassure prescribers that there was no ceiling on the amount of OxyContin a patient could be prescribed, even though it was aware [redacted]

322. Purdue emphasized to its sales representatives the importance of increasing dosages ("titration"), and even provided a guide to help the sales force "practice verbalizing the titration message" to get patients on higher doses of opioids.

323. Purdue's strategy to increase doses relied heavily on the in-person sales calls. An internal analysis "found that there is greater loss in the 60mg and 80mg strengths (compared to other strengths) when we don't make primary sales calls or stop making primary sales calls."

324. Purdue carefully analyzed how much of its profit depended on higher doses of opioids, internally reporting on the financial consequences of a shift in lower dosing: "[a] small shift of roughly 15K prescriptions from 20mg or 15mg down to 10mg has a $2MM impact." When the U.S. Centers for Disease Control warned against the highest and most dangerous doses of opioids, [redacted]

e) Purdue Promoted the False Notion of "Pseudoaddiction" to Encourage Increased Prescribing to Patients Presenting with Signs of Opiate Addiction

325. Finally, to deflect providers' concerns that individuals prescribed OxyContin were engaging in drug-seeking behavior consistent with addiction, Purdue promoted the fictional condition of "pseudoaddiction."

326. For example, Purdue widely distributed an unbranded pamphlet developed as part of its "Partners Against Pain" initiative, *Clinical Issues in Opioid Prescribing*, which urged doctors to look for symptoms of "pseudoaddiction":

> [Pseudoaddiction is a] term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug-seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

327. This pamphlet was distributed [redacted] Purdue was directly involved in its development, including providing direct

input from Dr. Haddox. [redacted]

328. Purdue's other widely-distributed materials similarly encouraged physicians to interpret signs of addiction as under-treatment of pain and urged them to treat pain "aggressively" despite indications of addiction. One pamphlet warned that "[m]isunderstanding of addiction and mislabeling of patients as addicts results in unnecessary withholding of opioid medications.'" A later edition of that same brochure claimed: "The term pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated."

329. Purdue's efforts worked: for example, one NY Nurse Practitioner told a Purdue detailer [redacted]

3. Purdue Continued its Deceptive Marketing Campaign Even After Pleading Guilty to Misbranding OxyContin

330. In 2007, Purdue's illegal and deceptive behavior finally caught up with it, and both the company and individual executives pleaded guilty to a federal felony based on its marketing practices. Yet even this did not stop Purdue's fraudulent and deceptive marketing of opioids.

a) Purdue's 2007 Guilty Plea

331. In May 2007, the Purdue board voted to have the Purdue Frederick Company, Inc. ("PFC") plead guilty to misbranding OxyContin, a felony under the federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 331(a), 332(a)(2). These intentional violations of the law happened while Richard Sackler was CEO, Jonathan, Kathe, and Mortimer were vice presidents, and Richard,

Jonathan, Kathe, Mortimer, Ilene, Beverly and Theresa Sackler were all on the board. PFC paid approximately $600 million in sanctions, and the individual defendants paid over $34 million.

332. The plea agreement plainly stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty."

333. Purdue specifically admitted that its supervisors and employees, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."

334. Purdue admitted that this deceptive marketing and advertising occurred through misstatements by its own trained sales representatives who mischaracterized the risks of OxyContin addiction and abuse.

335. Purdue also entered into a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS") to ensure compliance with relevant federal laws. This Agreement required Purdue to establish and maintain a Corporate Compliance Program, which would include a compliance officer who would report to Purdue's board and a Compliance Committee.

336. The Sackler Defendants specifically promised to comply with rules that prohibit deception about Purdue opioids. Defendants Richard, Ilene, Jonathan, Kathe, and Mortimer Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them. But as set forth below, they continued to direct Purdue's illegal and deceptive marketing schemes.

b) Purdue's Post-2007 Opioid Marketing Practices

337. As a result of the 2007 felony convictions, the Purdue Frederick Company effectively went out of business. The Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

338. Through these companies, Purdue continued its deceptive marketing, largely through more surreptitious means, fraudulently concealing its non-compliance and continued deception until recent renewed scrutiny revealed its elaborate efforts to avoid detection.

339. In the past few years, Purdue, often through its Front Groups, continued to mislead the public, influence public policy and public opinion, and resist efforts to place reasonable restrictions on opioid prescription activity that might have reduced the scale of the crisis.

340. In February 2018, the Senate publication *Fueling an Epidemic* revealed that Purdue had been the single largest funder of organizations that served as Front Groups or that otherwise advanced Purdue's interests, spending over $4.15 million between January 2012 and March 2017 on twelve different organizations that were examined by the Senate committee.[98] Indeed, Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continued to rise through fiscal year 2015.

341. Much of this funding went to organizations that, with Purdue's knowledge and in many cases Purdue's prior approval, minimized the risk of addiction and made other misleading statements set forth herein. Many of the payments from Purdue to these Front Groups were not adequately disclosed by Purdue or by the Front Groups themselves.

342. Purdue has worked directly and through its Front Groups, in some cases secretly, to defeat or delay measures aimed at mitigating the spiraling public health crisis, such as measures to create accountability for overprescribing physicians, and issuance of the CDC Guideline that could result in reduced prescribing.

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[98] *Fueling an Epidemic*, *supra* note 84, at 4-5.

343. As noted above, Purdue is a key force behind the Pain Care Forum, which has attempted to block efforts by New York and other states to adopt common-sense measures to alleviate the opioids epidemic. The organization is led by a Purdue lobbyist who uses a Purdue corporate email account to influence federal and state legislation and regulatory activities.

344. Sales representatives also touted the tamper-resistant properties of a reformulated version of OxyContin that began to be marketed in 2010, even though Purdue knew from its surveillance of online forums used by drug abusers that "abusers are accepting the change [in formulation] and working to overcome the tamper-resistant properties of the new formulation of OxyContin," and even though it was aware that oral ingestion—for which tamper resistance had no effect—was the most frequent method of abuse.

345. Moreover, Purdue paid for and promoted articles that stated or implied that its tamper-resistant drugs were safe, even while it was aware of the ease with which they could be abused through oral ingestion and other means. In 2014, for example, Purdue placed three articles in *The Atlantic* magazine as sponsored content, including one article by a physician that misleadingly called the tamper-resistant formulations (the most prominent of which was made by Purdue) "newer, safer alternatives" that were worth using despite their "higher price tag," and encouraged non-expert "physicians [to] embrace these additional choices, rather than decide to leave opioid prescribing[.]" Reports obtained from Purdue reflect that this promotional effort generated over 88,000 page views on *The Atlantic*'s website.

4. Purdue Failed to Prevent Diversion of OxyContin

346. In 2015, the OAG entered into an Assurance of Discontinuance ("AOD") with Purdue that narrowly focused on Purdue's failure to identify instances of possible abuse, diversion, or inappropriate prescribing through detailing visits. Purdue pledged to strengthen its oversight of

its sales representatives and bolster its identification of and response to signs of abuse, diversion, or inappropriate prescribing by removing prescribers from its sales call lists.

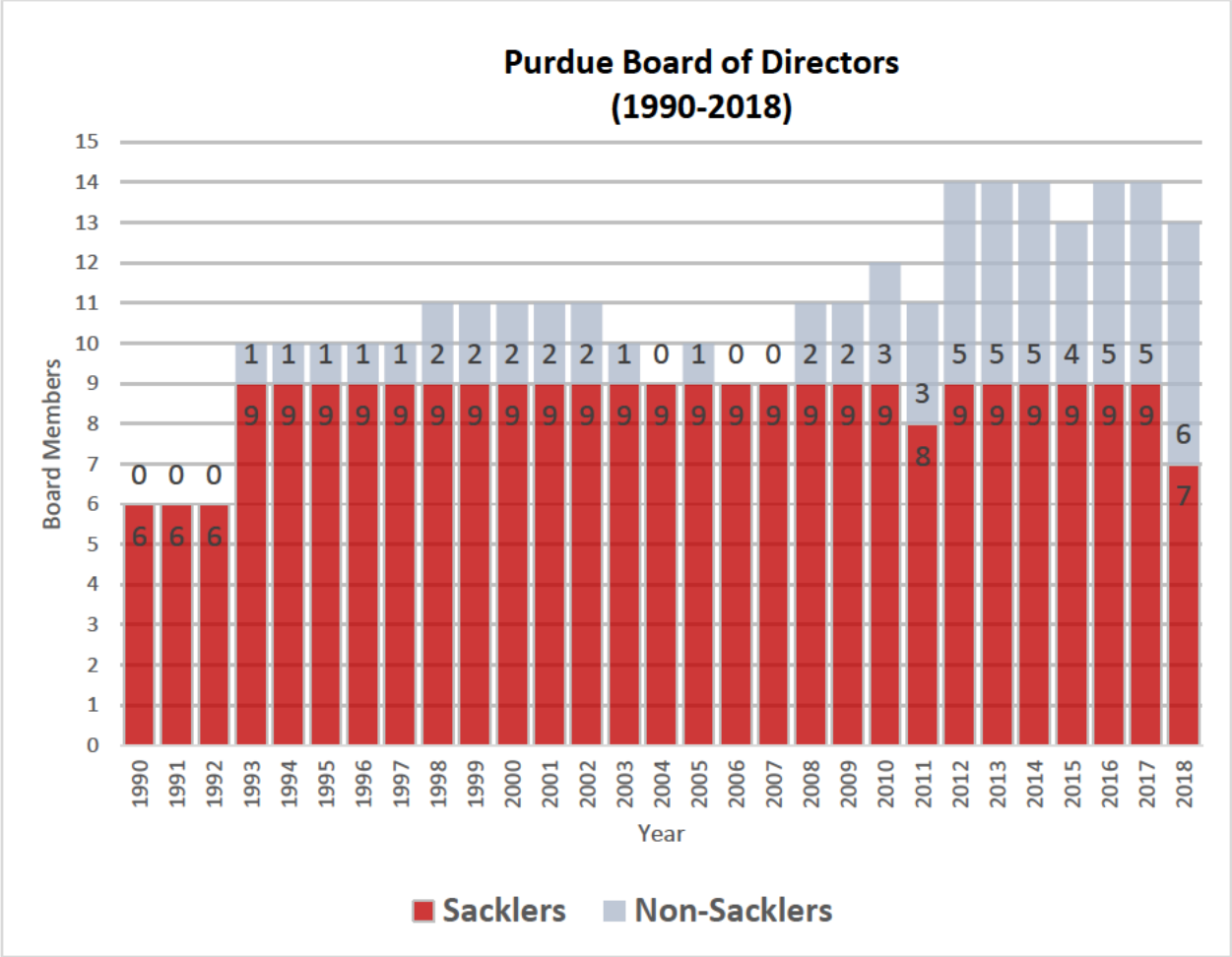
347. However, Purdue continued to aggressively promote its drugs without adequate safeguards against abuse and diversion. Up until Purdue stopped detailing in February 2018, it typically flagged a prescriber as potentially problematic only when it learned that the prescriber was arrested or the subject of an active investigation or disciplinary proceeding. Purdue declined to use available data sources to more robustly target problematic prescribers.

348. Purdue even continued to make sales calls to doctors previously disciplined for inappropriate prescribing.

5. 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

349. 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 developing and sanctioning Purdue's deceptive and illegal activities, and they each participated in its decisions to mislead New York providers, patients, government authorities, and insurers to normalize opioid prescribing and generate a financial windfall for themselves.

350. The Sacklers control Purdue. Each of them took seats on the board of Purdue Pharma Inc. 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.



351. Each of the Sacklers knew and intended that the sales representatives and Purdue's other marketing employees would not disclose to New York providers and patients the truth about Purdue's opioids. They each intended and directed Purdue staff to reinforce these misleading messages throughout New York, including by sending deceptive publications to New York doctors and deceptively promoting Purdue opioids at CME events in New York State. And they each knew and intended that patients, prescribers, pharmacists, and insurers in New York would rely on Purdue's deceptive sales campaign to request, prescribe, dispense, and reimburse claims for Purdue's opioids.

a) The Sacklers Run Purdue; Purdue's Officers and Staff Report to the Sacklers.

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

353. Richard Sackler played an active and central role in the management of Purdue. He is named as an inventor on dozens of patents relating to oxycodone and other paid 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.

354. 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 years 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."

355. 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.

356. 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.

357. 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 .

358. 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.

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

360. 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.

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

362. 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.

b) The Sacklers Had Knowledge of OxyContin's Risk of Abuse and Addiction as Early as 1999

363. 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.

364. 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.

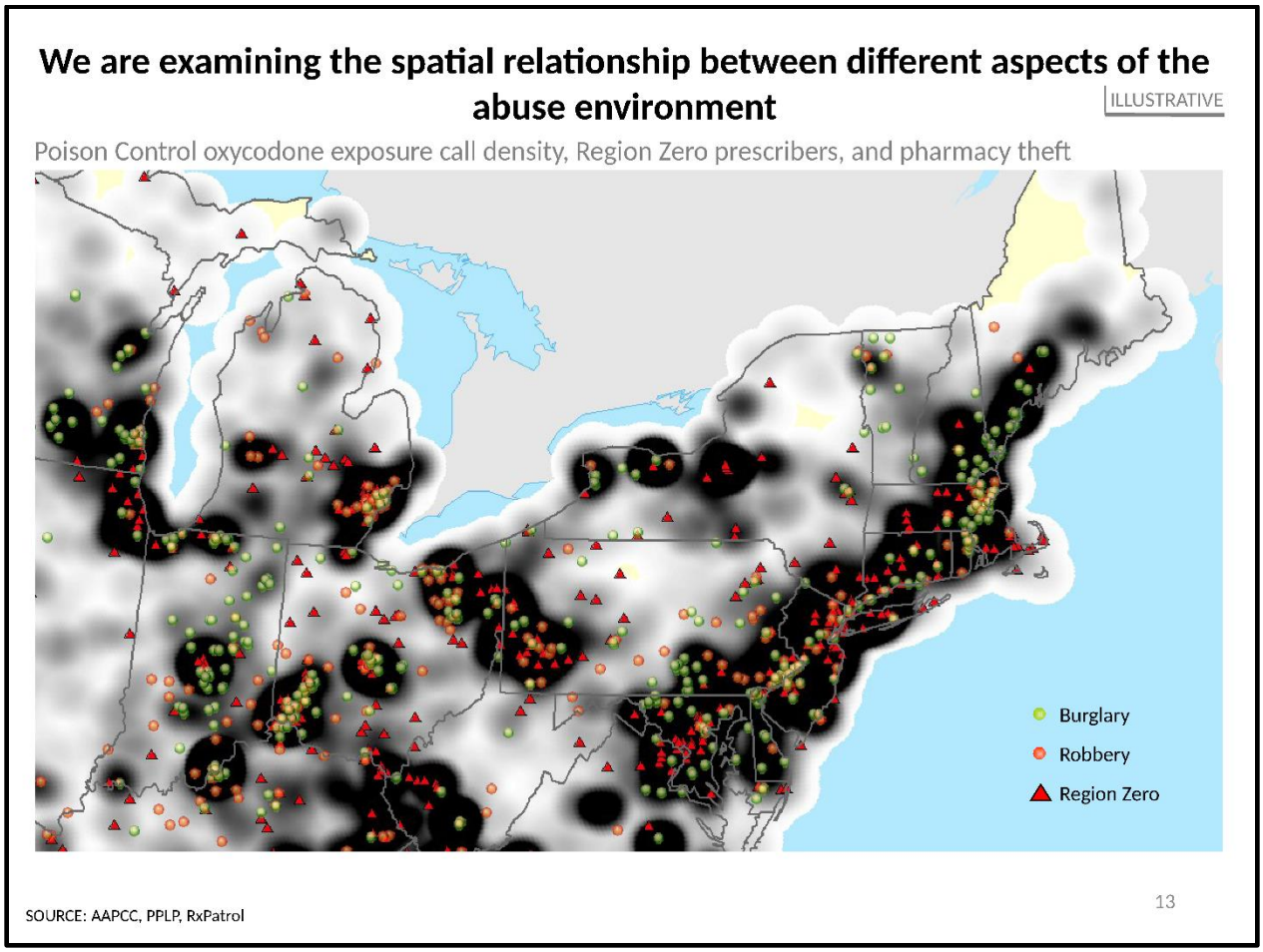
365. In January 2001, Richard Sackler received an email from a Purdue sales representative describing a community meeting at a local high school that organized by mothers whose children overdosed on OxyContin and died. The sales representative wrote: "Statements were made that OxyContin sales were at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

366. 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."

367. 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.

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

369. Instead, in 2010, staff gave the Sacklers the following map, correlating the location of dangerous prescribers with reports of oxycodone poisonings, burglaries and robberies:



370. 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.

371. 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."

i. The Sacklers Intentionally Blamed Individuals Instead of Directing Purdue to Address The Risk its Opioid Products Created

372. 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."

373.

374.

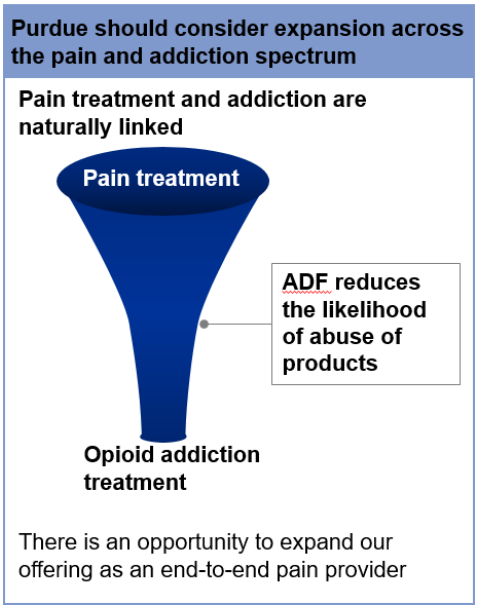
375. When *Time* magazine published an article about OxyContin deaths in New England, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths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

ii. The Sacklers' Efforts Directing Purdue to Develop, Market, and Sell Addiction Treatments Demonstrates their Full Knowledge of the Extent of Opioids' Addictive Qualities

376. 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.

377. 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 slide titled [redacted] states: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction."

378. 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:



379. The same presentation also provided: "[Opioid addiction] can happen to any-one—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."

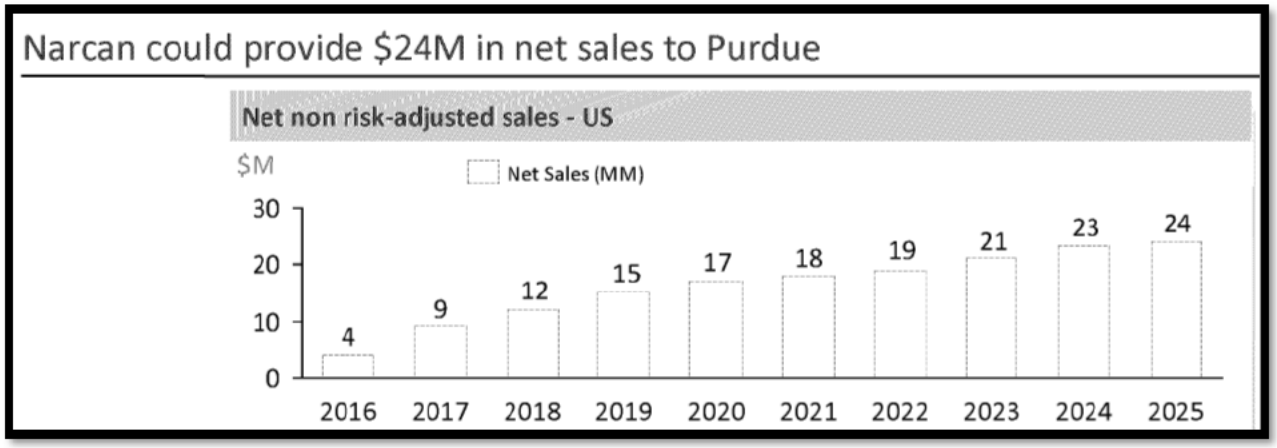
380. Defendant Kathe Sackler and Purdue's *Project Tango* team reviewed findings that the "market" of people addicted to opioids had doubled from 2009 to 2014. Kathe and the staff found that the national catastrophe they caused provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction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

381. Defendant Kathe Sackler ordered staff's "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*."

382. 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."

383. 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.

384. 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.



385. The Sacklers identified patients on Purdue's prescription opioids as the target market for NARCAN. Their 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.

386. 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."

c) The Sacklers Had Knowledge of, and Actively Participated in, Purdue's Illegal and Deceptive Marketing of Opioids

387. 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.

388. 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."

389. 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.

390. 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 laptops.

391. 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 [redacted]

392. 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.

393. 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.

394. 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. But in 2012, Richard Sackler complained that [redacted]

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

396. 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.

397. 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.

398. 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.

399. 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 "[c]ontinued 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.

400. 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.

d) The Sacklers Were Actively Involved in Concealing Ongoing Wrongdoing

401. 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

402. Purdue and the Sacklers generated and sanctioned the deceptive content used by

the KOLs and professional Front Groups.

403. 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.

e) The Sacklers Continue to Profit from their Deceptive and Illegal Practices Marketing Opioids Through a New Family-Owned Company to Manufacture Generic Opioids

404. 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."

405. 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.

406. In January 2008 [redacted]

[redacted]

407. [redacted]

408. 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.

409. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[99] Purdue has often argued that

[99] 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-b133-11e8-8d14-6f049d06439c.

it is a relatively small producer of opioids in the United States. However, when combined with Rhodes, 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.[100]

410. Whereas the Sacklers have reduced Purdue's operations and size, Rhodes continues to grow and sell opioids for the benefit of the Sackler families.

f) The Sacklers and their Families Enriched Themselves Through Illegal and Deceptive Actions at the Expense of Plaintiff and other Future Creditors

411. 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.

412. 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.

413. 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.

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[100] 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.

414. [redacted] Purdue later agreed to pay Kentucky $24 million over the course of eight years in a settlement announced in late 2015.

415. The Kentucky Attorney General's lawsuit was discussed by Purdue's sales staff who exchanged news reports of a lawsuit accusing Purdue of deceptive marketing in Kentucky. The report quoted Purdue's own attorney and chief financial officer stating that the company faced claims of more than a billion dollars that "would have a crippling effect on Purdue's operations and jeopardize Purdue's long-term viability." The same news reports regarding the 2015 Kentucky settlement, disposing of Kentucky's 2007 suit, noted that similar litigation "against Purdue and other opioid makers" would subject Purdue to the "billions" faced by "Big Tobacco in the 1990s."

416. In May 2019, Purdue was scheduled to face trial in Oklahoma in an action commenced by Oklahoma's Attorney General. In October 2019, Purdue will face trial in federal court in Cleveland, Ohio in the *National Prescription Opiate Litigation,* which includes 1,500 counties, and municipalities, hospitals, and others. To date, trial dates have been set in at least seven states against Purdue including California, Washington, South Carolina, New Jersey, Alaska, and Missouri. These cases, commenced by state attorneys general in 2017 and 2018, represent the culmination of investigations started years earlier during the second wave of litigation against Purdue beginning in 2014.

417. In early March 2019, Purdue began a well-thought out and deliberate media campaign to intimidate the litigating states, including New York, by threatening to commence bankruptcy proceedings. "As a privately-held company, it has been Purdue Pharma's longstanding

policy not to comment on our financial or legal strategy,"[101] Purdue said in a statement, but less than ten days later Purdue's president and CEO Craig Landau spoke with *The Washington Post* to double-down on the Purdue's threat to delay scheduled trials, frustrate ongoing discovery with New York State, and ultimately delay and otherwise limit states' recovery against Purdue.

418. On March 13, 2019, Purdue's Mr. Landau, "declined to discuss the pending [opioids] litigation" but, in the same interview with *The Washington Post*, announced that bankruptcy was something the company was weighing as it considers the impact of potential legal settlements or jury verdicts that could cost tens of billions of dollars. "It is an option," Landau said. "We are considering it, but we've really made no decisions on what course of actions to pursue. A lot depends on what unfolds in the weeks and months ahead."[102]

419. Despite knowing that Purdue faces certain liabilities to the states, including New York State, Purdue—at the Sackler Defendants' direction—continued to pay the Sackler Families 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 Families, assets are no longer available to satisfy Purdue's future creditor, the State of New York.

420. 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.[103] According to publicly available information, Purdue, at the

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[101] Mike Spector et al., *OxyContin maker Purdue Pharma exploring bankruptcy*, Reuters, Mar. 4, 2019, *available at* https://www.reuters.com/article/uk-purduepharma-bankruptcy-exclusive/exclusive-oxycontin-maker-purdue-pharma-exploring-bankruptcy-sources-idUSKCN1QL1KP

[102] Katie Zezima, *Purdue Pharma CEO says bankruptcy is 'an option' as company faces opioid lawsuits,* Wash. Post, Mar. 13, 2019, *available at* https://www.washingtonpost.com/national/purdue-pharma-ceo-says-bankruptcy-is-an-option-as-company-faces-opioid-lawsuits/2019/03/12/6f794e1a-450b-11e9-90f0-0ccfeec87a61_story html?utm_term=.4c0f9e37289a.

[103] 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.

direction of the Sackler-controlled board, paid the Sackler Families $4 billion in profits stemming from the sale of Purdue's opioids. In June 2010, Purdue's staff gave the Sackler s an updated 10-year plan for growing Purdue's opioid sales in which the Sacklers stood to receive 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 [redacted]

421. To defendant [redacted] the Sacklers voted to distribute the following amounts:

- $50,000,000 in April 2008;
- $250,000,000 in June 2008;
- $199,012,182 in September 2008;
- $200,000,000 in March 2009;
- $162,000,000 in June 2009;
- $173,000,000 in September 2009;
- $236,650,000 in February 2010 ;
- $141,000,000 in April 2010;
- [redacted]

422. [redacted]

423. [redacted]

424. [redacted]

425. [redacted]

426. [redacted]

[redacted]

427. By 2014, the writing for Purdue was on the wall. [redacted] Instead, as demonstrated above, Purdue and the Sackler Defendants distributed hundreds of millions of Purdue's opioid profits to the Sackler Families each year. Purdue has been involved in two decades of litigation for its misconduct vis-à-vis the sale and marketing of OxyContin. Purdue and the Sacklers thus always understood, and were aware of, the catastrophic effect of investigations and lawsuits relating to the opioids 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 New York State because distributions to Purdue's owners (the Sacklers) continued unabated during the relevant time period.

428. Purdue, at the direction of the Sacklers, fraudulently conveyed hundreds of millions of dollars of Purdue's profits from opioids to the Sackler Families each year during the relevant time period despite Purdue's and the Sacklers' knowledge that they faced certain, and significant, liabilities because of the multitude of litigations against Purdue by state attorneys general, including New York's Attorney General.

429. Purdue, at the direction of the Sacklers, distributed Purdue's profits to [redacted] No regard was given to Purdue's ability to pay creditors like New York, or even negotiate a settlement in good faith, given that hundreds of millions of dollars each year was squandered by distributing those funds to members of the Sacklers.

430. Now, when faced with the 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 New York.

431. 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 New Yorkers' expense. For example, the Sacklers made significant contributions to New York institutions, including:

- The American Museum of Natural History's Sackler Educational Laboratory, New York;
- The Dia Art Foundation's Sackler Institute, New York;
- The Guggenheim Museum's Sackler Center for Arts Education, New York;
- The Metropolitan Museum of Art's Sackler Wing, New York; and
- The Dr. Mortimer And Theresa Sackler Foundation's donation of $6 million to the New York Presbyterian Hospital in 2015.

B. Janssen

432. Janssen manufactured, marketed, sold, and/or distributed the following opioid drugs in New York:

Product Name	Chemical Name
Nucynta	Tapentadol hydrochloride, immediate release
Nucynta ER	Tapentadol hydrochloride, extended release
Duragesic	Fentanyl (patch)

433. In executing its methodical campaign of deceptive opioids marketing, Janssen borrowed liberally from both its corporate parent Johnson & Johnson's standard marketing tactics and the Purdue opioids playbook. In particular, Janssen deployed front groups, unbranded materials, sales representatives, and speaker programs, to spread the lies that opioids—in particular Janssen's Duragesic and Nucynta products—were not addictive and helped everyone, especially vulnerable seniors, enjoy vastly better lives.

434. Janssen's strategy to drive sales of Nucynta—in both immediate- and extended-release versions—was to "[b]roaden [the] future utility" of the drugs "beyond the [Schedule II] opioid foot print and differentiate [them] from 'traditional opioids,'" as evidenced by this excerpt from a 2011 promotional plan:

Evolving the choice in Chronic Pain Management beyond Traditional Opioids

1. Janssen's Misleading Marketing through Front Groups and Branded and Unbranded Materials

435. Janssen consistently downplayed the addictiveness of opioids. For example, Janssen's website for its fentanyl patch, Duragesic, included a section addressing "Your Right to

Pain Relief" and a hypothetical patient's fear that "I'm afraid I'll become a drug addict." Janssen's response: "Addiction is relatively rare when patients take opioids appropriately."

436. To broaden the impact of its deceptive marketing, Janssen worked closely with established Front Groups, providing the latter almost half a million dollars in funding between 2012 and 2017 alone. As described above, these groups have a singular agenda: to downplay fears about addiction from opioids so that prescribers will feel comfortable prescribing them early and often.

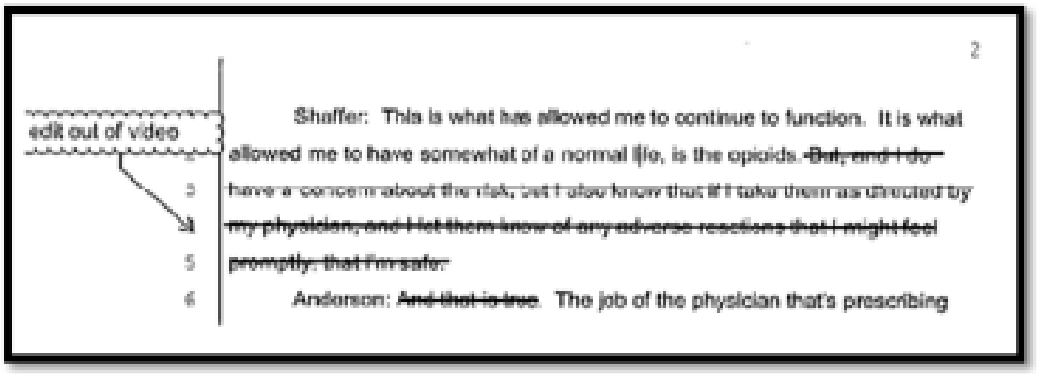
437. Front Groups served as extensions of Janssen's own marketing department. For example, Janssen teamed with the APF to "draft media materials and execute [a] launch plan" for Janssen's drugs at an upcoming meeting of the AAPM. Janssen also drew on APF publications to corroborate claims in its own marketing materials and its sales training. Janssen personnel participated in a March 2011 call with APF's "Corporate Roundtable," in which they worked with APF to develop strategies to promote chronic opioid therapy.

438. Janssen worked with AAPM and AGS to create a patient education guide titled *Finding Relief: Pain Management for Older Adults* ("*Finding Relief*"). To accompany this guide, Janssen produced a video that was accessible through the AAPM website. Janssen also worked with AGS to develop AGS's CME promoting its 2009 Guidelines for the Pharmacological Management of Persistent Pain in Older Persons.

439. Janssen frequently hid its deceptive messaging in elaborately produced, unbranded marketing materials. Most prominent among these efforts was the Janssen website, letstalkpain.org, which was directed at patients. Starting in 2009, Janssen financed the website and created its content in conjunction with APF and AAPM. Although the website is no longer publicly accessible, articles published on it remain accessible elsewhere on the internet today.

440. Janssen exercised substantial control over the content of its *Let's Talk Pain* website, internally referring to it as promoting tapentadol, the drug the company sold as Nucynta. Janssen regarded letstalkpain.org and another website, prescriberesponsibly.com (described below) as integral parts of Nucynta's launch:

441. Janssen personnel viewed APF and AAPM as "coalition members" in the fight to increase market share. Janssen and APF entered into a partnership to "keep pain and the importance of responsible pain management top of mind" among prescribers and patients, working to reach "target audiences" that included patients, pain management physicians, primary care physicians, and KOLs. One of the roles Janssen assumed in the process was to "[r]eview, provide counsel on, and approve materials." Janssen did in fact review and approve material for the *Let's Talk Pain* website, as evidenced by the following edits by a Janssen executive to the transcript of a video that was to appear on the site:



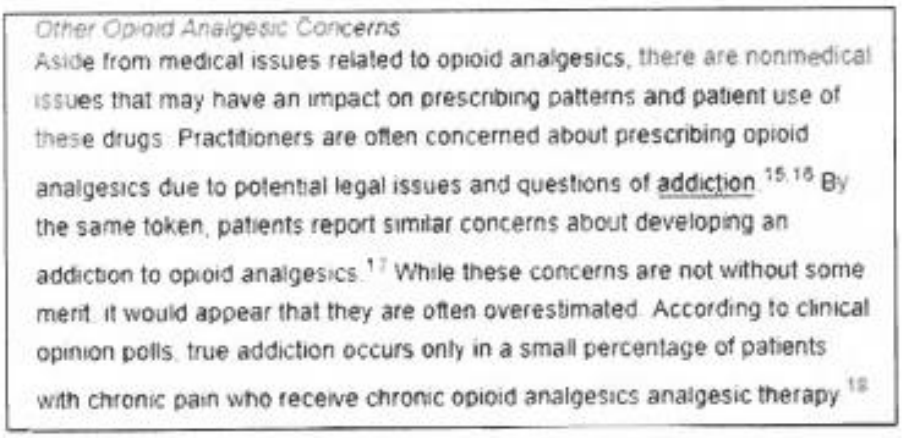
442. Even though Janssen's *Let's Talk Pain* website was hosted by APF, consulting agreements and internal memos confirm that Janssen had approval rights over its content. Thus, by Janssen's command, the final version of the video posted on the website omitted the stricken language above.

443. The *Let's Talk Pain* website misinformed consumers that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding about addiction." The website also promoted the spurious concept of "pseudoaddiction," which it described as "patient behaviors that may occur when pain is under-treated" but differs "from true addiction because such behaviors can be resolved with effective pain management." The website also misleadingly stated that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality and featured an interview claiming that opioids were what allowed a patient to "continue to function."

