UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
LAREDO DIVISION

COUNTY OF WEBB, TEXAS

Plaintiff,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; ENDO HEALTH SOLUTIONS, INC; ENDO PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; WATSON LABORATORIES, INC.; ALLERGAN PLC; ACTAVIS PHARMA, INC.; ACTAVIS, LLC; INSYS THERAPEUTICS, INC.; McKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION; EXPRESS SCRIPTS HOLDING COMPANY; EXPRESS SCRIPTS, INC; CVS HEALTH CORPORATION; CAREMARK RX, L.L.C.; CAREMARKPCS HEALTH, L.L.C.; CAREMARK, L.L.C.; CAREMARKPCS, L.L.C.; UNITEDHEALTH GROUP INCORPORATED; OPTUM, INC.; OPTUMRX, INC.; PRIME THERAPEUTICS LLC; NAVITUS HOLDINGS, LLC; NAVITUS HEALTH SOLUTIONS, LLC DOES 1-100,

Defendants.

Civil Action No.

COMPLAINT AND JURY DEMAND

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PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff, the County of Webb by and through the undersigned attorneys, (hereinafter ("Plaintiff," "Webb," or "Webb County") against Defendants: Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Abbott Laboratories; Abbott Laboratories, Inc.; Mallinckrodt PLC; Mallinckrodt LLC, Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Watson Laboratories, Inc.; Allergan PLC; Actavis Pharma, Inc.; Actavis, LLC; Insys Therapeutics, Inc. (collectively, "Manufacturer Defendants" or "Defendants"); McKesson Corporation, Cardinal Health, Inc.; AmerisourceBergen Drug Corporation; (collectively, "Distributor Defendants" or "Defendants"); Express Scripts Holding Company; Express Scripts, Inc.; CVS Health Corporation (in its pharmacy benefit management capacity); Caremark Rx, L.L.C.; CaremarkPCS Health, L.L.C. d/b/a CVS/Caremark; Caremark, L.L.C.; CaremarkPCS, L.L.C.; UnitedHealth Group Incorporated; Optum, Inc.; OptumRx Inc..; Prime Therapeutics LLC; Navitus Holdings, LLC; Navitus Health Solutions, LLC (collectively, "PBM Defendants" or "Defendants"); and DOES 1 through 100 inclusive (collectively, "Defendants") alleges as follows:

I. INTRODUCTION

1. Defendants have caused an opioid epidemic that has resulted in economic, social and emotional damage to virtually every community in the United States and tens of thousands of Americans. It is indiscriminate and ruthless. It has impacted across demographic lines harming every economic class, race, gender and age group. It is killing Americans—almost one hundred (100) every day.[1] Prescription and illegal opioids account for more than sixty percent (60%) of

[1] *Drug overdose deaths in the United States continue to increase in 2015*, CTRS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited June 28, 2017)

overdose deaths in the United States, a toll that has quadrupled over the past two decades, according to the United States Centers for Disease Control ("CDC"). Drug overdose deaths in 2015 far outnumbered deaths from auto accidents or guns."[2]

2. Prescription drug manufacturers, wholesalers/distributors and pharmacy benefit managers ("PBMs") have created this epidemic. The manufacturers make the opioids and lie about their efficacy and addictive properties. The wholesalers distribute the opioids from the point of manufacture to the point of delivery to the patient. And the PBMs control, through their formularies, which drugs go where and how they are paid for.

3. Each defendant group profits enormously from the movement of the opioid products. And they do so at the expense of Plaintiff, Webb County, and communities like it nationwide. Each has incentives to move certain drugs over others. Defendants themselves create the incentives and share in their perversity- usually without disclosure to those who reasonably rely on Defendants to abide by their federal, state and common law duties.

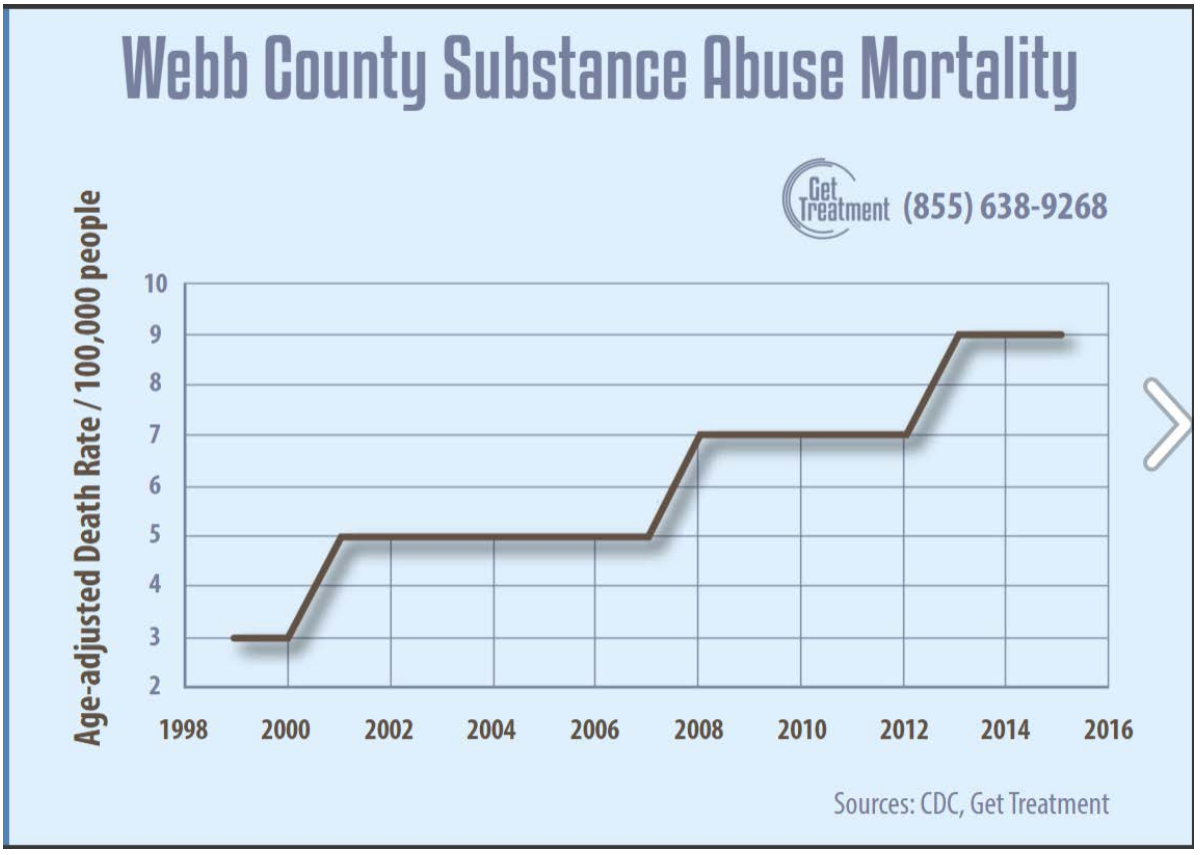
4. Each defendant group bears culpability in the crisis and is a necessary party to addressing the damage it has wreaked, including the costs of abatement. The drug manufacturers' lies would matter not, if the drugs themselves were not distributed. And no drug would reach any community were it not on a PBM formulary, which specifies which drugs will be covered and, in turn, paid for by private or public insurers.

5. The devastating impact of opioid abuse cannot be overstated. After years of decreasing death rates in the United States, they are now on the rise fueled by an increase in opioid-related drug overdose deaths. Drug overdoses are now the leading cause of death for Americans

[2] Jim Malewitz, *Amid opioid investigation, Texas and other states demand drug company documents*, THE TEXAS TRIBUNE, Sep. 19, 2017, https://www.texastribune.org/2017/09/19/amid-opioid-investigation-texas-and-other-states-demand-drug-company-d/

under the age of fifty (50). The number of Americans who died of drug overdose deaths in 2017 was roughly equal the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.[3]

6. Overdose deaths have surged in Webb County because of Defendants' conduct.[4]



7. In Laredo, the largest city in Webb County, "the number 1 drug to overdose on is heroin followed by cocaine, alcohol and medications," explains Assistant Police Chief Jesus R. Torres.[5]

[3] Nicholas Kristof, *Opioids, a Mass Killer We're Meeting With a Shrug*, NEW YORK TIMES, Jun. 22, 2017, https://www.nytimes.com/2017/06/22/opinion/opioid-epidemic-health-care-bill.html

[4] Texas state drug mortality statistics by county, Get Treatment, Jun. 19, 2017, https://issuu.com/gettrreatment/docs/texas_state_drug_mortality_statisti

[5] Cesar Rodriguez, *Prescription Opioid Abuse a growing Concern in Laredo*, *LAREDO MORNING TIMES*, Oct. 7, 2017, http://www.lmtonline.com/local/article/Prescription-opioid-abuse-a-growing-concern-in-12261549.php

8. Defendants' opioid scheme causes heroin abuse. A 2015 study found that four out of five users reported that their addiction started with opioid pain relievers.[6] In this way, prescription opioids—now, thanks to Defendants, provided to patients for everyday conditions such as chronic knee pain- can operate as a "gateway" drug to heroin use and involvement with the illegal drug market.

9. In addition, Webb County is now having to allocate substantial taxpayer dollars, resources, staff, energy and time to address the damage the opioid scourge has left in its wake and to address its many casualties. Fire and emergency medical services are over-utilized because of an increased number of opioid-related overdoses. The burden on law enforcement is substantially increased by opioid-related crimes related to prescription opioid theft, diversion, and sales on the black market. County jails, hospitals, clinics, treatment centers, intervention programs, social workers, courts, schools—virtually every aspect of County service and budget has been significantly and negatively impacted by this Defendant-made epidemic.

10. Defendants' efforts to deceive and make opioids widely accessible have also resulted in a windfall of profits to Defendants. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. While Americans represent only five percent (5%) of the world's population, they consume eighty percent (80%) of the world production of prescription opioids.[7]

11. The recipe for generating sky-high revenues is clear: patients who are prescribed opioids become physically and psychologically dependent on the drugs. When these opioid-

[6] NAT'L SAFETY COUNCIL, PRESCRIPTION NATION 2016: ADDRESSING AMERICA'S DRUG EPIDEMIC 9 (2016), http://www.nsc.org/RxDrugOverdoseDocuments/Prescription-Nation-2016-American-Drug-Epidemic.pdf

[7] Dina Gusovsky, *Americans Consume Vast Majority of the World's Opioids*, CNBC, Apr. 27, 2016 9:13 AM, http://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioid-supply.html

addicted patients can no longer legally obtain opioids, they seek the drugs on the black market or turn to heroin which provides a similar high to prescription opioids. By introducing and injecting a massive supply of opioids into the far larger population of patients with chronic pain, Defendants have generated a loyal customer base: hundreds of thousands of patients whose addiction guarantees an insatiable demand for the drugs and consistently high profits.