444. Janssen also produced and disseminated consumer-directed videos through its affiliation with the Let's Talk Pain Coalition. These videos were designed to encourage patients to seek treatment, *i.e.*, opioids, for chronic pain. One such video, titled "Safe Use of Opioids," and which is currently accessible via www.YouTube.com, overstates the benefits of chronic opioid use and omits discussion of the risks of addiction and abuse associated with opioids.

445. Another Janssen-controlled unbranded marketing project was a website ironically called prescriberesponsibly.com, which promoted the opposite of its title. This website, which was aimed at both prescribers and patients, claimed that concerns about opioid addiction are "overstated." A disclaimer at the bottom of the website stated that the "site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content."

446. Janssen's prescriberesponsibly.com website contains numerous articles—still accessible to both prescribers and patients—that misrepresent, trivialize, or fail to disclose the known risks of opioid products. For example, one article dismisses concerns about opioid addiction as "often overestimated," and proclaims that "true addiction occurs in only a small percentage of patients":



Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.[15,16] By the same token, patients report similar concerns about developing an addiction to opioid analgesics.[17] While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.[18]

447. The same article misleadingly suggests that "with appropriate dosing and titration, [opioids] can be effective and safe medications for the treatment of painful conditions." It is deceptive to describe chronic opioid therapy as "effective and safe" with appropriate dosing and titration while describing the risks of addiction associated with chronic opioid use as "overestimated" and occurring in "only a small percentage" of patients.

448. Other articles on prescriberesponsibly.com misleadingly instruct prescribers and patients that:

- Addiction risk screening tools allow HCPs to identify patients predisposed to addiction, thereby purportedly allowing prescribers to manage the risk of opioid addiction in their patient populations.

- "In those cases when a patient expresses concern about addiction," it is important to have a further discussion, because if the concern turns out to fall within the technical definition of "physical dependence," the patient's addiction concerns can be overcome by "reassurance from the healthcare professional." In other words, minimize the risk.

- Addiction might actually be "pseudoaddiction," defined as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed," and "[t]ypically when the pain is treated appropriately, the inappropriate behavior ceases."

2. Janssen's Misleading and Reckless Marketing to Health Care Providers and Consumers

449. Janssen knew that distinguishing Nucynta from competitor opioids would be crucial to the company's ability to create market share and generate a new profit stream, so it concocted a false narrative about the drug.

a) Janssen′s False Marketing of Nucynta as Not as Addictive as Other Opioids

450. To secure market share for Nucynta starting in 2009, Janssen had to create high demand among patients and prescribers. Janssen's internal business plans reveal that it sought to create that demand by stoking dissatisfaction with other pain treatments among pain patients and their prescribing physicians. Janssen referred to this effort as a "need to disrupt satisfaction by highlighting an unmet need," as a desire to "redefine pain management success," and as an effort to "disrupt [the] chronic [pain] market."

451. As early as 2009, Janssen identified as a primary "value platform" of tapentadol (the generic form of Nucynta) the misleading concept that the drug may have "non-opioid" properties, *i.e.*, that it might relieve pain without interacting with the body's opioid receptors, or that its interaction with those receptors was less drastic than other Schedule II opioids.

452. Evidence from preclinical studies had suggested that efficacy of tapentadol was thought to be due to two separate actions: (a) mu-opioid receptor agonism, meaning that it activates an opioid receptor; and (b) norepinephrine reuptake inhibition, meaning that it impacts neurotransmitters (such as norepinephrine) that communicate between brain cells. The FDA has warned that such preclinical studies are of limited utility and are "not a substitute for studies of ways the drug will interact with the human body."

453. Janssen nevertheless marketed Nucynta as having a "dual mechanism of action," *i.e.*, that the drug acts as ***both*** an opioid and a norepinephrine reuptake inhibitor ("NRI"). Janssen extensively relied on this unproven dual mechanism of action to deceptively portray Nucynta as a mild opioid that is less addictive than other Schedule II opioids such as OxyContin. For example, Janssen often described tapentadol as "potentiat[ing] mu-sparing properties," or offering "mu-receptor sparing benefits," or having a "dual [mechanism of action that] potentiates mu-sparing properties," or as providing a "multi-pathway approach [that has] mu receptor sparing effects." Janssen also maintained that the purported dual mechanism of action allowed Nucynta to be more effective at treating certain types of pain, with fewer side effects such as withdrawal.

454. In making these representations, Janssen routinely obscured or failed to disclose that Nucynta's exact mechanism of action is unknown and that the company's representations regarding the drug's dual mechanism of action were supported only by limited evidence gleaned from preclinical studies.

455. Janssen thus deceived prescribers into believing that Nucynta was not like other highly addictive and dangerous Schedule II narcotics, but was more akin to safer, over-the-counter pain medications. Janssen's business plans explicitly called for marketing Nucynta as [redacted]

b) Janssen's Misleading Detailing and Speakers' Programs

456. To execute its marketing strategy, among other tactics, Janssen deployed sales representatives to convey its Nucynta messaging directly to prescribers in their offices, often with a free lunch, to persuade them to prescribe the drug as frequently as possible.

457. Although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who took opioids such as Nucynta to treat chronic pain, it concluded that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug.

458. Janssen trained its sales force to trivialize addiction risk. A 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like Nucynta because of their fear of their patients becoming addicted, but this reluctance is unfounded because "the risks . . . are [actually] much smaller than commonly believed."

459. Janssen also trained its sales representatives to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A Janssen sales training module titled "*Selling Nucynta ER and Nucynta*" teaches that the purported "low incidence of opioid withdrawal symptoms" is a "core message" for the detailing force. This message was touted at Janssen's Pain

District Hub Meetings, at which Janssen periodically gathered its sales teams to discuss strategy.

460. To incentivize aggressive sales tactics, Janssen paid its New York sales representatives bonuses based on the number of prescriptions for Nucynta written by the prescribers they visited, with average bonus amounts ranging from $500 to $5,000 per quarter and the highest-performing representatives making bonuses of over $20,000 per quarter.

461. Call notes entered by Janssen sales representatives confirm that they communicated to New York HCPs the false and misleading message that Nucynta has a unique "mechanism of action"—*i.e.*, that it is milder and less addictive than other opioids [redacted] of times.

462. Janssen's call notes also show that [redacted] of New York HCPs [redacted] were later indicted or convicted for illegal prescribing of controlled substances. For example:

- [redacted]
- [redacted]
- [redacted]

463. Janssen also hired, trained, and deployed HCPs as part of its speakers' bureau to promote Nucynta, paying them to present Janssen materials containing deceptive information about the risks, benefits, and superiority of Nucynta. For example, a March 2011 presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia (increased pain), hormonal dysfunction, decline in immune function, mental clouding, confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR (Nucynta) reported no opioid withdrawal symptoms."

464. Janssen's speaker events typically occurred at upscale restaurants, with dinner and drinks paid for by the company. An invitation to join the speakers' bureau was both a reward for writing Nucynta prescriptions—because speakers were well compensated by Janssen—and an incentive to continue writing prescriptions.

3. Janssen's Targeting of Vulnerable Elderly Patients

465. Janssen's barrage of lies about opioids also was targeted at vulnerable elderly people, a population more susceptible to the adverse effects of opioids, including respiratory depression and risk of bone fracture.

466. Janssen's patient education guide *Finding Relief*, which the company distributed via its sales representatives tens of thousands of times throughout the U.S., was packed with large-print, bold-faced lies about the risks of opioids, dismissing as "myths" the proven facts that opioids are addictive, make functioning more difficult, and often must be prescribed in higher doses over time:

Opioid myths

Myth: Opioid medications are always addictive.

Fact: Many studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.

Myth: Opioids make it harder to function normally.

Fact: When used correctly for appropriate conditions, opioids may make it *easier* for people to live normally.

Myth: Opioid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

467. The guide falsely described as "facts" numerous unsupported claims about improved functioning, including that opioids can make it possible for people with chronic pain to "return to normal, *e.g.*, to get back to work, walk or run, play sports, and participate in other activities." In 2008, the FDA found such statements to be deceptive if made without substantial evidence. Until recently, *Finding Relief* was still available online.

468. The Janssen-sponsored AGS Guidelines falsely stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," although the study supporting this assertion did not analyze addiction rates by age. The AGS Guidelines also stated falsely that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)."

469. Janssen also sponsored, presented, or distributed studies suggesting that opioids should be prescribed to the elderly. For example, an article published in the *Journal of the American*

Geriatric Society and authored by physicians who received funding from Janssen concluded that persistent pain in elderly populations is under-assessed and harmful, and recommended that "[a]ll patients with moderate to severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy."

470. Finally, Janssen prioritized marketing its Nucynta products [redacted]

[redacted]

[redacted]

C. Mallinckrodt

471. 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 the number of prescriptions. In fiscal year 2017, Mallinckrodt's specialty generic products generated $682 million in net U.S. sales, including $85 million of hydrocodone and $88 million of oxycodone.

472. Mallinckrodt manufactured, marketed, sold, and/or distributed the following opioid drugs in New York:

Product Name	Chemical Name
Exalgo	Hydromorphone hydrochloride, extended release
Xartemis XR[104]	Oxycodone hydrochloride and acetaminophen (extended release)
Roxicodone[105]	Oxycodone hydrochloride
Generic	Oxymorphone hydrochloride (extended release) (generic Opana)
Generic	Oxycodone (extended release) (generic OxyContin)
Generic	Morphine sulfate, extended release
Generic	Morphine sulfate oral solution
Generic	Oxycodone and acetaminophen (Percocet)
Generic	Hydrocodone bitartrate and acetaminophen (Vicodin)
Generic	Hydromorphone hydrochloride
Generic	Hydromorphone hydrochloride, extended release (Generic Exalgo)
Generic	Fentanyl transdermal system
Generic	Oral transmucosal fentanyl citrate
Methadose	Methadone hydrochloride
Generic	Methadone hydrochloride
Generic	Buprenorphine and naloxone

473. In 2015, Mallinckrodt's production accounted for an estimated 25% of the DEA's entire annual quota for controlled substances. According to IMS health data for the same year, Mallinckrodt generic products had an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications. A substantial portion of Mallinckrodt's opioid products was manufactured, packaged, and distributed from the company's factory in Hobart, in New York's Catskills region.

474. Mallinckrodt's misleading marketing of its branded and generic opioid products vastly expanded demand for these dangerous narcotics, fueling abnormally high levels of opioid prescribing and unprecedented levels of diversion, addiction, and death. The impact of Mallinckrodt's illegal marketing was magnified by the company's systematic and callous disregard of obvious red flags of diversion over many years. For example, Mallinckrodt marketed its branded

[104] Mallinckrodt discontinued Xartemis XR in August 2015.
[105] Mallinckrodt acquired from Xanodyne Pharmaceuticals in 2012.

opioids to [redacted] whom it knew had an office that [redacted] Mallinckrodt's misconduct was so pervasive that the DEA [redacted]

475. By 2006, Mallinckrodt was well aware of the scale of the opioid epidemic. Rather than taking steps to stop the harm, it persistently goaded its distributors to sell more and more of the company's opioids.

476. In one exchange, an executive of a [redacted]—exhorted Mallinckrodt's national sales manager to [redacted] The Mallinckrodt executive responded: [redacted]

477. After 2006, Mallinckrodt ramped up its efforts to expand the lucrative opioids market and to grab a bigger piece of that pie. In 2011, Mallinckrodt sought to [redacted] despite the company's knowledge of widespread diversion.

478. In 2012, Mallinckrodt's five-year plan identified [redacted] At that time, Mallinckrodt considered [redacted]

479. In its filings with the SEC, Mallinckrodt has stated that it markets its controlled substances "principally through independent channels, including drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, food store chains with pharmacies, pharmaceutical benefit managers that have mail order pharmacies and hospital buying groups." In particular, Mallinckrodt has marketed its generic opioids to Distributor Defendants McKesson,

Cardinal, Amerisource, and Rochester Drug, causing enormous quantities of opioids to be delivered to New York pharmacies and dispensed. Mallinckrodt marketed its extensive catalogue of opioids on price and availability, [redacted]

480. Mallinckrodt built on Purdue's marketing techniques by creating new front groups—themselves composed of front groups—to amplify Mallinckrodt's messaging and to convince the public that it was a socially responsible company rather than just another greedy peddler of dangerous narcotics. Mallinckrodt's business plans, however, told another story: in 2014, for example, its five-year plan touted [redacted]

481. Mallinckrodt's approach to the opioids crisis is exemplified by [redacted] Mallinckrodt opposed these common-sense reforms because it saw reduced prescribing as a threat to its profits. The then head of Mallinckrodt's [redacted] boasted to a major customer—[redacted]—that Mallinckrodt [redacted]

1. Mallinckrodt's Misleading Marketing through Front Groups and Branded and Unbranded Materials

482. On its website and through other marketing channels, Mallinckrodt disseminated misleading messages about the risks and benefits of opioids. The Mallinckrodt Policy Statement on Opioids, for example, calls for a greater understanding of the opioid industry-created myth of pseudoaddiction—industry code for "opioids aren't addictive."

483. Mallinckrodt's brochure "*Your Guide to Taking Oxycodone Safely*" describes the side effects of oxycodone but omits meaningful discussion of the risks of addiction, simply advising patients worried about addiction to talk to their doctor. The brochure also states that "after a while, Oxycodone causes physical dependence," but omits mention of physical dependence as a symptom of addiction.

484. Mallinckrodt's brochure "*Ease your Pain—a Guide to Feeling Better*" touts the benefits of opioid medication for pain, without mentioning addiction risk at all: "Both generic and brand-name drugs can help control pain quickly and effectively."

485. Mallinckrodt's website claims, without citing any clinical evidence, 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."

486. A popular website founded by Mallinckrodt, pain-topics.org, featured materials from the American Pain Foundation, relentlessly overstated the benefits and minimized the risks of opioids, gave extensive coverage to made-up phenomena such as pseudoaddiction and opiophobia, and peddled blatantly false statements such as "the clinical benefits of opioid treatment dwarf the clinical risks."

487. Mallinckrodt also has funded and controlled Front Groups such as the American Pain Foundation, the American Academy of Pain Medicine/American Pain Society, the Academy of Integrated Pain Medicine, and the U.S. Pain Foundation. These groups—to which Mallinckrodt has given more than one million dollars (the majority since 2013)—have a singular agenda: to downplay fears about addiction so that prescribers will feel comfortable prescribing higher dosages of opioids.

488. After 2010, to expand the market for its opioids products, Mallinckrodt embarked [redacted] by creating a new front group (itself made up of front groups) called the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance.

489. Mallinckrodt described the C.A.R.E.S. Alliance 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." In reality, the C.A.R.E.S. Alliance was just another Mallinckrodt marketing project built on deception.

490. Through the C.A.R.E.S. Alliance, Mallinckrodt disseminated pro-opioid materials via pain organization meetings, grand rounds, dinner meetings, reprints, direct mail, and the web. These efforts were often coordinated with other front groups, as when the Alliance offered to send doctors (for free) the APS/AAPM *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*.

491. Mallinckrodt used the C.A.R.E.S. Alliance to promote a book titled *Defeat Chronic Pain Now*, which is still available online. The false claims and misrepresentations in this book include the fiction that "[o]nly 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." Mallinckrodt distributed copies of this book and the *Opioid Safe Use and Handling Guide* (described below) at [redacted]

492. Mallinckrodt used the C.A.R.E.S. Alliance to [redacted]

493. Mallinckrodt instructed its sales representatives to [redacted] including the *Opioid Safe Use and Handling Guide*, which, is still available, contained numerous misleading statements, including "[a]ddiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur." The guide, which referenced specific opioid drugs such as Exalgo, misleadingly stated that "[p]hysical dependence is not the same as addiction" and promoted the concept of pseudoaddiction to persuade the public that opioids are not addictive.

494. By 2014, Mallinckrodt had concluded that the C.A.R.E.S. Alliance [redacted] so it launched a bigger and better front group, the Alliance for Balanced Pain Management ("AfBPM"). AfBPM includes more than 20 groups, including some of the members of the C.A.R.E.S. Alliance.

495. Mallinckrodt hid from most AfBPM members that [redacted] however, Mallinckrodt was more revealing about its true motives. In 2015, the Mallinckrodt executive in charge of the AfBPM wrote [redacted]

496. Lest support for "balanced" approaches [redacted] too far, however, a Mallinckrodt executive noted that [redacted]

497. Mallinckrodt retained and paid large sums of money to KOLs to serve as consultants, advisory board members, researchers, and members of its speakers' bureau. Dr. Webster, whom Mallinckrodt paid millions of dollars for research and consulting fees, served on the

company's Advisory Board and performed a study on the allegedly abuse-deterrent effects of Mallinckrodt's drugs. As noted below, Dr. Webster also misleadingly promoted Xartemis on behalf of Mallinckrodt.

498. Mallinckrodt paid Dr. Sri Nalamachu, whom a Mallinckrodt executive referred to as [redacted] Dr. Nalamachu was featured in a brochure published by the Institute for Patient Access (a front group affiliated with the Alliance for Patient Access) titled "Preserving Patient Access While Curbing Abuse," in which he criticized efforts to restrict access to pain prescription medication due to concerns abuse and diversion. Mallinckrodt never disclosed that it paid Dr. Nalamachu more than $300,000 from 2013 to 2017.

499. KOL Dr. Scott Fishman's book, *Responsible Opioid Prescribing*, which advocates opioid use for non-cancer pain, was disseminated by Mallinckrodt's C.A.R.E.S. Alliance. KOL Dr. Perry Fine served on Mallinckrodt's Advisory Board.

2. Mallinckrodt's Misleading Marketing to Health Care Providers and Consumers

500. To market its branded opioid products, Mallinckrodt disseminated written materials to HCPs and consumers and targeted New York HCPs who were high prescribers of opioid drugs. Between 2010 and 2015, Mallinckrodt sales representatives visited the offices of and/or telephoned [redacted] of New York HCPs a combined total of [redacted] of times for the specific purpose of marketing Exalgo and Xartemis. Mallinckrodt sales representatives who convinced HCPs to prescribe these drugs received [redacted] of dollars in bonuses.

a) Mallinckrodt's Aggressive Sales Techniques

501. Mallinckrodt trained its sales representatives selling Exalgo [redacted] The supervisor of

Mallinckrodt's New York sales representatives exhorted his team to [redacted] Mallinckrodt used free trials and coupons extensively to stoke demand for its opioid products.

502. Mallinckrodt deployed the same motivational techniques to sell Xartemis: the supervisor of Mallinckrodt's New York sales representatives wrote to her team [redacted] that [redacted]

503. Sales representatives often conveyed the company's misleading messages to HCPs [redacted] Indeed, the company spent heavily on this marketing tactic, making hundreds of such payments, totaling almost $160,000—much of which was for food and beverages—to New York HCPs from 2013 through 2016 alone.

504. Mallinckrodt also promoted its branded opioids to HCPs via speaker programs. Mallinckrodt typically hired as speakers HCPs who were KOLs and/or high-volume prescribers of its branded drugs, and its sales representatives were instructed to [redacted]

505. Among the key messages that Mallinckrodt-paid speakers conveyed to HCPs regarding Exalgo was [redacted] After each speakers' event, [redacted] One Mallinckrodt sales representative contacted HCPs [redacted]

b) Mallinckrodt's False Advertising Regarding Addiction Risk and Abuse Deterrence

506. Mallinckrodt knew that patients taking Exalgo would be receptive to these misleading messages because [redacted]

507. In its branded advertising, Mallinckrodt even copied a misleading Purdue theme to spread deceptive claims about opioids' improvement of functioning. In a 2014 Xartemis brochure for consumers, Mallinckrodt used a photo of a man fly fishing to misleadingly imply that Xartemis allowed a man to go engage in strenuous activity, which was strikingly similar to a photo in a Purdue advertisement for OxyContin that the FDA found illegal in 2003.

508. Mallinckrodt also falsely marketed Exalgo and Xartemis to HCPs as safer than other opioids, advertising that these drugs were harder to manipulate and abuse. In fact, the FDA specifically barred Mallinckrodt from making such claims because it lacked any scientific basis.

509. In rejecting Mallinckrodt's request for permission to market Exalgo as "abuse deterrent," the FDA stated that the tablets "will increase the potential risks for overdose or abuse in those seeking to defeat the extended-release system" and that "we predict that Exalgo will have high levels of abuse and diversion."

510. Despite the FDA's findings, Mallinckrodt began marketing Exalgo as abuse-deterrent as early as May 2011, stating: "Although once-daily hydromorphone ER can still be misused or abused, these studies indicate that the pharmacological and physical properties of this formulation are performing as designed to make it less susceptible to blood plasma level peaks and

troughs and potentially difficult to manipulate." In 2012, Mallinckrodt misleadingly stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."

511. Mallinckrodt also made false abuse-deterrent claims about Xartemis, a drug for which it projected annual revenues [redacted]

512. Mallinckrodt's main selling point for Xartemis—a claim that was rejected by the FDA—was that Xartemis is less likely to be abused than other opioids because when the drug is tampered [redacted]

513. In 2013, several months before FDA approval of Xartemis, Mallinckrodt began publicizing the alleged "abuse-deterrent" features of the drug, especially through KOL Dr. Lynn Webster. In an interview published online, Dr. Webster stated that Xartemis "has abuse deterrent properties which mean that the new design and technology within this formulation may prevent people who try to manipulate, alter or convert the extended release into an immediate release in order to achieve a greater high." Dr. Webster failed to disclose that he had been paid millions of dollars by Mallinckrodt.

514. After reviewing scientific data provided by Mallinckrodt, the FDA rejected Mallinckrodt's request for abuse-deterrent labelling for Xartemis, concluding that "the results of the studies submitted by [Mallinckrodt] do not meet the standards for [abuse-deterrent] labeling described in the guidance," and that "Xartemis XR is an extended-release Schedule II opioid analgesic with no abuse-deterrent properties."

515. In March 2014, shortly after the FDA's release to Mallinckrodt of scientific findings explaining why the agency rejected abuse-deterrent labelling for Xartemis, Mallinckrodt instructed [redacted]

516. Notwithstanding the FDA's findings, on or about March 11, 2014, Mallinckrodt posted a document on its public website falsely stating that Xartemis "is more resistant to simple spoon crushing compared to Percocet" and that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."

3. Mallinckrodt's Failure to Monitor and Report Suspicious Orders of Opioids

517. As an entity registered with the New York Bureau of Narcotics Enforcement ("BNE") and the DEA as both a manufacturer and distributor, Mallinckrodt knew that it was required to: (a) set up a system designed to detect and investigate suspicious orders of opioids; (b) refuse to fill suspicious orders and fill orders flagged as potentially suspicious only if, after conducting due diligence, it could determine that such orders were not likely to be diverted; and (c) report all suspicious orders to DEA and BNE. These duties include monitoring the downstream flow of opioid products to detect potential diversion.

518. At all relevant times, Mallinckrodt possessed ample sources of data that allowed it to identify suspicious orders of opioids. For example, Mallinckrodt had prescribing data that allowed it to track HCPs' prescribing patterns over time, which it used to identify candidates to target for marketing and to monitor its own and competitors' sales. Mallinckrodt sales representatives also regularly visited pharmacies and HCPs, which allowed them to observe red

flags of diversion.

519. Mallinckrodt also obtained detailed data showing drug orders delivered to specific pharmacies that allowed it to precisely monitor the flow of its opioids.[106] Distributors provide manufacturers such as Mallinckrodt with this data to receive "chargebacks," which are payments from a drug manufacturer to a distributor, in which the manufacturer reimburses the distributor for the difference between the full price paid by the distributor for the drug and the price received by the distributor from a pharmacy for the drug.

a) Mallinckrodt's Suspicious Order Monitoring System was Deficient as Written and in Operation

520. Mallinckrodt purported to discharge its anti-diversion duties through its suspicious order monitoring program ("SOMP"), which was touted on its website as state-of-the-art and "exceeding" DEA requirements.[107] In reality, though, the company's SOMP was egregiously deficient.

521. [redacted]

[106] Mallinckrodt MOA with DEA, available at https://www.justice.gov/usao-edmi/press-release/file/986026/download; John J. Coleman, *The supply chain of medicinal controlled substances: addressing the Achilles heel of drug diversion*, 26 J. Pain & Palliative Care Pharmacotherapy 233-50 (Sept. 2012), *available at* https://www.ncbi.nlm.nih.gov/pubmed/22973912.

[107] *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014), *available at* http://webcache.googleusercontent.com/search?q=cache:la9jmYqD5-cJ:phx.corporate-ir.net/External.File%3Fitem%3DUGFyZW50SUQ9NTM1OTA4fENoaWxkSUQ9MjI0MDAzfFR5cGU9MQ%3D%3D%26t%3D1+&cd=1&hl=en&ct=clnk&gl=us.

[redacted]

522. From 2008 through 2010, Mallinckrodt [redacted]

523. By July 2010 at the latest, Mallinckrodt knew that its opioids were widely diverted across the United States.[108] [redacted]

[108] Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Wash. Post, Apr. 2, 2017, *available at* https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?noredirect=on&utm_term=.74f8e44b8d48.

[redacted]

524. Mallinckrodt's internal reviews of [redacted] Mallinckrodt staff, its front line against diversion, routinely went through the motions and rubber-stamped orders, including very large ones. For example, [redacted]

525. On the very rare occasions when the company [redacted]

526. Another flaw in Mallinckrodt's SOMP was that the company failed to require [redacted]

527. Starting in 2010, Mallinckrodt revised its SOMP to include review of data it possessed in its chargeback system, including [redacted] Because chargeback data allows visibility into pharmacies' orders, [redacted]

528. Since 2010, Mallinckrodt has occasionally sent letters to its distributors stating that it would not pay chargebacks on orders shipped to certain pharmacies that the company suspected of engaging in diversion. In New York, however, this occasional practice has done nothing meaningful to prevent diversion.

529. New York has nearly 5,500 pharmacies, and over the past nine years, Mallinckrodt has chargeback restricted only [redacted] of them, and [redacted] of those restrictions were later lifted. Moreover, merely restricting chargebacks did nothing to prevent diversion even at those pharmacies, since Mallinckrodt continued shipping their distributors opioids, and when pharmacies were cut off by one distributor, they could still order from another.

b) Mallinckrodt Shipped Suspicious Orders to New York Pharmacies

530. Mallinckrodt also knew that its oxycodone pills were [redacted] and that its oxycodone pills [redacted]. But

despite possessing detailed information about pharmacies [redacted] Mallinckrodt did not stop shipments it knew were destined for New York pharmacies that were likely engaged in diversion.

531. For example, Mallinckrodt received a report on Pharmacy A, which noted that [redacted] Mallinckrodt also knew that the pharmacy's top prescriber of oxycodone pills [redacted]

532. With respect to the tiny number of New York pharmacies for which Mallinckrodt did restrict chargebacks, [redacted] For example, Mallinckrodt delayed restricting chargebacks on shipments to the following pharmacies:

- Pharmacy B: A report on this Manhattan pharmacy noted that [redacted]
- Pharmacy C: A report on this Manhattan pharmacy noted that [redacted]
- Pharmacy D: A report on this Staten Island pharmacy noted that [redacted]

[redacted]

c) Mallinckrodt Marketed Opioids to Pill Mill HCPs

533. Mallinckrodt not only failed to cut off supply from customers most likely to be servicing suspicious HCPs, it actually aggressively targeted those overprescribers in New York, including a number of whom were later indicted or convicted. Because Mallinckrodt carefully tracked their prescribing patterns using detailed pharmacy-level data, at a minimum the company knew that these HCPs were potentially engaged in diversion. Nevertheless, Mallinckrodt sales representatives repeatedly visited their offices and bought meals for dozens of them, including:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

534. A senior DEA official in New York stated that [redacted] Yet Mallinckrodt marketed its branded opioids to [redacted] even after the company learned that he was likely engaged in illegal diversion. On [redacted]

[redacted] Notwithstanding this report, Mallinckrodt kept sending sales representatives to his office.

d) Mallinckrodt's 2017 Settlement with the Federal Government Confirmed the Deficiencies of its SOMP

535. The deficiencies in Mallinckrodt's SOMP were confirmed by the July 2017 Memorandum of Agreement ("MOA") between Mallinckrodt and DEA and DOJ, in which Mallinckrodt agreed to pay fines of $35 million to resolve an investigation of Mallinckrodt that began in 2011.

536. In the MOA, Mallinckrodt agreed that "at certain times during the Covered Time Period prior to January 1, 2012, certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007," and that "at certain times during the Covered Time Period, at Mallinckrodt's Hobart plant, certain of Mallinckrodt's recordkeeping and physical security practices at that facility were, in some respects, not consistent with DEA regulation."

537. At the company's Hobart plant, located in New York's Catskills region, an employee was able to steal oxycodone powder because the plant lacked adequate security protocols, and sold the powder to a drug dealer who supplied 95% of the oxycodone powder in Delaware County. Local authorities seized five ounces of oxycodone—with an estimated street value of $50,000—from the employee when he was arrested.

538. The oxycodone theft enabled by Mallinckrodt's lax security at the plant worsened the opioid epidemic in central New York. The area also experienced increased criminal activity after the theft, as felony drug arrests in Delaware County more than doubled from 2011 to 2013. Neighboring Schoharie and Otsego Counties also saw large increases in felony drug arrests.

539. [redacted]

D. Endo

540. Endo manufactured, marketed, sold, and/or distributed the following opioid drugs in New York:

Product	Chemical Name
Opana ER	Oxymorphone hydrochloride, extended release
Opana	Oxymorphone hydrochloride
Percodan	Oxymorphone hydrochloride and aspirin
Percocet	Oxymorphone hydrochloride and acetaminophen
Generic	Oxycodone
Generic	Oxymorphone
Generic	Hydromorphone
Generic	Hydrocodone

541. Endo also implemented and maintained a sustained campaign of deceptive marketing of opioids, in particular using Front Groups, egregious misrepresentations, and aggressive detailing. An earlier investigation by the OAG of limited aspects of Endo's opioid-related marketing resulted in a narrow 2016 settlement agreement, the terms of which do not encompass or preclude relief for this misconduct, described below.

1. Endo's Misrepresentations Regarding Opioids

542. Like the other Manufacturer Defendants, Endo promoted its opioid products, and opioids generally, in New York through a multitude of marketing channels—including detailing, Front Groups, and unbranded promotional materials—in an effort to influence prescriber and patient decisions.

543. Opioid products accounted for roughly $403 million of Endo's overall revenues of

$3 billion in 2012, representing over 10 percent of Endo's total revenue. Endo's branded Opana ER line produced revenue of $1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

544. Endo's quarterly promotional spending increased from the $2 million to $4 million range in 2000 to 2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007). When it launched the reformulated version of Opana in 2012, Endo's quarterly spending was more than $8 million (and nearly $34 million for the year).

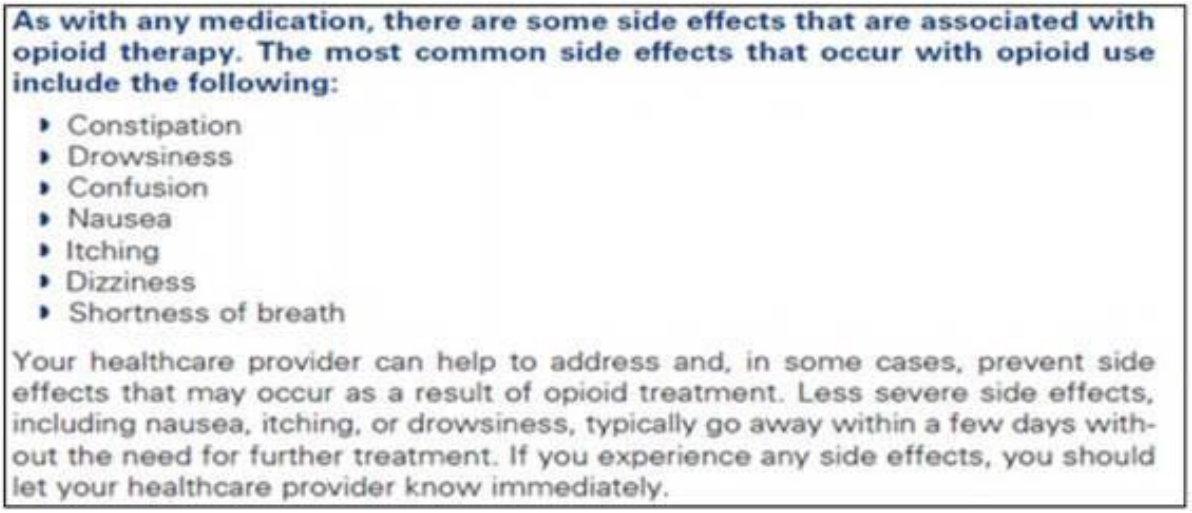
545. In the first quarter of 2010 alone, Endo's sales representatives made nearly 72,000 visits to prescribers nationwide to detail Opana ER. From 2009 through 2013, Endo detailed its sales representatives to New York providers on over 164,000 occasions. Endo improperly instructed these sales representatives to diminish and distort the risk of addiction associated with opioids and Opana ER. Endo's training materials for its sales representatives in 2011, for example, prompted sales representatives to answer "true" to the statement that addiction to opioids is not common.

546. One of the Front Groups with which Endo worked most closely was the American Pain Foundation ("APF"). Endo funded, provided substantial assistance to, and developed and exercised editorial control over, the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC") and its website www.painknowledge.com. Endo provided substantial financial support to NPIC and selected APF to manage NPIC, even as Endo obscured its involvement with NIPC.

547. Endo made numerous false representations regarding addiction through NPIC and painknowledge.com. NIPC and the painknowledge.com claimed, for example, that "[p]eople who take opioids as prescribed usually do not become addicted."

548. A brochure available on painknowledge.com titled "*Pain: Opioid Facts*" stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." Endo repeated this deceptive message in numerous other patient materials.

549. Also posted on painknowledge.com was a patient education guide entitled "*Pain: Opioid Therapy*," which omitted the material fact that addiction was one of the "common risks" of opioids, as shown below:



As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

550. Painknowledge.com also falsely claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website misleadingly touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement.

551. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials. By September 14, 2010, painknowledge.com had 10,426 registrants, 86,881 visits, 60,010 visitors, and 364,241 page views.

552. Another NIPC initiative that Endo sponsored was a series of CMEs titled *Persistent Pain in the Older Patient*, which misleadingly claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was available via webcast to New York physicians.