12. The scheme begins with Manufacturer Defendants who deliberately polluted the national marketplace, including in Webb County, with falsehoods regarding the efficacy of opioids to treat chronic pain and the risks of addiction. Using hired guns, advertising and marketing materials, the Manufacturers promoted fictitious concepts of "pseudoaddiction," advocated that signs of addiction should be treated with more opioids, falsely claimed that opioid dependence and withdrawal could be easily managed and denied the risks of higher and protracted opioid dosages.

13. Wholesale distributors, such as the Distributor Defendants, could have and should have been able to stem the excess flow of opioids into Texas and Webb County, but they did not. Wholesale drug distributors receive prescription opioids from drug manufacturers and transfer the opioids to hospitals, pharmacies, doctors, and other healthcare providers who then dispense the drugs to patients. Distributors are required by federal and state law to control and report unlawful drug diversions. The Distributor Defendants purposefully ignored these responsibilities, lobbied for higher reporting thresholds and pocketed profits at the expense of Webb County.

14. The Manufacturer and Distributer Defendants' efforts to promote their scheme to distribute unnecessary opioids would not have succeeded had the opioids not been paid for, reimbursed, or covered by public and private pharmacy benefit plans.

15. PBMs are a necessary party to any discussion of opioid-related misconduct committed by pharmaceutical supply chain actors, and its ramifications. Neither courts nor the governmental entities left to clean up the opioid crisis can address the flow of opioids or the costs

of abatement without including the parties that are in fact capable of controlling that flow, across all manufacturers and distributors, *i.e.* the PBMs.

16. PBMs are the gatekeepers to the vast majority of opioid prescriptions filled in the United States. Caremark, Express Scripts, and OptumRx (all named defendants here) manage the drug benefits for approximately ninety-five percent (95%) of the United States' population or 253 million American lives.[8] PBMs control drug formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed. In this way, PBMs control prescription drug utilization overall.

17. PBMs' complicity in the overall fraudulent scheme is purposeful given the nature of the financial arrangements between PBMs and drug manufacturers and others in the supply chain. Drug manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBMs incentives to avoid pre-authorization requirements that would slow down flow.

18. PBMs require, and receive, incentives from Manufacturer Defendants to keep certain drugs on and off formularies. These incentives include the payment of rebates by Manufacturers Defendants to PBMs based on utilization, bonuses for moving product and hitting volume targets, and the payment of lucrative administrative fees to maximize PBM profits. Much of this activity is not transparent to anyone, including those who in good faith hire PBMs to manage their benefits.

19. PBMs are the middlemen between the manufacture and the availability of opioids. The PBM formularies determine what drugs (a) will be available (or not available) to patients; (b)

[8] Brittany Hoffman-Eubanks, *The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1*, PHARMACY TIMES, Nov. 14, 2017, http://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1

for what diagnosis, efficacious or otherwise; (c) in what quantities; (d) at what co-pay; (e) what level of authorization will be required; and (f) what beneficial drugs will not be available. PBMs collude with Manufacturers who pay fees in the form of rebates, administrative fees and other, in order to ensure good placement on the formulary to the financial benefit of the PBMs. This leads to more prescriptions and more pills available to the general public, many of which find their way to the black market. PBMs have in their exclusive power the ability to limit the number of pills available for legitimate and illegitimate consumption. Even though PBMs were well aware of the effect of their decisions about formulary placement, they chose to make decisions purely for their own financial gain.

20. PBMs not only control the majority of this country's prescriptions through their formularies, they generate massive profits from that work. "[N]early one third of all expenditures on branded drugs in 2015 were eventually rebated back. And, most of these rebates directly benefited the PBM."[9]

21. PBMs can extract rebates and other incentives from Manufacturer Defendants because of the PBMs' market power. Today, PBMs have leveraged their position as the middlemen and now impact almost every aspect of the prescription drug marketplace.

22. "The position of the three major PBMs at the center of the drug distribution system appears to be unassailable for now. Last year CalPERS, California's public employee benefits system, awarded OptumRx a five-year, $4.9-billion contract to manage prescriptions for nearly

[9] Wayne Winegarden, *To Improve Pharmaceutical Pricing, Reform PBMs And Fix Health Care's Systemic Problems*, FORBES, Apr. 4, 2017, https://www.forbes.com/sites/econostats/2017/04/04/to-improve-pharmaceutical-pricing-reform-pbms-and-fix-health-cares-systemic-problems/#4da58c5a3322

500,000 members and their families enrolled in non-HMO health plans. The only other finalists in the bidding were CVS Caremark and Express Scripts,"[10] all defendants here.

23. The power of the PBMs has evolved over time. Originally mere claims processors, PBMs now play a major role in managing pharmaceutical spending and enhancing health benefits for end-users.[11]

24. PBMs quietly became an integral part of the pharmaceutical supply chain—that is, the path a drug takes from the manufacturing facility to a bathroom medicine cabinet—following the passage of the Medicare Modernization Act in 2003.[12]

25. Because PBMs are the intermediary between drug manufacturers, pharmacies, and ultimately patients, these companies control everything from pharmacy reimbursements, to what drugs are covered under formularies.[13] In these ways, the PBMs control which drugs enter the marketplace. Their fingerprints are on nearly every opioid prescription filled and they profit in myriad ways on every pill.

26. The harm caused by the PBMs is not just monetary: "[t]he PBMs and insurers are harming the health of patients with chronic and rare diseases by limiting access and charging them retail for drugs they buy at deep discounts."[14]

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[10] Michael Hiltzik, *How 'price cutting' middlemen are making crucial drugs vastly more expensive*, LOS ANGELES TIMES, Jun. 9, 2017, http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html

[11] Zacks Equity Research, *PBM Industry Shows Strength: 3 Stocks in Focus*, NASDAQ, Dec. 13, 2017, http://www.nasdaq.com/article/pbm-industry-shows-strength-3-stocks-in-focus-cm891506

[12] Jessica Wapner, *Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers*, NEWSWEEK, Mar. 17. 2017, http://www.newsweek.com/big-pharma-villain-pbm-569980

[13] Matthew Kandrach, *PBM stranglehold on prescription drug market demands reform*, THE HILL, May 2, 2017, http://thehill.com/blogs/pundits-blog/healthcare/331601-pbm-stranglehold-on-prescription-drug-market-demands-reform

[14] Jonathan Wilcox, *PBMs Must Put Patients First*, HUFFINGTON POST, Feb. 28, 2017, https://www.huffingtonpost.com/entry/pbms-must-put-patients-first_us_58b60bd8e4b02f3f81e44dcc

27. *MedPageToday*, a source for clinical and policy coverage that directly affects the lives and practices of health care professionals, describes the PBMs' complicity in the opioid crisis this way:

> If you are looking for someone to blame for the opioid epidemic, you can certainly blame physicians. You can blame pharmaceutical companies. But while you are at it, don't forget to include payers [PBMs]. This conclusion should not be surprising. We live in a world where payers -- not physicians -- determine what drugs and treatments patients receive. If patients have a life-threatening condition, it is not unusual for a payer to demand that a physician first prescribe a cheaper and less effective alternative. Physicians know that the drugs they are allowed to use may not work very well, but frequently, payers demand that they be tried first anyway.
>
> What happens if the patient doesn't respond to the cheap drug? Often, the physician continues to prescribe it, because -- to gain access to the more effective drug -- physicians need to go through a painful process of preauthorization. For many practitioners, it isn't worth it.
>
> So we spend more for healthcare than any other country in the world, but Americans do not get the care they need. There is a simple reason. Treatment decisions are not being driven based on a physician's knowledge or judgment. They are being driven by what payers are willing to pay for.[15]

28. Upon information and belief, this Webb County complaint marks the first pleading in the Country to identify PBMs as among those bearing responsibility for the opioid scheme. The omission of PBMs from most legal efforts to address the opioid crisis has been noted. "Drugmakers, pharmaceutical distributors, pharmacies and doctors have come under intense scrutiny in recent years, but the role that insurers — and the pharmacy benefit managers that run their drug plans — have played in the opioid crisis has received less attention."[16]

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[15] Milton Packer MD, *Are Payers the Leading Cause of Death in the United States?*, MEDPAGETODAY, Nov. 1, 2017, https://www.medpagetoday.com/blogs/revolutionandrevelation/68935

[16] Katie Thomas and Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, THE NEW YORK TIMES, Sep. 17, 2017, https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?mwrsm=Email

29. As one news outlet described it, "[o]ne overlooked culprit worsening the epidemic, however, comes straight from our health care system: pharmacy benefit managers, or PBMs. To improve their bottom line, they're blocking access to prescriptions that can help prevent overdoses."[17]

30. The novelty of Webb County's approach should not distract from the reality of the PBMs' complicity—indeed, necessity—in the scheme before this Honorable Court. None of the manufacturers' or distributors' wrongdoing would have succeeded without the PBMs' ability to control and move product.

31. In sum, while opioids have touched nearly every corner of the country, Texas is one of the states that has been hit hardest by this catastrophe. Texas has four of the top twenty-five cities in the country for opioid abuse[18] and the State is second in the United States in terms of health care costs associated with opioid abuse.[19] Also, Texas ranked fifth in the nation in terms of states with the most people dying from overdoses in 2014[20] and the CDC estimated that 2,801 people died from drug overdoses in Texas in 2016.[21]

32. Accordingly, the Plaintiff brings this action to recover damages and costs it has incurred as a result of the prescription drug abuse problem in Webb County. The Plaintiff seeks

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[17] Peter J. Pitts, *Pharmacy benefit managers are driving the opioid epidemic*, SW NEWS MEDIA, Nov. 21, 2017, http://www.swnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managers-are-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-, 61d29d25c84b.html

[18] *The Opioid Crisis in America's Workforce*, CASTLIGHT HEALTH, http://archive.castlighthealth.com/typ/the-opioid-crisis/?aliId=32419579

[19] Matrix Global Advisors, LLC, *Health Care Costs from Opioid Abuse: A State-by-State Analysis*, DRUGFREE, Apr. 2015, https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf

[20] *States With The Most Overdose Deaths*, FORBES, https://www.forbes.com/pictures/572cf3c94bbe6f123f285b9c/5-texas/#6f8fe31c5991

[21] *Drug Overdose Death Data*, CENTERS FOR DISEASE CONTROL AND PREVENTION, last updated Dec. 19, 2017, https://www.cdc.gov/drugoverdose/data/statedeaths.html

to recover those costs and damages from the Defendants because they are the entities that have substantially contributed to and profited from the scourge of opioid abuse in Webb County.