553. Endo commissioned a supplement available for CME credit in the *Journal of Family Practice* called "*Pain Management Dilemmas in Primary Care: Use of Opioids*," in which it deceptively minimized the risk of addiction by emphasizing the effectiveness of risk screening tools, falsely claiming that with the use of such tools, even patients at high risk of addiction could safely receive chronic opioid therapy. Endo distributed 96,000 copies of this CME nationwide, including to prescribers within New York.

554. Endo co-sponsored and distributed copies of the FSMB's *Responsible Opioid Prescribing*, 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, were all really signs of "pseudoaddiction."

555. In a patient education pamphlet titled "*Understanding Your Pain: Taking Oral Opioid Analgesics*," Endo deceptively minimized the risks of addiction by stating, "[a]ddicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction." New Yorkers can still access this publication online.

556. Endo sponsored and distributed in New York an article published in *Pain Medicine News*, entitled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain." The

article asserted that "[o]pioids represent a highly effective but controversial and often misunderstood class of analgesic medications," and then focused on and emphasized the risks of extended use of NSAIDs as an alternative to opioids, but omitted the same detail concerning the serious side effects associated with opioids. Endo distributed the publication to 116,000 prescribers in 2007, including primary care physicians.

557. Endo distributed or facilitated the distribution of these messages with the intent that prescribers and consumers in New York and elsewhere would rely on them in choosing to use opioids, and Endo's opioids in particular, to treat chronic pain. Endo tracked the breadth and depth of its marketing and messaging efforts, and confirmed that its marketing efforts were translating directly into increased prescriptions for its opioids.

558. The FDA requested that Endo remove Opana ER from the market in June 2017 due to its risk of abuse. The product was removed in July 2017.

2. New York's Settlement with Endo

559. In March 2016, the OAG closed an investigation and entered into an Assurance of Discontinuance (the "Endo AOD") with Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. The Endo AOD covered certain misrepresentations that the OAG alleged that Endo had made regarding Opana ER, and the company's failure to prevent its sales staff from detailing providers who may have been involved in the abuse and illegal diversion of opioids. The AOD covered the following specific conduct:

- Endo's marketing of reformulated Opana ER as "designed to be crush resistant";
- A statement on www.opana.com that patients who take Opana ER "usually do not become addicted";
- Endo's use of the term "pseudoaddiction" in certain training materials for its sales representatives;
- Statements Endo made in certain marketing materials and by Endo's sales

representatives that patients taking Opana ER require less "rescue medication" than patients taking OxyContin;

- This statement in certain Endo materials: "Most doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted";
- An Opana ER advertisement featuring construction workers and chefs;
- Endo's statements and omissions in certain marketing materials regarding Opana ER studies; and
- Endo's lack of an effective program to detect abuse and diversion among health care providers it detailed.

560. The Endo AOD expressly stated that nothing in it "in any way limits the OAG's ability to investigate or take other action with respect to any noncompliance at any time by Endo with respect to this Assurance, or Endo's noncompliance with any applicable law with respect to any matters that are not part of the Covered Conduct."

E. Teva

561. Teva manufactured, marketed, sold, and/or distributed the following opioid drugs in New York:

Product	Chemical Name
Actiq	Fentanyl citrate (lollypop)
Fentora	Fentanyl citrate (buccal tablet/lozenge)
Generic	Oxycodone hydrochloride (generic OxyContin)
Generic	Oxycodone
Generic	Oxymorphone
Generic	Hydrocodone
Generic	Fentanyl

1. Teva's Misrepresentations Regarding its Fentanyl Drugs

562. Teva, including its Cephalon unit, has engaged in deceptive marketing of opioids and other illegal conduct for more than a decade, and now owns the former generic opioids unit of Allergan, which has a similarly tainted legacy.

563. Teva's annual promotional spending on opioids steadily climbed from under $4 million in 2000 to more than $13 million in 2014, including a peak, coinciding with the launch of Fentora, of more than $27 million in 2007.

564. Teva's branded opioid products, Actiq and Fentora, are extremely powerful and dangerous rapid onset fentanyl drugs—up to 100 times stronger than morphine—and approved only for the treatment of "breakthrough" cancer pain in patients. Moreover, the drugs are approved for use only by cancer patients who are already receiving and who are tolerant to around-the-clock opioids for their underlying cancer pain. Actiq and Fentora carry the strictest warning required by the FDA, which includes information about the risk of fatal respiratory depression when used by non-opioid tolerant patients.

565. Despite the potentially fatal consequences of inappropriately prescribing these fentanyl-based drugs, Teva deployed its sales force to promote the drugs off-label in New York, beyond the patient types and indications for which they were approved, in order to claim its piece of the broader chronic non-cancer pain market. This campaign was deceptive because it represented that Actiq and Fentora were safe, effective, and approved for patients and uses for which they were not.

566. Teva also promoted off-label through Front Groups and KOLs. For example, at an AAPM annual meeting held in February 2006, Teva sponsored a presentation by Dr. Webster and others that purported to show good safety results from fentanyl buccal tablets in patients with chronic pain and "breakthrough pain." At the time, however, Teva's product was the only fentanyl buccal tablet on the market. Because the drug was not approved for chronic pain and non-cancer breakthrough pain, the CME was nothing but thinly veiled deceptive off-label promotion.

567. A Teva executive explicitly acknowledged that if Teva were able to expand its approved indications, "the opportunity that Fentora represents is enormous." Teva did in fact seek FDA approval for a broader indication for Fentora in 2008, but did not receive it. Nevertheless, it continued its relentless pursuit of sales and profits, disregarding the safety of New Yorkers.

568. Indeed, Teva employed its deceptive and dangerous marketing strategy despite knowing that people were dying when taking these powerful fentanyl drugs.

569. In September 2008, Teva paid a $425 million federal fine to resolve allegations of off-label marketing of Actiq, because Teva promoted the drug for non-cancer patients, and for patients who were not opioid tolerant.

570. Undeterred, Teva continued its deceptive marketing of opioids. In 2009, it received a warning letter from the FDA that its materials for Fentora were deceptive because they broadened the indication for the drug beyond cancer patients with breakthrough pain.

571. Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, in 2012, Teva published an insert in *Pharmacy Times* regarding Actiq and Fentora. The first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

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

573. Teva tracked its prescriptions and was well aware that its drugs were being written off-label, as was intended by its promotion of the drugs. The company's sales increased exponentially throughout the period it detailed its drugs.

2. Teva's Misrepresentations Regarding Opioids

574. Teva's deceptive conduct in marketing Actiq and Fentora was an extension of, and reaped the benefits of, Teva's generally deceptive promotion of opioids for chronic pain in New York.

575. Like the other Manufacturer Defendants, Teva directly engaged in misleading and deceptive marketing of opioids through not only its sales force, but also using Front Groups, physician speakers, promotional materials, KOLs, and CMEs. Through these vehicles, Teva intentionally misrepresented the risk of addiction as modest, manageable, and outweighed by the benefits of opioid use.

576. For example, Teva sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included misleading claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids."

577. Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain*, which included numerous false or misleading statements, including that opioids have "no ceiling dose" and therefore are safer than NSAIDs. It also taught that addiction is rare and involves unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

578. If patients did not exhibit those behaviors, Teva represented that they were merely exhibiting signs of "pseudoaddiction:" Teva co-sponsored and distributed FSMB's *Responsible Opioid Prescribing*, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, were not

signs of addiction but were all really signs of "pseudoaddiction." Teva spent $150,000 to purchase copies of the publication and used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide, including in New York.

579. A final example of Teva's repeated and persistent deceptive conduct is a CME presentation it sponsored titled *Pharmacologic Management of Breakthrough or Incident Pain*, which is posted on Medscape and still available online. The CME teaches prescribers that "[C]hronic pain is often undertreated, particularly in the noncancer patient population," discusses the "stigmatization of opioids" as a barrier to effective treatment, and further claims that the "[t]he concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse."

F. Allergan

580. Allergan manufactured, marketed, sold, and/or distributed in the following opioid drugs in New York:

Product Name	Chemical Name
Kadian	Morphine sulfate, extended release
Kadian (generic)	Morphine sulfate, extended release
Norco	Hydrocodone bitartrate and acetominophen
Generic	Oxymorphone hydrochloride, extended release (generic Opana ER)
Generic	Oxymorphone hydrochloride
Generic	Oxycodone
Generic	Fentanyl patch (generic Duragesic)
Maxidone	Hydrocodone and acetominophen
Reprexain	Hydrocodone bitartrate and ibuprofen
Combunox	Oxycodone/ibuprofen
Fiorinal with Codeine	Butalbital, aspirin, caffeine, and codeine phosphate

581. Allergan engaged in deceptive marketing of these opioids for more than a decade. Allergan has vied with Mallinckrodt for the top spot among manufacturers of generic opioids.

Because Allergan lacked a meaningful suspicious order monitoring program, its opioids flooded the market without pause, worsening the opioids epidemic.

1. Allergan's Misrepresentations Regarding Opioids

582. Allergan's deceptive and misleading representations followed the opioid marketing playbook, and included such messages as: (i) minimizing the risk of addiction from opioids generally; (ii) minimizing the risk of addiction due to the "abuse-deterrent" features of Allergan products; (iii) promoting the spurious concept of "pseudoaddiction" to assuage prescribers' concerns about addiction; (iv) claiming that opioid use improves functioning; and (v) exaggerating the risks of alternative pain treatments.

583. Allergan's promotional spending on opioids, which was virtually nonexistent in the 2004-2008 period, began to sharply rise in 2009, when it began marketing Kadian. The third quarter of 2011 saw a peak of $3 million and nearly $7 million for the year.

584. To ensure that these messages reached individual physicians, Allergan deployed sales representatives to visit HCPs in New York and across the country. Between 2009 and 2012, Allergan sales representatives visited the offices of New York health care providers 2,866 times to push Allergan opioid drugs. Allergan chose its detailing targets based on the likelihood of higher numbers of prescriptions at higher doses, with no consideration as to the risk of misuse. Allergan carefully tracked the prescription trends of the HCPs whom it detailed.

585. Allergan also promoted opioids in New York and nationwide through Front Groups, using a combination of CMEs, websites, and purportedly educational and other materials that Allergan directed, sponsored, reviewed, and/or approved. Allergan's marketing plan recognized that "[d]irect-to-consumer marketing affects prescribing decisions," and so it put its relationships with Front Groups to work to spread deceptive messages about opioids and the treatment of pain.

586. For example, Allergan advertised that its extended-release morphine drug Kadian could allow chronic pain patients to return to work, relieve "stress on your body and your mental health," and otherwise enjoy their lives. In 2010, the FDA warned Allergan that its claims were misleading and there was insufficient evidence to show that the drug "results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."

587. Through its "*Learn more about customized pain control with Kadian*" patient material, Allergan claimed that while it is possible to become addicted to drugs like Kadian, it is "less likely" to happen in those who "have never had an addiction problem," suggesting the addiction risk was *de minimis*. The piece went on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

588. Allergan's "*Kadian Marketing Update*," and the "*HCP Detail*" aid contained therein, noted that Kadian's [redacted] than other opioids, the implication of which was that Kadian did not produce a euphoric effect, and therefore was less addictive and less likely to be abused. In a separate presentation, Allergan also falsely trumpeted Kadian as safer than other opioids when taken with alcohol.

589. These and other themes were repeated in a guide for prescribers under Allergan's copyright, which deceptively represented that Kadian is more difficult to abuse and less addictive than other opioids. The guide included the following statements: 1) [redacted] and 2) Kadian may be less likely to be abused because of [redacted]

[redacted] These statements, which are unsupported by substantial clinical evidence, convey both that (a) Kadian does not cause euphoria and therefore is less addictive and that (b) Kadian is less prone to tampering and abuse, even though the FDA did not approve Kadian as an abuse deterrent formulation.

590. When Kadian was first approved in 1996, it was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." But by 2014, after years of Kadian's deceptive marketing, the FDA changed the indication to use only for "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

591. Allergan trained its sales representatives to deceptively minimize the risk of addiction by: (i) attributing addiction to [redacted] (ii) emphasizing the difference between substance dependence and substance abuse; and (iii) promoting the unsupported term "pseudoaddiction."

592. Allergan misleadingly instructed its sales team that opioid doses could be escalated during long-term opioid therapy, without hitting a dose ceiling, which purportedly made them safer than other forms of therapy such as acetaminophen or NSAIDs.

593. Allergan intended for prescribers to rely on its deceptive messages and surveyed its prescribers to ensure that happened. Allergan conducted market studies on prescribers' impressions of promotional pieces and other marketing efforts, observing that [redacted]

2. Allergan's Impact on the Generic Market

594. Allergan actively marketed not only its branded drugs but its generic drugs. Prior to the sale of its generic business to Teva, Allergan's marketing strategy included promotion of its generic opioids, including generic Kadian (morphine sulfate), directly to New York HCPs. Allergan

sales representatives received bonuses for both branded and generic Kadian sales, and used the same selling points for both versions of the drug. Indeed, Allergan explicitly adopted the deceptive Kadian promotional campaign when it instructed its sales staff that its messaging should be:

595. Allergan also promoted its generic Opana ER (oxymorphone ER). Allergan saw a

Allergan also paid bonuses to its sales team bonuses for meeting sales goals for generic Opana ER.[109]

596. Allergan also promoted its generics through direct mail and email campaigns and journal advertisingand aggressively marketed its generic opioids through its distributors, in particular . To promote Allergan's generic oxymorphone ER, oxycodone, and generic morphine sulfate, deployed a variety of tactics, including notifying pharmacies about the products using Allergan talking points and posting sell sheets on its website. had an incentive to maximize Allergan's

[109] In December 2012, Endo sued Actavis Inc., arguing that Actavis was deceptively marketing generic Opana ER by piggybacking on Endo's allegedly "abuse deterrent" reformulation. Endo alleged that Actavis described the tablets as being "crush-resistant tablets." Endo claimed this constituted deceptive marketing because "[w]holesale distributors, prescribing physicians, dispensing pharmacies and patients are likely to rely on and have relied on Actavis's misrepresentations in distributing, prescribing, dispensing and purchasing the Generic Oxymorphone ER Tablets." Indeed, describing generic Opana ER as crush-resistant is facially deceptive (as was Endo's campaign to market its drug as "designed to be crush-resistant"), and as Endo acknowledged, a company's customers rely on marketing messages in their decisions to purchase, prescribe, dispense, and take a company's drugs.

597. Allergan similarly collaborated with [redacted] to promote Allergan's generic opioids through targeted telemarketing and direct mail campaigns aimed at pharmacies. Allergan collaborated with Amerisource in an initiative to drive generic conversion at a faster rate than what would normally occur without its intervention.

598. Allergan also worked with [redacted] to send a letter to patients who had filled a prescription for Opana ER within the prior year, informing them that although Endo no longer manufactured certain dosages of Opana ER, a generic was now available from Allergan.

3. Allergan's Failure to Maintain Effective Controls against Diversion

599. Through its misleading marketing, Allergan expanded the market for opioids in New York. Not only did Allergan deceptively promote opioids, it compounded this harm by failing to put in place appropriate procedures to ensure that suspicious orders—orders of unusual size, frequency, or those deviating from a normal pattern—would be reported to governmental authorities as required by law. Instead, Allergan continued to supply far more opioids than were justified, flooding the New York market.

600. As an entity registered with the DEA and BNE, Allergan knew it was required to maintain effective controls against diversion of opioids and to report suspicious orders.

601. Allergan possessed ample sources of data that allowed it to detect and report suspicious orders of opioids, both from its direct and indirect customers. The company's sales representatives regularly visited pharmacies and HCPs to promote Allergan's products, which allowed them to observe red flags of diversion.

602. Despite these available sources of information regarding potential diversion, Allergan failed to properly design and operate a system that would be capable of detecting suspicious opioid orders. Prior to 2011, any process that Allergan had that could be considered an opioid order monitoring system was not even properly automated. After 2011, Allergan finally

began to acknowledge its responsibility to create an opioid order monitoring system, but the procedures it put in place were severely lacking, and were focused on *approving*—not restricting—orders of excessive quantities of opioids.

603. To the extent Allergan established thresholds to detect suspicious orders, they were wholly inadequate. Allergan also adjusted and otherwise manipulated its thresholds so that it could ship its opioid products without any obstacles.

604. Allergan failed to perform appropriate due diligence on its customers, both generally and at the time it should have been alerted to a suspicious order. Instead of independently investigating customers and the reasons behind suspicious orders, Allergan reached out to customers and simply asked them to provide a justification for large orders. Allergan even required customers to provide a reason for *reduced* orders.

605. Allergan failed to stop shipments after it knew or should have known that opioid orders remained suspicious, had no requirement to stop shipments on suspicious indirect sales, and failed to report suspicious orders to BNE or the DEA. Eventually, Allergan ceased operating any suspicious order monitoring program at all, when it [redacted].

606. Finally, Allergan failed to discontinue detailing HCPs who were suspected of diversion. On the contrary, Allergan chose its detailing targets based on the likelihood of higher numbers of prescriptions.

III. Specific Misconduct of Each of the Distributor Defendants

607. While the Manufacturer Defendants created the initial surge in demand for opioids, and maintained it with their ongoing fraudulent conduct, the explosion in opioid overuse in New York could not have been perpetuated and expanded over the past decade to such devastating effect without the grossly negligent and/or willful misconduct of the Distributor Defendants.

608. New York has entrusted pharmaceutical distributors, through the duties enshrined in the NYCSA, with an essential role in cutting off the flow of controlled substances from manufacturers to pharmacies when there are warning signs of potential misuse. As a practical consequence, pharmaceutical distributors who do business in New York have to accept the costs of both implementing effective compliance functions and losing prospective but noncompliant sales to pharmacies that are successfully blocked by those functions.

609. The Distributor Defendants refused this legally-required bargain, choosing instead to profiteer by repeatedly and continuously violating the NYCSA over the past decade, enabling lucrative sales of massive volumes of opioid products to pharmacies displaying even the brightest red flags of misuse.

610. Even if Plaintiff could point to no articulable injury resulting from the Distributor Defendants' routine, everyday violations of the NYCSA, they would still be liable to pay the penalties sought here for each such violation, which serve as New York's primary deterrent against well-resourced corporations being tempted to skimp on (or ignore) their duty to provide robust compliance mechanisms.

611. But the Distributor Defendants have injured the State and its residents. Their pervasive and persistent course of misconduct enabled and perpetuated vast increases in opioid over-prescription, caused numerous false medical-cost payment claims to be made to (and fulfilled by) the State, and exponentially multiplied the toll of death, destruction, and suffering that the State and its residents have already endured, and will still face for years to come.

612. The Distributor Defendants knew they were doing this at all relevant times, yet they not only failed to fix the yawning holes in their compliance systems, but also lied to the State about those systems in order to maintain their licenses and their ability to profit from the misery of New

York residents. The Distributors' ongoing, slow-motion compliance train wreck was so apparent from within these companies, and the injuries it would inevitably inflict were so entirely foreseeable, that if the Distributor Defendants did not actually know and intend their misconduct and its results, it could have only been because they deliberately blinded themselves to those realities as they clawed for profits and competitive advantage in a race to the regulatory-compliance bottom.

613. Even at this preliminary stage of Plaintiff's investigation, Plaintiff can identify glaring examples of each Distributor Defendant's violations of its duties.

A. Cardinal

614. Cardinal was New York's leading distributor of opioid drugs between 2010 and 2018, selling nearly 780 million oxycodone pills to its customers in New York in that period.[110]

615. Of particular importance to New York, Cardinal's business in the State during this time vastly expanded through its acquisition of smaller pharmaceutical distributors including its 2006 purchase of ParMed Pharmaceuticals, and its November 2010 purchase of Kinray, which is based out of Whitestone, New York and focuses primarily on customers in New York State and some surrounding areas.

1. Cardinal's Flawed Written Policies Enabled Opioid Diversion

616. Cardinal's written policies for compliance with the NYCSA were and are contained in Standard Operating Procedures ("SOPs") that apply to its various operating and sales departments. These SOPs were first implemented in December 2008 and have since undergone several revisions.

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[110] Unless otherwise specified below, information concerning shipments and prescriptions are derived from Manufacturers and Distributors of Controlled Substances (MADOCS) shipment data, prescription data, and related opioid data provided by DOH. Suspicious order reporting figures are derived from DOH and DEA data.

617. These policies were fundamentally flawed in that they were not coordinated within the context of a consistent, unified umbrella policy to prevent the diversion of controlled substances, resulting in employees governed by one of the SOPs being unaware of the obligations imposed by other SOPs on other employees, even when effective anti-diversion measures required that understanding and coordination. Furthermore, these documents are not readily available even to the employees charged with implementing them.

618. In addition, Cardinal's SOPs and policies contained numerous gaps that would have prevented them from effectively preventing diversion, even if enforced. For example, these policies:

- Allowed compliance staff to approve onboarding new accounts with no formal mechanism to ensure review and approval by a supervisor;
- Allowed onboarding of new accounts even where customers failed to provide requested information about other suppliers, dispensing data, and top prescriber information;
- Allowed staff to [redacted];
- Allowed compliance staff to release a customer's first order in excess of its monthly threshold, regardless of whether the customer made other orders in excess of the same drug threshold at the same time; and
- Allowed compliance staff to [redacted].

2. Cardinal's Failure to Effectively Prevent Diversion in Practice

619. At all relevant times, Cardinal failed to employ qualified compliance staff to implement these policies, failed to adequately train those compliance staff or its sales representatives concerning Cardinal's anti-diversion duties, and failed to enforce even the defective policies it had in place.

620. Cardinal failed to install qualified personnel in key compliance positions. For example, Cardinal's front-line "New Account Specialists" and "Analysts," responsible for onboarding new customers and monitoring existing customers, respectively, were routinely recruited from the ranks of the company's existing pool of administrative assistants. These employees, who had no experience in regulatory compliance, were generally supervised by pharmacists or other professionals with no prior experience in supervising investigative functions.

621. Moreover, Cardinal failed to provide meaningful training to either these unqualified compliance personnel or sales representatives. Instead, Cardinal expected the compliance staff to "learn on the job" through informal in-person "team meetings." Due to the lack of proper training and clear guidelines, compliance staff did not fully understand critical components of their jobs and often developed their own procedures and benchmarks for reviewing customers.

622. Unsurprisingly, these unqualified and untrained staff routinely failed to follow even the most basic procedures required under the company's various SOPs.

623. For example, while Cardinal's SOP for onboarding new customers called for their New Account Specialists to [redacted]

624. Moreover, even when a New Account Specialist provided information about [redacted] Indeed, even where the New Account Specialist indicated that [redacted]

625. Finally, even when a New Account Specialist [redacted]

626. Illustrative examples of New York pharmacies that were allowed to become Cardinal customers in this way include:

- [redacted]
- [redacted]
- [redacted]

627. In addition, Cardinal allowed customers to reinstate their accounts through the new account onboarding process despite having compliance red flags. In or around June 2012, for example, a Nassau County pharmacy that had [redacted]

628. Even to staff charged with investigations and anti-diversion, the message was clear: without sales, there is no Cardinal. Indeed, many of Cardinal's policies and practices have prioritized sales over regulatory obligations.

629. In 2012 and 2013, Cardinal took significant steps to renew focus on increased sales at the cost of a robust and responsible compliance structure, thereby keeping as customers pharmacies that it knew or should have known were high risk for diversion of opioids. For example, Cardinal:

- Continuously reduced the due diligence information collected from prospective and existing customers, diluting the customer questionnaire, removing the requirements to collect photos of the pharmacies, and ceasing to ask about top prescribers;
- Expanded the geographic scope of investigators with essential regional knowledge of, for example, top prescribers and their locations relative to the pharmacies where their prescriptions were being filled, thus reducing the investigators' efficacy;
- Restricted the information reviewed from site visits by first removing the investigator comment section and for a time eliminating written reports entirely; and
- Demoted, moved to non-compliance functions, or let go several staff members who articulated an interest in expanding the company's compliance functions, aggressively scrutinizing pharmacy customers, and/or terminating problematic customers.

630. Cardinal was known by its competitors to [redacted]

631. As to existing customers, Cardinal routinely failed to follow the SOP's procedures for detecting, monitoring, and reporting suspicious orders.

632. For one, Cardinal's compliance staff routinely released orders in excess of a customer's threshold without conducting the follow-up investigation and providing the detailed written justification called for by the SOPs. Indeed, Cardinal regularly [redacted] As another example, in the five months between July and November 2015, Cardinal [redacted]

633. Even in instances where Cardinal's staff [redacted]

634. In addition, in several instances, occurring at least as recently as 2017, Cardinal [redacted]

635. Even where Cardinal did block customers' orders and report them as suspicious to the DEA, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

636. Between 2012 and 2017, for example, Cardinal reported twelve or more opioid-related suspicious orders for at least one year—the equivalent of one per month—for 195 separate

pharmacies in New York. For nearly half of these pharmacies, Cardinal reported an average of one opioid-related suspicious order per month for two or more years.

637. Those pharmacies had several known red flags in their shipment orders and prescription data. More than half of these pharmacies: (a) exceeded the 90th percentile in the State in terms of opioid volume shipped; (b) exceeded the 90th percentile in the State in terms of oxycodone volume shipped; and (c) exceeded the 90th percentile in the State in terms of median strength of opioids prescribed per day.

638. After the first year in which Cardinal reported twelve or more opioid-related suspicious orders for one of these pharmacies, Cardinal continued to ship opioids, on average, for *more than three years.* In fact, as of 2018, it appears that Cardinal was still shipping opioids to 149 of these pharmacies, or 76% of the group.

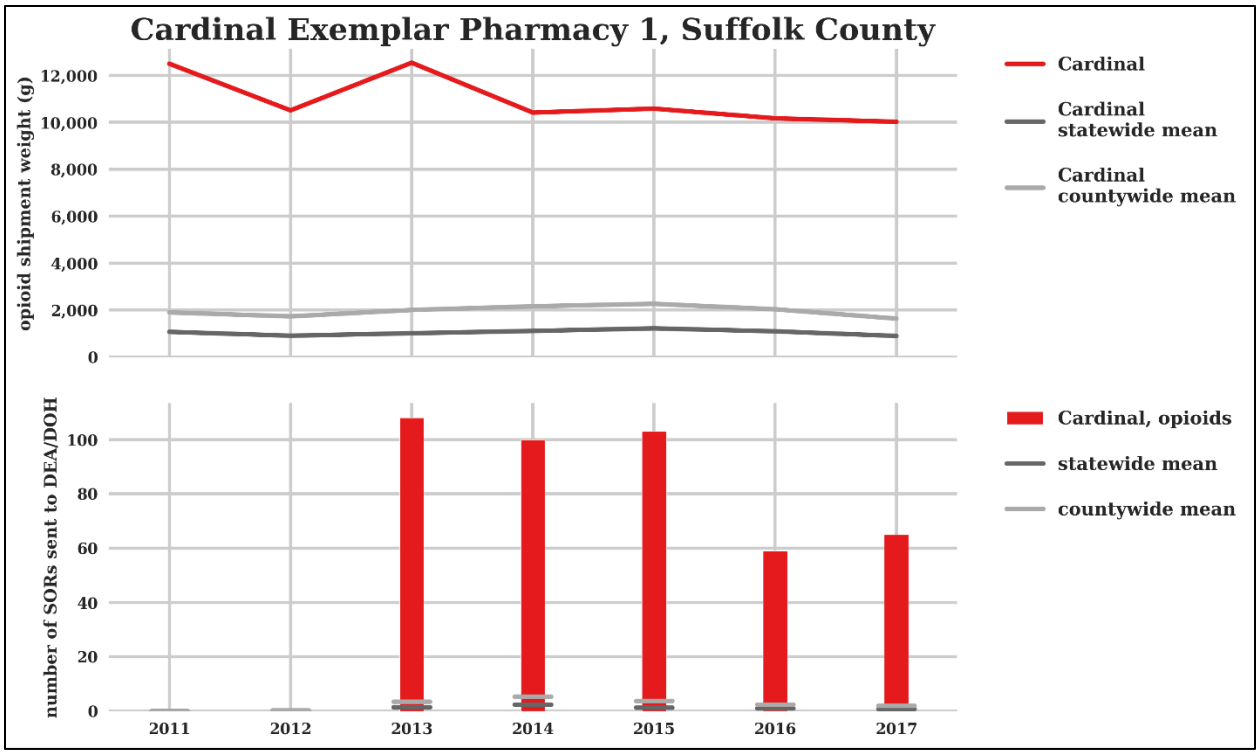
639. Moreover, as of 2018, 85% of this group of pharmacies had filled prescriptions by at least one prescriber who was subsequently indicted or convicted on opioid-related prescribing and distribution charges.

640. Within this group of suspect pharmacies that Cardinal did nothing to control, five stand out as particularly egregious. In each case, Cardinal reported more than 50 opioid-related suspicious orders per year—the equivalent of *one suspicious order per week* to either the New York State Department of Health ("DOH") or the Drug Enforcement Agency ("DEA")—*for three or more consecutive years*. This, despite the fact that all five pharmacies separately exhibited numerous known indicators of illicit activity.

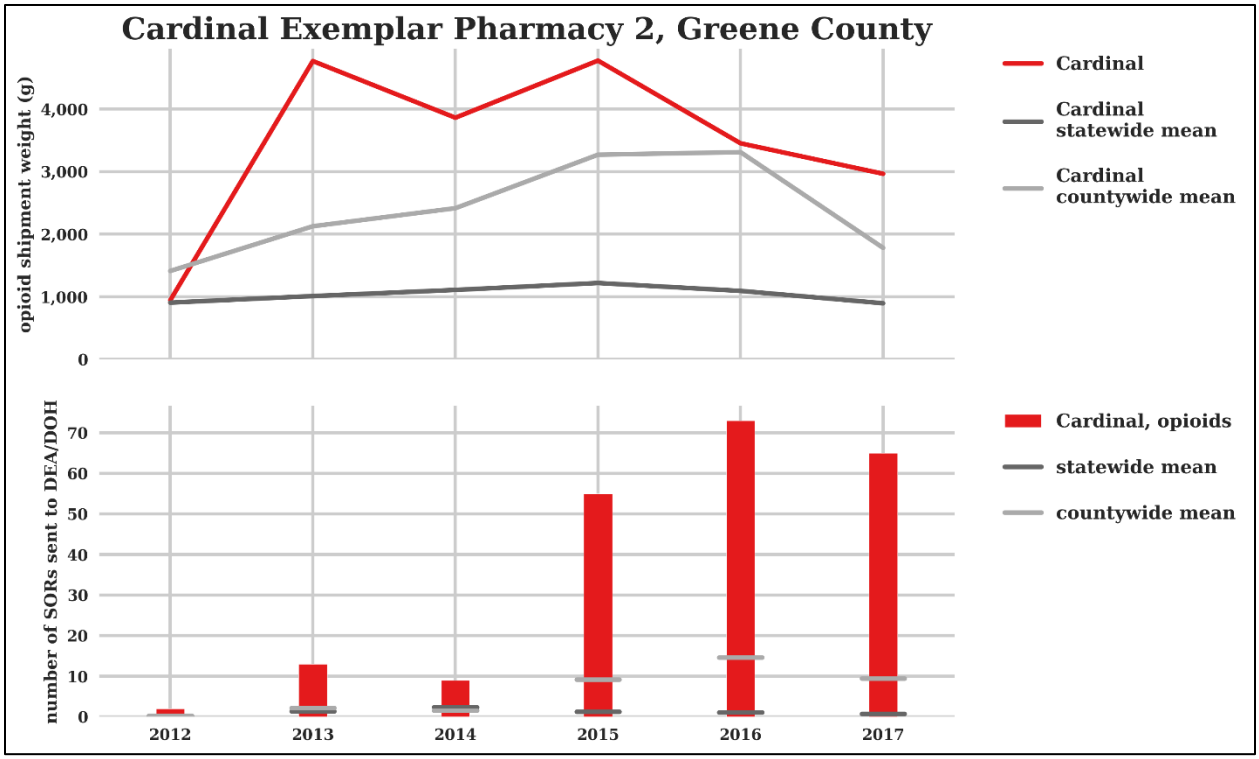
641. Some examples of these pharmacies include:

- **Cardinal Exemplar Pharmacy 1** was the number-one pharmacy in terms of opioid volume in Suffolk County and in the 99th percentile for the State *from 2011 through the first quarter of 2018.* Its median MME per day exceeded the 95th percentile for the entire State for

all of 2013 to 2017. Cardinal reported an average of 85 suspicious orders per year for five years, the equivalent of more than once a week, yet as of 2018, this pharmacy continued to receive opioids from Cardinal.



- **Cardinal Exemplar Pharmacy 2** located in Greene County, with a population of about 50,000, exceeded the 95th percentile in terms of opioid and oxycodone volume shipped, relative to *all other pharmacies in the State* in at least one year. From 2012 to 2018, Cardinal shipped more than 20,000 grams of opioids to this pharmacy, the equivalent of about thirteen 30mg oxycodone pills for every person in the county. As of 2018, it was the largest pharmacy in the county in terms of opioid volume, oxycodone volume, oxycodone orders, and percentage of oxycodone volume relative to all controlled substances. For 2013 to 2017, an average of 20% of customers filled prescriptions from three or more prescribers per year (likely "doctor-shoppers"). From 2015 to 2017, Cardinal wrote a total of 993 Suspicious Order Reports ("SORs")—the equivalent of *three every single day for three years*—193 of which were opioid-related. Yet as of 2018, Cardinal has continued to ship opioids to this pharmacy.



642. In many other instances, however, Cardinal simply failed to block suspicious orders at all, despite overwhelming and telltale signs of suspicious activity. For these pharmacies, rather than file a single opioid-related SOR, Cardinal shipped opioids for years on end.

643. For example, Cardinal had 70 pharmacy customers as to which other distributors reported at least six opioid-related suspicious orders per year, the equivalent of one every other month, while *Cardinal did not report a single opioid-related suspicious order*.

644. Most of these pharmacies exhibited one or more known "red flags" indicating suspicious activity:

- Exceeded 90th percentile in county in terms of opioid orders;
- Exceeded 90th percentile in county in terms of opioid volume;
- Exceeded 90th percentile in county in terms of oxycodone volume;
- Exceeded 90th percentile in State in terms of oxycodone volume;

- More than 20% of customers filled opioid prescriptions at three or more pharmacies in a single calendar year, the 90th percentile of pharmacies visited by a single customer;

- More than 20% of customers filled opioid prescriptions written by three or more different prescribers in a single calendar year, the 90th percentile of providers visited by a single patient; and

- Opioid prescriptions written by a provider who was subsequently indicted or convicted on opioid-related prescribing and distribution charges.