33. Plaintiff also seeks a declaration that Defendants' conduct has violated Texas Law, an order requiring Defendants to cease their unlawful promotion, distribution, reimbursement and sale of opioids and to correct their misrepresentations, and an order requiring Defendants to abate the public nuisance they have created, knew their actions would likely create and from which they profited. Plaintiff also seeks punitive damages, treble damages, and attorneys' fees and costs in addition to granting any other equitable relief authorized by law.

II. VENUE AND JURISDICTION

34. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*. ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

35. This Court has personal jurisdiction over Defendants because they conduct business in Texas, purposefully direct or directed their actions toward Texas, consented to be sued in Texas by registering an agent for service of process, and/or consensually submitted to the jurisdiction of Texas when obtaining a manufacturer or distributor license and have the requisite minimum contacts with Texas necessary to constitutionally permit the Court to exercise jurisdiction.

36. This Court also has personal jurisdiction over all defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the

interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.[22]

37. Venue is proper in this Court under 28 U.S.C. § 1391 (b) and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to this action occurred in this judicial district and because all defendants are subject to this Court's exercise of personal jurisdiction.

38. Venue is proper within this District pursuant to 28 U.S.C. § 1391, as this District is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c), as well as Tex. Civ. Prac. & Rem. Code § 17.042, the Texas Long-Arm statute.

39. Certain Defendants are non-domiciliaries of Texas and regularly engage in business within Texas. These defendants have committed tortious acts outside and within Texas that have caused injury within Texas and to Webb County. Defendants expect or should reasonably have expected those acts to have consequences in Texas. Defendants, moreover, solicited business within Texas, engaged in persistent courses of conduct in Texas, and derived substantial revenue from goods used and services rendered in Texas through interstate commerce.

40. Defendants are regularly engaged in the business of manufacturing, distributing, dispensing and reimbursing prescription opioids in Texas and, specifically, in Webb County. Defendants' activities in Webb County in connection with the manufacture, distribution, dispensation and reimbursement of prescription opioids was, and is, continuous and systematic, and gave rise to the causes of action alleged herein.

[22] *See, e.g. Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.* 23 F. Supp. 796 (1998).

III. PARTIES

A. PLAINTIFF

41. Plaintiff, Webb County, is a county created under the authority of the State of Texas and is located in southern Texas. According to the United States Census Bureau, in 2016 it was estimated that 271,193 people live in Webb County.

42. Webb County is governed by the Webb County Commissioners Court and the office of the County Executive. Plaintiff's offices are located at 1000 Houston Street, Laredo Texas 78040.

43. Plaintiff directly and foreseeably sustained the economic damages alleged herein. Defendants' conduct has imposed an extraordinary financial burden on Plaintiff, for which Plaintiff seeks relief. Plaintiff has sustained, and continues to sustain, damages including, *inter alia*: (a) county costs for providing additional health and mental health services to people suffering from opioid-related addiction, opioid-related diseases, and opioid dependence, overdose and death; (b) county costs for providing additional law-enforcement services, additional emergency-response services, and additional judicial and public safety services relating to the opioid epidemic; and (c) county costs for providing additional treatment and care for minors affected by parents and/or guardians suffering from prescription opioid-related addiction, dependence, overdose and death; (d) county costs related to treatment, prevention, education, and victim services. These are only a few of the many additional costs the opioid epidemic has imposed on Plaintiff—while Defendants' bottom lines have soared. Plaintiff has suffered, and continues to suffer, damages as a direct and foreseeable result of Defendants' reckless, intentional and unlawful conduct, as well as Defendants' conduct that was, at times, fraudulent.

44. The damages Plaintiff has suffered are not derivative of third party's injury or injuries.

45. The Defendants' conduct was extraordinary, unexpected, and rare. It is a repeated course of conduct that did, does, and will- given the realities of addiction- continue to result in recurring costs to the Plaintiff. Defendants' conduct is especially pernicious when one considers the harm it wreaks on governmental entities such as plaintiff who, in good faith, endeavor to provide a wide variety of necessary services to its residents on a limited budget funded with taxpayer dollars. The magnitude of the acts of the Defendants was neither discrete nor of a sort that a county, including Plaintiff, could reasonably expect to have to respond to at any time during its existence as such. It would be unreasonable, wrong, and inequitable not to allocate the additional governmental expenses, and any other costs associated with the harms Defendants' wrongful conduct has caused, to the very parties responsible for creating the need for the resources to be expended as they are and were.

46. Plaintiff has standing to bring the instant claims including, *inter alia*, claims for violations under the Racketeer Influenced and Corrupt Organizations Act ("RICO Act"), because Plaintiff qualifies as a "person" within the meaning of the RICO Act. *See* 18 U.S.C. § 1961(3); 18 U.S.C. § 1964(c).

47. Plaintiff additionally seeks the means to abate the ongoing opioid epidemic—an epidemic that was created by Defendants' reckless, intentional, negligent and unlawful conduct.

B. MANUFACTURER DEFENDANTS

48. Defendant, PURDUE PHARMA, L.P., is a limited partnership organized under the laws of Delaware. Defendant, PURDUE PHARMA, INC., is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant, THE PURDUE FREDERICK COMPANY, INC., is a Delaware corporation with its principal place of business in Stamford, Connecticut.

49. PURDUE PHARMA, L.P. may be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. PURDUE PHARMA INC. may be served through its registered agent: The Prentice-Hall Corporation System, Inc., 80 State Street, Albany, New York 12207. THE PURDUE FREDERICK COMPANY may be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

50. PURDUE PHARMA, L.P. also has a Texas taxpayer number and one of its subsidiaries, Purdue Pharmaceutical Products L.P., a Delaware limited liability company for which PURDUE PHARMA, L.P. is the sole limited partner, is registered to do business in Texas and may be served in Texas through its registered agent: The Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E 7th Street, Suite 620, Austin, Texas 78701.

51. PURDUE PHARMA, L.P., PURDUE PHARMA, INC., and THE PURDUE FREDERICK COMPANY, INC. are referred to collectively as "Purdue."

52. In Texas and nationally, Purdue is engaged in the manufacture, promotion, and distribution of opioids, including: (a) OxyContin (OxyContin hydrochloride extended release), a Schedule II opioid agonist tablet first approved in 1995 and marketed by Purdue for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." OxyContin was indicated, or legally approved, for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."; (b) MS OxyContin (morphine sulfate extended release), a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

53. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up almost four-fold from 2006 sales of $800 million. OxyContin constitutes roughly thirty percent (30%) of the entire market for analgesic drugs (painkillers).

54. Purdue transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Purdue hires employees to service the Texas market. For example, Purdue recently advertised online that it was seeking a Territory Business Manager to operate out of Plano, Texas.[23] Purdue also directs advertising and informational materials to impact Texas physicians and potential users of Purdue products. For example, in December 2016, Purdue announced that it was entering into a long-term research and education alliance with The University of Texas Health Science Center at Houston, Texas to "connect researchers across disciplines, lower traditional barriers between industry and academics, and create unique educational experiences for students and trainees in the process."[24]

55. Defendant, ABBOTT LABORATORIES, is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Defendant, ABBOTT LABORATORIES, INC., is an Illinois corporation with its principal place of business in Abbott Park, Illinois.

56. ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. are both registered to do business in Texas and both may be served in Texas through their registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

[23] https://www.theladders.com/job/territory-business-manager-i-purdue-pharma-plano-tx_35053169

[24] *UTHealth, Purdue Pharm Enter Long-Term Reseach & Education Alliance*, PURDUE NEWS & media, Nov. 16, 2016 http://www.purduepharma.com/news-media/2016/11/uthealth-purdue-pharma-enter-long-term-research-education-alliance/

57. Defendants ABBOTT LABORATORIES and ABBOTT LABORATORIES, INC. are referred to collectively as "Abbott."

58. Abbott was primarily engaged in the promotion and distribution of opioids nationally due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products as set forth above.

59. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006.

60. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

61. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million. At the time, this was one of the largest settlements with a drug company for marketing misconduct.

62. Abbott transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Abbott hires employees to service the Texas market. For example, Abbott recently advertised online that it was seeking a Regional Manager for the North Texas area and a Sales Operation Manager to operate out of Austin, Texas. Abbott also directs advertising and informational materials to impact Texas physicians and potential users of Abbott products.

63. Abbott and Purdue's conspiring with PBMs to drive opioid use is well established. As described in an October 28, 2016 article from Psychology Today entitled *America's Opioid Epidemic*:

> Abbott and Purdue actively misled prescribers about the strength and safety of the painkiller [OxyContin]. To undermine the policy of requiring prior authorization, they offered lucrative rebates to middlemen such as Merck Medco [now Express Scripts, a defendant herein] and other pharmacy benefits managers, on condition that they eased availability of the drug and lowered co-pays. The records were part of a case brought by the state of West Virginia against both drug makers alleging inappropriate and illegal marketing of the drug as a cause of widespread addiction. … One reason the documents are so troubling is that, in public at least, the drug maker was carefully assuring authorities that it was working with state authorities to curb abuse of OxyContin. Behind the scenes, however, as one Purdue official openly acknowledged, the drug maker was "working with Medco (PBM) [now Express Scripts] to try to make parameters [for prescribing] less stringent.[25]

64. Defendant, MALLINCKRODT PLC, is an Irish public limited company with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG, United Kingdom and it may be served through its registered agent in the United States: CT Corporation System, 120 South Central Avenue, Suite 400, Clayton, Missouri 63105.

65. Defendant, MALLINCKRODT LLC, is a wholly owned subsidiary of MALLINCKRODT PLC and is a Delaware limited liability company with its principal place of business in St. Louis, Missouri. MALLINCKRODT LLC is registered to do business in Texas and has been since 1989. Mallinckrodt LLC may be served in Texas through its registered agent: The CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

[25] American Society of Addiction Medicine, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to curb prescribing,* PSYCHOLOGY TODAY, Oct. 28, 2016, https://www.psychologytoday.com/blog/side-effects/201610/america-s-opioid-epidemic

66. MALLINCKRODT PLC and MALLINCKRODT LLC are referred to collectively as "Mallinckrodt."

67. In Texas and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of Roxicodone and oxycodone among other drugs. Mallinckrodt transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Mallinckrodt hires employees to service the Texas market. For example, Mallinckrodt has recently advertised for the positions of Acute Care Business Manager and Sales Specialist to operate out of Houston, Texas. Mallinckrodt also directs advertising and informational materials to impact Texas physicians and potential users of Mallinckrodt products.

68. Defendant, ENDO HEALTH SOLUTIONS, INC., is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant, ENDO PHARMACEUTICALS, INC., is a wholly owned subsidiary of ENDO HEALTH SOLUTIONS, INC. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

69. ENDO HEALTH SOLUTIONS, INC. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. ENDO PHARMACEUTICALS, INC. is registered to do business in Texas (since 1997) and may be served in Texas through its registered agent, the CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

70. ENDO HEALTH SOLUTIONS, INC. and ENDO PHARMACEUTICALS, INC. are referred to collectively as "Endo".

71. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, throughout the United States, including Texas. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 to 2013, and it accounted for ten percent (10%) of

Endo's total revenue in 2012. Endo, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products across the United States, including Texas.