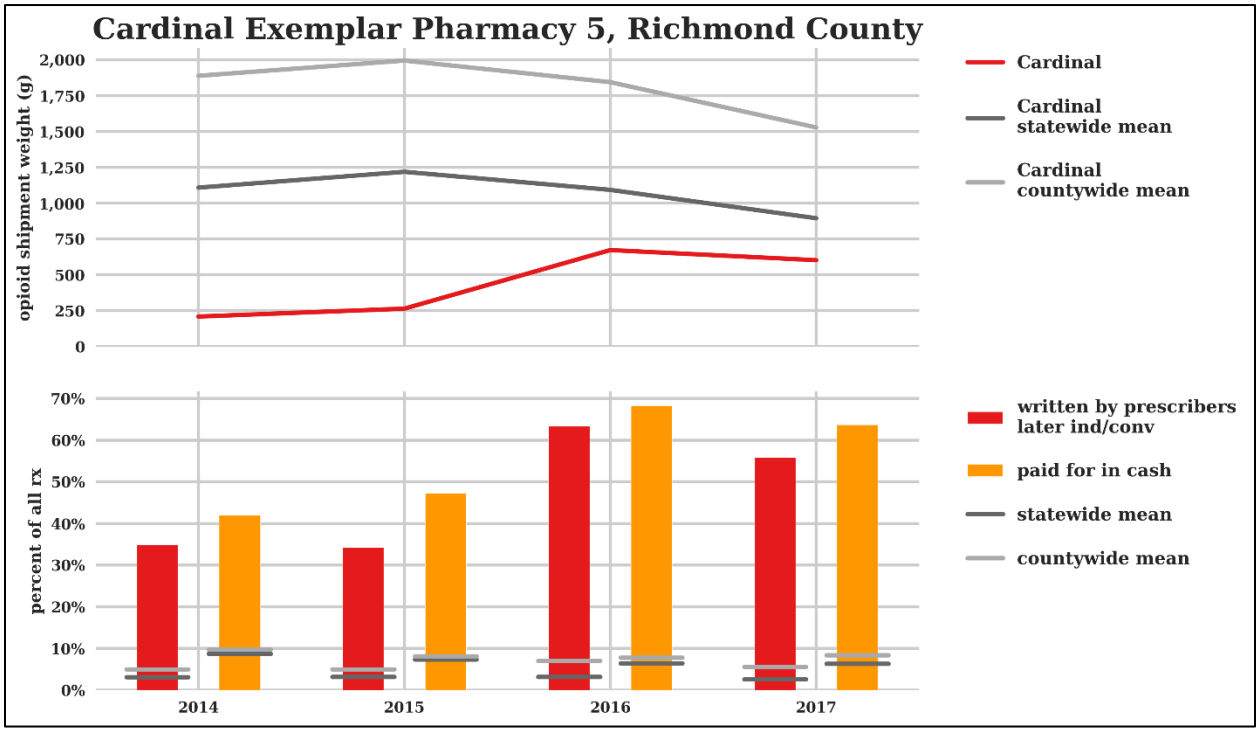
645. Some of these pharmacies exhibited several red flags. Two examples stand out:

- **Cardinal Exemplar Pharmacy 3** located in Erie County, exceeded the 90th percentile in the state for number of opioid orders and total opioid volume from 2010 to 2018. Its median MME per day for prescriptions exceeded the 90th percentile for the state for 2013-2016. More than 20% of its customers have received opioid prescriptions by three or more doctors in the same period. Between 2010 and 2014, McKesson, another supplier, [redacted] and issued 223 SORs. Yet Cardinal appears to have continued shipping opioids to the pharmacy until 2015. In 2016, the pharmacy settled with the State for charges related to Medicaid fraud.

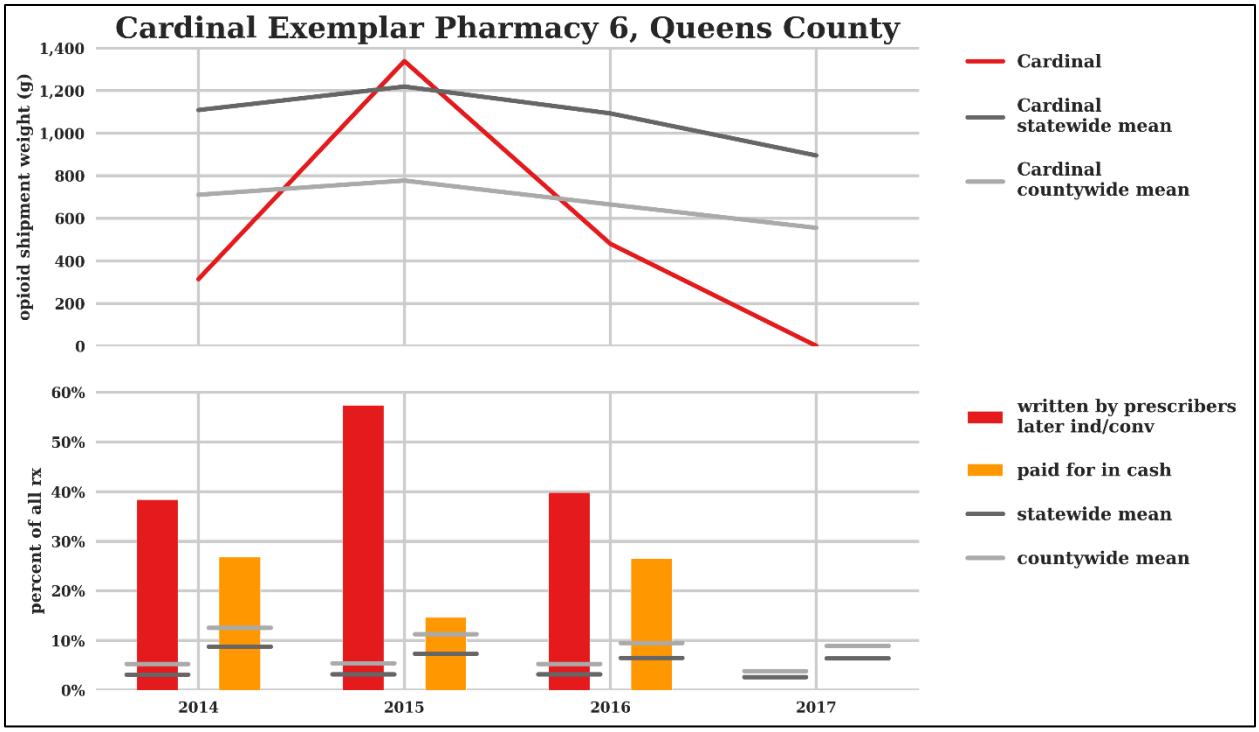
- **Cardinal Exemplar Pharmacy 4** located in Nassau County, had a median MME per day that exceeded the 90th percentile from 2013 to 2017. For five consecutive years, it exceeded the 90th percentile in terms of number of oxycodone orders and oxycodone volume shipped, relative to all other pharmacies in the State. Despite these signs, Cardinal issued only two opioid-related SORs, which occurred in 2016. By this point, McKesson, another supplier, had issued 57 SORs, 24 of which were opioid-related.

646. In still other instances, neither Cardinal nor other distributors reported numerous suspicious orders, but almost certainly should have, given that a handful of prescribers were responsible for writing an unusually high percentage of the pharmacy's opioid prescriptions. By itself, having a high concentration of opioid prescriptions written by a small number of providers is a known red flag for opioid diversion. Subsequently, these pharmacies had among the highest percentage of prescriptions written by providers who were indicted or convicted on opioid-related prescribing and distribution charges. Some examples of these pharmacies include:

- **Cardinal Exemplar Pharmacy 5** located on Staten Island: In 2016 and 2017, approximately 60% of prescriptions were written by prescribers who were later indicted or convicted. The median MME per day was about 170, nearly twice the CDC's recommended maximum of 90 MME per day. About 60% of prescriptions were paid for in cash in 2016 and 2017. This pharmacy is in the 98th percentile in oxycodone shipped as a percentage of all controlled substances for 2016. All of these indicators are significant outliers when compared with other pharmacies. Cardinal had yet to issue a single SOR related to this pharmacy as of December 2017.



- **Cardinal Exemplar Pharmacy 6** located in Queens County: Between 2014 and 2016, approximately 45% of prescriptions were written by prescribers who were later indicted or convicted on opioid-related prescribing or distribution charges; its prescriptions had a high median MME per day of 135; and it ranked in the 97th percentile in the State terms of opioids volume as a percentage of all controlled substances. Cardinal has only issued one SOR for this pharmacy.



- **Cardinal Exemplar Pharmacy 7** located in New York County: In 2013, 89% of prescriptions were written by prescribers who were later indicted or convicted, and 92% of payments were made in cash. Median MME per day was at or exceeded 135 for 2013-2015 and was as high as 180 in 2017. Cardinal had yet to issue a single SOR or stop shipping to this pharmacy as of 2018.

647. Finally, even if Cardinal had conducted due diligence to investigate its high-volume opioids customers in New York, Cardinal's failure to implement any system to store and share information about their suspicious customers and/or suspicious prescribers would have compromised the effectiveness of any such investigation.

648. Due to these flaws, Cardinal routinely continued to supply pharmacies that filled prescriptions for prescribers that had been flagged in its own (infrequent) investigations of other pharmacies as likely sources of diversion. For example, Cardinal [redacted] But because this

information was not made available through the retention of a shared list of suspect prescribers, Cardinal continued to supply other pharmacies that [redacted] until just months before Dr. Cubangbang was arrested in 2018 on opioid-related charges.

649. Cardinal's acquisitions of ParMed and Kinray led to substantial additional violations. Cardinal took on these new subsidiaries' customers despite their deficient new customer screening, conflicting policies, and faulty anti-diversion measures. The integration process itself also created gaps that allowed controlled substances to process through the system without adhering to Cardinal's suspicious order monitoring policies. For example:

- In 2017, Cardinal staff discovered that several ParMed customers [redacted]
- During the integration process, a number of ParMed customers [redacted]
- In one example of Kinray new customer onboarding, a pharmacy in Ulster County [redacted] Dr. Longmore was convicted in early 2013 for improperly dispensing drugs, including nearly 10,000 hydrocodone prescriptions, during the time Kinray and Cardinal serviced the pharmacy; and
- Kinray sales representatives regularly [redacted]

[redacted] at least one Cardinal compliance staff member has since acknowledged that practice as inappropriate.

650. In addition to numerous instances, including those cited above, in which Cardinal's own employees acknowledged failures in its compliance systems, the company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties, including those it owed to Plaintiff.

651. For example, in 2007 and 2008, the DEA issued suspension orders against four of Cardinal's distribution centers for failure to maintain effective anti-diversion controls, and alleged that such failures occurred at three additional Cardinal distribution centers. Cardinal entered into a settlement with the DEA in 2008 agreeing to reform its policies and practices and pay a total of $34 million in penalties to seven states.

652. Notwithstanding this settlement and Cardinal's agreement to maintain effective controls, the DEA issued another suspension order in 2012 against another Cardinal distribution center, based on the company's continuing failure to maintain effective anti-diversion controls. Cardinal settled this matter with the DEA first in 2012 by agreeing to maintain an effective compliance program; that agreement included specific requirements, some of which were not formalized into Cardinal's SOPs until 2016. In 2016, Cardinal entered into yet another settlement with the DEA, agreeing to pay a $44 million fine and to implement better policies and procedures.

653. Also in 2012, the State of West Virginia sued Cardinal, alleging that the mere volume of opioid pills the company shipped into the state over the preceding five years was *prima facie* evidence that Cardinal did not have effective policies and procedures for preventing diversion. In 2016, Cardinal settled that case for $20 million.

654. Despite knowing of the broad failures of its compliance policies, both as written and as actually enforced, and knowing of numerous instances in which those failures had led to

individual instances in which the company improperly distributed opioids in New York and other states, Cardinal never took meaningful steps towards adjusting its program to better prevent diversion, never told New York (as it was required to) that violations had occurred, and instead, lied in its licensing applications as to the efficacy of its systems and the absence of violations.

B. McKesson

655. McKesson has been the second-leading distributor of opioids into New York over the last decade, dumping more than 540 million oxycodone pills into pharmacy dispensaries in the State from 2010 to 2018 alone.

1. McKesson's Flawed Written Policies Enabled Opioid Diversion

656. The inadequacy of McKesson's compliance policies was aptly summarized by a high-level McKesson compliance officer [redacted]

657. Indeed, prior to 2007, in complete violation of its obligations under the NYCSA, McKesson had no written policies specifically dedicated to preventing the diversion of opioids.

658. In 2008, McKesson entered into a settlement agreement with the DEA, wherein the company admitted to failure to maintain adequate controls against diversion; failure to report thefts and losses of controlled substances; and failure to detect and report suspicious orders of controlled substances. McKesson also paid $13.25 million in civil penalties.

659. Pursuant to this settlement agreement, in 2008, McKesson finally established an anti-diversion policy for all controlled substances—the "Controlled Substances Monitoring Program" ("CSMP"). McKesson continued to update the program through the years, through modifications to the CSMP and other guidance, culminating in the current CSMP.

660. McKesson's CSMPs were riddled with flaws and loopholes that rendered them substantially ineffective. Specifically, the CSMPs at various points:

- Directed that customers' monthly threshold limits be set by reference to customers' prior ordering volumes, without requiring investigation of those volumes' appropriateness, effectively building all prior diversion activity into the company's future shipments of opioids to those customers;
- Allowed customers to resolve investigations into orders in excess of their monthly threshold and into requests to increase monthly thresholds ("TCRs") by self-reporting the answers to three yes or no questions, without requiring validation of those answers;
- Failed to require key indicators of diversion as part of the company's due diligence of pharmacies, including but not limited to obtaining prescriber-level information;
- Exempted some customers from scrutiny who consistently placed orders in excess of their threshold;
- Alerted customers when they were nearing their monthly threshold limit for opioid products;
- Failed to adequately design and operate a system to disclose suspicious orders to the DEA; and
- Required little to no diligence on chain pharmacy orders, so as to maintain these large customer accounts regardless of the consequences.

661. These and other deficiencies resulted in the unexamined and unrestrained flow of opioids to New York residents. McKesson's failure to establish effective controls against diversion is illustrated by its decision not to require, and later, a directive not to obtain, prescriber information. McKesson never required pharmacies to provide prescriber-level dispensing data when granting threshold increases or investigating suspicious orders, despite [redacted]. Moreover, when compliance staff did receive prescriber-level data and identified suspicions about particular pharmacies based on doctors for whom they filled prescriptions, the company lacked any system

by which it could identify other pharmacies that filled prescriptions for the same physicians. Finally, by late 2013, McKesson [redacted] —deliberately blinding itself to that key data—resulting in continued shipments of opioids to many New York pharmacies that the company should have scrutinized due to the dominance of suspicious prescribers whose prescriptions were being filled in those locations.

662. Another McKesson policy was to avoid performing any diligence on customers that [redacted] McKesson continued to ship opioids to these high-risk pharmacies [redacted], continuing to fill their orders up to their thresholds *without any diligence at all*. One New York pharmacy, for example, [redacted]

663. McKesson also employed the practice of alerting customers when they were approaching their thresholds, which had a natural tendency to encourage the manipulation of the compliance system. Indeed, it appears to have originally been designed for that purpose—[redacted]

664. As a result of this advance-warning practice, McKesson's highest-volume opioid customers in New York, including pharmacies that were later suspended, terminated, or disciplined, were proactively contacted by McKesson's compliance department and distribution center and sales staff so that those customers could structure their orders and justify threshold increase requests, and thereby avoid suspicious order reporting and any additional scrutiny. McKesson itself later

[redacted]

665. Finally, McKesson's system for identifying and reporting suspicious orders swung from inadequate to inscrutable. Between 2008 and 2013, McKesson reported virtually no suspicious orders to the DEA or the State. Specifically, of the *1.6 million* orders for controlled substances processed between 2008 and 2013 by its Aurora, Colorado Distribution Center, McKesson reported *only sixteen* as suspicious.

666. Then in 2013, McKesson began to report *every order* placed in excess of a customer's threshold as a suspicious order. In 2015, for example, McKesson provided the DEA with over 230,000 suspicious order reports, or over 630 per day from McKesson alone. McKesson's automatic submission of every order in excess of a threshold without any review thereby shifted the burden to the DEA to determine whether the order was in fact suspicious. Indeed, McKesson was well aware that this was not an adequate system to disclose suspicious orders to the DEA, as McKesson had previously reported every order in excess of a specified quantity before its 2008 settlement, and at that time, was informed that "inundating local DEA office[s]" was not useful.

667. With respect to its chain pharmacy customers, McKesson did almost no due diligence at all, [redacted]. This reliance proved to be misplaced, as chain pharmacies' outlets also contributed to the massive flow of opioids to New York residents, filling the prescriptions of doctors charged with running pill mills, and other suspicious activities.

668. McKesson adopted this "hands-off" approach to its largest customers for one reason only—fear of losing the large chains' business. When debating whether to subject its largest chain customer, CVS, to the operation of its CSMP, [redacted] And that is exactly what McKesson did: [redacted]

2. McKesson′s Failure to Effectively Prevent Diversion in Practice

669. In addition to adopting ineffective (indeed, counterproductive) anti-diversion policies, McKesson vastly under-resourced its compliance department, assigned unqualified and untrained personnel to implement these policies, routinely ignored these policies in practice, and otherwise failed to take reasonable steps to prevent diversion.

670. McKesson's lack of attention to its compliance and anti-diversion obligations is evidenced by the *de minimis* resources the company invested in regulatory staff. From 2008 to 2012, implementation of the CSMP for all McKesson pharmacy customers across the country was

left to four regional Directors of Regulatory Affairs ("DRAs"). Each of these four DRAs—a number that grew to six in 2012—was responsible for onboarding new pharmacy customers, reviewing and increasing thresholds, and conducting all due diligence for all of the pharmacies across their region, with no other dedicated regulatory staff.

671. The DRAs themselves regularly [redacted] Upon learning in 2008 that a competing distributor had increased its regulatory department to at least 30 employees, a DRA suggested that [redacted]. No such position was created until five years later, in 2013. The DRAs did not receive any designated regulatory staff to assist them until 2014, and the training eventually provided to that staff was inadequate to allow them to perform their jobs effectively.

672. Also in 2014, supervision over regulatory affairs shifted from the senior vice president of distribution operations, for whom the CSMP had been just one of many responsibilities, to a new head of regulatory affairs, for whom oversight of the CSMP was a full-time job. McKesson itself acknowledged its failure to [redacted]

673. In the absence of a dedicated regulatory staff, McKesson assigned virtually all of its front-line compliance functions for New York customers to operations and sales staff and administrative assistants with no experience with controlled substance regulations, or indeed any corporate compliance experience at all. These operations and administrative staff reported directly to the East Region's DRA, who himself had never had a specialized role in regulatory compliance

prior to being given that job. Sales staff reported to sales management, and rarely interacted with compliance personnel at all.

674. Moreover, McKesson provided minimal training to these operations, administrative, and sales personnel with respect to their roles in ensuring the company's compliance with state and federal controlled substances laws and regulations, including the NYCSA. Senior regulatory staff also did not do audits or even ask for feedback on the CSMPs from these front-line sales personnel.

675. Finally, as discussed above, McKesson's policies tasked sales staff with front-line compliance duties, without providing any mechanism to ensure that these employees' responsibility and incentive to promote sales did not compromise their ability and/or willingness to perform their compliance-related functions, when doing so could result in the loss of those sales. Not surprisingly, [redacted] Even McKesson management recognized this inherent problem, [redacted]

676. McKesson's under-resourced, under-qualified, and untrained staff routinely bypassed critical procedures set forth in the CSMPs and frequently failed to obtain and maintain the records called for by its CSMPs in the due diligence files of its customers.

677. For example, McKesson employees regularly failed to ensure completion of even the minimal, three-question form used to resolve inquiries into orders in excess of the customer's threshold. [redacted]

678. When customers requested increases in their threshold allowance for opioid orders, McKesson routinely approved those increases within days, hours, or even minutes, before any independent, diligent investigation could possibly have been conducted, and without being provided any reasonable justification. On many occasions, McKesson uncritically and immediately accepted the most perfunctory explanations from its customers, [redacted]

679. Moreover, McKesson made it a practice to [redacted]

680. Even though McKesson's CSMP required it to keep records of each request for a threshold change, McKesson routinely failed to complete and maintain those records. [redacted]

681. When McKesson did conduct any more searching due diligence investigations than the perfunctory steps discussed above, it routinely failed to identify obvious red flags of diversion, such as:

- A pharmacy that obtained an increase in its opioids threshold [redacted] and who would all later be arrested for diversion, one of whom was indicted two months after the threshold increase was granted;
- A pharmacy located in [redacted] that sought an increase of over [redacted]; and
- A pharmacy whose pharmacist was previously disciplined for dispensing without a prescription, and which [redacted]

682. In the cases where McKesson's compliance staff did identify issues with a particular pharmacy, the company lacked any mechanism to ensure the retention and sharing of information to identify other customers with related red flags.

683. For example, when McKesson identified suspicions about particular pharmacies based on doctors for whom they filled prescriptions, the company lacked any system by which it could identify other pharmacies that filled prescriptions for the same physician. As a result, McKesson continued to sell opioids to pharmacies that were filling prescriptions for [redacted] until both were eventually indicted in 2018. McKesson's head of compliance had explicitly recognized this [redacted]—but the company did nothing to remedy this key failure in its compliance system. Moreover, as discussed above, McKesson [redacted], willfully blinding itself to key evidence of diversion.

684. Finally, even when McKesson actually did identify customers' obvious red flags, it frequently failed to implement suspensions or terminations. Examples of such customers include:

- A pharmacy that submitted a request to increase its [redacted] McKesson continued to service the pharmacy for at least four more years. Subsequently another distributor [redacted] but still McKesson took no action;
- A pharmacy that [redacted], with McKesson maintaining the pharmacy as a customer;
- A pharmacy [redacted], later indicted, [redacted] McKesson took no action;

- A pharmacy that had exceeded its threshold of [redacted] but McKesson took no such action;
- A pharmacy that ordered only [redacted] and yet continued as a McKesson customer;
- A pharmacy that sought to [redacted] who were both later arrested, and continued as a McKesson customer; and
- A pharmacy that was identified as suspicious because [redacted] the doctor was later sentenced to seven years in prison for illegally prescribing opioids. One of this doctor's patients, who died of an overdose, was a New York resident.

685. Even where McKesson did block customers' orders and report them as suspicious to the DEA, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead simply allowed them to continue receiving their threshold amount of opioids month after month thereafter, regardless of whether the customer continued to make additional suspicious orders.

686. For example, between 2011 and 2017, McKesson submitted twelve or more opioid-related SORs for at least one year for 245 distinct pharmacies, representing one *opioid-related SOR every month for more than ten percent of its New York State pharmacies.* Of these pharmacies, McKesson submitted opioid-related SORs roughly twice a month for a full year (24 SORs in total per year) for 133 distinct pharmacies. During the first year in which McKesson sent at least two opioid-related SORs per month, those pharmacies exhibited several telltale red flags.

687. Specifically, more than half of those pharmacies: (a) exceeded the 90th percentile in the (entire) state in terms of volume of oxycodone shipped; (b) exceeded the 90th percentile in the (entire) state in terms of number of oxycodone orders; and (c) filled over one hundred opioid

prescriptions in a year—in other words, more than *two opioid prescriptions per week*—by one or more prescribers later indicted or convicted by law enforcement of medically unnecessary prescribing, opioid diversion, or related crimes.

688. Following the first year in which McKesson submitted 24 or more opioid-related SORs for a year, McKesson continued to ship to these pharmacies, on average, for nearly *three years*. In fact, as of 2018, it appears that McKesson is still shipping to 116 of these pharmacies, or 77% of the group.

689. Moreover, as of 2018, 67% of these pharmacies had filled prescriptions by one or more prescribers later indicted or convicted of opioid-related crimes. Indeed, some of these pharmacies had a majority of their opioid prescriptions written by prescribers who were later indicted or convicted.

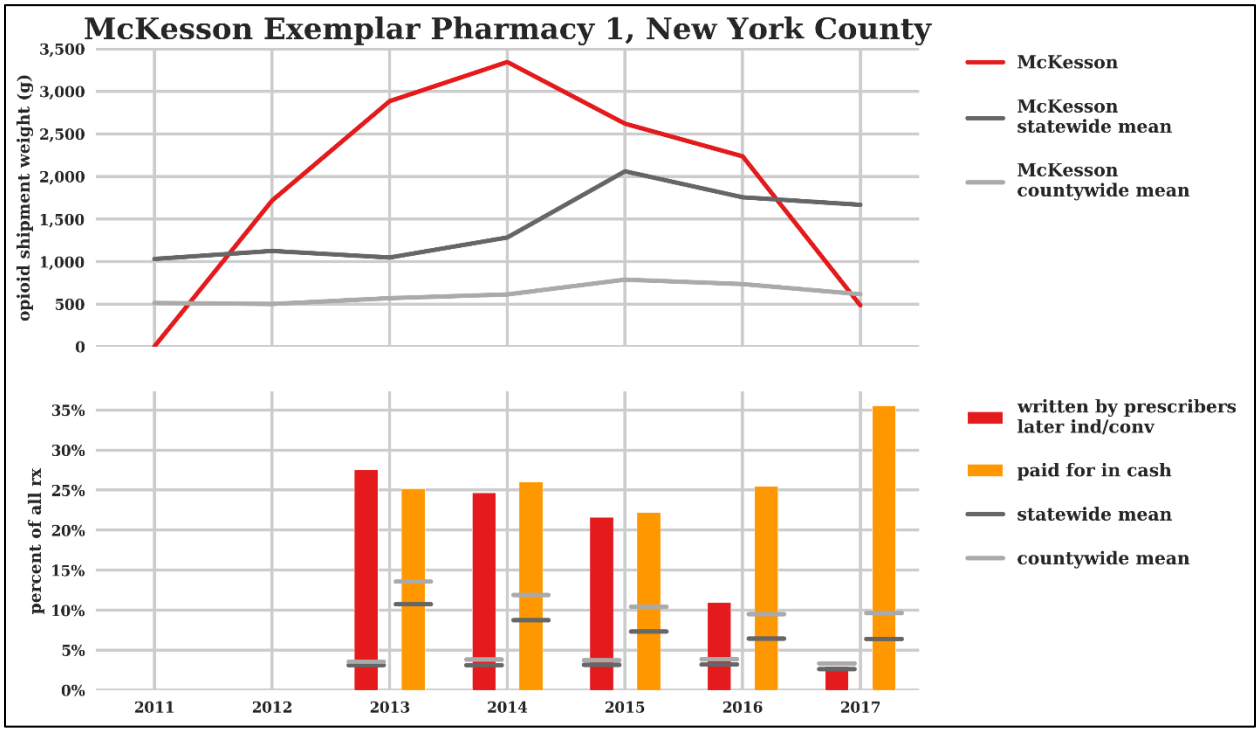
690. Even worse than its record in dealing with pharmacies it *did* identify suspicious orders for, though, is McKesson's pattern of failing to even identify and block as suspicious any orders at all for pharmacies that persistently displayed red flags of diversion.

691. For example, between 2008 and 2013, McKesson shipped to 145 pharmacies that exceeded their monthly threshold for an opioid order at least twelve times in a year, while failing to identify a single suspicious order. McKesson continued to ship to these pharmacies for, on average, *more than six years.*

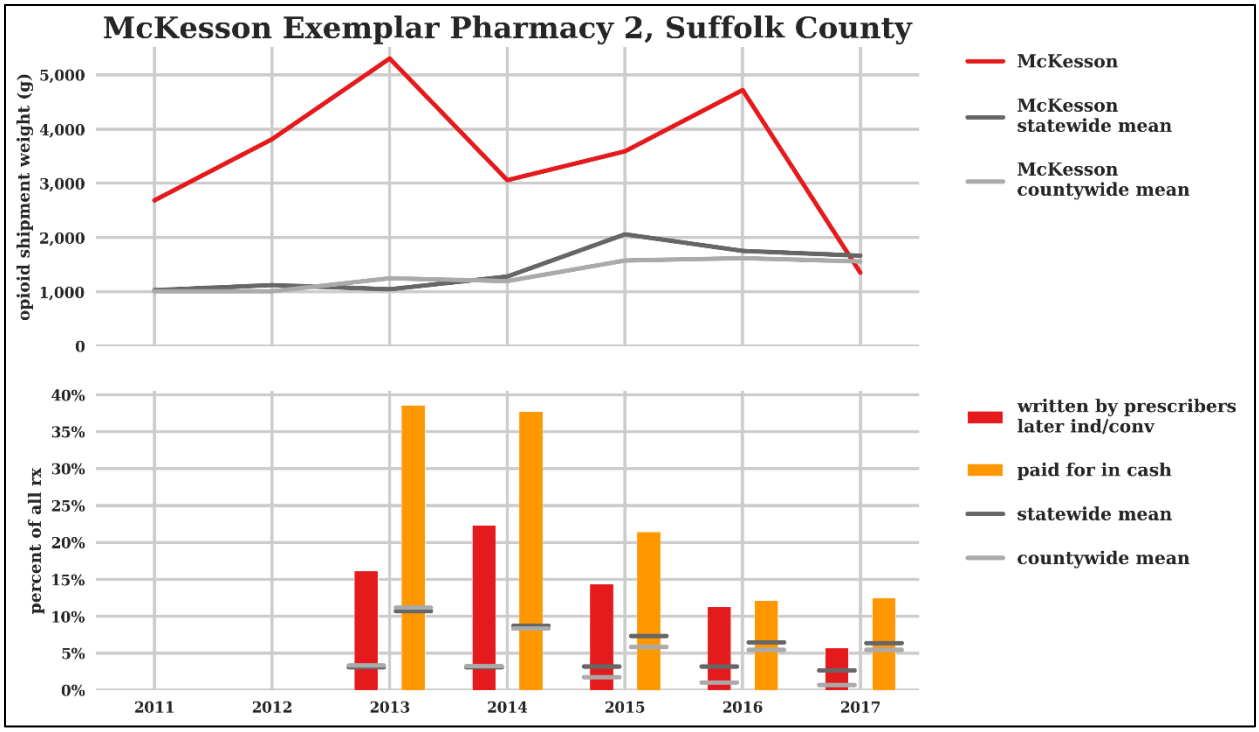
692. Three examples from this group of McKesson's most at-risk pharmacies stand out:

- **McKesson Exemplar Pharmacy 1**, located in New York County, received concurrent opioid shipments from the top four distributors between 2010 and 2017, with shipments from McKesson beginning in 2012. Between 2010 and 2015, it consistently exceeded the 90th percentile in the State for number of opioid orders and volume shipped, with oxycodone-specific orders and volumes surpassing the 97th percentile. In fact, it was the top pharmacy for oxycodone shipments (relative to all controlled substances) in New York

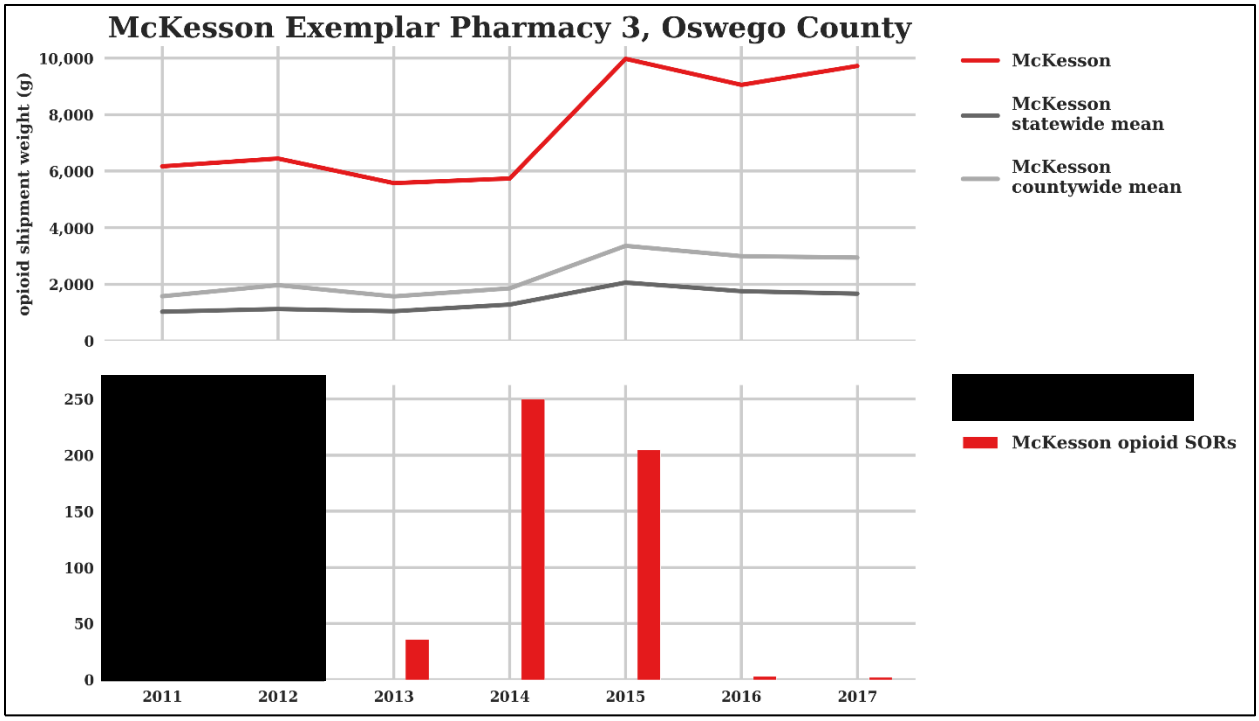
County in 2011, though no SORs were issued by any of the distributors at the time. While McKesson did eventually issue 507 SORs for this pharmacy between 2013 and 2016, in each of these years, the pharmacy's median MME per day for prescriptions exceeded the 96th percentile for the State, with a median MME per day volume ranging from 90-144 MME per day.



- **McKesson Exemplar Pharmacy 2**, located in Suffolk County, received opioid shipments from both McKesson and Cardinal between 2012 and 2017, frequently exceeding the 95th percentile for volume of shipments of oxycodone in New York State. Between 2013 and 2017, the median MME per day for these prescriptions exceeded the 97th percentile, with an MME ranging from 90 to 135. Furthermore, cash payments exceeded the 87th percentile in the State with yearly totals as high as 38% of total payments. While McKesson did issue [redacted] order omits in the first four years, it continued to ship over 12,000 grams of opioids in subsequent years.



- **McKesson Exemplar Pharmacy 3** is located in Oswego County. Between 2011 and 2017, McKesson issued [redacted] omits and 496 opioid-related SORs for this pharmacy, yet continued to ship opioids to the pharmacy. In fact, for several years, this pharmacy received the largest number (100th percentile) of orders and volume of shipments for both all opioids and oxycodone-specific orders and shipments in the county; meanwhile, it exceeded the 98th percentile for statewide orders. In 2016 and 2017, doctor shopping reached the 92nd percentile, with 60% of patients having filled prescriptions with three or more doctors.



693. In each of these cases, instead of suspending or terminating these pharmacies, McKesson continued to supply them with high volumes of opioids, in many cases for years after the risk of diversion they posed should have been obvious.

694. The company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties, including those it owed to Plaintiff.

695. In 2008, McKesson entered into a settlement with the DEA based on that agency's investigation of the company's compliance failures. Shortly thereafter, [redacted]

- [redacted]
- [redacted]

- [redacted]
- [redacted]"

696. In 2017, after almost a decade of not fulfilling the agreement it made with the DEA, McKesson made yet another settlement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 settlement, as well as its failure to identify and report suspicious orders at multiple distribution centers, following the DEA's finding that McKesson "failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with [its] obligations."

697. Despite knowing of the broad failures of its compliance policies, both as written and as actually enforced, and knowing of numerous instances in which those failures had led to individual instances in which the company improperly distributed opioids in New York and other states, McKesson never reported any of that information to the State as it was required to by the NYCSA.

C. Amerisource

698. Amerisource is the nation's third largest drug distributor in the country and in New York. Since 2010, Amerisource has sold nearly 275 million oxycodone pills in the State.

699. A significant portion of Amerisource's activity in New York is generated through Bellco Health ("Bellco"), a pharmaceutical distributor acquired by Amerisource in 2007. Bellco is based in North Amityville, New York, and is comprised of Bellco Drug Corporation ("Bellco Drug"), which primarily serves independent retail pharmacies in New York and New Jersey, and Bellco Generics ("BG"), with customers throughout the country.

700. Though Amerisource has represented that Bellco integration was complete as of September 30, 2008, Bellco employees and accounts were separate from those of Amerisource until in or around November 2015.

1. Amerisource′s Flawed Written Policies Enabled Opioid Diversion

701. Amerisource's written policies for compliance with the NYCSA were and are contained within its Diversion Control Program and its Order Monitoring Program ("OMP"). The programs are administered by Amerisource's Corporate Security and Regulatory Affairs ("CSRA") staff. From 2007 to 2015, the program's specifics were scattered through a series of policy and procedure documents, which were not uniform for Bellco and Amerisource. Amerisource implemented a revised Diversion Control Program in 2015 and into 2016.

702. Amerisource compliance policies are flawed from the point of initial new customer onboarding. Since 2007, Amerisource has generally required a customer questionnaire, a site visit, license verification, and online investigation as part of its new customer due diligence process. A central component of Amerisource's new customer procedure is its Retail Pharmacy Questionnaire ("590 Form"), [redacted]. The form asks for information about other distributors, disciplinary history, customer payment methods, percentages of controlled substances, usage numbers for specific high risk drugs, and top prescribers of opioids, among other questions. Though the form requests information about prescribing physicians, it is not Amerisource's policy to perform news searches on those prescribers as part of the new customer procedure.

703. Staff reviewing the form have high benchmarks for these numbers before considering them red flags. For example, cash payments could comprise up to [redacted] of payments

and controlled substances could account for up to [redacted] of prescriptions dispensed before triggering additional investigation.

704. Amerisource does not require new customers to provide usage reports or dispensing data as part of the onboarding process. By relying on these customers to self-report without any documented verification, Amerisource does not fulfill its obligation of truly knowing its customers' business practices.

705. Both prior to and after program revision, Amerisource's policies have allowed for frequent threshold manipulation to avoid orders being held for review, rejected from shipment, or reported as suspicious. For example:

- In and around 2011, [redacted], ensuring that thresholds were only hit for orders that were far from the norm;
- Prior to 2012, Amerisource policy allowed [redacted];
- During the same time period, [redacted] armed with such information, they were free to order exactly to their limit, preemptively request an increase, and/or purchase those products from another provider;
- As of January 2010, Amerisource sales and/or customer care employees [redacted] presumably to ensure an increased threshold and avoid held orders going forward; and
- Today's OMP system includes [redacted] thus relying on a customer's high sales of a product to justify further increased sales.

706. Today, Amerisource's current OMP uses a complex, automated approach that, in essence, increases ordering flexibility for its customers rather than limits it.

707. The OMP has three defined parameters for specific product groups for any given customer: [redacted]

[redacted] and the "Fail Safe", [redacted]

To be held for further review, an order must exceed either *both* of the first two parameters or the Fail Safe. This criteria does not fulfill Amerisource's obligations under the NYCSA, which broadly defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency"—benchmarks that are disjunctive. By limiting the orders even held for review, Amerisource's policy does not fulfill its obligation to identify even orders of interest, much less suspicious orders.

708. [redacted] can process the order, reject it as an error, reject and report it as suspicious, or escalate it to the Diversion Control Team. [redacted]

2. **Amerisource's Failure to Effectively Prevent Diversion in Practice**

709. At all relevant times, Amerisource failed to employ sufficient numbers of qualified compliance staff to implement these policies, failed to ensure those compliance staff were meeting Amerisource's anti-diversion duties, and failed to enforce even the defective policies it had in place.

710. Among other deficiencies, Amerisource failed to sufficiently staff its compliance departments. For example, from 2007 to 2015, Bellco had only two employees dedicated to front-line diversion control, a clerk and a supervisor. Together, these staff members were responsible for performing due diligence on all prospective new customers, setting new customers at the appropriate tolerance level, doing monthly reviews of current customers, monitoring and reviewing

flagged orders of existing customers, responding to threshold issues and adjustment requests, and executing a portion of site visits, as required. During this period, the Bellco arm of Amerisource served over [redacted] customers nationwide, including over [redacted] in New York alone. With a team of only two responsible for thousands of customers, it is unsurprising that Bellco failed in its anti-diversion obligations.

711. Since the integration of Bellco into Amerisource and the revamp of its Diversion Control Program in 2015, the company has increased anti-diversion staffing, but has not significantly increased the number of fully trained ground level employees. Since that time, Amerisource has maintained only five to seven front-line employees on its Diversion Control Team, responsible for reviewing new customers and monitoring its existing [redacted] customers.

712. In a 2015 review [redacted]

713. Many of Amerisource's compliance violations begin with its new customer policy. The process relies heavily on the customer 590 Form, given that Amerisource only requests dispensing information from new customers when it already knows of potential issues. For example, dispensing data was requested recently in considering customers moving from distributor Morris & Dickson Company—including customers that prompted a DEA investigation because of their high-volume opioid purchasing.

714. Despite the 590 Form being so critical to understanding its customers and ensuring it can fulfill its regulatory obligations, and despite numerous other Amerisource procedures relying on reviewing or updating this form, Amerisource has had significant issues related to failing to perform even this baseline screening.

715. In May 2016, the company began a project [redacted] Amerisource ultimately discovered [redacted]

716. As another example, Bellco Generics customers regularly completed the 590 Form independently, submitted it to Bellco, and were onboarded thereafter without receiving a site visit. [redacted]

717. Disjunction between Amerisource and Bellco has led to additional failures. Until system integration in or around November 2015, staff had no systematic way of identifying dual customers. Though diversion staff at Bellco would reach out to counterparts at Amerisource when onboarding a new customer or reviewing a held order, and vice versa, these staff members did not have direct access to the customer's history, thus preventing a proper review and evaluation of the

customer's likelihood of diversion. The external 2015 review [redacted]

718. The lack of an integrated system also meant that thresholds were not coordinated between Amerisource and Bellco at any point. As a result, a dual customer could have high thresholds set with both, could be exceeding both thresholds, or even having its threshold periodically increased with both, without detection.

719. In or around April 2013, Amerisource implemented a policy for dual customers that prevented both Amerisource and Bellco from supplying controlled substances to the same customer. Implementation, however, was problematic. In one example, a New York City pharmacy [redacted]

720. Even now, Bellco accounts remain particularly problematic because [redacted]

721. When an order is triggered for review, Amerisource's Diversion Control Team can make three possible adjudications: [redacted] In practice, under Amerisource's system, only a small percentage of orders flagged for review are cancelled, and even fewer are deemed suspicious.

722. In 2017, Amerisource flagged [redacted] of its placed orders for additional review, accounting for [redacted] of its total orders. Of those, [redacted] were released to the customer, and [redacted] were reported. Amerisource essentially represents that, of orders exceeding its already broad parameters, it receives more than [redacted] for every one suspicious order. Diversion employees recognize the holes in Amerisource's program. In preparing for a meeting with [redacted] Seeming to recognize that they looked poor—[redacted]

723. Amerisource has a high tolerance for compliance issues before it will terminate a customer. Prior to 2015, the company had a regular practice [redacted] Today, it still lacks an internal rule or policy that requires investigation of a customer based on a specific number of suspicious order reports.

724. A pharmacy in Manhattan, for example, [redacted]

[redacted] As recently as January 2018, [redacted]

725. Within the [redacted] are New York pharmacies that have been supplied by Amerisource [redacted] Amerisource did not implement a system to identify and review [redacted]

726. Even when customers were restricted, blocked, or terminated, Amerisource's system failed to ensure their accounts were de-activated. In November 2017, a compliance staff member [redacted] but continued receiving shipments through 2016; the owner was charged the following year with conspiracy to distribute oxycodone and pled guilty.

727. The one area in which Amerisource has consistently stood out as compared to its major competitors is its unwillingness to identify suspicious orders, even among customers that regularly exceeded their thresholds and presented multiple red flags of diversion.

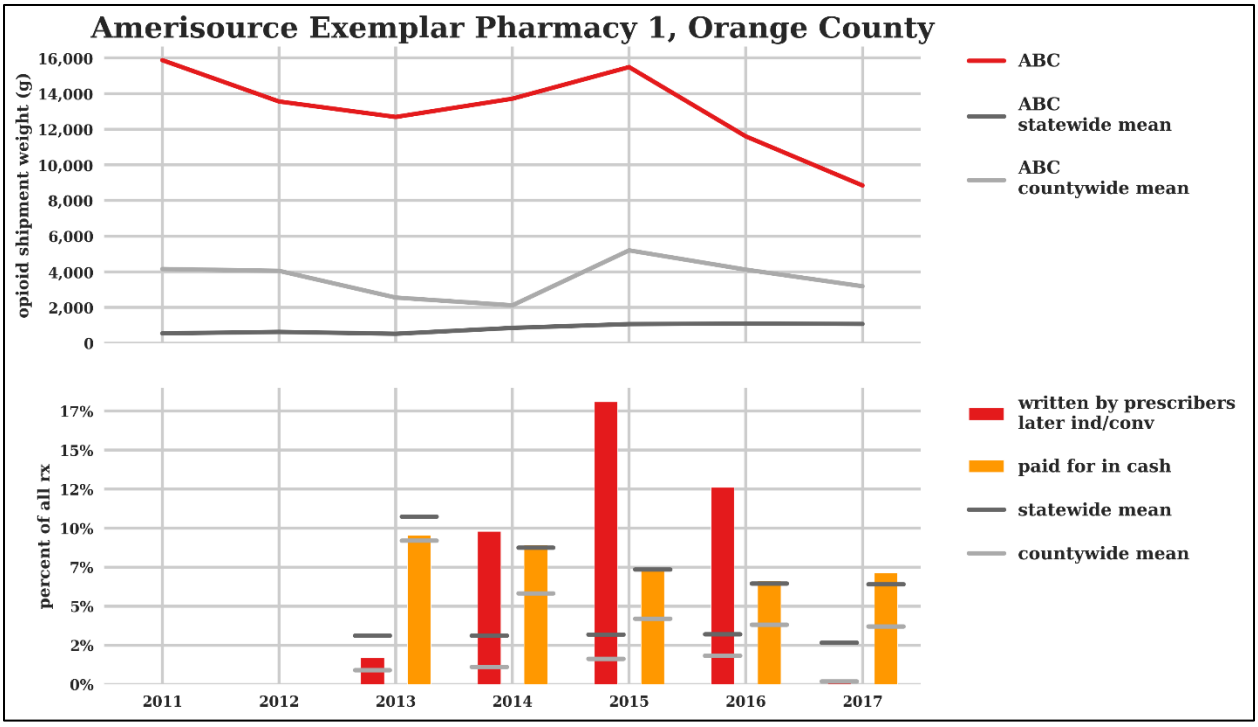
728. Specifically, Amerisource shipped opioids to approximately 2,430 pharmacies in New York from 2010 to 2018. Between 2014 and 2017, Amerisource appears to have identified [redacted] per year, but reported only [redacted] of them as suspicious. In 2017, that rate fell to less than [redacted]

729. During this time, numerous Amerisource opioid customers exhibited several common indicators of suspicious activity for multiple years. These flags included:

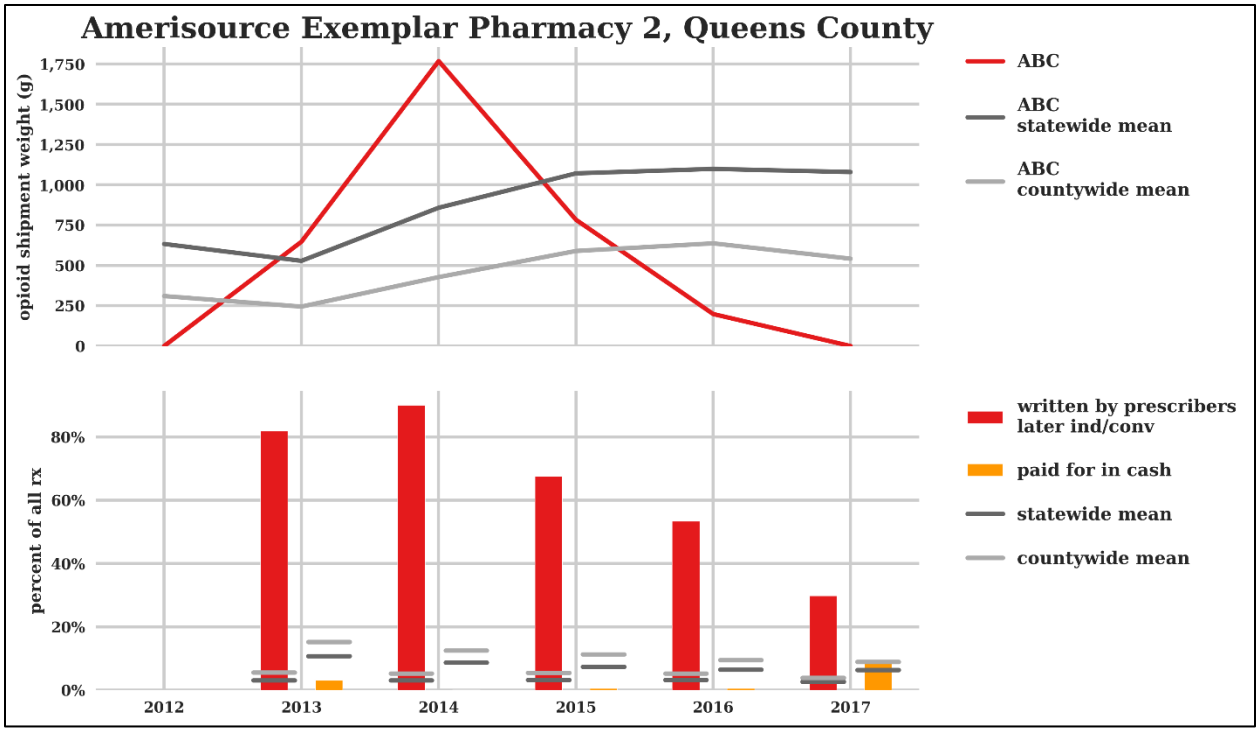
- Scoring above the 90th percentile in the county for opioid order volume;
- Scoring above the 90th percentile in the county for total opioid orders;
- Scoring above the 90th percentile in the county for oxycodone order volume;
- Scoring above the 90th percentile in the county for total oxycodone orders;
- Scoring above the 90th percentile in the state for the percentage of oxycodone volume shipped out of all controlled substances shipped;
- Filling prescriptions by prescribers who were later indicted or convicted on opioid-related prescribing and distribution charges;
- Scoring above the 90th percentile in terms of percentage of patient doctor-shoppers;
- Scoring above the 90th percentile in terms of percentage of cash payments; and
- Scoring above the 90th percentile in terms of the median MME prescribed per day.

730. Three examples of such pharmacies are:

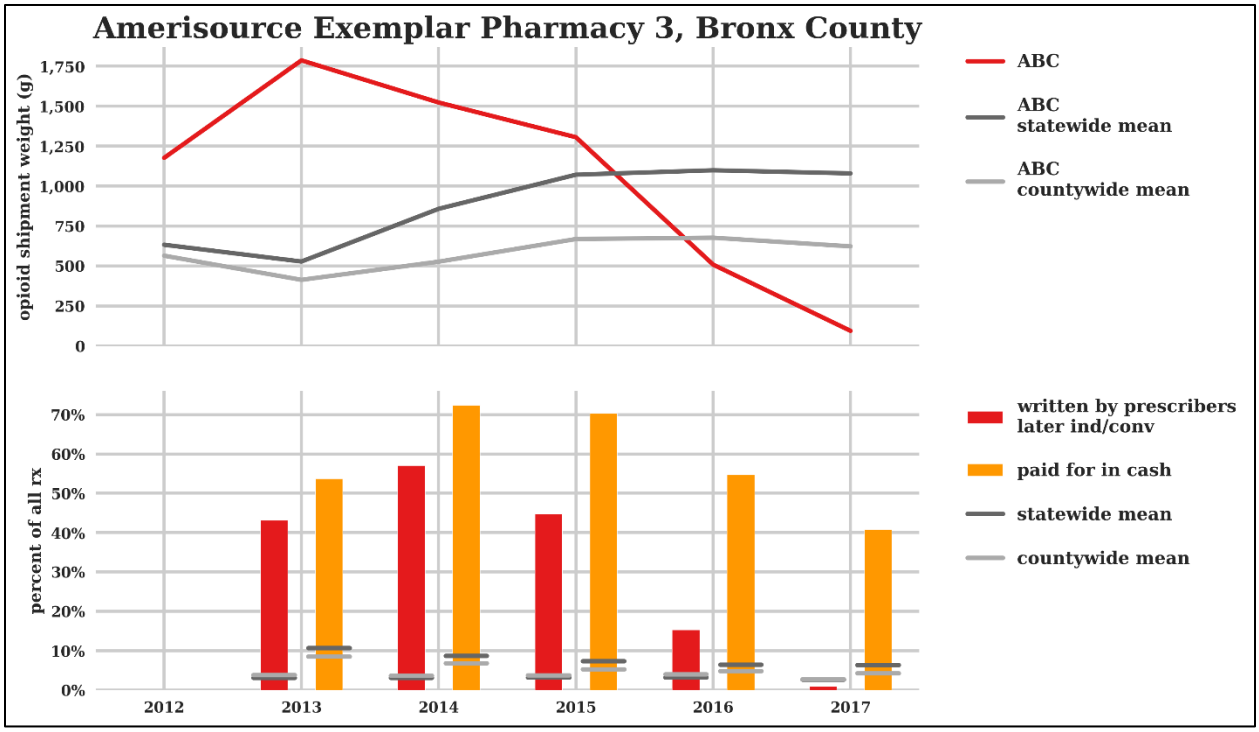
- **Amerisource Exemplar Pharmacy 1**, located in Orange County (about 300,000 people), was consistently at or above both the 99th percentile in the State in terms of both number of opioid orders and total opioid weight. Between 2014 and 2016, more than 10% of its prescriptions were written by prescribers who were later indicted or convicted of opioid-related prescribing and distribution charges. And while Amerisource reported 105 SORs for this pharmacy in 2013 and 83 in 2014, that number dwindled to [redacted] over the next three years, and as of 2018, Amerisource was still serving as this pharmacy's primary opioid distributor.



- **Amerisource Exemplar Pharmacy 2**, located in Queens County, is a customer of Amerisource's Bellco Drug subdivision. Between 2013 and 2017, 77% of its prescriptions, on average, were written by prescribers who were later indicted or convicted, including Rogelio Lucas and Moshe Mirilashvili. In 2014 specifically, 90% of prescriptions filled by this pharmacy were made by prescribers who were later indicted or convicted. Amerisource appears to have only stopped shipping in 2017—Amerisource itself only identified [redacted] SORs for this pharmacy between 2013 and 2017.



- **Amerisource Exemplar Pharmacy 3**, located in Bronx County, exceeded the 95th percentile for the percentage of oxycodone volume shipped for five years straight (2012 to 2016). On average, 58% of its opioid prescriptions were paid in cash (99th percentile in the State). For three consecutive years (2013 to 2015), approximately half of all opioid scripts were filled by prescribers who were later convicted, including Robert Terdiman and Rogelio Lucas. Amerisource reported two SORs in 2010 and [redacted] As of 2018, this pharmacy was still a customer of Amerisource.



731. Amerisource's deficiencies and failures did not go undetected. The company was explicitly put on notice on multiple occasions by government agencies that it was not fulfilling its duties, including those it owed to Plaintiff.

732. For example, in 2007, the DEA issued a Suspension Order against Amerisource's distribution center in Florida, alleging that the company failed to maintain effective anti-diversion controls. Amerisource settled that matter by accepting a suspension of the distribution center's DEA registration.

733. Later that year, when Amerisource acquired Bellco, it was forced to acknowledge in a press release that the reduced price it was paying for Bellco was due to the costs associated with Bellco's failure to report more than 2,000 suspicious opioid orders to the DEA over the prior three years, and its $800,000 fine from that agency.

734. In 2012, the State of West Virginia sued Amerisource, alleging that the more than 100 million opioid pills the company shipped into the state over the preceding five years was *prima*

facie evidence that Amerisource did not have effective policies and procedures for preventing diversion. In 2016, Amerisource settled that case for $16 million.

735. Despite knowing of the broad failures of its compliance program, both as written and as executed, and knowing of numerous instances in which those failures led to individual instances of improper distribution of opioids in New York and other states, Amerisource never reported any of that information to the State as it was required to by the NYCSA.

D. Rochester Drug

736. Rochester Drug is among the nation's ten largest drug wholesalers, and the fourth largest distributor in the State. Between 2010 and 2018, Rochester Drug sold more than 143 million oxycodone pills to its customers in New York.

737. Rochester Drug is unique among the Distributor Defendants in that it is a cooperative business organization whose members include many of its own pharmacy customers. Rochester Drug's business model gives rise to an inherent conflict with its compliance obligations, in that its members have direct financial interests in limiting both pharmacy-level compliance costs and Rochester Drug's own compliance costs, and corresponding interests in obtaining from Rochester Drug all the opioid products it can sell.

1. Rochester Drug's Flawed Written Policies (or Lack Thereof) Enabled Diversion

738. Prior to 2015, Rochester Drug did not have *any* formal written standard operating procedures governing its compliance with its anti-diversion duties.

739. Before 2015, Rochester Drug relied on a series of vaguely articulated policies, including those found in letters to customers and the DEA. In a 2009 letter to the DEA, Rochester Drug stated that it established a program to monitor its sales of controlled substances. Under this program, Rochester Drug stated that it would establish monthly usage thresholds and prepare a

"DEA Month End Orders of Suspicion Report" for orders it identified as suspicious. Rochester Drug also told the DEA that it would hold and investigate any "Orders of Interest," which it defined as those exceeding a customer's monthly usage limit.

740. Notwithstanding Rochester Drug's 2009 commitments to the DEA, none of these inadequate policies were actually memorialized in a written policy of standard operating procedures made available to the company's employees.

741. In any event, the system described in Rochester Drug's 2009 letter to the DEA was riddled with flaws that enabled diversion. For example, Rochester Drug set monthly usage thresholds for its customers by averaging a customer's purchases over a twelve-month period and then multiplying that amount by an arbitrary number that varied based on the particular category of controlled substances. For Schedule II drugs, such as the opioids at issue here, that arbitrary number was *three* for several years. As such, the thresholds set by Rochester Drug's "policy" were invariably so high that customers could not reach them unless their order volumes tripled from their historical purchasing patterns, rendering the system virtually useless at detecting many suspicious orders. In 2009, Rochester Drug had told the DEA that its threshold monitoring system would provide its customers with "room for growth," and at least on this issue, Rochester Drug was not understating the situation.

742. In 2012, Rochester Drug told the DEA that it would hold all "Orders of Interest" until it received "proper information" from its customers, and that if those orders were not released because of "insufficient information" from the pharmacy they would be reported to the DEA as suspicious.

743. Again, Rochester Drug's 2012 update to its policies was not actually memorialized in a formal written policy.

744. In 2014, Rochester Drug informally implemented a change to its threshold procedures, applying an arbitrary multiplier of two, instead of three, to its customers' historical purchasing patterns of Schedule II prescription opioids. This still left customers "room to grow" their monthly opioid orders by *double* their normal volumes before even qualifying for scrutiny.

745. At the time, Rochester Drug's head of compliance acknowledged major deficiencies in its order monitoring system, writing in an email that the company had lowered its factor multipliers "to force better cooperation from our customers" while referencing "not receiving our loyal pharmacies dispensing records the way we require them."

746. In 2015, Rochester Drug finally enacted a written Standard Operating Procedure ("SOP") governing its anti-diversion compliance mechanisms. Rochester Drug's 2015 SOP, among other things, required the company to: (i) obtain and review pharmacy dispensing data prior to selling controlled substances to that pharmacy; (ii) verify customers' DEA registrations; (iii) obtain a completed customer questionnaire requesting information that could disclose red flags of potential diversion; (iv) investigate and hold Orders of Interest; and (v) "assess whether each prospective and current customer dispenses controlled substances for legitimate medical purposes."

747. The 2015 SOP remained fundamentally flawed. For one thing, the SOP did not effectively reform Rochester Drug's arbitrary and enabling procedures for setting customers' monthly thresholds; nor did Rochester Drug endeavor to conduct any investigation into the appropriateness of its customers' prior average ordering volumes, a failure which effectively rolled all prior diversion activity into the company's future shipments of opioids to those customers. Instead, under the SOP, the arbitrary multiplier for Schedule II drugs was simply cut from two to one and half—again, meaning that customers had to increase their monthly opioid volumes by 50% before they would even trigger a compliance check by Rochester Drug.

748. In addition, the 2015 SOP did not require compliance employees to review dispensing data prior to releasing orders of interest or provide guidance on acceptable justifications for releasing an order of interest or raising a purchase threshold.

749. Further, under the 2015 SOP, Rochester Drug continued its longstanding practice of warning customers that they were approaching their monthly purchase limits, including when their purchases "reached 75% of their threshold."

750. Moreover, although the 2015 SOP defined suspicious orders as those orders of interest that the company decided not to ship and specified that these orders must be reported to the DEA, it was entirely silent on whether, when, or how suspicious orders should be reported to any State authorities. Nevertheless, even pursuant the 2015 SOP, Rochester Drug failed to adequately design and operate a system to disclose suspicious orders.

751. Finally, as Rochester Drug struggled to implement any meaningful compliance program, it also faltered in its mandatory Automation of Reports and Consolidated Orders System ("ARCOS") reporting obligations.

752. In 2013, a DEA audit concluded that Rochester Drug had underreported thousands of drug sales made to its customers throughout the Northeast. Following the audit, Rochester Drug assured the DEA that it was implementing a new electronic order system that would address any concerns with its order reporting. In June 2014, however, when the DEA reexamined Rochester Drug's compliance systems, it discovered that Rochester Drug had not implemented the promised new system, and had instead simply failed to enter any of its orders into ARCOS for the entire preceding year.

753. In July 2015, the U.S. Attorney for the Southern District of New York brought a civil complaint against Rochester Drug for its failure to report orders in ARCOS, and for failing to

report the loss and/or theft of controlled substances, both in violation of the federal Controlled Substances Act.

754. Shortly thereafter, Rochester Drug entered into a settlement agreement with the U.S. Attorney. *See* Consent Order, *United States v. Rochester Drug Cooperative*, Case No. 15 Civ. 5219 (S.D.N.Y.) (ECF No. 2; filed July 8, 2015). As part of the agreement, Rochester Drug admitted to its failures to report orders and lost/stolen drugs, agreed to pay a $360,000 fine, and provided the DEA with reconstructed ARCOS data for the preceding five years.

2. Rochester Drug′s Failure to Effectively Prevent Diversion in Practice

755. Prior to the end of 2013, Rochester Drug's compliance staff consisted of just two individuals. One of these employees handled customer service; the other held the dual responsibilities of managing compliance and operations at Rochester Drug's distribution facility—a conflicting and time-competitive function.

756. From approximately 2013 to 2016, Rochester Drug spent only about $150,000 on compliance per year.

757. While the compliance department expanded gradually from 2013 to the present, Rochester Drug continued to rely on only a handful of front-line staff to review orders of interest and other due diligence materials for the entirety of its growing customer base—and even after the company expanded to open a second distribution facility.

758. On several occasions, Rochester Drug's senior management expressed frustration to compliance employees regarding the costs and the length of time of due diligence reviews. For example, in a 2014 email discussing the hiring of an outside compliance consultant, Rochester Drug's then-CEO stated that it was "making me ill as to how much this is going to cost us." In another email, Rochester Drug's then-CEO stated "we are wasting a lot of energy and pissing

people off," referring to the compliance program and the minimal burden that program placed on Rochester Drug's sales staff.

759. Rochester Drug also failed to provide its compliance employees with meaningful training and supervision on how to perform various due diligence tasks. And it allowed untrained front-line compliance employees to onboard customers, change purchase thresholds, and even release orders that hit those thresholds without any further review by other staff.

760. As noted above, before 2015, Rochester Drug had no written policies governing compliance procedures for onboarding new pharmacy customers. In the absence of such policies, Rochester Drug failed to conduct any meaningful due diligence of new customers until at least 2013, when it finally began requiring prospective customers to submit historical dispensing data.

761. Even after adopting the SOP in 2015, on several occasions, Rochester Drug approved new customers for the sale of prescription opioids despite the presence of conspicuous red flags.

- For example, in March 2016, Rochester Drug approved the onboarding for the sale of controlled substances to a Queens, NY pharmacy whose dispensing data a compliance employee identified as showing a high percentage of cash purchasers, several out of state prescribers, and prescriptions from a doctor who had been arrested earlier that year on charges stemming from his oxycodone prescribing practices.

- Similarly, in June 2016, Rochester Drug approved the onboarding of another Queens, NY pharmacy despite acknowledging that the pharmacy's dispensing information showed that it had: (i) high levels of cash payments for controlled substances in violation of the pharmacy's own due diligence policy; (ii) filled controlled substances prescriptions from "prescriber[s] practicing medicine outside the scope of their documented medical specialty"; and (iii) filled prescriptions written for large amounts of highly diverted drugs, including "high amounts of Oxycodone [prescriptions] for a number of Physicians [sic] Assistants and Nurse practitioners."

762. In 2016, Rochester Drug's management directed an override of the SOP instituted only the year before by allowing new customers to purchase prescription opioids and other controlled substances before Rochester Drug's compliance team reviewed those customers' dispensing reports, as called for by the SOP. At the time, the company's then-CEO justified the change by stating, "I do not want to slow this down" in referring to the customer onboarding process.

763. Rochester Drug not only failed to train its sales employees on how to effectively screen new accounts, it actually incentivized those employees to sign up new customers (regardless of the diversion risk they posed) by offering bonuses of up to $1,000 for each new account they opened.

764. Despite setting its customers' monthly thresholds at unreasonably high levels, customers still frequently exceeded them. By 2016, for example, Rochester Drug had allowed some customers to double their orders for oxycodone and Subsys fentanyl within a year.

765. Rochester Drug did not conduct due diligence before filling these increasing orders. For example:

- In February 2015, Rochester Drug noted that it had released an order for OxyContin to a Hudson Valley pharmacy without first reviewing the pharmacy's dispensing data. At the time, a compliance employee noted that the order had been released "in good faith" based on the promise that the pharmacy would provide updated dispensing data that evening, which it did not. In fact, the pharmacy had not provided *any* dispensing data to the company since 2012, and it was further noted that the pharmacy was "loaded" with "Oxy scripts" from an out-of-area doctor that Rochester Drug's compliance team was concerned about (the prescriber was, years later, indicted on charges related to his opioid prescribing practices).

- In May 2015, Rochester Drug released an order of the dangerous opioid Subsys fentanyl to a Queens pharmacy even though the pharmacy's orders for that drug for the current month were double the pharmacy's average over the previous twelve months. Just prior

to that order of interest, a compliance employee had even raised the pharmacy's threshold. Rochester Drug released the Subsys order within hours of it being made without updated dispensing data and despite the fact that the order placed the pharmacy over the recently-raised threshold for that drug.

- In July 2015, when a Bronx pharmacy's order of oxycodone hit its purchase threshold, Rochester Drug released the order despite acknowledging that in the past the customer had promised to submit dispensing data and had not, and based its approval of the order on a summary report which did not allow the company to view prescriber information or information indicating method of payment—key indicators of potential diversion.

766. On several occasions, Rochester Drug even took measures to raise customers' thresholds for opioids without first consulting current dispensing data or documenting justifications for the change. Even when Rochester Drug did block a customer's order that hit a threshold, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead allowed the customer to continue receiving its threshold amount of opioids month after month thereafter.

767. In the four years between 2012 and 2016, Rochester Drug consistently underreported suspicious orders to the DEA, reporting at most just four orders during that time period. Rochester Drug also failed to report suspicious orders to New York as required by the NYCSA during this same time period. Indeed, a Rochester Drug compliance manager who has been with the company since 2013 stated that she could not recall any reporting to New York State prior to some period in 2016 or 2017 and that she did not think that Rochester Drug had "an understanding or knowledge" of the New York reporting requirement until recently.