72. Endo transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Endo hires employees to service the Texas market. For example, Endo recently posted online that it was seeking a Sales Representative to work out of Dallas, Texas, and a Senior Specialty Sales Professional to work out of Houston, Texas. Endo also directs advertising and informational materials to impact Texas physicians and potential users of Endo products. Upon information and belief, Endo recently acquired HealthTronics, which is headquartered in Austin, Texas.

73. Defendant, TEVA PHARMACEUTICALS USA, INC., is a Delaware corporation with its principal place of business in North Whales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

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

75. TEVA PHARMACEUTICALS USA, INC. has a Texas taxpayer number and may be served through its registered agent: Corporate Creations Network Inc., 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, Delaware 19810. CEPHALON, INC. is registered to do business and Texas may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

76. TEVA USA and CEPHALON, INC. are referred to collectively as "Cephalon."

77. Cephalon manufactures, promotes, distributes and sells both brand name and generic versions of opioids nationally, and in Webb County, including the following: (a) Actiq,

and (b) Fentora. Cephalon was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Webb County.

78. Cephalon transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Cephalon hires employees to service the Texas market. For example, Cephalon recently advertised online that it was seeking Sales Representatives to operate out of College Station and San Antonio, Texas. Cephalon also directs advertising and informational materials to impact Texas physicians and potential users of their products.

79. Defendant, JOHNSON & JOHNSON, is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

80. Defendant, JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON. JANSSEN PHARMACEUTICALS, INC. was formerly known as ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., which in turn was formerly known as JANSSEN PHARMACEUTICA, INC.

81. Defendant, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

82. Defendant, JANSSEN PHARMACEUTICA, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

83. JOHNSON & JOHNSON is the only company that owns more than ten percent (10%) of JANSSEN PHARMACEUTICALS, INC.'s stock. Upon information and belief, JOHNSON & JOHNSON controls the sale and development of JANSSEN

PHARMACEUTICALS, INC.'S drugs and JANSSEN PHARMACEUTICALS, INC. profits inure to JOHNSON & JOHNSON's benefit.

84. JOHNSON & JOHNSON may be served at its registered office One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. JANSSEN PHARMACEUTICALS, INC. is registered to do business in Texas and may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

85. JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC, and JANSSEN PHARMACEUTICA, INC. are collectively referred to as "Janssen."

86. Janssen is or has been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Webb County, including the following: (a) Duragesic, (b) Nucynta and (c) Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

87. Janssen transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Janssen hires employees to service the Texas market. For example, Janssen recently advertised online that it was seeking a Clinical Account Specialist to operate out of Houston, Texas. Janssen also direct advertising and informational materials to impact Texas physicians and potential users of their products.

88. Defendant, WATSON LABORATORIES, INC., is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Defendant, ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.), a public limited company incorporated under the laws of the State of Ireland with its headquarters and principal place of business in Dublin, Ireland.

89. Defendant, ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

90. Defendant, ACTAVIS, LLC, is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

91. Each of these defendants is owned by Defendant, ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

92. WATSON LABORATORIES, INC. may be served through its registered agent: Corporate Creations Network Inc., 8275 South Eastern Avenue, #200, Las Vegas, Nevada 89123. ACTAVIS PHARMA, INC. is registered to do business in Texas may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201. ACTAVIS, LLC may be served through its registered agent: Corporate Creations Network Inc., 3411 Silverside Road Tatnall Building, Suite 104, Wilmington, Delaware 19810.

93. ALLERGAN PLC, ACTAVIS LLC, ACTAVIS PHARMA, INC., and WATSON LABORATORIES, INC. are collectively referred to as "Actavis."

94. Actavis manufactures, promotes, sells and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana throughout the United States, including New Jersey, and in this district. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

95. Actavis transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Actavis hires employees to service the Texas market.

For example, Actavis recently advertised online that it was seeking Account Specialists to operate out of Webster and Austin, Texas. Actavis also direct advertising and informational materials to impact Texas physicians and potential users of their products.

96. Defendant, INSYS THERAPEUTICS, INC. ("Insys"), is a Delaware corporation with its headquarters and principal place of business in Chandler, Arizona. Insys is registered to do business in Texas may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

97. Insys manufactures, promotes, distributes and sells prescription opioids such as Subsys. These opioids are manufactured in the United States and promoted, distributed, and sold across the United States— including in Texas and Webb County.

98. Insys transacts business in Texas, targeting the Texas market for its products, including the opioids at issue in this lawsuit. Insys hires employees to service the Texas market. For example, Insys recently advertised online that it was seeking Specialty Sales Professional to operate out of Houston, Texas. Insys also direct advertising and informational materials to impact Texas physicians and potential users of their products.

99. The manufacturer defendants listed above are all engaged in the manufacturing of opioids. The manufacturer defendants listed above are collectively referred to herein as the "Manufacturer Defendants."

100. The failure of all Manufacturer Defendants to effectively monitor and report suspicious orders of prescription opioids, their aggressive misinformation campaign aimed at increasing public consumption of highly addictive opioids, their failure to forthrightly provide accurate information to the United States Food and Drug Administration ("FDA"), their failure to adhere to FDA regulations regarding misbranding, their failure to implement measures to prevent the filling of suspicious orders, and their perverse utilization of so-called "patient advocacy"

groups to evade FDA regulations concerning consumer drug-marketing greatly contributed to a vast increase in opioid overuse and addiction. Manufacturer Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in Webb County.

C. DISTRIBUTOR DEFENDANTS

101. Defendant McKESSON CORPORATION ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

102. McKesson has been registered to do business in Texas since at least 1994 and does substantial business in Texas. McKesson has a Texas taxpayer number and may be served in Texas through its registered agent: The Corporation Service Company D/B/A CSC-Lawyers Incorporating Service Company, 211 E 7th Street, Suite 620, Austin, Texas 78701.

103. McKesson is the largest pharmaceutical distributor in North America. It distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Texas.

104. Upon information and belief, McKesson is one of the largest distributors of opioid pain medications in the country, including Texas. In 2015, McKesson had a net income in excess of $1.5 billion.

105. In its 2017 Annual Report, McKesson states that it "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively."[26]

106. According to the 2017 Annual Report, McKesson "pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution

[26] McKesson 2017 Annual Report found at investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_Annual_R eport_0.pdf

centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico."[27]

107. Defendant CARDINAL HEALTH, INC. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Texas.

108. Cardinal may be served in through its registered agent: CT Corporation System, 4400 Easton Commons Way Suite 125, Columbus, Ohio 43219.

109. Cardinal, through its many subsidiaries, including Cardinal Health Care Services, Inc., has been registered to do business in Texas since at least 2008 and may be served in Texas through its registered agent: Fulgencio P. Duremides, Jr., 2714 Trailridge Court, Missouri City, Texas 77459.

110. Upon information and belief, Cardinal is one of the largest distributors of opioid pain medications in the country, including Texas.

111. Defendant AMERISOURCEBERGEN CORPORATION ("Amerisource") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Texas.

112. Amerisource has been registered to do business in Texas since at least 1989 and may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Ave., Suite 900, Dallas, Texas 75201.

[27] *Id.*

113. According to its 2016 Annual Report, Amerisource is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."[28]

114. Upon information and belief, Amerisource is one of the largest distributors of opioid pain medications in the country, including Texas.

115. The distributor defendants listed above are all engaged in the wholesale distribution of opioids. The distributor defendants listed above are collectively referred to herein as the "Distributor Defendants."

116. The Distributor Defendants purchased opioids from manufacturers, such as the Manufacturer Defendants herein, and sold them to pharmacies throughout Texas, including in Webb County. The Distributor Defendants played an integral role in opioids being distributed across Texas, including Webb County.

117. The failure of all Distributor Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent the filling of invalid and medically unnecessary prescriptions greatly contributed to the vast increase in opioid overuse and addiction. Distributor Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in Webb County.

D. PHARMACY BENEFIT MANAGER DEFENDANTS

118. The Pharmacy Benefit Manager Defendants ("PBM Defendants") are defined below. At all relevant times the PBM Defendants acted as the gatekeepers of prescription drugs including opioids. Pharmacy benefit managers ("PBMs") negotiate with drug manufacturers to

[28] Amerisource 2016 Annual Report found at http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-irhome

offer preferred drug formulary placement for the manufacturers' drugs. PBMs establish reimbursement rates for the drugs dispensed. PBMs earn revenue from at least the following sources: fees from health plans and insurers, rebates and other incentives such as volume target bonuses negotiated with drug manufacturers, and fees from maintaining pharmacy networks.[29]

119. Defendant, EXPRESS SCRIPTS HOLDING COMPANY ("ESHC"), is a Delaware corporation with its principal place of business in St. Louis, Missouri. ESHC is registered to do business in Texas and has a Texas taxpayer number. ESHC may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

120. Defendant, EXPRESS SCRIPTS, INC. ("ESI"), is incorporated in the State of Delaware with its principal place of business located in St. Louis, Missouri, is a pharmacy benefit management company, and is a wholly-owned subsidiary of ESHC. ESI has been registered to do business in Texas since at least 1992 and has a Texas taxpayer number. ESI may be served in Texas through its registered agent: The Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E 7th Street, Suite 620, Austin, Texas 78701.

121. ESHC and ESI are collectively referred to as "Express Scripts".

122. In 2012, ESI acquired its rival, Medco Health Solutions Inc., in a $29.1 billion deal. As a result of the merger, ESHC was formed and became the largest PBM in the nation, filing a combined 1.4 billion prescriptions for employers and insurers.[30]

[29] Health Policy Brief, *On behalf of payers, pharmacy benefit managers negotiate rebates from drug makers in exchange for preferred formulary placement,* HEALTH AFFAIRS, Sep. 14, 2017, https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/

[30] Peter Frost, *Express Scripts closes $29.1-billion purchase of Medco*, LOS ANGELES TIMES (Apr. 3, 2012), http://articles.latimes.com/2012/apr/03/business/la-fi-medco-20120403

123. According to the Pharmacy Benefit Management Institute, in 2015, Express Scripts was the top ranking PBM nationwide with twenty-six percent (26%) of the industry market share.[31]

124. Express Scripts derives substantial revenue managing pharmacy benefits in Texas through several different means, including, but not limited to, providing services and formulary to the Texas A&M Care Health Plans.[32] During much of the relevant period of this complaint, ESI provided services and formulary to the Teacher Retirement System of Texas.[33]

125. Current and former employees of the Webb Consolidated Independent School District are members of the Teacher Retirement System of Texas which means they receive their pharmacy benefits from Express Scripts and pursuant to an Express Scripts formulary. Upon information and belief, this is only one of the many ways in which Express Scripts reimburses for claims in Webb County, including opioids.

126. At all times relevant hereto, Express Scripts has operated offices throughout Texas, including in Austin and Irving, Texas. ESI publishes employment vacancies related to its Texas PBM business activities on its website.[34]

127. Defendant, CVS HEALTH CORPORATION ("CVS Health"), formerly known as CVS Caremark Corporation, is a Delaware corporation with its principal place of business located

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[31] *PBM Market Share, by Total Prescription Claims*, 2015, PHARMACY BENEFIT MANAGEMENT INSTITUTE, INDUSTRY RESEARCH, https://www.pbmi.com/PBMI/Research/Industry_Research/PBMI/Research/PBMI___Industry_Research.aspx?hkey=22023612-80c4-4ada-a17e-85e7dfcbc1f8

[32] The Texas A&M University System, Prescription Drugs (Express Scripts), Jan. 18, 2018, https://www.tamus.edu/business/benefits-administration/employeeretiree-benefits/prescriptions-express-scripts/

[33] Express Scripts Medicare Prescription Drug Plan (PDP), 2017 Benefit Overview. https://www.trs.texas.gov/TRS%20Documents/express_script_benefit_overview_2017.pdf

[34] Express Scripts employment listings in the State of Texas, e.g., (i) Sr. Manager, Software Development Engineer, Austin, Texas (https://careers.express-scripts.com/us/en/job/ESMEUS2769/Sr-Manager-Software-Development-Engineer?jobsource=indeed&utm_source=media&utm_medium=appfeeder&utm_campaign=Bayard&src=JB-10044 (ii) Sr. Technical Manager, Software Development, Austin Texas (https://careers.express-scripts.com/us/en/job/ESMEUS2881/Sr-Technical-Manager-Software-Development?jobsource=indeed&utm_source=media&utm_medium=appfeeder&utm_campaign=Bayard&src=JB-10044); and (iii) Pharmacy Technician (CPhT) – Accredo, Irving, Texas (https://careers.express-scripts.com/us/en/job/ESMEUS2934/Pharmacy-Technician-CPhT-Accredo?jobsource=indeed&utm_source=media&utm_medium=appfeeder&utm_campaign=Bayard&src=JB-10044

in Woonsocket, Rhode Island. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange, Street, Wilmington, Delaware 19801.

128. Defendant, CAREMARK RX, L.L.C., is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct parent company of CAREMARK RX, L.L.C. According to CVS Health's 2016 Annual Report, Defendant CAREMARK RX, L.L.C. is "the parent of [CVS Health]'s pharmacy services subsidiaries, is the immediate or indirect parent of many mail order, pharmacy benefit management, infusion, Medicare Part D, insurance, specialty mail and retail specialty pharmacy subsidiaries, all of which operate in the United States and its territories." CAREMARK RX, L.L.C. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange, Street, Wilmington, Delaware 19801.

129. Defendant, CAREMARKPCS HEALTH, L.L.C., is a Delaware limited liability company doing business as CVS/Caremark and CVS Caremark in Texas and whose principal place of business is at the same location as CVS Health. On information and belief, CVS Health is the direct or indirect parent company of CAREMARKPCS HEALTH, L.L.C. CAREMARKPCS HEALTH, L.L.C. is registered to do business in Texas (since at least 2009) and may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

130. Defendant, CAREMARK, L.L.C., is a California limited liability company whose principal place of business is at the same location as CVS Health. Defendant, CAREMARK PCS, L.L.C., is a Delaware limited liability company formerly known as AdvancePCS Inc., which was founded in 1996 and is based in Irving, Texas. On information and belief, CAREMARK RX, L.L.C. is the sole member of both CAREMARK, L.L.C. and CAREMARK PCS, L.L.C. Both

CAREMARK, L.L.C. and CAREMARK PCS, L.L.C. are registered to do business in Texas and may be served by their registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

131. Defendants CAREMARK RX, L.L.C., CAREMARKPCS HEALTH, L.L.C., CAREMARK, L.L.C. and CAREMARK PCS, L.L.C. are collectively referred to as "Caremark."

132. CVS Health describes itself in a September 3, 2014 press release as a "pharmacy innovation company helping people on their path to better health. Through our 7,700 retail pharmacies, 900 walk-in medical clinics, a leading pharmacy benefits manager with nearly 65 million plan members, and expanding specialty pharmacy services, we enable people business and communities to manage health in more affordable, effective ways. This unique integrated model increases access to care, delivers better health outcomes and lowers overall health care costs." In 2016, CVS Health reported an operating income of $10 billion.

133. In the above-referenced September 3, 2014 press release CVS Health announced its change of name from CVS Caremark Corporation to CVS Health. CVS Health explained that it was changing its name "to reflect its broader health care commitment and its expertise in driving the innovations needed to shape the future of health." CVS Health explained that the newly-named company included "its pharmacy benefit management business, which is known as CVS/Caremark." In that same press release, CHS Health touted, "[f]or our patients and customers, ***health is everything*** and…we are advising on prescriptions [and]helping manage chronic and specialty conditions." [emphasis supplied].

134. According to the Pharmacy Benefit Management Institute, CVS Health (Caremark) was the second highest ranking PBM in 2015 with twenty-five percent (25%) of the industry market share.[35]

135. At all times relevant hereto, CVS Health and Caremark offered pharmacy benefit management services nationwide and maintained a national formulary or formularies that are used nationwide, including in Texas.

136. At all times relevant hereto, CVS Health, through Caremark, derives substantial revenue providing pharmacy benefits in Texas through several different means including, but not limited to, providing services and formulary to the Texas A&M Care Health Plans[36] and the Teacher Retirement System of Texas. At all times relevant hereto, Caremark has served as the PBM for the Texas Association of Counties Health and Employees Benefits Pool[37] and has reimbursed for opioids throughout Texas, including in Webb County.

137. Defendant, UNITEDHEALTH GROUP INCORPORATED ("UnitedHealth"), a Delaware corporation with its principal place of business located in Minnetonka, Minnesota, is a diversified managed health care company with two business platforms. UnitedHealth serves approximately 115 million individuals throughout the United States. For 2016, UnitedHealth reported an operating income of $12.9 billion.

138. UnitedHealth, though its subsidiaries United HealthCare Services, Inc. and United HealthCare, Inc., is the parent company of United HealthCare of Texas, Inc. ("UHC Texas"). UHC

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[35] Pharmacy Benefit Management Institute, Industry Research, *supra* note 31.

[36] *PharmaCare is Now CVS Caremark*, THE TEXAS A&M UNIVERSITY SYSTEM, Jul 2, 2007, https://news.tamus.edu/pharmacare-is-now-cvs-caremark-caremark/

[37] *See* Texas Association of Counties, TAC Health and Employee Benefits Pool, Prescription Benefits that Improve Outcomes and Control Your Costs, https://www.county.org/pool-and-risk-services/group-health/prescriptionbenefits/Pages/default.aspx

Texas is registered to do business in Texas and may be served in Texas through its registered agent: CT Corporation System, 1999 Bryan St. Suite 900, Dallas, Texas 75201.

139. Defendant, OPTUM, INC., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OPTUM, INC. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OPTUMRX, INC. On information and belief, OPTUM, INC. is a subsidiary of UnitedHealth.

140. Defendant, OPTUMRX, INC. ("OptumRx"), is a Delaware corporation with its principal place of business located in Irvine, California. OptumRx operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of OPTUM, INC. OptumRx operates as the PBM for UnitedHealth.

141. UnitedHealth and OPTUM, INC. may be served through their registered agent: CT Corporation System, Inc., 1010 Dale Street North, St. Paul, Minnesota 5517.

142. OptumRx is registered to do business in Texas, has a Texas taxpayer number and may be served through its registered agent CT Corporation System, 1999 Bryan St. Suite 900, Dallas, Texas 75201.

143. At all times relevant hereto, OptumRx derives substantial revenue providing pharmacy benefits in Texas through several different means, including, but not limited to, providing services and formulary through the HealthSelect Prescription Drug Program for the Employee Retirement System of Texas[38] and, for at least the years 2015-17, the Public Employee Benefits Alliance (PEBA) of Texas.[39]

[38] See https://www.ers.texas.gov/

[39] See Public Employee Benefits Alliance, brochure for 2015 Benefit Purchasing Year, http://www.buypeba.org/documents/PEBABrochure.pdf; Public Employee Benefits Alliance, Alliance Alert, http://buypeba.org/documents/AAPBM.pdf

144. According to the Pharmacy Benefit Management Institute, OptumRx (UnitedHealth) was the third highest ranking PBM in 2015 with twenty-two (22%) of the industry market share.[40]

145. In one case, OptumRx, which is owned by UnitedHealth, suggested that a member taking Butrans consider switching to a "lower cost alternative," such as OxyContin or extended-release morphine, according to a letter provided by the member. Mr. Wiggin, the UnitedHealthcare spokesman, said the company's rules and preferred drug list "are designed to ensure members have access to drugs they need for acute situations, such as post-surgical care or serious injury, or ongoing cancer treatment and end of life care, as well as for long-term use after alternatives are tried."[41]

146. "UnitedHealthcare places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a non-opioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first."[42]

147. Defendant, PRIME THERAPEUTICS LLC ("Prime Therapeutics"), a limited liability company organized under the laws of Delaware with its principal place of business located in Eagan, Minnesota, provides pharmacy benefit management solutions for health plans, employers, and government programs in Texas.

148. Prime Therapeutics may be served in Texas through its registered agent Corporation Service Company d/b/a CSC-Lawyers Incorporated, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

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[40] Pharmacy Benefit Management Institute, Industry Research, *supra* note 31.

[41] Thomas and Ornstein, *supra* note 16.

[42] *Id.*

149. Prime Therapeutics maintains an office at 2901 Kinwest Parkway, Irving, Texas 75063.

150. Prime Therapeutics does substantial business in Texas providing pharmacy benefit management services to clients such as BlueCross BlueShield of Texas.[43]

151. Defendant, NAVITUS HOLDINGS, LLC, is a limited liability company organized under the laws of Wisconsin with its principal place of business located in Madison Wisconsin. NAVITUS HOLDINGS, LLC may be served through its registered agent: CT Corporation System, 301 South Bedford Street, Suite 1, Madison , Wisconsin 53703.

152. Defendant, NAVITUS HEALTH SOLUTIONS, LLC, a pharmacy benefit manager, is a limited liability company organized under the law of Wisconsin with its principal place of business located in Madison, Wisconsin and is a wholly owned subsidiary of NAVITUS HOLDINGS, LLC. NAVITUS HEALTH SOLUTIONS, LLC is registered to do business in Texas (since at least 2008) and may be served in Texas through it registered agent: CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201.