768. Even in instances where the company's minimal compliance efforts identified customers whose opioid dispensing demonstrated red flags Rochester Drug knew were indicative of diversion, the company failed to report those customers' orders to the DEA or the State as

suspicious, let alone terminate, suspend those customers, or refuse to ship opioids to those customers. For example:

- In 2013, Rochester discovered that two Manhattan pharmacy customers were filling a high percentage of cash prescriptions for high dosage oxycodone and other opioids written by a pediatric physician who news reports described as operating an alleged "pill mill." Rochester Drug's compliance consultant even noted at the time that the average quantities of opioids dispensed by the pharmacies was "like a stick of dynamite waiting for DEA to light the fuse." Rochester Drug did not file suspicious order reports regarding these pharmacies' orders at the time, and it continued to ship prescription opioids to the pharmacies.

- In June 2014, Rochester Drug's permissive due diligence system allowed a Hudson Valley customer to order oxycodone five times over its already inflated threshold for that drug despite the fact that a year before the company had become aware of red flags associated with the customer, including that it was filling prescriptions for out-of-area patients up to 150 miles away. Rochester Drug continued to ship to the customer; and even released orders of interest initially held when the customer hit its threshold without first reviewing or obtaining any dispensing or other information to justify those orders.

- In November 2015, Rochester Drug compliance employees noted that a Manhattan pharmacy had demonstrated a "disturbing" pattern of dispensing oxycodone, including a "staggering" increase in the prior month's order, in which the customer ordered 28,600 units of oxycodone, which nearly doubled the previous six months' ordering average of 15,380 units. The compliance employee also identified high percentages of cash purchases and prescriptions filled by "multiple prescribers using inactive/not found" or otherwise inaccurate DEA registration numbers, out-of-state prescribers and doctors Rochester discovered had been "restricted from practicing medicine in NY State", and multiple doctors on a Rochester Drug-identified "Watch list." Despite these red flags of diversion, Rochester Drug continued to ship prescription opioids to this customer for more than two years without reporting any of the orders it flagged as suspicious to federal and State authorities.

769. As another example, Rochester Drug continued to ship massive amounts of prescription opioids, including the highly addictive fentanyl drug Subsys, to a mail order pharmacy in Nassau County, despite numerous red flags and indicia of diversion. Indeed, in 2013, Rochester

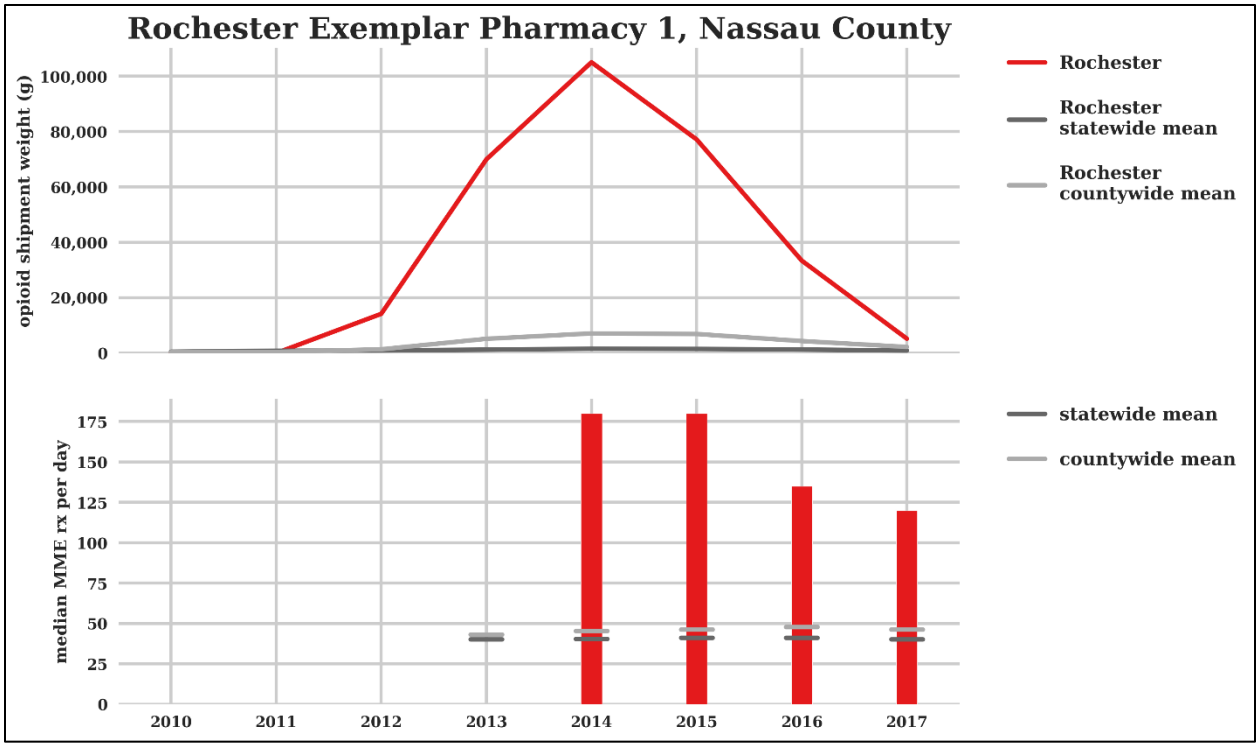
Drug shipped approximately 70,000 grams of opioids to this pharmacy, which represented a more than 400% increase in opioids shipped to the pharmacy when compared to Rochester Drug's shipments for the prior year. In addition:

- In 2013, because of the increased shipments to the pharmacy, Rochester Drug engaged an outside consultant to review the pharmacy's due diligence efforts. Following a review, the consultant recommended that Rochester Drug ensure that the pharmacy provide it with regular dispensing reports, among other recommendations—and in March of 2013, in response to a report from the consultant, the pharmacy certified in writing that it would provide Rochester Drug with "quarterly dispensing reports." But Rochester Drug failed to hold the pharmacy to that promise, depriving its front-line compliance employees of critical due diligence information. At one point a compliance employee even commented that it appeared "very very suspicious" that the pharmacy had delayed producing updated dispensing information by demanding to review the data prior to its submission. In another instance, despite its history with this pharmacy, Rochester Drug did not notice that it lacked dispensing data from the pharmacy for the entire year of 2016 until late-October 2016.

- Rochester Drug identified other red flags at this pharmacy, including multiple high-risk prescribers, but continued to ship it opioids. For instance, in 2014, the pharmacy provided Rochester Drug with dispensing data showing that it had filled cash prescriptions for doctors Rochester Drug knew were on a "watch list" due to their prescribing practices.

- On other occasions, instead of fulfilling its compliance obligations, Rochester Drug went out of its way to accommodate the pharmacy's large orders and ignore red flags. In 2014, for example, a Rochester Drug brand relationship manager emailed one of the pharmacy's executives to warn the pharmacy to "slow down" on its orders of Fentora, a fentanyl product, "or give a valid reason that we can share" with the product's manufacturer, noting that Rochester Drug had "already sold [it] more than a normal month usage to all customers" for that month and that its ordering was "going to cause red flags."

- The amount of opioids shipped to this pharmacy was within the 99th percentile in the State during the time it was a Rochester Drug customer (2012-2017). [redacted] but Rochester Drug did not.



770. And in the few cases where Rochester Drug decided to stop shipping or otherwise limit its sales of controlled substances to customers following a due diligence investigation, it failed to report the orders of controlled substances that it had already—and very recently—shipped to those customers, despite the suspicions acknowledged internally about those customers' ordering patterns.

- For example, in 2013, Rochester Drug discovered that a number of Bronx pharmacies sharing common ownership were filling cash prescriptions and large amounts of prescriptions for oxycodone, including for a prescriber who did not have an active DEA registration. Indeed, a company sales employee even described how Rochester Drug's compliance consultant admitted that, in referring to his site visit to one of the pharmacies, had his visit been a "real DEA audit" the agency would have "gone after their DEA license." Although Rochester Drug limited the customer's ability to purchase oxycodone, it did not report the suspicious orders—which it had already shipped to the pharmacy—to the DEA or State authorities. In fact, Rochester Drug never submitted a suspicious order report regarding this customer to the DEA or State authorities.

- In addition, in November 2015, Rochester Drug cut off two related New York, NY pharmacies due to concerns that the pharmacies were filling high percentages of cash prescriptions for controlled substances from doctors not in the "correct field of Pain Management" and for numerous doctors on a Rochester Drug "watch list." Although the two pharmacies had been on Rochester Drug's radar for months leading up to the termination—and the company had warned the customer about specific red flags regarding its dispensing in the spring of 2015—Rochester Drug never reported any of the pharmacies' orders as suspicious prior to or in conjunction with the termination.

IV. Defendants' Misconduct Has Injured Plaintiff

A. The Statutory Duties Owed to Plaintiff by Drug Manufacturers and Distributors

771. While any individual or corporation doing business in New York has a duty not to injure the State or its residents through fraud, willful misconduct, gross negligence, deceptive business practices, or false advertising, the Defendants here also took on special, additional duties when they elected to participate in the State's highly-regulated system for allowing the limited use of controlled substances for medically-necessary purposes.

772. Indeed, New York's most essential means of defense against the misuse of these drugs, and particularly opioids, are the identical regimes of compliance duties imposed on pharmaceutical manufacturers and distributors by the NYCSA. These duties consist of both a series of affirmative obligations and one critical prohibition.

773. In terms of affirmative obligations, the NYSCA requires any pharmaceutical manufacturer or distributor selling controlled substances in New York to:

(a) At the time of obtaining its initial license:

(i) Provide evidence that it is "able to maintain effective control against diversion of…controlled substances";[111]

[111] N.Y. PHL § 3312(1)(c).

(ii) Provide evidence that it is "able to comply with all applicable state…laws";[112] and

(iii) State, under penalty of perjury, whether or not it, or any of its employees, subsidiaries, managing officers, or directors "failed to comply with the…laws of any State relating to controlled substances," and if so, to submit a statement and explanatory documentation;[113]

(b) At the time of renewing its license:

(i) Report "any material change in the circumstances or factors" relevant to its initial license application;[114] and

(ii) Report all known governmental investigations of incidents involving the theft, loss, or possible diversion of controlled substances it distributed, or into its compliance with…state controlled-substances laws;[115]

(c) At all times:

(i) "[R]eport…any change in facts or circumstances…or any newly discovered or occurring fact or circumstance which is required to be included" in its applications for an initial and/or renewal license;[116]

(ii) "[N]otify the [state] of any incident involving the theft, loss or possible diversion of controlled substances…distributed by the licensee";[117]

(iii) "[E]stablish and operate a system to disclose to the license[e] suspicious orders for controlled substances and inform the [New York State Department of Health] of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[118]

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[112] N.Y. PHL § 3312(1)(d).
[113] *License Application to Engage in a Controlled Substance Activity*, N.Y. Department of Health Form 4330.
[114] N.Y. PHL § 3315(2)(a).
[115] N.Y. PHL § 3315(2)(b).
[116] N.Y. PHL §§ 3312(3), 3315(3).
[117] N.Y. PHL § 3322(3).
[118] 10 NYCRR § 80.22.

774. These affirmative obligations are complemented by one critical prohibition, contained within the very first operative subsection of the NYCSA: "It shall be unlawful for any person to…manufacture, sell, distribute…or transport a controlled substance except as expressly allowed by this article."[119]

775. In order to deter and remedy violations of these duties, and ensure that manufacturers and distributors fulfill their crucial role in preventing the improper use of controlled substances, New York law requires that any distributor who "violates, disobeys, or disregards" any provision of the NYSCA be assessed a separate and substantial civil penalty "for every such violation."[120]

776. That penalty is set at an minimum amount of $2,000 per violation,[121] but can be increased to $5,000 for any subsequent violation within twelve months of the first where both violations "were a serious threat to the health and safety of an individual or individuals,"[122] and to $10,000 for each violation that "directly results in serious physical harm to any patient or patients."[123]

777. Companies subject to the NYCSA are expected to develop and enforce specific written policies to ensure compliance, which are sometimes referred to as controlled substance monitoring programs ("CSMPs") or order monitoring programs ("OMPs"). These policies are supposed to explain for compliance staff how the company determines what a suspicious order is and how suspicious order reports ("SORs") to the State and other regulators are to be made.

[119] N.Y. PHL § 3304(1).
[120] N.Y. PHL § 3396(2) (emphasis added).
[121] N.Y. PHL § 12(1)(a).
[122] N.Y. PHL § 12(1)(b).
[123] N.Y. PHL § 12(1)(c).

778. The NYCSA, as noted above, includes a non-exclusive list of factors to be considered in monitoring potentially-suspicious orders. But companies subject to the NYCSA, including all of the Defendants here, typically have (or should have) a wealth of additional data to rely on, including their customers' relative reliance on cash payments, prior business with suspect prescribers, and the number and frequency of times that their customers have exceeded periodic limits (usually 30-day limits called "thresholds") for ordering controlled substances, or made requests for increases in those thresholds ("threshold change requests").

B. General Categories of Injury

779. As a result of the foregoing patterns of misconduct, and regardless of variations between the Manufacturer and Distributor Defendants as groups, and individual variations within those groups, the Defendants caused identical categories of injuries to Plaintiff.

780. First, the Defendants all contributed significantly to the presently-existing public nuisance posed by the massive and continuing overprescription and oversupply of opioid drugs to the New York pharmaceutical market. The Distributor Defendants effectively acted as gasoline poured on the opioid misuse epidemic in New York that was initially sparked by the fraudulent practices of the Manufacturer Defendants; expanding, accelerating, and perpetuating the flow of opioid drugs into the State. As a result, the Defendants are all jointly and severally responsible for abating the continuing injury caused by the present distortion of the New York pharmaceutical market by the overprescription and oversupply of opioids.

781. Second, the Defendants have all injured Plaintiff by repeatedly violating the NYCSA and the General Business Law. These are *per se* injuries that do not require quantification, and are instead subject to the mandatory penalties provided by the NYCSA and the New York General Business Law ("GBL") for each such violation.

782. Third, the Defendants have all caused quantifiable past economic injuries to Plaintiff by: (i) causing the State to pay false claims for payments related to inappropriately prescribed opioid products; (ii) depriving the State of the productivity and/or service of its employees who were inappropriately prescribed opioids and who became addicted and/or died as a result; and (iii) requiring the State to expend additional resources to address the public health and safety dangers created by the epidemic of opioid overprescription.

783. Fourth, Defendants have all caused injury not readily capable of quantification to the State and its residents, which can only be addressed through equitable remedies such as disgorgement and restitution.

C. Facts Particular to False Claims

1. The Defendants' False and Misleading Marketing and Improper Distribution of Opioids Caused Increased Expenditures by New York State Health Care Programs

784. The State, which continues to experience an epidemic of opioid addiction, has been damaged in many ways, including through: (a) a sharp rise since 2008 in false claims for opioid prescriptions to its Medicaid program, its employee and retiree health plans, and its Workers' Compensation Program; and (b) additional claims for medications and services to treat the physical and behavioral health conditions that accompany opioid use disorder, including inpatient and outpatient treatment for substance use disorder (including medication-assisted treatment), opioid overdose, neonatal abstinence syndrome, hepatitis c, and other conditions.

a) The New York Medicaid Program

785. The State provides comprehensive health care benefits, including prescription drug coverage, to low- and moderate-income residents through the New York Medicaid Program ("Medicaid"). Medicaid is a joint state and federal program administered by the New York State Department of Health ("DOH"), and approximately 6.5 million New York residents were enrolled

in Medicaid as of July 2018. The majority received services through health plans provided by a Medicaid Managed Care Organization ("MCO"), under contract with the State. Currently, nineteen different insurance companies run MCOs in New York. To administer drug benefits to enrollees, all of the largest MCOs contract with a pharmacy benefit manager ("PBM").

786. Through regulations, provider manuals and policy manuals, and periodic Medicaid Updates, DOH sets the rules and regulations for reimbursement requests that are applicable to all Medicaid providers statewide. In particular, New York law establishes certain "unacceptable practice[s]" that "constitute[] fraud or abuse" against Medicaid; this expressly includes "submitting or causing to be submitted, a claim or claims for… medical care, services or supplies provided at a frequency or in an amount not medically necessary…." 18 NYCRR § 515.2(b)(1)(i)(c).

b) New York State Employee and Retiree Health Plans

787. The Department of Civil Service ("DCS") administers the New York State Health Insurance Program ("NYSHIP"), which was established in 1957 and has provided health insurance coverage to active and retired State, participating public authority, local government, and school district employees, retirees, and their eligible dependents. NYSHIP provides health insurance benefits to approximately 1.1 million individuals and is one of the largest public employer health insurance programs in the nation. NYSHIP offers coverage through its own preferred provider organization health plan, called The Empire Plan ("the Plan"), and through HMOs located around New York State, the Excelsior Plan and the Student Employee Health Plan ("SEHP"), which is a health insurance plan for graduate student employees of the State University system and certain CUNY graduate students. DCS has contracted with a number of vendors to administer the prescription drug benefit portion of the Plan, the Empire Plan Prescription Drug Program, and based

on these contracts DCS reimburses the vendor for claims paid by either the vendor or its subcontractor.

788. The Empire Plan explicitly disclaims coverage for non-medically necessary drugs. *See* Empire Plan Certificate PA/2014, at 114 ("charges for the following items are not covered expenses: … V. Any non-medically necessary drugs"). Thus, DCS's 2014 contract with the PBM for the Empire Plan defined a "medically necessary drug" as any drug which is: (i) provided for the diagnosis or treatment of a medical condition; (ii) appropriate for the symptoms, diagnosis, or treatment of a medical condition; (iii) within the standards of generally accepted health care practice; and (iv) not used for cosmetic purposes." Contract § 1.56.0.

c) The New York Workers' Compensation Program

789. The New York State Insurance Fund ("NYSIF") serves two roles for the State of New York. NYSIF was created in 1914 pursuant to New York Workers' Compensation Law Section 76 as a self-sustaining fund for the purpose of insuring employers against liability for personal injuries or death sustained by their employees. NYSIF also administers claims of employees of the State of New York with respect to injuries or deaths from accidents arising out of and in the course of employment in accordance with New York Workers' Compensation Law Section 88-c. NYSIF contracts with a PBM to distribute and accept payment for prescribed medication, including opioids. NYSIF covers only medically necessary treatment.[124]

[124] *See Medical Treatment Guidelines*, New York State Workers' Compensation Board, http://www.wcb.ny.gov/content/main/hcpp/MedicalTreatmentGuidelines/MTGOverview.jsp (last visited Mar. 25, 2019).

2. Defendants Caused False Claims to be Submitted to State-Funded Health Plans

790. The State's requirement that medical treatments be medically necessary—a condition of coverage for any medical treatment under the State's health plans and Workers' Compensation Program—necessarily includes the requirement that each prescription or procedure for which reimbursement is sought be the result of untainted and independent medical judgment that adequately assesses the risks and benefits of that product or procedure for the particular patient. But because each Manufacturer Defendant's marketing practices flooded the State with fraudulent and deceptive information, including misrepresentations regarding whether patients were likely to become addicted to opioids, would be able to resume life activities, and would experience long-term relief, prescribers of opioids were rendered unable to accurately assess the risks and benefits of opioids. Because the Manufacturer Defendants' misrepresentations rendered prescribers unable to assess the risks and benefits of opioids, they necessarily rendered false those prescribers' certifications that opioid prescriptions were medically necessary. Moreover, the use of opioids in those circumstances was not supported by substantial scientific evidence about the benefits and was outweighed by potential harms including the risk of addiction. In addition, New York does not allow claims for drug supplies distributed by unlicensed companies, and classifies controlled substances distributed in violation of the NYCSA as illegal contraband, and a public nuisance.

a) The Manufacturer Defendants Caused False Claims by Making it Impossible for Prescribers to Accurately Assess the Risks and Benefits of Opioids

791. The Manufacturer Defendants engaged in a marketing campaign designed to encourage prescribers to use opioids as the first line of treatment for chronic pain while inundating them with false information that rendered those prescribers unable to adequately assess the risks and benefits of prescribing opioids. In doing so, each Manufacturer Defendant caused prescribers

or health care providers ("HCPs") and pharmacies to submit, and the State to cover claims for New York Medicaid, New York employee and retiree health plans, and New York's Workers' Compensation Program that were false by:

a. Causing prescribers to write prescriptions for opioid therapy based on each Manufacturer Defendant's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs; and

b. Causing HCPs to certify that these prescriptions and associated services were medically necessary, when, in fact, the prescriptions were not supported by substantial scientific evidence because prescribing physicians were unable to adequately assess whether the risks associated with the drugs were outweighed by the benefits.

792. A substantial number of medically unnecessary claims for opioid prescriptions paid under State health programs were induced and caused by Defendants' violations of laws, including misleading marketing and violations of their obligations under State laws governing the distribution of controlled substances. In particular, many claims for opioid prescriptions for non-cancer and non-palliative care were not medically necessary because they were not based on an adequate evaluation of the risks and benefits of the prescription.

793. The State would not knowingly have allowed the Medicaid program to reimburse claims for prescription drugs that were not eligible for coverage. A New York regulation, 18 N.Y.C.R.R. 515.2(b)(1)(i)(c), "Unacceptable Practices under the Medical Assistance Program", states in pertinent part that "[a]n unacceptable practice is conduct which constitutes fraud or abuse and includes…False claims [defined to include] causing to be submitted…claims for medical care, services or supplies provided at a frequency or in an amount not medically necessary." Whether a service is "medically necessary" is the primary check against loss to the public fisc and primary check to ensure the health and safety of Medicaid recipients. An "unacceptable practice" by any person is grounds for both sanctions (exclusion, censure, or conditional participation) and

"repayment of overpayment determined to have been made as the result of an unacceptable practice." 18 NYCRR 515.3(a) and (b). New York Medicaid unwittingly reimbursed claims for opioid prescriptions that were not medically necessary, including the following claims for excessive, long-term dosages of opioids prescribed for non-cancer patients by practitioners who, because of their repeated and direct exposure to the Manufacturing Defendants' misleading marketing, were incapable of adequately assessing the risks and benefits of these prescriptions:

a) Purdue. As described above, Purdue repeatedly and persistently made false and misleading statements downplaying the risks and overstating the benefits of opioids, including OxyContin, through unbranded and branded marketing that was targeted at and did reach New York HCPs. Purdue's detailing of, and payments to, specific New York HCPs caused those HCPs to write medically unnecessary prescriptions for OxyContin—by starting new patients on the drug, keeping patients on the drug, and prescribing the drug at higher dosages. For example:

   i. New York Medicaid Patient A, who was diagnosed with a herniated disc, chronic fatigue syndrome and a rotator cuff sprain, received 98 prescriptions for OxyContin—totaling a 2,932-day supply—between September 2008 and April 2013, at a cost of $90,785 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 570 MMEs per day of OxyContin during this five-year period, were written by Dr. William Gibbs, who was detailed by [redacted] Dr. Gibbs's New York State medical license was suspended in April 2013 due to his federal conviction for health care fraud.

   ii. New York Medicaid Patient B, who was diagnosed with a herniated disc, chronic fatigue syndrome, and shoulder tendinitis, received 96 prescriptions for OxyContin—totaling a 2,880-day supply—between July 2009 and April 2013, at a cost of $67,749 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 540 MMEs per day of OxyContin during the majority of this five-year period, were written by Dr. William Gibbs.

   iii. New York Medicaid Patient C, who was diagnosed with chronic fatigue syndrome and osteoarthrosis, received 21 prescriptions for OxyContin—

totaling a 630-day supply—between July 2011 and March 2013, at a cost of $38,068 in claims paid by the State's Medicaid program. These prescriptions, which called for at least 480 MMEs per day of OxyContin during the entire period, and at least 720 MMEs per day of OxyContin for eight months during that period, were written by Dr. William Gibbs.

b) Janssen. As described above, Janssen repeatedly and persistently made false and misleading statements downplaying the risks and overstating the benefits of opioids, including Nucynta, through unbranded and branded marketing that was targeted at and did reach New York HCPs. Janssen's detailing of, and payments to, specific New York HCPs caused those HCPs to write medically unnecessary prescriptions for Nucynta—by starting new patients on the drug, keeping patients on the drug, and prescribing the drug at higher dosages. For example:

i. New York Medicaid Patient D, who was diagnosed with a degenerated disc and lumbago (lower back pain), received 58 prescriptions for Nucynta—totaling a 1,598-day supply—between November 2011 and February 2014, at a cost of $18,054 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 240 MMEs per day of Nucynta during the vast majority of the period, were written by Practitioner A, who was detailed by Janssen [redacted].

ii. New York Medicaid Patient E, who was diagnosed with a degenerated disc, received 35 prescriptions for Nucynta—totaling a 777-day supply—between November 2011 and June 2014, at a cost of $22,897 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 320 MMEs per day of Nucynta during the vast majority of the period, were written by Practitioner A.

iii. New York Medicaid Patient F, who was diagnosed with radiculitis, unspecified, received 35 prescriptions for Nucynta—totaling a 1,040-day supply—between November 2011 and September 2013, at a cost of $13,101 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 240 MMEs per day of Nucynta during the vast majority of the period, were written by Practitioner A.

c) Allergan. As described above, Allergan repeatedly and persistently made false and misleading statements downplaying the risks and overstating the benefits of

opioids, including Kadian, through unbranded and branded marketing that was targeted at and did reach New York HCPs. Allergan's detailing of, and payments to, specific New York HCPs caused those HCPs to write medically unnecessary prescriptions for Kadian—by starting new patients on the drug, keeping patients on the drug, and prescribing the drug at higher dosages. For example:

i. New York Medicaid Patient G, who was diagnosed with displacement of lumbar intervertebral disc without myelopathy, received 14 prescriptions for Kadian—totaling a 420-day supply—between January 2011 and November 2011, at a cost of $21,431 in claims that were paid under the State's Medicaid program. These prescriptions, which called for at least 300 MMEs per day of Kadian during this entire period, and more than 400 MMEs per day for the majority of the period, were written by Practitioner B, who was detailed by Allergan [redacted].

ii. New York Medicaid Patient H, who was diagnosed with thoracic or lumbosacral neuritis or radiculitis, unspecified, received 66 prescriptions for Kadian—totaling a 1925-day supply—between February 2008 and October 2014, at a cost of $228,198 in claims that were paid under the State's Medicaid program. These prescriptions, which called for at least 400 MMEs per day of Kadian during this entire period, and at least 600 MME per day during the majority of the period, were written by Practitioner C, whom Allergan detailed [redacted].

d) Mallinckrodt. As described above, Mallinckrodt repeatedly and persistently made false and misleading statements downplaying the risks and overstating the benefits of opioids, including Exalgo, through unbranded and branded marketing that was targeted at and did reach New York HCPs. Mallinckrodt's detailing of, and payments to, specific New York HCPs caused those HCPs to write medically unnecessary prescriptions for Exalgo—by starting new patients on the drug, keeping patients on the drug, and prescribing the drug at higher dosages. For example:

i. New York Medicaid Patient I, who was diagnosed with thoracic or lumbosacral neuritis or radiculitis, unspecified, received 22 prescriptions

for Exalgo—totaling a 660-day supply—between January 2011 and March 2014, at a cost of $40,155 in claims that were paid under the State's Medicaid program. These prescriptions, which called for at least 190 MMEs per day of Exalgo during the vast majority of this period, were written by Practitioner D, who was detailed by [redacted] Mallinckrodt paid Practitioner D—[redacted] as part of its speakers' bureau. In 2013, Mallinckrodt's [redacted]

ii. New York Medicaid Patient J, who was diagnosed with postlaminectomy syndrome, lumbar region, received 19 prescriptions for Exalgo—totaling a 540-day supply—between July 2011 and May 2013, at a cost of $30,550 in claims that were paid under the State's Medicaid program. These prescriptions, which called for at least 190 MMEs per day of Exalgo during the majority of the period, were written by Practitioner D.

iii. New York Medicaid Patient K, who was diagnosed with thoracic or lumbosacral neuritis or radiculitis, unspecified and lumbago, received 20 prescriptions for Exalgo—totaling a 585-day supply—between May 2010 (several weeks after the first detailing visit to this HCP) and August 2013, at a cost of $38,266 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 190 MMEs per day of Exalgo during the vast majority of this period, were written by Practitioner D.

e) Endo. As described above, Endo repeatedly and persistently made false and misleading statements downplaying the risks and overstating the benefits of opioids, including Opana, through unbranded and branded marketing that was targeted at and did reach New York HCPs. Endo's detailing of, and payments to, specific New York HCPs caused those HCPs to write medically unnecessary prescriptions for Opana—by starting new patients on the drug, keeping patients on the drug, and prescribing the drug at higher dosages. For example:

i. New York Medicaid Patient L, who was diagnosed with thoracic or lumbosacral neuritis or radiculitis, unspecified, received 24 prescriptions for Opana—totaling a 714-day supply—between October 2009 and September 2011, at a cost of $21,473 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 240

MMEs per day of Opana during the vast majority of the period, and more than 360 MMEs per day during the majority of the period, were written by Practitioner E, who was detailed by Endo [redacted]

ii. New York Medicaid Patient M, who was diagnosed with lumbago, and postlaminectomy syndrome, lumbar region, and thoracic or lumbosacral neuritis or radiculitis, unspecified, received 38 prescriptions for Opana—totaling a 1,119-day supply—between November 2009 and December 2012, at a cost of $37,912 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 240 MMEs per day of Opana during the vast majority of the period, and at least 360 MMEs per day during the majority of the period, were written by Practitioner E.

iii. New York Medicaid Patient N was diagnosed with thoracic or lumbosacral neuritis or radiculitis, unspecified, and received 24 prescriptions for Opana—totaling a 618-day supply—between February 2011 and May 2012, at a cost of $24,140 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 240 MMEs per day of Opana during the entire period, and at least 360 MMEs per day during the vast majority of the period, were written by Practitioner E.

f) Teva. As described above, Teva repeatedly and persistently made false and misleading statements downplaying the risks and overstating the benefits of opioids, including Fentora, through unbranded and branded marketing that was targeted at and did reach New York HCPs. Teva's detailing of, and payments to, specific New York HCPs caused those HCPs to write medically unnecessary prescriptions for Teva—by starting new patients on the drug, keeping patients on the drug, and prescribing the drug at higher dosages. For example:

i. New York Medicaid Patient O was diagnosed with generalized anxiety disorder and abdominal pain, and received 70 prescriptions for Fentora—totaling a 1,759-day supply—between October 2008 and March 2018, at a cost of $1,991,837 in claims paid under the State's Medicaid program. These prescriptions, which called for at least 400 MMEs per day of Fentora for the vast majority of the period, were written by Dr. Gordon Freedman, a Manhattan pain management physician whom Teva detailed extensively, at least as early as 2006, and paid thousands of dollars for Fentora speaker programs, including after 2012. In March 2018, the U.S. Attorney for the Southern District of New York charged Dr. Freedman with violations of the

federal anti-kickback statute, participation in an anti-kickback conspiracy, and honest services fraud, in connection with his involvement with Insys, the maker of a sublingual fentanyl spray.

ii. New York Medicaid Patient P was diagnosed with an ulcerated lower limb and received 16 prescriptions for Fentora—totaling a 244-day supply—between July 2010 and November 2010, at a cost of $82,343 in claims paid under the State's Medicaid program. These prescriptions, which called for least 1250 MMEs per day of Fentora for the entire period, were written by Dr. Gordon Freedman.

b) All of the Defendants Induced False Claims Based on Illegally-Sourced Opioid Drugs

794. In each of the above specific cases, the prescribed opioid medication was provided by one of the Manufacturer Defendants, who sold the drugs in question to one of the Defendant Distributors, who then, in turn, sold the drugs in question to the licensed dispensaries that ultimately provided the drugs to the relevant patients. But as shown in Part V.D, below, at the time of those claims, all of the Defendants had made false statements to the State as to their prior and ongoing compliance with the NYCSA.

795. These false statements to the State regarding the Defendants' eligibility for licenses to conduct Controlled-Substance Activity in New York rendered false each relevant HCP's express and/or or implied certification that the supplies being paid for were supplied in compliance with applicable State law.

796. In addition, or alternatively, these false statements rendered each relevant HCP's claims factually false, because drugs actually supplied to each patient through each specific chain of relevant Manufacturer Defendant and Distributor Defendant were illegal contraband (and a statutorily-defined public nuisance) pursuant to Public Health Law § 3387, and thus not the "genuine article" represented as the item for which reimbursement was sought.

c) The Defendants' Misrepresentations Foreseeably Caused the State's Decision to Cover False Claims for Opioid Drug Prescriptions

797. Each Manufacturer Defendant's marketing scheme was designed to achieve the basic goal of inducing as many prescriptions as possible for its opioid products, spending millions of dollars to carry out that scheme. A foreseeable—and largely inevitable—consequence of that scheme was that the State would ultimately pay for opioids prescribed by HCPs who were not able to properly assess the significant risks and limited benefits of opioids.

798. Each Manufacturer Defendant's misrepresentations caused HCPs to submit claims that contained false express or implied certifications that the treatments provided were medically necessary. In addition and/or in the alternative, each Manufacturer Defendant's misrepresentations constituted false statements that were material to evaluation of the HCP's claims.

799. Under either alternative, the false claims or false statements relating to those claims were material, because they had a natural tendency to affect the State's evaluation of whether its core requirement that medical treatments be medically necessary—a condition of coverage for any medical treatment under the State's health plans and Workers' Compensation Program—had been met as to each claim.

800. In addition and/or in the alternative, each Defendant's false statements on their Applications to Engage in Controlled-Substance Activity caused HCPs to falsely claim supplies were provided in compliance with the CSA, and/or related to the evaluation of the HCP's claims in a material fashion. Again, these false claims and/or false statements were material because they had a natural tendency to affect the State's decision whether to: (a) not license each such Defendant to engage in controlled-substance activity in New York, precluding payments for their opioid drugs; and/or (b) decline to pay specific claims that were medically unnecessary on the separate grounds that the drug supplies themselves were illegally provided.

801. The State not only paid these medically-unnecessary claims for illegally-sourced opioids but also subsequently bore the consequential costs in treating overdose, addiction, and other side effects of opioid use.