153. NAVITUS HOLDINGS, LLC and NAVITUS HEALTH SOLUTIONS, LLC are collectively referred to as "Navitus."

154. Navitus derives substantial revenue managing pharmacy benefits in Texas through the services it provides and the formulary it maintains in its relationships with health plans including, but not limited to, Community First Health Plans, Community Health Choice, El Paso

[43] BlueCross BlueShield of Texas brochures, years 2016 and 2018, states that BlueCross BlueShield of Texas contracts with Prime Therapeutics for its pharmacy benefit management services and mail-order pharmacy services. https://www.bcbstx.com/pdf/sbc/2016-texas-plan-overview.pdf; https://www.bcbstx.com/static/tx/pdf/brochure/2018/tx-plan-overview.pdf

First Health Plans, FirstCare Health Plans, Parkland Community Health Plan, and Senders Health Plans.[44]

155. According to the Texas Medical Association "of the roughly 20 Medicaid plans operating in the state, more than half say they collectively use the same PBMs — Navitus or CVS."[45]

156. The Navitus pharmacy directory denotes numerous pharmacies located in Webb County.[46]

157. At all relevant times, Navitus Health Solutions operated a campus office in Texas, which is currently located in Austin, Texas.

158. The opioids at issue in this case were reimbursed by the PBM Defendants. Without the PBM Defendant reimbursement for the opioids at issue herein, the opioids would not have entered the marketplace and the entire scheme would have failed.

E. DOE DEFENDANTS

159. Doe DEFENDANTS 1 to 100 are sued herein under fictitious names because after diligent and good faith efforts their names, identities, and capacities, whether individual, corporate, associate, or otherwise, are presently unknown to Plaintiff. Plaintiff will make the names or identities of said Defendants known to the Court after the information has been ascertained. Plaintiff is informed and believes, and based thereupon alleges, that each of the Defendants designated herein as a DOE DEFENDANT has taken part in and participated with, and/or aided

[44] Texas Association of Community Based Health Plans Partnership with Navitus Health Solutions Provides Pharmacy Benefits to 1.3 Million Medicaid Members, https://www.navitus.com/Utility/news-events/press-releases/2012/Texas-Association-of-Community-Based-Health-Plans.aspx

[45] Amy Lynn Sorrel, *Drug Debacle*, TEXASMEDICINE, Jul. 2016, https://www.texmed.org/Template.aspx?id=36624

[46] Navitus Pharmacy Directory, https://www.navitus.com/Misc-Pages/PDF-Form-Viewer.aspx?FormID=9cc570be-73ce-4402-a2bc-1af32e88f461

and abetted, some or all of the other Defendants in some or all of the matters referred to herein and the State is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

IV. FACTUAL ALLEGATIONS

A. BACKGROUND ON PRESCRIPTION OPIOIDS

160. The term opioid includes (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone oxycodone and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.[47]

161. Prior to the 1990's, doctors used opioid pain relievers sparingly, and only in the short term, for cases of acute injury or illness, during surgery or end-of-life ("palliative") care.[48] Doctors' reluctance to use opioids for an extended period of time was due to the legitimate fear of causing addiction.[49]

162. Beginning in the late 20th century, however, and continuing through today, the pharmaceutical industry acted to dramatically expand the marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in three ways. *First*, pharmaceutical manufacturers engaged in a misinformation campaign which altered public perception of opioids, and deceived doctors, federal regulators, and the general public about their addictive qualities. *Second*, PBMs ensured that opioids were widely available, regularly prescribed and reimbursed. *Third*, opioid manufacturers and wholesalers/distributors flouted their federally imposed

[47] 21 U.S.C. § 812 Schedule II (2012).

[48] Meldrum ML, *Progress in Pain Research and Management*, Vol. 25 Seattle, WA: IASP Press; 2003.

[49] *Id.*

requirements to report suspicious opioid orders to the DEA and state agencies. These facilitated an explosion in the illegitimate marketplace for prescription opioids.

163. As a result of Defendants' wrongful conduct, the number of prescriptions for opioids increased sharply, reaching nearly 250 million prescriptions in 2013, almost enough for every person in the United States to have a bottle of pills. This represents an increase of three hundred percent (300%) since 1999.

B. IMPACT ON TEXAS AND WEBB COUNTY

164. While the Defendants have profited from the alarming rate of opioids used in the United States, communities across the country, especially those in lower-income areas, have suffered. According to the CDC, the nation is experiencing an opioid-induced "public health epidemic." The CDC reports that prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. Based on the latest data, nearly two million Americans met criteria for prescription opioid abuse and dependence in 2013.[50] Aggregate costs for prescription opioid overdose, abuse, and dependence were estimated at over $78.5 billion (in 2013 dollars).[51]

165. While Defendants were reaping billions of dollars in profits off their wrongful conduct, Plaintiff has been required to allocate substantial public monies and resources to combat the opioid crisis in Webb County and deal with its fall out.

166. Plaintiff has incurred and continues to incur substantial costs because of Defendants' conduct as described herein, including, but not limited to, costs of increased county services with respect to law enforcement, first responders such as emergency medical services,

[50] Wolters Kluwer Health, *Costs of US prescription opioid epidemic estimated at $78.5 billion*, SCIENCE DAILY, Sept. 14, 2016, https://www.sciencedaily.com/releases/2016/09/160914105756.htm

[51] *Id.*

county health facilities including hospitals and clinics, detention centers and jails, county courts, drug courts, diversion programs, prevention and treatment centers, community outreach programs, equipment and supplies, victim services supports, inmate services including housing, health and support staff, intervention programs together with general societal costs, and lost productivity costs.

167. Webb County has had to allocate substantial additional resources through staffing at departments providing all of the services listed above (i.e. additional full time employees "FTEs"); has incurred substantial increases in overtime; has had to re-allocate personnel to Regional Task Forces, provide additional Mutual Aid (law enforcement assistance to other agencies), training (of staff and Community Partners such as schools, youth groups, private security), and Court services.

168. According to the CDC, in Texas there were 2,831 drug overdose deaths in 2016, with opioids being the main driver, a seven percent (7%) percent increase over drug overdose deaths in 2015.[52]

169. The CDC reports that Webb County mortality rates doubled in the ten (10) year period between 2007 and 2016. These drug-related deaths grew steadily from 4-5.9 in 2007 to 10-11.9 in 2016. During the same period the population grew from 234,594 in 2007 to 271,193 in 2016, a mere fifteen percent (15%) increase.[53]

170. Researchers have flagged opioids as one possible factor in Texas' staggering rise in women's deaths during and shortly after pregnancy."[54]

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[52] CDC Drug Overdose Data, https://www.cdc.gov/drugoverdose/data/statedeaths.html

[53] Centers for Disease Control and Prevention Drug Poisoning Mortality Rates in the United States, 1999-2016, https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/

[54] Malewitz, *supra* note 2.

171. Although these numbers are staggering, they do not fully describe the extent of the impact that the opioid epidemic has had in Texas. Experts say the Texas data is dangerously misleading, "[u]nfortunately, that [appearance] is a direct result of bad data collection," said Mark Kinzly, co-founder of the Texas Overdose Naloxone Initiative. "Out of 254 counties in the state of Texas, the CDC will only report on nine of those counties because of how the data is reported."[55]

172. As Operation Naloxone director Lucas Hill explains, "there is a grave underreporting of opioid overdoses in rural areas, because they believe justices of the peace are unable to differentiate between causes of respiratory failure."[56]

173. Texas underreporting of opioid related deaths is confirmed by the University of Texas at Austin. "The rates per 100,000 for Texas counties vary. Only 9 counties had reliable overdose death rates per 100,000 for opiates according to 2014 data from CDC, but they provide evidence of the extent of the opiate overdose problem in the largest Texas counties."[57]

174. There are several factors that point to the severity of the opioid crisis in Texas. Texas has four out of the top five cities for prescription painkiller abuse in the nation, and the State is second in the United States in terms of health care costs associated with opioid abuse. In sum, the scale of the opioid epidemic in Texas is likely obscured by incomplete public data. [58]

175. So, while on its face and compared with states like Ohio and West Virginia, Texas may appear to have dodged the worst of the opioid crisis (Texas had 2,588 drug overdose deaths

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[55] Chase Karacostas, *Scale of opioid epidemic in Texas likely obscured by bad data, experts say*, THE DAILY TEXAN, Nov. 17, 2017, http://www.dailytexanonline.com/2017/11/17/scale-of-opioid-epidemic-in-texas-likely-obscured-by-bad-data-experts-say

[56] *Id.*

[57] Prof. Jane C. Maxwell, Ph.D., *Brief Report on the Current Epidemic of Drug Poisoning Death*s, THE UNIVERSITY OF TEXAS AT AUSTIN SCHOOL OF SOCIAL WORK, https://socialwork.utexas.edu/dl/files/cswr/institutes/ari/pdf/opioid-overdose-2014.pdf

[58] Karacostas, *supra* note 55.

in 2015, a rate of 9.4 per 100,000 residents, one of the lowest reported rates in the country) other indicators confirm that Texas does indeed have a severe opioid problem. "The state has the country's highest rate of maternal mortality, which includes deaths during pregnancy and childbirth and in the year following delivery. Maternal mortality nearly doubled between 2010 and 2014, and the latest data show the leading cause is a drug overdose. Additionally, the number of neonatal abstinence syndrome cases, in which babies are born dependent on a drug, has continued to rise."[59]

176. The State's Maternal Mortality and Morbidity Task Force has been conducting an in-depth investigation into the death records of women to try to understand the state's high maternal death rate. The Task Force's latest report, released on September 29, 2017, revealed new data showing that drug overdose was the leading cause of pregnancy-associated deaths (women who die two months to one year after giving birth) between 2012 and 2015.[60]

177. And, despite Texas' rank of 48 out of 50 in opioid overdose deaths nationally, four of the country's 25 worst cities for opioid abuse rates are in the state: Texarkana (#10), Amarillo (#13), Odessa (#15), and Longview (#17). Again, this leads researchers such as Robin Ross to conclude "[i]t is important to note that the state does not currently have reliable data that tracks the number of people who die year-to-year because of a drug overdose in general, largely due to an inconsistent system of investigating and reporting causes of death. It is very likely the number of overdose deaths in the state is underreported."[61]

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[59] Robyn Ross, *How Texas Is Trying to Stay Ahead of the Opioid Epidemic*, ALCADE, Jan. 1, 2018, http://alcalde.texasexes.org/2018/01/how-texas-is-trying-to-stay-ahead-of-the-opioid-epidemic/

[60] *Measuring and Responding to the Texas Opioid Crisis*, CPPP BLOG CENTER FOR PUBLIC POLICY PRIORITIES, http://bettertexasblog.org/2017/11/measuring-and-responding-to-the-texas-opioid-crisis/

[61] *Id.*

178. To experts like Lisa Ramirez, the Texas Targeted Opioid Response project director for the Health and Human Services Commission, these numbers suggest an under-the-radar opioid problem the state would do well to recognize. "'The misconception that Texas does not have an opioid problem is dangerous and a myth we need to address,' Ramirez says. 'If we're not prepared, the problem will definitely get worse in Texas.'"[62]

179. "Health officials say Texas is experiencing a drug overdose crisis, and one of the big indicators is women dying while pregnant or shortly after giving birth. "The Texas Maternal Mortality and Morbidity Task Force has been combing through death records for years now to try to understand why the maternal death rate in the state is so high." Drug overdose was the leading cause of pregnancy-associated death,' said Karen Ruggiero, a member of the task force."