D. Facts Specific to Defendants' Illegally-Obtained Licenses to Engage in Controlled-Substance Activity in New York State

802. Each Defendant except Janssen has submitted Applications to Engage in Controlled Substance Activity to the New York State Department of Health in order to acquire and/or renew their licenses to do such business in the State.

803. Since 2006, these applications have required all applicants to swear, under penalty of perjury: (i) that they were "knowledgeable concerning…and shall comply with [the] requirements" of the NYCSA; and (ii) that they would "promptly report to the Department of Health each incident or alleged incident or…possible diversion of…controlled substances."

804. Since 2016, these applications have also required all applicants to truthfully disclose, under penalty of perjury, whether any of their "employees, subsidiaries, managing officers, or directors" had "failed to comply with the provisions" of the NYCSA in the past.

805. Each such Defendant procured their initial license and/or a renewal of their license by swearing falsely in response to one or more of these requirements.

806. Specifically, each such Defendant falsely swore averment of the two acknowledgements required since 2006, when it knew that it: (i) did not comprehend the requirements of the NYCSA, had not complied with them in the past and would not comply with them in the future, and/or willfully blinded themselves to and/or recklessly disregarded those facts; and (ii) had not made and would not make the required reports of "alleged incidence of possible diversion," and/or willfully blinded themselves to and/or recklessly disregarded that fact.

807. Moreover, Actavis, Cardinal, Endo, Mallinckrodt, McKesson, Purdue, Rochester and Teva have each submitted false responses to the disclosure requirement instituted in 2016, in that each of them falsely swore that neither they nor any of their "employees, subsidiaries, managing officers, or directors" had "failed to comply with the provisions" of the NYCSA in the past, when they knew that they had in fact so failed, and/or willfully blinded themselves to and/or recklessly disregarded that fact.

808. As a result of the foregoing false averments, statements, and/or omissions on its Applications to Engage in Controlled-Substance Activity, each license that each such Defendant procured allowing it to deal in controlled substances in the State was void *ab initio*.

809. As such, each separate instance in which such a Defendant manufactured, sold, possessed, transported and/or distributed controlled substances in New York during any period of non-licensure constituted a separate violation of Public Health Law §§ 3300 *et seq*. punishable by a separate civil penalty pursuant to Public Health Law § 12.

V. Any Statute of Limitations is Tolled

810. Any applicable statute of limitations is tolled because: (a) each Defendant is engaged in a continuing violation; and (b) each Defendant fraudulently concealed its misconduct.

A. Each Defendant is Engaged in a Continuing Violation

811. As detailed above, each Defendant's misconduct has continued to the present, through its continued failures to:

- Make public corrections to its various false and misleading statements in connection with its marketing of opioids and its Applications to Engage in Controlled Substance Activity;
- Maintain effective controls to prevent the diversion of opioids;
- Identify, block, and report suspicious orders to the New York State Department of Health;

- Report changes in its ability to: (i) maintain effective controls to prevent the diversion of opioids; and/or (ii) identify, block, and report suspicious orders to the New York State Department of Health;

- Refrain from engaging in an ongoing public nuisance; and/or

- Refrain from engaging in a persistent and ongoing fraud or illegality.

B. Fraudulent Concealment

812. Each Manufacturer Defendant fraudulently concealed the deceptive, misleading, and fraudulent nature of their advertising, marketing, and promotional activities. Each purposefully hid behind the KOLs and Front Group organizations to avoid regulatory scrutiny and to prevent HCPs and the public from discounting their messages. And while each of them was also listed as a sponsor in one or more of the deceptive publications cited herein, they never disclosed their role in shaping, editing, and exerting final approval over those publications' content.

813. Each Defendant fraudulently concealed from the State that statements and/or omissions contained in its Applications to Engage in Controlled Substance Activity were false, in order to ensure that it would be granted initial or renewal licenses allowing it to deal in controlled substances in New York.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
Public Nuisance
(All Defendants except the Sackler Entities)

814. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

815. Residents of the State of New York enjoy common rights, including, without limitation: (i) an honest and effective marketplace for healthcare treatment; (ii) the maintenance of a well-regulated system for the manufacture, distribution, and sale of controlled substances for medically-necessary purposes; (iii) public safety and public order, unburdened by the introduction of foreseeable dangers such as those caused by the over-prescription and oversupply of controlled substances.

816. Each Defendant owed a duty to the public not to offend, interfere with, or cause damage to such common rights through illegal actions and omissions in violation of applicable laws and regulations.

817. Each Defendant engaged in such actions and omissions which offend, interfere with, and/or cause damage to the public in the exercise of rights common to all in violation of said duties, in a manner such as to endanger or injure the property, health, safety, or comfort of a considerable number of persons in the State of New York, in the course of their manufacture, promotion, marketing, and/or distribution of opioids.

818. Each Defendant knew, or should have foreseen, that its actions and omissions would result in offense, interference, and/or damage to the public in the exercise of common rights.

819. The offense, interference, and/or damage to the public in the exercise of common rights caused by Defendants' collective actions and omissions remain unabated.

SECOND CAUSE OF ACTION
Violation of State Finance Law § 189(1)(a)
(All Defendants except the Sackler Entities)

820. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

821. Each Defendant caused third-party health care providers to present false claims for payment of public money by Plaintiff, its political subdivisions, and/or their agents, in violation of State Finance Law §189(1)(a) on multiple and continuous occasions over the past decade.

822. Specifically, in the course of presenting each claim for reimbursement of opioid drugs prescribed to patients, HCPs made express and/or implied certifications that the opioid drug prescriptions being reimbursed were medically necessary, and that the services and drugs in question were otherwise provided in accordance with applicable State law, including, without limitation, Public Health Law §§ 3300 *et seq.* (the New York Controlled Substances Act or "NYCSA").

823. Each Manufacturer Defendant, through its fraudulent marketing, caused HCPs to present legally false certifications that prescriptions were medically necessary, when they were not.

824. Each Manufacturer Defendant and each Distributor Defendant, through its violations of the NYCSA, caused HCPs to present legally and/or factually false certifications that the opioid drug supplies being reimbursed had been supplied in compliance with the NYCSA.

825. The falsity of these claims was material, in that such falsity would have a natural tendency to affect whether the State would determine that the claims would be deemed permissible.

826. At the time each Defendant caused these false claims to be presented by third-party health care providers, it had actual knowledge and/or acted in deliberate ignorance of the truth or

falsity of the information, and/or recklessly disregarded that they were causing those claims to be legally and/or factually false.

827. As a result of each Defendant causing such false claims to be submitted by HCPs in violation of State Finance Law § 189(1)(a), Plaintiff suffered damages, including, without limitation, the amount of the claims paid, and the consequential injuries resulting from patients' receipt of improperly prescribed and/or supplied opioid drugs.

THIRD CAUSE OF ACTION
Violation of State Finance Law § 189(1)(b)
(All Defendants except the Sackler Entities)

828. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

829. Each Defendant has made false statements and/or records that were material to claims presented by HCPs for payment of public money by Plaintiff, its political subdivisions, and/or their agents, in violation of State Finance Law §189(1)(b) on multiple and continuous occasions over the past decade.

830. Specifically, in the course of presenting each claim for reimbursement of opioid drugs prescribed to patients, HCPs made express and/or implied certifications that the opioid drug prescriptions being reimbursed were medically necessary, and that the services and drugs in question were otherwise provided in accordance with applicable State law, including, without limitation, Public Health Law §§ 3300 *et seq.* (the New York Controlled Substances Act or "NYCSA").

831. Each Manufacturer Defendant, in the course of its fraudulent marketing, made false statements and/or records material to each claim presented by HCPs that asserted that prescriptions were medically necessary, when they were not.

832. Each Manufacturer Defendant and each Distributor Defendant made false statements and/or records concerning its compliance with the NYCSA that were material to each claim presented by HCPs that certified that the supplies being reimbursed had been provided in compliance with the NYCSA.

833. At the time each Defendant made these false statements, it had actual knowledge and/or acted in deliberate ignorance of the truth or falsity of the information, and/or recklessly disregarded that they were causing those claims to be legally and/or factually false.

834. The falsity of these statements and/or records was material, in that such falsity would have a natural tendency to affect whether the State would determine that the claims would be deemed permissible.

835. As a result of each Defendant making such false statements and/or records material to claims presented by third-party health care providers in violation of State Finance Law § 189(1)(a), Plaintiff suffered damages, including, without limitation, the amount of the claims paid, and the consequential injuries resulting from patients' receipt of improperly prescribed and/or supplied opioid drugs.

FOURTH CAUSE OF ACTION
Violation of State Finance Law § 189(1)(c)
(All Defendants except the Sackler Entities)

836. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

837. Each Defendant knowingly agreed, explicitly in communications exclusively in the possession of Defendants, and/or implicitly as evidenced by the acts set forth above, that collectively they would violate State Finance Law §§ 189(1)(a) and/or (b).

838. Each Defendant committed at least one overt act in furtherance of this conspiracy, as set forth above.

839. As a result of Defendants' conspiracy to violate State Finance Law §§ 189(1)(a) and/or (b), Plaintiff suffered has damages, including, without limitation, the amount of the claims paid, and the consequential injuries resulting from patients' receipt of improperly prescribed and/or supplied opioid drugs.

FIFTH CAUSE OF ACTION
Violation of N.Y. Social Services Law § 145-b
(All Defendants except the Sackler Entities)

840. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

841. Each Defendant knowingly made one or more false statements and/or representations, or deliberately concealed at least one material fact, or otherwise conducted a fraudulent scheme or device, attempting to obtain or obtaining payment, on behalf of itself or others, from public funds for services or supplies furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law, in violation of SSL § 145-b.

842. By reason of each Defendant's violation(s) of SSL § 145-b, Plaintiff has been damaged through the payments of public funds each such Defendant falsely induced the State of New York and/or its local social services districts to make to third-party health care providers.

SIXTH CAUSE OF ACTION
Violation of N.Y. General Business Law § 349
(All Manufacturer Defendants except the Sackler Entities)

843. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

844. Each Manufacturer Defendant engaged in deceptive practices in the conduct of business, trade and/or commerce in New York State, in violation of GBL § 349(a) in the course of manufacturing, selling, distributing, promoting, and/or marketing opioid drugs, as set forth above.

845. The Attorney General timely provided each Manufacturer Defendant with the pre-litigation notice required by GBL § 349(c).

846. Each Manufacturer Defendant has damaged Plaintiff and numerous other individuals and entities resident in New York through its deceptive practices in violation of GBL § 349(a).

847. Each Manufacturer Defendant has wrongfully obtained money and/or property, directly and/or indirectly, by these deceptive practices from Plaintiff and numerous other individuals and entities resident in New York.

SEVENTH CAUSE OF ACTION
Violation of N.Y. General Business Law § 350
(All Manufacturer Defendants except the Sackler Entities)

848. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

849. Each Manufacturer Defendant made representations and/or omissions of fact that were materially misleading, and thereby made false advertisements in the conduct of business, trade and/or commerce in New York State, in violation of GBL § 350, in the course of manufacturing, selling, distributing, promoting, and/or marketing opioid drugs, as set forth above.

850. The Attorney General timely provided each Manufacturer Defendant with the pre-litigation notice required by GBL § 349(c).

851. Each Manufacturer Defendant has damaged Plaintiff and numerous other individuals and entities resident in New York through its false advertisements in violation of GBL § 350.

EIGHTH CAUSE OF ACTION
Violation of the New York Controlled Substance Act (Public Health Law §§ 3300 *et seq.*)
(All Defendants except the Sackler Defendants)

852. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

853. Each Defendant is strictly liable for violating the NYCSA in each separate instance in which it: (i) failed to maintain effective controls to prevent the diversion of controlled substances; (ii) failed to report suspicious orders for controlled substances; (iii) failed to report actual or alleged incidents of known or possible diversion of controlled substances; (iv) failed to provide truthful statements in its licensing filings with New York authorities; (v) and/or failed to notify New York authorities when its actions and/or omissions caused it to violate the NYCSA.

854. In addition and/or in the alternative, each Defendant is strictly liable for violating the NYCSA in each and every one of the instances in which it manufactured, sold, possessed, transported and/or distributed opioids in New York, due to the ongoing nature of the above violations, and/or its lack of a valid license to manufacture and/or distribute controlled substances in New York.

NINTH CAUSE OF ACTION
Repeated and Persistent Fraud in Violation of N.Y. Executive Law § 63(12)
(All Defendants except the Sackler Entities)

855. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

856. Each Defendant engaged in repeated and/or persistent fraud in violation of Executive Law § 63(12) in the course of its manufacture, promotion, marketing, and/or distribution of opioids in New York State.

857. Each Manufacturer Defendant engaged in repeated and/or persistent fraud in violation of Executive Law § 63(12) through its: (i) fraudulent scheme to promote and market opioids described above; and/or (ii) false statements and/or omissions to the State on each of its Applications to Engage in a Controlled Substance Activity.

858. Each Distributor Defendant engaged in repeated and/or persistent fraud in violation of Executive Law § 63(12) through its false statements and/or omissions to the State on each of its Applications to Engage in a Controlled Substance Activity.

859. Each Defendant damaged Plaintiff and numerous other individuals and entities resident in New York, and obtained ill-gotten profits, through its repeated and persistent fraud in violation of Executive Law § 63(12).

TENTH CAUSE OF ACTION
Repeated and Persistent Illegality in Violation of N.Y. Executive Law § 63(12)
(All Defendants except the Sackler Entities)

860. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

861. Each Defendant engaged in repeated and/or persistent illegality in violation of Executive Law § 63(12) in the course of its manufacture, promotion, marketing, and/or distribution of opioids in New York State.

862. Each Manufacturer Defendant engaged in repeated and/or persistent illegality in violation of Executive Law § 63(12) through its violations of: (i) State Finance Law § 189; (ii) Social Services Law § 145-b; (iii) General Business Law § 349; (iv) General Business Law § 350; and/or (v) Public Health Law §§ 3300 *et seq.* (the New York Controlled Substances Act or "NYCSA").

863. Each Distributor Defendant engaged in repeated and/or persistent illegality in violation of Executive Law § 63(12) through its violations of: (i) State Finance Law § 189; (ii) Social Services Law § 145-b; and/or (iii) Public Health Law §§ 3300 *et seq.* (the New York Controlled Substances Act or "NYCSA").

864. Each Defendant damaged Plaintiff and numerous other individuals and entities resident in New York, and obtained ill-gotten profits, through its repeated and persistent illegality in violation of Executive Law § 63(12).

ELEVENTH CAUSE OF ACTION
Common-Law Fraud
(All Defendants except the Sackler Entities)

865. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

866. Each Defendant knowingly made material misrepresentations and/or omissions of facts to Plaintiff, its agents and employees, and third parties, in order to induce them to license them to do business, and/or purchase, administer, and consume opioids, as set forth in detail above.

867. Each Defendant knew at the time that it made these misrepresentations and/or omissions that they were false, or alternatively, recklessly disregarded their falsity.

868. Each Defendant intended that Plaintiff, HCP's, patients, and/or others would rely on its misrepresentations and/or omissions.

869. Numerous agents of Plaintiff, as well as HCPs, patients, and others did in fact reasonably rely upon each Defendant's misrepresentations and/or omissions.

870. By reason of their reliance on each Defendant's misrepresentations and omissions of material fact, Plaintiff suffered direct and consequential economic injuries.

871. Each Defendant's fraudulent conduct was egregious, directed at the public generally, and involved a high degree of moral culpability.

TWELFTH CAUSE OF ACTION
Common-Law Gross Negligence
(All Defendants except the Sackler Entities)

872. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

873. Each Defendant had a duty of care to Plaintiff and residents of New York to conduct its business of manufacturing, promoting, marketing, and/or distributing opioids in compliance with applicable State law.

874. Each of the Defendants breached its duties through its false and misleading statements and omissions, and/or its violations of the New York Controlled Substances Act, in the course of its manufacture, distribution, sale, and/or marketing of opioid drugs within the State.

875. As a foreseeable consequence of each Defendant's breaches of its duties, Plaintiff suffered direct and consequential economic injuries.

876. Each Defendant's breaches of its duties involved an indifference to duty amounting to recklessness and actions outside the bounds of reason, so as to constitute gross negligence.

877. Each Defendant's gross negligence was egregious, directed at the public generally, and involved a high degree of moral culpability.

THIRTEENTH CAUSE OF ACTION
Common-Law Willful Misconduct

(All Defendants except the Sackler Entities)

878. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

879. Each Defendant committed intentional acts of an unreasonable character in disregard of known or obvious risks so great as to make it highly probable that harm would result in the course of its manufacture, distribution, sale, and/or marketing of opioid drugs within the State.

880. As a consequence of each such intentional act, Plaintiff suffered direct and consequential economic injuries.

881. Each Defendant's willful misconduct was egregious, directed at the public generally, and involved a high degree of moral culpability.

FOURTEENTH CAUSE OF ACTION
Unjust Enrichment
(All Defendants)

882. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

883. As an expected and intended result of each Defendants' conscious and continuing wrongdoing, each has unjustly enriched itself at Plaintiff's expense.

884. It is against equity and good conscience to permit Defendants to retain the benefits they received as a result of its wrongful and continuing acts, practices, and omissions.

FIFTEENTH CAUSE OF ACTION
Intentionally Fraudulent Conveyances
in Violation of Debtor and Creditor Law § 276
(Purdue and Sackler Defendants)

885. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

886. Plaintiff's litigation against Purdue constitutes a claim against Purdue rendering the State a creditor of Purdue within the meaning of DCL § 270.

887. All of the transfers of assets from Purdue to the Sackler Defendants described above constituted conveyances, and were made with actual intent to hinder delay, and/or defraud present and/or future creditors of Purdue, including the State.

888. Accordingly, pursuant to DCL §§ 276, 276-a, and 279, Plaintiff is entitled to a judgment: (a) restraining all of the Sackler Defendants from disposing of any property; (b) setting aside the transfers of Purdue assets and profits to the Sackler Defendants; and (c) ordering defendants to return the assets transferred or equivalent value, together with an award of reasonable attorney's fees.

SIXTEENTH CAUSE OF ACTION
Constructively Fraudulent Conveyances
in Violation of Debtor and Creditor Law §§ 273, 273-a, 274, and/or 275
(Purdue and Sackler Defendants)

889. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

890. Plaintiff's litigation against the Purdue constitutes a claim against Purdue rendering the State a creditor of Purdue within the meaning of DCL § 270.

891. All of the transfers of assets from Purdue to the Sackler Defendants described above constituted conveyances, and were made without fair consideration.

892. At the time those conveyances were made, Purdue: (a) was insolvent or would thereby be rendered insolvent; (b) was a defendant in an action for money damages brought by Plaintiff; (c) was engaged or about to engage in a business or transaction for which the property remaining in its hands after the conveyance was an unreasonably small capital; and/or (d) intended or believed that it would incur debts beyond its ability to pay as they matured.

893. In addition and/or in the alternative, those conveyances were made at a time when Purdue was insolvent, nearing insolvency or such conveyances rendered the company insolvent because Purdue's conduct relating to the sale and marketing of Purdue's opioids was fraudulent from day one; at no point did Purdue and the Sacklers conduct their business within the boundaries of the law.

894. The distributions of Purdue's opioids profits left Purdue with unreasonably small capital to pay off its certain creditors in the opioids litigation, including plaintiff New York State.

895. Accordingly, pursuant to DCL §§ 273, 273-a, 274, 275, and 279, Plaintiff is entitled to a judgment: (a) restraining all of the Sackler Defendants from disposing of any property; and (b) setting aside the transfers of Purdue assets to the Sackler Defendants; and (c) ordering defendants to return the assets transferred or equivalent value, together with an award of reasonable attorney's fees.

SEVENTEENTH CAUSE OF ACTION
Declaratory Judgment Pursuant to CPLR § 3301
(All Defendants Except Janssen and the Sackler Defendants)

896. Plaintiff realleges and incorporates by reference each and every allegation in the paragraphs above as if the same were fully set forth herein.

897. Plaintiff seeks relief under CLPR § 3301 in order to declare and settle the rights and obligations of the parties.

898. Each Defendant, except for Janssen, obtained one or more initial and/or renewal licenses from the New York State Department of Health, which authorized it to manufacture, distribute, import, and/or export controlled substances within, into, and/or from the State.

899. Each such Defendant procured each such initial and/or renewal license under false pretenses through false and/or misleading statements and/or omissions contained in each such Defendant's Applications to Engage in a Controlled Substance Activity, as set forth above.

900. As a result, Plaintiff seeks a judgment declaring that each of such Defendant's licenses to manufacture, distribute, import, and/or export controlled substances within, into, or from the State was void *ab initio*.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, The People of the State of New York, respectfully requests that a judgment and order be entered that:

1. Directs the Defendants jointly and severally to endow an abatement fund with sufficient capital to eliminate the public nuisance they are responsible for creating, exacerbating, and/or perpetuating;

2. Enjoins each Defendant, pursuant to Executive Law § 63(12):

   a. From manufacturing, distributing, selling, or marketing opioids within the State unless it complies with heightened, independently-monitored safeguards against the recurrence of its fraudulent, illegal, and/or unlawful practices, which are to be set forth in a compliance plan reviewed and approved by Plaintiff and the Court; and

   b. To issue public corrective statements regarding their false and misleading public statements and omissions;

3. Awards Plaintiff, pursuant to State Finance Law § 189:

   a. Treble damages, including consequential damages, caused by each Defendant's violations of that statute, in an amount to be determined at trial; and

   b. Civil penalties from each Defendant in the amount of $12,000 for each separate instance in which it violated that statute;

4. Awards Plaintiff, pursuant to Social Services Law § 145-b, treble damages caused by each Defendant's violations of that statute, in an amount to be determined at trial;

5. Awards Plaintiff, pursuant to General Business Law § 350-d, civil penalties from each Manufacturer Defendant in the amount of $5,000 for each separate instance in which it employed a deceptive or unlawful act or practice in violation of GBL Article 22-A;

6. Awards Plaintiff, pursuant to General Business Law § 349-c, additional civil penalties from each Manufacturer Defendant in the amount of $10,000 for each such violation of GBL Article 22-A it perpetrated against the elderly;

7. Awards Plaintiff, pursuant to Public Health Law § 12(1), civil penalties from each Defendant for each separate instance in which it violated the New York Controlled Substance Act, Public Health Law §§ 3300 *et seq.*, in the amount of:

   a. $2,000 for every such violation;

   b. $5,000 for every subsequent instance of the same violation within twelve months of the first, in instances where the violations were a serious threat to the health and safety of an individual or individuals; and

   c. $10,000 for every violation that directly resulted in serious physical harm to any

patient or patients.

8. Awards Plaintiff, pursuant to common law:

   a. Direct and consequential damages from each Defendant caused by its fraud, gross negligence, and/or willful misconduct, in an amount to be determined at trial;

   b. Punitive damages from each Defendant on account of the egregiousness, publicly-directed nature, and high moral culpability of its fraud, gross negligence, and/or willful misconduct, in an amount to be determined at trial; and

   c. Equitable disgorgement from each Defendant of all benefits it wrongfully received.

9. Directs each Defendant, pursuant to Executive Law § 63(12), to:

   a. Pay restitution and damages for its fraudulent and/or illegal practices that violated that statute and caused compensable injuries to Plaintiff or any other person; and

   b. Disgorge all profits it wrongfully obtained as a result of its fraudulent and/or illegal practices in violation of that statute;

10. Directs each Manufacturer Defendant, pursuant to General Business Law § 349, to pay restitution of all money or property it directly or indirectly obtained by its unlawful acts or practices in violation of that statute;

11. Requires, pursuant to Debtor and Creditor Law §§ 273, 273-a, 274, 275, 276 and 279, that:

   a. The Sackler Defendants refrain from disposing of any property; and

   b. The Sackler Defendants to return the assets transferred or equivalent value.

   c. All fraudulent conveyances of any Purdue assets to the Sackler Defendants be set aside; and

   d. Purdue and the Sackler Defendants jointly and severally pay Plaintiff its reasonable attorneys' fees relating to any fraudulent conveyances from Purdue to the Sackler Defendants.

12. Declares that each license each Defendant obtained to manufacture, distribute, import and/or export controlled substances within, into, and/or from the State was void *ab initio* on the grounds that each such license was procured under false pretenses through false and/or misleading statements and/or omissions contained in each such Defendant's Applications to Engage in a Controlled Substance Activity;

13. Awards Plaintiff its costs; and

14. Grants such other relief the Court may deem just.

New York, New York
March 28, 2019

Respectfully submitted,

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Attorney for Plaintiff

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ORIGINAL

2021 OK 54

IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

STATE OF OKLAHOMA ex rel. MIKE HUNTER, Attorney General of Oklahoma,

Plaintiff/Appellee/
Counter-Appellant,

v.

JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-McNEIL JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; and JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.,

Defendants/Appellants/
Counter-Appellees,

and

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN, PLC, f/k/a ACTAVIS, PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; and ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

No. 118,474

FOR OFFICIAL PUBLICATION

ON APPEAL FROM THE DISTRICT COURT OF CLEVELAND COUNTY

The Honorable Thad Balkman, Trial Judge

¶0 An opioid manufacturer appealed a $465 million verdict following a bench trial in a public nuisance lawsuit. The district court held the opioid manufacturer liable under Oklahoma's public nuisance statute for its prescription opioid marketing campaign. The State of Oklahoma counter-appealed, and this Court retained the appeal. We hold the opioid manufacturer's actions did not create a public nuisance. The district court erred in extending the public nuisance statute to the manufacturing, marketing, and selling of prescription opioids.

DISTRICT COURT'S JUDGMENT REVERSED.

Mike Hunter, Attorney General for the State of Oklahoma, Abby Dillsaver, General Counsel to the Attorney General, and Ethan A. Shaner, Deputy General Counsel, Oklahoma Office of the Attorney General, Oklahoma City, Oklahoma, for Plaintiff/Appellee/Counter-Appellant.

Michael Burrage, Reggie Whitten, and Randa K. Reeves, Whitten Burrage, Oklahoma City, Oklahoma, for Plaintiff/Appellee/Counter-Appellant.

Bradley E. Beckworth, Lisa Baldwin, and Nathan B. Hall, Nix Patterson, LLP, Oklahoma City, Oklahoma, for Plaintiff/Appellee/Counter-Appellant.

John Thorne, Brendan J. Crimmins, and Ariela M. Migdal, Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C., Washington, D.C., for Plaintiff/Appellee/Counter-Appellant.

Larry D. Ottaway, Amy Sherry Fischer, and Andrew M. Bowman, Foliart, Huff, Ottaway & Bottom, Oklahoma City, Oklahoma, for Defendants/Appellants/ Counter-Appellees.

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Benjamin H. Odom, John H. Sparks, and Michael W. Ridgeway, Odom & Sparks, PLLC, Norman, Oklahoma, for Defendants/Appellants/Counter-Appellees.

Charles C. Lifland and Jonathan P. Schneller, O'Melveny & Myers, LLP, Los Angeles, California, for Defendants/Appellants/Counter-Appellees.

Stephen D. Brody, O'Melveny & Myers, LLP, Washington, D.C., for Defendants/Appellants/Counter-Appellees.

Jeffrey L. Fisher, O'Melveny & Myers, LLP, Menlo Park, California, for Defendants/ Appellants/Counter-Appellees.

Winchester, J.

¶1 An opioid drug epidemic exists in the United States. Oklahoma has experienced abuse and misuse of opioid medications, opioid use disorder, and thousands of opioid-related deaths in the past two decades. Specifically, opioid-related deaths increased during the early 2000s, plateaued around 2007, and then declined.[1] What we cannot ignore is that improper use of prescription opioids led to many of these deaths; few deaths occurred when individuals used pharmaceutical opioids as prescribed. We also cannot disregard that chronic pain affects millions of Americans. It is a persistent and costly health condition, and opioids are currently a vital treatment option for pain. The U.S. Food and Drug Administration ("FDA") has endorsed properly managed medical use of opioids (taken as prescribed) as safe, effective pain management, and rarely addictive.[2] Yet opioid abuse is still prevalent and has become a complex social problem.

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[1] *See* Emily Piercefield, MD, DVM, Pam Archer, MPH, Philip Kemp, Ph.D. & Sue Mallonee, RN, MPH, *Increase in Unintentional Medication Overdose Deaths Oklahoma, 1994-2006*, 39 Am. J. Preventive Med. 357, 357-59 (Oct. 2010), *available at* https://www.ajpmonline.org/article/S0749-3797(10)00389-2/pdf; John Scully, Okla. Bureau of Narcotics, *Oklahoma Drug Threat Assessment* 1 (2017), *available at* https://www.obndd.ok.gov/home/showpublisheddocument/20/637395998276800000.

[2] *See* U.S. Food & Drug Admin., A Guide to Safe Use of Pain Medications 3 (February 23, 2009), *available at* https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/dph/environmental_health/occupationalhealth/Opioid-Symposium-March-2017/FDA-Guide-to-Safe-Use-of-Pain-Medicine.pdf.

¶2 To address this problem, the State of Oklahoma *ex rel.* Mike Hunter, Attorney General of Oklahoma ("State"), sued three prescription opioid manufacturers and requested that the district court hold opioid manufacturers liable for violating Oklahoma's public nuisance statute. The question before the Court is whether the conduct of an opioid manufacturer in marketing and selling its products constituted a public nuisance under 50 O.S.2011, §§ 1 & 2. We hold that the district court's expansion of public nuisance law went too far. Oklahoma public nuisance law does not extend to the manufacturing, marketing, and selling of prescription opioids.

FACTS AND PROCEDURE

¶3 Since the mid-1990s, Appellant Janssen Pharmaceuticals, Inc. (and its related entities), a wholly-owned subsidiary of Appellant Johnson & Johnson (collectively "J&J"), has manufactured, marketed, and sold prescription opioids in Oklahoma. J&J specifically manufactured two FDA-approved Schedule II[3] opioid medications: (1) Duragesic—a transdermal patch that provides a controlled dose of pharmaceutical fentanyl[4]; and (2) Nucynta and Nucynta ER—tablets with

[3] The Drug Enforcement Administration ("DEA") classifies drugs that contain controlled substances into five "schedules" based on currently accepted medical use in the U.S. and abuse potential. Schedule I controlled substances have no accepted medical use. Schedules II through V controlled substances do have medical use but range from high potential for abuse (Schedule II) to low potential for abuse (Schedule V). *See, e.g.*, Uniform Controlled Dangerous Substances Act, 63 O.S., §§ 2-201 to -212.

[4] *See* Duragesic Label 3, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/19813s039lbl.pdf. The Court notes that Fentanyl is a synthetic opioid used as a surgical anesthetic and intravenous pain reliever for postoperative pain; it is not an illicit drug.

tapentadol.[5] J&J also manufactured a Schedule IV opioid medication: Ultram and Ultram Extended Release—tablets with tramadol.[6] J&J marketed several other medications containing tramadol.

¶4 The State presented evidence that J&J used branded and unbranded marketing, which actively promoted the concept that physicians were undertreating pain. Ultimately, the State argued J&J overstated the benefits of opioid use, downplayed the dangers, and failed to disclose the lack of evidence supporting long-term use in the interest of increasing J&J's profits.

¶5 J&J no longer promotes any prescription opioids and has not done so for several years. J&J ceased to actively promote its Schedule II branded products by 2015. Specifically, J&J ceased to actively promote Duragesic in 2007, and it divested its U.S. Nucynta product line in 2015. Even with J&J's marketing practices, these two Schedule II medications amounted to less than 1% of all Oklahoma opioid prescriptions. Overall, J&J sold only 3% of all prescription opioids statewide, leaving the other opioid manufacturers named in this suit responsible for selling 97% of all prescription opioids.[7]

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[5] *See* Nucynta ER, Highlights of Prescribing Information, 1 (2018), *available at* https://www.nucynta.com/assets/pdf/Nucynta%20IR%20for%20web_02d.pdf.

[6] *See* Ultram ER, Highlights of Prescribing Information 1 (2017), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021692s015lbl.pdf.

[7] The district court's judgment recognizes that J&J formerly owned two companies that produced and sold opioid raw materials and active pharmaceutical ingredients (APIs) used in opioid medications. The DEA authorized the sales of the raw materials under a federal regulatory scheme. The State conceded that the federally controlled sale of opioid raw materials and APIs was not a basis for imposing liability. The companies formally owned by J&J also did not

¶6 On June 30, 2017, the State sued three opioid manufacturers—J&J (and its related entities[8]), Purdue Pharma L.P. (and its related entities[9]), and Teva Pharmaceuticals USA, Inc. (and its related entities[10]) alleging the companies deceptively marketed opioids in Oklahoma. The State settled with the other opioid manufacturers[11] and eventually dismissed all claims against J&J except public nuisance. The district court conducted a 33-day bench trial with the single issue being whether J&J was responsible for creating a public nuisance in the marketing and selling of its opioid products. The district court held J&J liable under Oklahoma's public nuisance statute for conducting "false, misleading, and dangerous marketing campaigns" about prescription opioids. The district court ordered that J&J pay $465 million to fund one year of the State's Abatement Plan, which consisted of the district court appropriating money to 21 government

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manufacture, promote, or sell J&J's opioid medications at issue in this case, and the Court agrees that the sale of raw materials and APIs are not a basis for imposing liability in this case.

[8] The State sued Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc., n/k/a Janssen Pharmaceuticals, Inc.

[9] The State sued Purdue Pharma L.P., Purdue Pharma, Inc., and The Purdue Frederick Company.

[10] The State sued Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Allergan, PLC, f/k/a Actavis, PLC, f/k/a Actavis, Inc., f/k/a Watson pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC; and Actavis Pharma, Inc., f/k/a Watson Pharma, Inc.

[11] The State settled with Purdue for $270 million, and the State settled with Teva for $85 million.

programs for services to combat opioid abuse.[12] The amount of the judgment against J&J was not based on J&J's percentage of prescription opioids sold. The district court also did not take into consideration or grant J&J a set-off for the settlements the State had entered into with the other opioid manufacturers. Instead, the district court held J&J responsible to abate alleged harms done by all opioids, not just opioids manufactured and sold by J&J.

¶7 J&J appealed. The State cross-appealed contending that J&J should be responsible to pay for 20 years of the State's Abatement Plan, or approximately $9.3 billion to fund government programs. This Court retained the appeal.

[12] The district court appropriated the funds to the following governmental programs:

Opioid Use Disorder Treatment Program	$232,947,710
Addiction Treatment – Supplementary Services	$ 31,769,011
Public Medication and Disposal Programs	$ 139,883
Screening, Brief Intervention and Referral to Treatment (SBIRT) Program	$ 56,857,054
Pain Prevention and Non-Opioid Pain Management Therapies	$103,277,835
Expanded and Targeted Naloxone Distribution and Overdose Prevention Education	$ 1,585,797
Medical Case Management/Consulting (Project Echo)	$ 3,953,832
Developing and Disseminating NAS Treatment Evaluation and Standards	$ 107,683
Development of NAS as a Required Reportable Condition	$ 181,983
Implementing Universal Substance Use Screening for Pregnant Women	$ 1,969,000
Medical Treatment for Infants Born with NAS or Opioid Withdrawal	$ 20,608,847
Investigatory and Regulatory Actions	$ 500,000
Additional Staffing for OBN Additional Staffing for Oklahoma Licensure Boards Additional Staffing for Oklahoma Veterinary Board Additional Staffing for Oklahoma State Osteopathic Board Additional Staffing for Oklahoma Board of Nursing Additional Staffing for Oklahoma Board of Medical Licensure and Supervision Additional Staffing for Oklahoma Board of Dentistry Additional Staffing for Office of the Chief Medical Examiner Additional Staffing for Office of the Attorney General Additional Staffing for Medicaid Fraud Control Unit	$ 11,101,076
TOTAL	**$465,026,711**

¶8 The issue before this Court is whether the district court correctly determined that J&J's actions in marketing and selling prescription opioids created a public nuisance. We hold it did not. The nature of the nuisance claim pled by the State is the marketing, selling, and overprescribing of opioids manufactured by J&J. This Court has not extended the public nuisance statute to the manufacturing, marketing, and selling of products, and we reject the State's invitation to expand Oklahoma's public nuisance law.

¶9 In reaching this decision, we do not minimize the severity of the harm that thousands of Oklahoma citizens have suffered because of opioids. However grave the problem of opioid addiction is in Oklahoma, public nuisance law does not provide a remedy for this harm.

STANDARD OF REVIEW

¶10 This public nuisance action comes to us as an appeal from a judgment rendered in a bench trial. The district court's judgment presented for review is a compilation of both findings of facts and conclusions of law. *K & H Well Serv., Inc. v. Tcina, Inc.*, 2002 OK 62, ¶ 9, 51 P.3d 1219, 1223. "When, as here, the case is tried to the court, its determination of facts [is] accorded the same force as those made by a well-instructed jury." *Id.* Our case law instructs that where "any competent evidence supports the trial court's findings of fact, the same will be affirmed." *Id.*

¶11 An action for abatement of a nuisance is equitable in nature. *See, e.g.*, *Jackson v. Williams*, 1985 OK 103, ¶ 9, 714 P.2d 1017, 1020. "In a case of

equitable cognizance, a judgment will be sustained on appeal unless it is found to be against the clear weight of the evidence or is contrary to law or established principles of equity." *McGinnity v. Kirk*, 2015 OK 73, ¶ 8, 362 P.3d 186, 190. When reviewing a case at equity, this Court is not bound by the district court's findings and will consider the whole record and weigh the evidence. *Harrell v. Samson Res. Co.*, 1998 OK 69, ¶ 31, 980 P.2d 99, 107.

¶12 Issues in this appeal concern the district court's legal interpretation of Oklahoma's nuisance statutes, specifically 51 O.S.2011, §§ 1 and 2. Statutory construction poses a question of law. *State ex rel. Prot. Health Servs. State Dep't of Health v. Vaughn*, 2009 OK 61, ¶ 9, 222 P.3d 1058, 1064. We review issues of law *de novo*, "since an appellate court has plenary, independent and non-deferential authority to reexamine a trial court's legal rulings." *Id.*

DISCUSSION

I. ORIGINS AND HISTORY OF OKLAHOMA PUBLIC NUISANCE LAW

¶13 Public nuisance began as a criminal remedy primarily employed to protect and preserve the rights and property shared by the public. It originated from twelfth-century England where it was a criminal writ to remedy actions or conditions that infringed on royal property or blocked public roads or waterways. Michelle L. Richards, *Pills, Public Nuisance, and Parens Patriae: Questioning the Propriety of the Posture of the Opioid Litigation*, 54 U. Rich. L. Rev. 405, 418 (2020). The king had the authority to bring such claims, seeking only injunction or abatement as

remedies. During the sixteenth century, other individuals began to bring private nuisance claims seeking only injunctive relief when they had a "special" injury. *Id.*

¶14 Public nuisance came to cover a large, miscellaneous and diversified group of minor criminal offenses. Restatement (Second) of Torts § 821B cmt. b (Am. Law Inst. 1979). The offenses involved an "interference with the interests of the community at large—interests that were recognized as rights of the general public entitled to protection." *Id.* The Restatement (Second) of Torts explained the interests as follows:

> Interference with the public health, as in the case of keeping diseased animals or the maintenance of a pond breeding malarial mosquitoes; with the public safety, as in the case of the storage of explosives in the midst of a city or the shooting of fireworks in the public streets; with the public morals, as in the case of houses of prostitution or indecent exhibitions; with the public peace, as by loud and disturbing noises; with the public comfort, as in the case of widely disseminated bad odors, dust and smoke; with the public convenience, as by the obstruction of a public highway or a navigable stream; and with a wide variety of other miscellaneous public rights of a similar kind.

Id.

¶15 Public nuisance evolved into a common law tort. It covered conduct, performed in a location within the actor's control, which harmed those common rights of the general public. *Id.* It has historically been linked to the use of land by the one creating the nuisance. *Nichols v. Mid-Continent Pipe Line Co.*, 1996 OK 118, ¶ 8, 933 P.2d 272, 276. A public entity that proceeds against the one in control of the nuisance may only seek to abate, at the expense of the one in control of the

nuisance. Courts have limited public nuisance claims to these traditional bounds. *See, e.g.*, *In re Lead Paint Litig.*, 924 A.2d 484, 499 (N.J. 2007).

¶16 Oklahoma's nuisance statute codifies the common law. *Nichols*, 1996 OK 118, ¶ 8, 933 P.2d at 276. It states:

> A nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either:
>
> First. Annoys, injures or endangers the comfort, repose, health, or safety of others; or
> Second. Offends decency; or
> Third. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake or navigable river, stream, canal or basin, or any public park, square, street or highway; or
> Fourth. In any way renders other persons insecure in life, or in the use of property, provided, this section shall not apply to preexisting agricultural activities.

50 O.S.2011, § 1. The Oklahoma Legislature has long defined public nuisance as a nuisance that contemporaneously affects an entire community or large group of people, but need not damage or annoy equally to all. *Id.* § 2.

¶17 Oklahoma's nuisance and public nuisance statutes became law in 1910. *Id.* §§ 1, 2. The Legislature has amended the nuisance statute once, to exempt certain preexisting agricultural activities. *See* Act of May 12, 1980, Ch. 189, Sec. 1, 1980 Okla. Sess. Laws, 425, 425. The Legislature has never amended the public nuisance statute. 50 O.S.2011, § 2.

¶18 For the past 100 years, our Court, applying Oklahoma's nuisance statutes, has limited Oklahoma public nuisance liability to defendants (1) committing crimes constituting a nuisance, or (2) causing physical injury to property or participating in

an offensive activity that rendered the property uninhabitable.[13] When the Legislature reenacts a statute that has been previously construed by a court of last resort in the same or substantially the same terms, we presume the Legislature is familiar with its construction and adopted such construction as an integral part of the statute. *Special Indem. Fund v. Bedford,* 1993 OK 60, ¶ 8, 852 P.2d 150, 154. We are not limiting public nuisance to a defendant's use of real property as the Dissent asserts. This Court relies on Oklahoma precedent, and the limitations set by Oklahoma case law guide our consideration of whether J&J's conduct created a public nuisance.

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[13] *See, e.g.*, *Nichols*, 1996 OK 118, 933 P.2d 272 (pollution from a leaking oil pipeline considered a public nuisance); *Sharp v. 251st St. Landfill, Inc.*, 1991 OK 41, 810 P.2d 1270 (pollution in water from a waste disposal facility considered a public nuisance); *State ex rel. Fallis v. Mike Kelly Constr. Co.*, 1981 OK 158, 638 P.2d 455 (open saloon in violation of Oklahoma law not considered a public nuisance); *State ex rel. Field v. Hess*, 1975 OK 123, 540 P.2d 1165 (obscene works in violation of Oklahoma law considered a public nuisance); *Mackey v. State ex rel. Harris*, 1972 OK 37, 495 P.2d 105 (conduct outside of saloon considered a public nuisance); *Phillips v. Altman*, 1966 OK 46, 412 P.2d 199 (pollution by crude oil considered a public nuisance); *Crushed Stone Co. v. Moore*, 1962 OK 65, 369 P.2d 811 (limestone quarry dust considered a public nuisance); *Boudinot v. State ex rel. Cannon*, 1959 OK 97, 340 P.2d 268 (forty cats in a home considered a public nuisance); *Updegraff v. City of Norman*, 1955 OK 195, 287 P.2d 909 (overgrown hedges obstructing street considered a public nuisance); *State ex rel. Brown v. Armstrong*, 1952 OK 70, 241 P.2d 959 (barn in disrepair considered a public nuisance); *Peerson v. Mitchell*, 1950 OK 329, 239 P.2d 1028 (harboring a vicious dog in violation of Oklahoma law considered a nuisance); *Goodall v. City of Clinton*, 1945 OK 235, 161 P.2d 1011 (installation of toilets causing sewage backflow and pollution to city water considered a public nuisance); *City of Oklahoma City v. West*, 1931 OK 693, 7 P.2d 888 (dumping of untreated sewage considered a public nuisance); *McNulty v. State ex rel. Seaver*, 1923 OK 509, 217 P. 467 (gambling on dog races in violation of Oklahoma law considered a public nuisance); *Jones v. State*, 1912 OK 806, 132 P. 319 (gambling on horse races in violation of Oklahoma law considered a public nuisance); *State ex rel. West v. State Capital Co.*, 1909 OK 200, 103 P. 1021 (advertising liquor in violation of Oklahoma law was not a nuisance); *Territory v. Long Bell Lumber Co.*, 1908 OK 263, 99 P. 911 (monopoly in violation of Oklahoma law was a nuisance); *see also Swanson v. City of Tulsa*, 1981 OK CR 101, 633 P.2d 1256 (smoking indoors in violation of Oklahoma law considered a public nuisance); *Gordon v. State*, 1955 OK CR 100, 289 P.2d 396 (dance hall activities in violation of Oklahoma law considered a public nuisance).

¶19 The State's allegations in this case do not fit within Oklahoma nuisance statutes as construed by this Court. The Court applies the nuisance statutes to unlawful conduct that annoys, injures, or endangers the comfort, repose, health, or safety of others. But that conduct has been criminal or property-based conflict. Applying the nuisance statutes to lawful products as the State requests would create unlimited and unprincipled liability for product manufacturers; this is why our Court has never applied public nuisance law to the manufacturing, marketing, and selling of lawful products.[14]

II. OKLAHOMA'S PUBLIC NUISANCE LAW DOES NOT COVER THE STATE'S ALLEGED HARM.

¶20 The central focus of the State's complaints is that J&J was or should have been aware and that J&J failed to warn of the dangers associated with opioid abuse and addiction in promoting and marketing its opioid products. This classic articulation of tort law duties—to warn of or to make safe—sounds in product-related liability.[15]

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[14] The cases where this Court has considered whether a defendant was liable for public nuisance involving the marketing or selling of goods was when the marketing or selling of that product was illegal. *See, e.g.*, *Hess*, 1975 OK 123, 540 P.2d 1165; *State Capital Co.*, 1909 OK 200, 103 P. 1021.

[15] *See, e.g.*, *Kirkland v. Gen. Motors Corp.*, 1974 OK 52, ¶ 0, 521 P.2d 1353, 1355 (Syllabus by the Court) (adopting the Restatement (Second) of Torts § 402A (Am. Law Inst. 1965)); *Cunningham v. Charles Pfizer & Co., Inc.*, 1974 OK 146, ¶¶ 24-32, 532 P.2d 1377, 1380-81 (holding that the "defendant had a duty to warn plaintiff or his parents of the risk of contracting polio from the vaccine and the failure to warn of this risk rendered the vaccine defective within the meaning of [the Restatement (Second) of Torts] § 402A").

¶21 Public nuisance and product-related liability are two distinct causes of action, each with boundaries that are not intended to overlap. *State v. Lead Indus. Ass'n, Inc.*, 951 A.2d 428, 456 (R.I. 2008). The Restatement explains as follows:

> Tort suits seeking to recover for public nuisance have occasionally been brought against the makers of products that have caused harm, such as tobacco, firearms, and lead paint. These cases vary in the theory of damages on which they seek recovery, but often involve claims for economic losses the plaintiffs have suffered on account of the defendant's activities; they may include the costs of removing lead paint, for example, or of providing health care to those injured by smoking cigarettes. Liability on such theories has been rejected by most courts, and is excluded by this Section, because the common law of public nuisance is an inapt vehicle for addressing the conduct at issue. Mass harms caused by dangerous products are better addressed through the law of products liability, which has been developed and refined with sensitivity to the various policies at stake.

Restatement (Third) of Torts: Liab. for Econ. Harm § 8 cmt. g (Am. Law. Inst. 2020).

¶22 The U.S. Court of Appeals for the Eighth Circuit explained this concept in *Tioga Public School District No. 15 of Williams County, State of North Dakota v. United States Gypsum Co.*, 984 F.2d 915 (8th Cir. 1993). The *Tioga* court examined North Dakota cases applying the state's nuisance statute and concluded that North Dakota courts only applied the statute in the classic context of a landowner or other person in control of property conducting an activity on his or her land in such a manner as to interfere with the property rights of a neighbor. *Id.* at 920. The Eighth Circuit determined that the North Dakota Supreme Court would not extend its nuisance statute—which is the source of, and remains identical to Oklahoma's nuisance statute, *see* O.S. 1910, §§ 4250-4251 (citing Dakota Terr.

Comp. Laws §§ 4681-4682 (1887))—to cases involving the sale of products. *Id.* In reaching its decision, the *Tioga* court warned:

> Under Tioga's theory, any injury suffered in North Dakota would give rise to a cause of action under [its nuisance statute] regardless of the defendant's degree of culpability or of the availability of other traditional tort law theories of recovery. Nuisance thus would become a monster that would devour in one gulp the entire law of tort, a development we cannot imagine the North Dakota legislature intended when it enacted the nuisance statute.

Tioga, 984 F.2d at 921. And the court refused to extend public nuisance liability to harms caused by asbestos.

¶23 We agree with the *Tioga* court's analysis of nuisance law and the sale of products. Public nuisance is fundamentally ill-suited to resolve claims against product manufacturers, including J&J in this case.[16] In reaching this decision, we identify three reasons not to extend public nuisance law to envelop J&J's conduct as an opioid manufacturer: (1) the manufacture and distribution of products rarely cause a violation of a public right, (2) a manufacturer does not generally have control of its product once it is sold, and (3) a manufacturer could be held perpetually liable for its products under a nuisance theory. We address each in turn.

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[16] A leading treatise states:

> A product which has caused injury cannot be classified as a nuisance to hold liable the manufacturer or seller for the product's injurious effects, since a defendant who does not control the enterprise in which the product is used is not in the situation of one who creates a nuisance; consequently, negligent manufacture or failure to warn of product-caused dangers does not give rise to a nuisance cause of action.

Charles J. Nagy, Jr., American Law of Products Liability § 1:19 (3d ed. 2021).

A. The manufacture and distribution of products rarely cause a violation of a public right.

¶24 One factor in rejecting the imposition of liability for public nuisance in this case is that the State has failed to show a violation of a public right. A public nuisance involves a violation of a public right; a public right is more than an aggregate of private rights by a large number of injured people. *See Territory v. Long Bell Lumber Co.*, 1908 OK 263, ¶ 23, 99 P. 911, 917; Restatement (Second) of Torts § 821B cmt. g (Am. Law. Inst. 1979); *see also City of Chicago v. Am. Cyanamid Co.*, 823 N.E.2d 126, 131 (Ill. 2005) (holding a public right is not "an assortment of claimed private individual rights"). Rather, a public right is a right to a public good, such as "an indivisible resource shared by the public at large, like air, water, or public rights-of-way." *Am. Cyanamid Co.*, 823 N.E.2d at 131. Unlike an interference with a public resource,

> [t]he manufacture and distribution of products rarely, if ever, causes a violation of a public right as that term has been understood in the law of public nuisance. Products generally are purchased and used by individual consumers, and any harm they cause—even if the use of the product is widespread and the manufacturer's or distributor's conduct is unreasonable—is not an actionable violation of a public right. . . . The sheer number of violations does not transform the harm from individual injury to communal injury.

Donald Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. Cin. L. Rev. 741, 817 (2003); *see also Lead Indus. Ass'n, Inc.*, 951 A.2d at 448, 454 (holding the right of a child to not be poisoned by lead is a nonpublic right). The damages the State seeks are not for a communal injury but are instead more in

line with a private tort action for individual injuries sustained from use of a lawful product and in providing medical treatment or preventive treatment to certain, though numerous, individuals.

¶25 The State characterizes its suit as an interference with the public right of health. We disagree with the State's characterization. *See City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 116 (Mo. 2007) (en banc) (rejecting the city's argument that its nuisance claim regarding lead paint was an injury to public health). This case does not involve a comparable incident to those in which we have anticipated that an injury to the public health would occur, e.g., diseased animals, pollution in drinking water, or the discharge of sewer on property. *See Okla. Water Res. Bd. v. Tex. Cty. Irrigation & Water Res. Ass'n*, 1984 OK 96, ¶ 15, 711 P.2d 38, 44; *City of Okla. City v. West*, 1931 OK 693, ¶ 15, 7 P.2d 888, 893; *One Hudson Super-Six Auto., Model J, No. 4197, Engine No. 39527 v. State*, 1920 OK 50, ¶ 21, 187 P. 806, 810. Such property-related conditions have no beneficial use and only cause annoyance, injury, or endangerment. In this case, the lawful products, prescription opioids, have a beneficial use in treating pain.

¶26 We consider *City of Chicago v. Berreta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004), instructive on this issue. In *Berreta*, the City of Chicago and Cook County brought public nuisance claims against manufacturers, distributors, and dealers of handguns. The city and county alleged that the manufacturing defendants knowingly oversupplied the market with their products and marketed their products to appeal to those who intended to use them for criminal purposes. *Id.* at 1108.

The state and county sought compensation for the abatement of the nuisance, including costs of medical services, law enforcement efforts, and prosecutions for violations of gun control ordinances. *Id.* at 1106. The Illinois Supreme Court rejected these claims and sustained the trial court's dismissal of the public nuisance claims. The court acknowledged "[t]he tragic personal consequences of gun violence are inestimable." *Id.* at 1105. However, the state and county failed to show an unreasonable interference with a public right. *Id.* at 1116. The *Berreta* court ultimately concluded that a public right to be free from the threat that others "may defy [criminal] laws would permit nuisance liability to be imposed on an endless list of manufacturers, distributors, and retailers of manufactured products." *Id.* It acknowledged the far-reaching effects of a decision otherwise:

> If there is a public right to be free from the threat that others may use a lawful product to break the law, that right would include the right to drive upon the highways, free from the risk of injury posed by drunk drivers. This public right to safe passage on the highways would provide the basis for public nuisance claims against brewers and distillers, distributing companies, and proprietors of bars, taverns, liquor stores, and restaurants with liquor licenses, all of whom could be said to contribute to an interference with the public right.

Id. Similarly, a public right to be free from the threat that others may misuse or abuse prescription opioids—a lawful product—would hold manufacturers, distributors, and prescribers potentially liable for all types of use and misuse of prescription medications. Just as in *Beretta,* the State has failed to show a violation of a public right in this case. *Id.* at 1116 (holding "there is no authority for the unprecedented expansion of the concept of public rights to encompass the right

asserted by plaintiffs"). And as the manufacture and distribution of products rarely cause a violation of a public right, we refuse to expand public nuisance to claims against a product manufacturer.

B. A manufacturer does not have control of its product once it is sold.

¶27 Another factor in rejecting the imposition of liability for public nuisance in this case is that J&J, as a manufacturer, did not control the instrumentality alleged to constitute the nuisance at the time it occurred. *See, e.g.*, *City of Manchester v. Nat'l Gypsum Co.*, 637 F. Supp. 646, 656 (D.R.I. 1986). The State asks this Court to broadly extend the application of the nuisance statute, namely to a situation where a manufacturer sold a product (for over 20 years) that was later alleged to constitute a nuisance. *See Tioga*, 984 F.2d at 920. A product manufacturer's responsibility is to put a lawful, non-defective product into the market. There is no common law tort duty to monitor how a consumer uses or misuses a product after it is sold.[17] Without control, a manufacturer also cannot remove or abate the

[17] *See Bloomington v. Westinghouse Elec. Corp.,* 891 F.2d 611, 614 (7th Cir.1989) (noting the absence of cases "holding manufacturers liable for public or private nuisance claims arising from the use of their product subsequent to the point of sale"); *see also* Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. Cin. L. Rev. at 820 ("The essence of public nuisance law . . . is ending the harmful conduct. This is impossible for the manufacturer or distributor who has relinquished possession by selling or otherwise distributing the product."); Victor E. Schwartz & Phil Goldberg, *The Law of Public Nuisance: Maintaining Rational Boundaries on a Rational Tort,* 45 Washburn L.J. 541, 568 (2006) ("[F]urnishing a product or instrumentality—whether it be chemicals, asbestos, guns, lead paint, or other products—is not the same as having control over that instrumentality.").

nuisance—which is the remedy the State seeks from J&J in this case. *See, e.g.*, *Tioga*, 984 F.2d at 920.[18]

¶28 A public nuisance claim against a gun manufacturer parallels the State's claims against J&J and its opioid production and distribution. We again find *Beretta* persuasive as it discussed a manufacturer's control of its product in determining public nuisance liability. Federal and state laws regulate the manufacture, distribution, and use of both firearms and opioids. As in *Beretta*, the alleged nuisance in this case is several times removed from the initial manufacture and distribution of opioids by J&J. *See Beretta*, 821 N.E.2d at 1137. Multiple agencies and boards across different jurisdictions oversee and enforce statutes and regulations that control the developing, testing, producing, manufacturing, distributing, labeling, advertising, prescribing, selling, possessing, and reselling of prescription opioids; this is a highly regulated industry.

¶29 J&J had no control of its products through the multiple levels of distribution, including after it sold the opioids to distributors and wholesalers, which were then dispersed to pharmacies, hospitals, and physicians' offices, and then prescribed by doctors to patients. J&J also had no control over the laws and regulations that govern the disbursement of its prescription opioids or whether prescribers follow the laws. Regulation of prescription opioids belongs to the federal and state

[18] A seller loses control of its products when they are sold and "lacks the legal right to abate whatever hazards its products may pose; under these circumstances, the purchaser's proper remedies are products liability actions for negligence or breach of warranty rather than a nuisance action." 63A Am. Jur. 2d *Products Liability* § 867 (2021).

legislatures and their agencies. For example, the Oklahoma Legislature passed the Anti-Drug Diversion Act, 63 O.S.Supp.2020, § 2-309A *et seq.*, requiring among other things that all "dispenser[s] of a Schedule II, III, IV or V controlled dangerous substance dispensed pursuant to a valid prescription" to send that information to a central depository, as controlled by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. 63 O.S.2011, § 2-309C. This is known as Oklahoma's Prescription Monitoring Program and allows prescribers to check the prescription history of their patients to determine if the patient has recently obtained identical prescriptions from other doctors. This is just one example of legislation governing prescription opioids over which J&J has no control.

¶30 Even with its influential marketing, J&J ultimately could not control: (1) how wholesalers distributed its products, (2) how regulations and legislation governed the distribution of its products by prescribers and pharmacies; (3) how doctors prescribed its products, (4) how pharmacies dispersed its products, and (5) how individual patients used its product or how a patient responded to its product, regardless of any warning or instruction given.[19] Just as in *Berreta*, J&J did not control the instrumentality (prescription opioids) alleged to constitute the nuisance at the time the nuisance occurred. *See Beretta*, 821 N.E.2d at 1138.

[19] *See also State ex rel. Stenehjem v. Purdue Pharma, L.P.*, No. 08-2018-cv-01300, 2019 WL 2245743, at *13 (N.D. Dist. Ct. May 10, 2019) (holding that "Purdue has no control over its product after it is sold to distributors, then to pharmacies, and then prescribed to consumers, i.e. after it enters the market")

¶31 Even more, J&J could not control how individuals used other pharmaceutical companies' opioids. A manufacturer traditionally does not have a duty to people who use other manufacturers' products.[20] Evidence at trial demonstrated that J&J sold only 3% of all prescription opioids statewide; other pharmaceutical companies were responsible for marketing and selling 97% of the prescription opioids. Yet the district court held J&J responsible for those alleged losses caused by other pharmaceutical companies' opioids. Where the law does not expressly allow, J&J should not be responsible for the harms caused by opioids that it never manufactured, marketed, or sold. To expand public nuisance to cover a manufacturer's production and sale of a product would cause the manufacturer to be responsible for products it did not produce. We refuse to expand Oklahoma's nuisance law so greatly.

¶32 Further, J&J cannot abate the alleged nuisance. The condition, opioid use and addiction, would not cease to exist even if J&J pays for the State's Abatement Plan. *See, e.g.*, *id.* at 1137 (holding the nuisance would not cease to exist even if the defendants stopped selling firearms). The State's Abatement Plan is not an abatement in that it does not stop the act or omission that constitutes a nuisance. The abatement is not the opioids themselves. Neither is it an injunction to halt the promoting and marketing of opioids as J&J has not promoted opioids for several

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[20] *See* Honorable Luther J. Strange III, *A Prescription for Disaster: How Local Governments' Abuse of Public Nuisance Claims Wrongly Elevates Courts and Litigants into A Policy-Making Role and Subverts the Equitable Administration of Justice*, 70 S.C. L. Rev. 517, 537 (2019).

years. It is instead an award to the State to fund multiple governmental programs for medical treatment and preventive services for opioid abuse, investigatory and regulatory activities, and prosecutions for violations of Oklahoma law regarding opioid distribution and use—activities over which J&J has no control. Our Court, over the past 100 years in deciding nuisance cases, has never allowed the State to collect a cash payment from a defendant that the district court line-item apportioned to address social, health, and criminal issues arising from conduct alleged to be a nuisance. We therefore reject the district court's remedy in this case as it does not abate the alleged nuisance; it does not abate the opioid epidemic, any act or omission of J&J, or any act or omission of other opioid manufacturers.

C. A manufacturer cannot be held perpetually liable for its products.

¶33 The final factor in rejecting the imposition of liability for public nuisance in this case is the possibility that J&J could be held continuously liable for its products. Nuisance claims against products manufacturers sidestep any statute of limitations. *See, e.g.*, *Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W.2d 513, 521 (Mich. Ct. App. 1992). In this case, the district court held J&J responsible for products that entered the stream of commerce more than 20 years ago, shifting the wrong from the manufacturing, marketing, or selling of a product to its continuing presence in the marketplace. The State's public nuisance claims could hold manufacturers perpetually liable for their products; Oklahoma law has

rejected such endless liability in all other traditional tort law theories.[21] We again reject perpetual liability here.

III. THIS COURT WILL NOT EXTEND OKLAHOMA PUBLIC NUISANCE LAW TO THE MANUFACTURING, MARKETING, AND SELLING OF PRESCRIPTION OPIOIDS.

¶34 Extending public nuisance law to the manufacturing, marketing, and selling of products—in this case, opioids—would allow consumers to "convert almost every products liability action into a [public] nuisance claim." *Cty. of Johnson v. U.S. Gypsum Co.*, 580 F. Supp. 284, 294 (E.D. Tenn. 1984). As one court explained:

> All a creative mind would need to do is construct a scenario describing a known or perceived harm of a sort that can somehow be said to relate back to the way a company or an industry makes, markets and/or sells its non-defective, lawful product or service, and a public nuisance claim would be conceived and a lawsuit born.

New York ex rel. Spitzer v. Sturm, Ruger & Co., 761 N.Y.S.2d 192, 196 (App. Div. 2003).

¶35 Other jurisdictions have refused to allow products-based public nuisance claims, signaling a clear national trend to limit public nuisance to land or property use. *See, e.g.*, *Beretta*, 821 N.E.2d at 1116; *In re Lead Paint Litig.*, 924 A.2d at 505 (ruling "were we to permit these complaints to proceed, we would stretch the concept of public nuisance far beyond recognition and would create a new and

[21] For example, a typical Oklahoma negligence action and products liability action have a statute of limitations of two years. 12 O.S.2011, § 95(a)(3); *Kirkland*, 1974 OK 52, ¶ 24, 521 P.2d at 1362.

entirely unbounded tort antithetical to the meaning and inherent theoretical limitations of the tort of public nuisance"); *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055 (N.Y. 2001) (rejecting the contention that gun manufacturers have a general duty to lessen the risk of illegal gun trafficking because they have the power to restrict marketing and product distribution); *Sturm, Ruger & Co., Inc.*, 761 N.Y.S.2d at 196 (ruling "giving a green light to a common-law public nuisance cause of action will, in our judgment, likely open the courthouse doors to a flood of limitless, similar theories of public nuisance, not only against these defendants, but also against a wide and varied array of other commercial and manufacturing enterprises and activities"); *Lead Indus. Ass'n, Inc.*, 951 A.2d at 456 (holding "[t]he law of public nuisance never before has been applied to products, however harmful"); *see also, e.g.*, *Sills v. Smith & Wesson Corp.*, No. 99C-09-283-FSS, 2000 WL 33113806 (Del. Super. Ct. Dec. 1, 2000) (unpublished) (holding the design, marketing, and advertising of handguns was not a public nuisance because the state did not recognize a cause of action for public nuisance based upon products).

¶36 In the same way, this Court will not extend Oklahoma public nuisance law to J&J's conduct in the manufacturing, marketing, and selling of prescription opioids. We follow North Dakota and South Dakota courts who rejected public nuisance claims against the same defendants for the same conduct as complained of in this case. Although unpublished opinions, we find both courts' reasonings for dismissing the claims persuasive as the courts applied nuisance statutes identical

to Oklahoma's nuisance statute.[22] The North Dakota court dismissed the case because public nuisance law does not apply to cases involving the sale of goods. *State ex rel. Stenehjem v. Purdue Pharma, L.P.*, No. 08-2018-cv-01300, 2019 WL 2245743, at *13 (N.D. Dist. Ct. May 10, 2019). The South Dakota court dismissed

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[22] North Dakota's nuisance statute states:

> A nuisance consists in unlawfully doing an act or omitting to perform a duty, which act or omission:
> 1. Annoys, injures, or endangers the comfort, repose, health, or safety of others;
> 2. Offends decency;
> 3. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake, navigable river, bay, stream, canal, basin, public park, square, street, or highway; or
> 4. In any way renders other persons insecure in life or in the use of property.

N.D. Cent. Code. § 42-01-01 (2021). North Dakota defines public nuisance as follows:

> A public nuisance is one which at the same time affects an entire community or neighborhood or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal.

N.D. Cent. Code. § 42-01-06 (2021).

South Dakota's nuisance statute states:

> A nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either:
> (1) Annoys, injures, or endangers the comfort, repose, health, or safety of others;
> (2) Offends decency;
> (3) Unlawfully interferes with, obstructs, or tends to obstruct, or renders dangerous for passage, any lake or navigable river, bay, stream, canal, or basin, or any public park, square, sidewalk, street, or highway;
> (4) In any way renders other persons insecure in life, or in the use of property.

S.D. Codified Laws § 21-10-1 (2021). South Dakota defines public nuisance as follows:

> A public nuisance is one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal. Every other nuisance is private.

S.D. Codified Laws § 21-10-3 (2021).

the public nuisance claim based on the same reason as the North Dakota court and held the defendants did not have control of the instrumentality of the nuisance when the damage occurred. Tr. of Bench Decision at 17-24, *State ex rel. Ravnsborg v. Purdue Pharma L.P.*, No. 32CIV18-000065 (S.D. Cir. Ct. Jan. 13, 2021) (Appellants' App. in Supp. of Rep. Br. and Answer Br. to Counter-Appeal 169-71).

¶37 The common law criminal and property-based limitations have shaped Oklahoma's public nuisance statute. Without these limitations, businesses have no way to know whether they might face nuisance liability for manufacturing, marketing, or selling products, i.e., will a sugar manufacturer or the fast food industry be liable for obesity, will an alcohol manufacturer be liable for psychological harms, or will a car manufacturer be liable for health hazards from lung disease to dementia or for air pollution. We follow the limitations set by this Court for the past 100 years: Oklahoma public nuisance law does not apply to J&J's conduct in manufacturing, marketing, and selling prescription opioids.

CONCLUSION

¶38 This case challenges us to rethink traditional notions of liability and causation. Tort law is ever-changing; it reflects the complexity and vitality of daily life.[23] The State presented us with a novel theory—public nuisance liability for the marketing and selling of a legal product, based upon the acts not of one

[23] *Hamilton*, 750 N.E.2d at 1068.

manufacturer, but an industry. However, we are unconvinced that such actions amount to a public nuisance under Oklahoma law.

¶39 The Court has allowed public nuisance claims to address discrete, localized problems, not policy problems. Erasing the traditional limits on nuisance liability leaves Oklahoma's nuisance statute impermissibly vague.[24] The district court's expansion of public nuisance law allows courts to manage public policy matters that should be dealt with by the legislative and executive branches; the branches that are more capable than courts to balance the competing interests at play in societal problems. Further, the district court stepping into the shoes of the Legislature by creating and funding government programs designed to address social and health issues goes too far. This Court defers the policy-making to the legislative and executive branches and rejects the unprecedented expansion of public nuisance law. The district court erred in finding J&J's conduct created a public nuisance.

DISTRICT COURT'S JUDGMENT REVERSED.

Darby, C.J., Kane, V.C.J., Winchester, Gurich, and Kuehn (**by separate writing**), JJ., concur.

Edmondson, J. (**by separate writing**), dissents.

Kauger and Combs, JJ., disqualified.

Rowe, J., recused.

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[24] *See, e.g.*, *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212 (2018) (holding statutes must be clear enough to give ordinary people fair note of the conduct a statute proscribes and to prevent arbitrary enforcement).