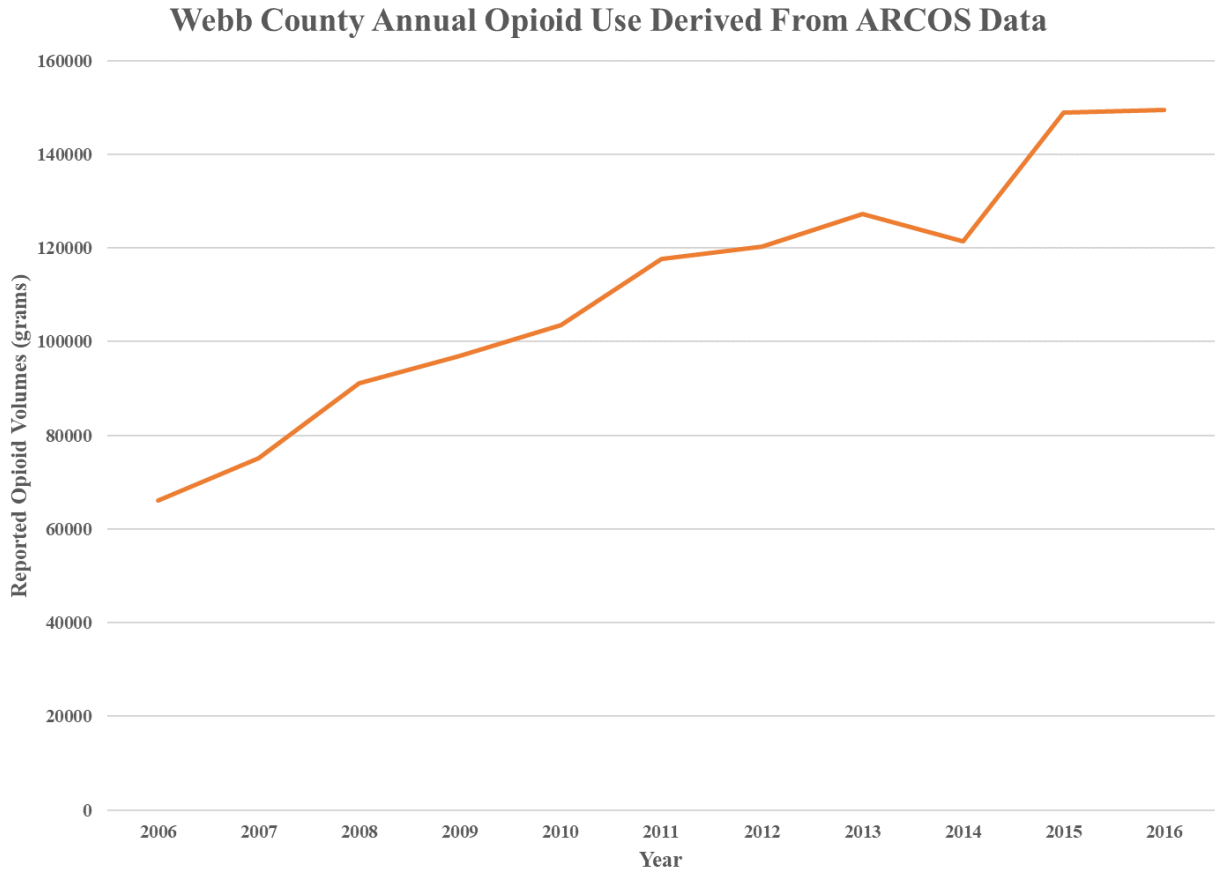
180. "In Texas, there is no reliable data of how many people die year-to-year because of drug overdoses in general. That's largely because the state has a hodge-podge system about how deaths are investigated and reported."[63]

181. In all events, retail drug summary reports available through the DEA's Automation of Reports and Consolidated Orders System ("ARCOS") confirm that Webb County is experiencing the same startling trend of soaring opioid use as is seen nationwide. The Webb County ARCOS Data table below reflects transactional data for Schedule II opioid drugs submitted by the drug manufacturers and distributors doing business in Webb County. The volume of Schedule II opioid drugs distributed in Webb County between 2006 and 2016 reflects a one hundred twenty-six percent (126%) increase, dramatically outpacing the population growth for the

[62] Ross, *supra* note 59.

[63] Ashley Lopez, *Opioid Crisis Is Killing Texas Mother, Task Force Finds*, KUT 90.5, Sep. 29, 2017, http://kut.org/post/opioid-crisis-killing-texas-mothers-task-force-finds

same period, which according to United States Census estimates amounted to only a twenty percent (20%) increase.[64]



[64] The ARCOS transactional data reflected in this chart includes the following drugs categorized as opioids: codeine, buprenorphine, dihydrocodeine, oxycodone, hydromorphone, hydrocodone, levorphanol, meperidine (pethidine), methadone, morphine, opium (powdered), oxymorphone, alfentanil, remifentanil, sufentanil base, tapentadol, and fentanyl base.

C. PARTICULARS REGARDING EACH DEFENDANT GROUP'S ROLE IN THE OPIOID EPIDEMIC

i. Manufacturer Defendants' Campaign of Deception

a. Manufacturer Defendants' Campaign to Normalize Widespread Opioid Use

182. Unsatisfied with the market for opioid use in the context of acute and palliative care, during the 1980s and 1990s, Manufacturer Defendants introduced new opioid drugs and began promoting their use for chronic pain therapy in an effort to increase the number of people taking opioids.

183. Those new drugs included, but were not limited to: Purdue's MS Contin (introduced 1987) and OxyContin (1995); Janssen's Duragesic (1990), Nucynta (2008), and Nucynta ER (2011); Cephalon's Actiq (1998) and Fentora (2006); Endo's Opana and Opana ER (2006); and Insys' Subsys (2012).

184. Recognizing the enormous financial possibilities associated with expanding the opioid market, the Manufacturer Defendants rolled out a massive and concerted campaign to misrepresent the addictive qualities of their product, and to push opioids as safe, effective drugs for the treatment of chronic pain associated with conditions such bad backs, arthritis, headaches and the like.

185. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain. As just one example, on information and belief, the Manufacturer Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

186. Further, each Defendant promoted the use of opioids for chronic pain throughsales representatives who visited individual doctors and medical staff in their offices and small group speaker programs. Defendants devoted massive resources to direct such sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors, including $108 million by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. These amount to twice as much as Defendants spent on detailing in 2000.

187. The deceptive marketing schemes included, among others, (a) the hiring of certain physicians, "hired guns," to pollute the marketplace with false information regarding the efficacy and risks of opioids for chronic pain treatment; (b) false or misleading materials, speaker programs, webinars, and brochures by purportedly neutral third parties that were really designed and distributed by the Manufacturer Defendants; (c) false or misleading direct, branded advertisements and marketing materials; and (d) the misuse of treatment guidelines.

188. Manufacturer Defendants' misinformation campaign worked as intended. Across the country, demand for prescription opioids exploded including in Webb County. Doctors and medical professionals, swayed by Manufacturer Defendants' sophisticated propaganda machine, began prescribing prescription opioids for ailment ranging from headaches to neck pain to fibromyalgia. That unleashed a wave of addiction—increasing the demand for opioids yet further. Manufacturer Defendants' profits soared.

b. The Manufacturer Defendants' Hired Guns

(1) DR. PORTENOY AND WEBSTER

189. Manufacturer Defendants' campaign of deception regarding the addictive nature of opioids was rooted in two pieces of purportedly "scientific" evidence. The first piece of evidence was a five-sentence letter to the editor published in 1980 in the New England Journal of Medicine.

The letter was drafted by Hershel Jick, a doctor at Boston University Medical Center, with the help of a graduate student, Jane Porter. It noted, anecdotally, that a review of "current files" did not indicate high levels of addiction among hospitalized medical patients who received narcotic preparation treatment. In full, the letter reads:

> Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients 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, 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.[65]

190. The second major piece of "evidence" used by Manufacturer Defendants was a 1986 study by Dr. Russell Portenoy in the medical journal Pain. The study, which had a patient cohort of merely 38 patients, claimed that opioids could be used for long periods of time to treat non-cancer related chronic pain without any risk of addiction. The rationale behind the study was that patients in pain would not become addicted to opioids because their pain drowned out the euphoria associated with opioids. As such, the study concluded that opioids should be freely administered to patients with fibromyalgia, headaches, finicky backs, and a host of other issues. According to Portenoy and his co-author, Dr. Kathleen Foley, "opioid maintenance therapy can be a safe, salutary and more humane alternative … in those patients with intractable non-malignant pain and no history of drug abuse." Portenoy RK, Foley KM, Chronic use of opioid analgesics in non-malignant pain: report of 38 cases, 25 Pain 171 (1986). Portenoy's study also cited Jick's one-paragraph letter to the New England Journal of Medicine.

[65] *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980).

191. Dr. Portenoy's study dovetailed perfectly with Manufacturer Defendants' marketing strategy and, within a decade, Dr. Portenoy was financed by "at least a dozen companies, most of which produced prescription opioids."[66]

192. Dr. Portenoy went on to serve as one of the pharmaceutical industry's most vocal advocates, regularly appearing at conferences and gatherings of medical professionals to promote the use of opioids for chronic, long-term pain.

193. The Manufacturer Defendants disseminated fraudulent and misleading messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

194. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

195. Hired guns like Dr. Portenoy promoted opioid analgesics and the myth that opioids could be liberally prescribed for non-cancer related chronic pain, without any risk of addiction.

196. Others like Dr. Portenoy would speak at academic conferences to primary care physicians in an effort to destigmatize opioids and encouraged liberal prescription of narcotics for the treatment non-cancer related chronic pain. They claimed that opioid analgesics have no "ceiling dosage" in that prescribing physicians should increase dosages for patients as high as necessary to treat non-cancer related chronic pain. Invariably, the key piece of "data" cited in support of the

[66] Meier B., Pain Killer: A Wonder Drug's Trail of Addiction and Death, New York, NY: St. Martin's Press; 2003.

proposition that opioids could be safely used to treat chronic pain was the New England Journal of Medicine article.

197. Defendants also paid Dr. Lynn Webster, the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah, to promote opioids. Dr. Webster was President of the American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous continuing medical education programs ("CMEs") sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly $2 million from Cephalon).

198. In the years that have followed, both the New England Journal of Medicine letter and Dr. Portenoy's 1986 study have been expressly disavowed. Neither actually demonstrates that opioids can be safely prescribed for long-term, chronic pain.

199. In a taped interview in 2011, Dr. Portenoy admitted that the information Manufacturer Defendants were pushing was false. "I gave innumerable lectures in the late 1980s and '90s about addiction that weren't true," Dr. Portenoy told a fellow doctor in 2010. "It was the wrong thing to do."[67]

> 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. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, ***none of which represents 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 … Because the primary goal was to de-stigmatize, ***we often left evidence behind***."

[67] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012).

> ***It was clearly the wrong thing to do*** and to the extent that some of the adverse outcomes now are as bad as they have become in terms of endemic occurrences of addiction and unintentional overdose death, it's quite scary to think about how the growth in that prescribing driven by people like me led, in part, to that occurring.[68]

200. As to the New England Journal of Medicine letter, Dr. Jick, in an interview with Sam Quinones decades after the letter was published, stated: "[t]hat particular letter, for me, is very near the bottom of a long list of studies that I've done. It's useful as it stands because there's nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain."[69]

201. The New England Journal of Medicine itself has since disavowed the letter, stating "[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy."[70] "We believe," the journal provided, "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."[71]

(2) DEFENDANT-FUNDED ORGANIZATIONS

202. Manufacturer Defendants also funded multiple organizations to advocate for the use of opioids to treat chronic pain. The names of the organizations suggest neutrality, but they were anything but. They included the American Pain Foundation ("APF"); the American Academy of Pain Management (which received funding from Manufacturer Defendants Endo, Janssens, and

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[68] Live interview with Dr. Russell Portenoy. Physicians Responsible for Opioid Prescribing. https://www.youtube.com/watch?v=DgyuBWN9D4w. Accessed December 3, 2017 (emphases added).

[69] Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, BUSINESS INSIDER, Mar. 26, 2016, http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5

[70] 376 New Eng. J. Med. 2194, 2194–95 (2017).

[71] *Id.*

Purdue); the American Pain Society ("APS"), American Geriatrics Society ("AGS"), and the Pain Care Forum ("PCF").

(A) American Pain Foundation

203. The most prominent nonparty advocate for opioids, funded by Defendants, was the American Pain Foundation ("APF"). APF received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

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

205. Dr. Perry Fine (an opioid advocate from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Dr. Portenoy, and Dr. Scott Fishman (an advocate the University of California who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all served on APF's board and reviewed its publications. Another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

206. In 2009 and 2010, more than eighty (80%) of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its

budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

207. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. But in reality, APF functioned as an advocate for the interests of Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

208. APF caught the attention of the United States Senate Finance Committee in May 2012 as the Committee sought to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation raised red flags as to APF's credibility as an objective and neutral third party; Defendants stopped funding it. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[72]

(B) The American Academy of Pain Medicine

209. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored

[72] Charles Ornstein and Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, WASH. POST, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html

and hosted CME programs for doctors essential to Defendants' deceptive marketing of chronic opioid therapy.

210. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate in activities and conferences. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council.

211. AAPM was viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its corporate events, and distributed its publications. The conferences sponsored by AAPM promoted opioids-37 out of roughly 40 sessions at one conference alone were opioid-focused.

212. AAPM's presidents have included the same opioid advocates mentioned above, i.e. Drs. Fine, Portenoy, Webster and Fishman. Dr. Fishman, a past AAPM president, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."[73]

213. AAPM's staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid advocates within the organization.

(C) The Pain Care Forum

214. On information and belief, Defendants also combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the

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

forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

215. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations, almost all of which received substantial funding from Defendants.

216. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long- acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients. This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts. On information and belief, the recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

217. All of these purportedly neutral, industry-funded organizations took aggressive stances to convince doctors and medical professionals that America was suffering from an epidemic of untreated pain—and that opioids were the solution. Their efforts were successful nationwide, including in Webb County.

c. The Manufacturers' False and Misleading Direct Advertising and Marketing of Opioids

218. The Manufacturer Defendants have intentionally made false and misleading statements regarding opioids in their advertising and marketing materials disseminated nationwide, including in Webb County. They have, among other things, (1) downplayed the serious risk of addiction; (2) created and promoted the imaginary concept of "pseudoaddiction", advocating that when signs of actual addiction begin to appear, the patient should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher dosages; (6) described their opioid products as "steady state" – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction; (7) touted the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction; (8) stated that patients would not experience withdrawal if they stopped using their opioid products; (9) stated that their opioid products are effective for chronic pain without disclosing the lack of evidence for the effectiveness of long-term opioid use; and (10) stated that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

219. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

220. Manufacturer Defendants engaged in deceptive direct-to-physician marketing, promoting the use of opioids for chronic pain through controlled and trained sales representatives who visited individual doctors and medical staff in their offices and small group speaker programs.

221. On information and belief, throughout the relevant time period these sales representatives have spread (and may continue to spread) misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors.

222. Actavis was notified by the FDA in 2010 that certain brochures were "false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."[74]

223. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use in patient education brochures and pamphlets, websites, ads and other marketing materials

224. For example:

(a) Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

(b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication is available today.[75]

(c) Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become

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

[75] Available at https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf

addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

(d) Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem."

(e) Janssen reviewed and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

(f) Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."[76]

(g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain& Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.[77]

(h) Consistent with the Manufacture Defendants' published marketing materials, upon information and belief, detailers for the Manufacturer Defendants in Texas have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Texas about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

(i) Endo, on information and belief, has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement

(j) On information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

[76] Available at, http://www.prescriberesponsibly.com/articles/opioid-pain-management

[77] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers- guide.pdf

(k) The New York Attorney General ("NY AG") found in its settlement with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue,[78] and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.[79]

225. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction should not be seen as warnings but are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon "pseudoaddiction" and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Dr. Webster was a leading proponent of this notion, stating that the only way to differentiate the two was to increase a patient's dose of opioids.[80]

226. Other examples of the Manufacturer Defendant's advocacy for the fictional concept of "pseudoaddiction" include, but are not limited to:

(a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name", "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. The 2012 edition of *Responsible Opioid Prescribing* remains for sale online.[81]

(b) On information and belief, Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain *is under-treated*.…Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

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[78] *See New York State Office of the Attorney General, A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer* (August 20, 2015), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent (last accessed December 20, 2017)

[79] The New York Attorney General, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the New York Attorney General found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Upon information and belief, Endo continues to make these false statements elsewhere.

[80] Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).

[81] *See* Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2d ed. 2012).

(c) Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

(d) Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

(e) Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long acting opioid.

227. However, Defendants' own hired gun has now conceded that pseudoaddiction is fictional. Dr. Webster has acknowledged that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[82.]

228. The 2016 CDC Guidelines also reject the concept of pseudoaddiction. The Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[83]

[82] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012

[83] *CDC Guidelines for Prescribing Opioids for Chronic Pain*, available at https://www.cdc.gov/drugoverdose/prescribing/guideline.html

229. The Manufacturer Defendants also falsely claimed that there were addiction risk screening tools – such as patient contracts, urine drug screens, and other similar strategies – that allowed them to reliably identify and safely prescribe opioids to patients predisposed to addiction.

230. In addition, the Manufacturer Defendants widely spread misleading information about the risks of addiction associated with increasing dosages of opioids over time, and downplayed the risks created by the tolerance for opioids that patients would develop after consuming the drugs over a period of time.

231. For example,

(a) On information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

(b) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available online.[84]

(c) Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

(d) Endo distributed a pamphlet edited by an opioid advocate entitled Understanding Your Pain: Taking Oral Opioid Analgesics (2004 endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . .You won't 'run out' of pain relief."[85]

(e) Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

[84] Available at, https://assets.documentcloud.org/documents/277605/apf- treatmentoptions.pdf

[85] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

(f) On information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

(g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.[86]

(h) In 2007, Purdue sponsored a CME entitled *Overview of Management Options* that was available for CME credit and available until at least 2012. It taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

(i) Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.[87]

232. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[88]

233. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients nationwide, and in Webb County, would look to opioids first for the treatment of chronic pain. The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.[89]

234. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain

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[86] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers- guide.pdf

[87] Brief of the American Pain Foundation (APF), the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) at 9

[88] 2016 CDC Guidelines *supra* note 83.

[89] *See, e.g.*, Case Challenges in Pain Management: Opioid Therapy for Chronic Pain (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

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

235. Notwithstanding their knowledge, in order to maximize profits, the Manufacturer Defendants continued to advocate in the false and deceptive manners described herein with the goal of increasing opioid use, purposefully ignoring the foreseeable consequences of their activity in terms of addiction and public health throughout the United States, and in Webb County.

d. Manufacturer Defendants' Misuse of Treatment Guidelines

236. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits including visits throughout Texas and Webb County.

(1) FEDERATION OF STATE MEDICAL BOARDS (FSMB)

237. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

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

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

240. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."[90]

241. Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were

[90] *Responsible Opioid Prescribing*, Scott M. Fishman published by Waterford Life Services (2007)

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

(2) AAPM/APS GUIDELINES

242. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement, *The Use of Opioids for the Treatment of Chronic Pain*, that endorsed opioids to treat chronic pain and claimed that the there was little risk of addiction or overdose in pain patients. [91] The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website and remained until 2011 and was taken down only after a doctor complained, though it lingers on the internet elsewhere.

243. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

244. The 2009 Guidelines promote Opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan

[91] The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf (as viewed 3/31/2016).

Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in nationwide and in Massachusetts during the relevant time period, were reprinted in the *Journal of Pain* and are still available online.

245. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

246. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug company funding – reached very different conclusions.

247. The 2012 Guidelines for *Responsible Opioid Prescribing* in Chronic Non- Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence

monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[92]

248. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."[93]

249. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the United States Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.[94]

ii. PBMs Ensured that Opioids Were Regularly Prescribed and Flooded the Market.

250. PBMs are brokers between payers (representing patients), drug manufacturers, and retailers and they influence which drug products are used most frequently and set prices for pharmacies.

251. The big three PBMs manage the drug benefits for nearly 95% of the population.[95] They control what drugs are covered by virtually all health insurance providers for over 260 million

[92] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

[93] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids* (2011).

[94] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full- er.pdf (accessed March 31, 2016).

[95] Hoffman-Eubanks, *supra* note 8.

people. PBMs made almost $260 billion last year.[96] In 2015 they covered most of the 4 billion retail prescriptions that were covered in the United States.[97] They are key participants and play a crucial role in the administration of prescription drugs.[98]

252. PBM influence is notable especially considering the lack of competition in the PBM space. Market concentration is an important indicator of a company's ability to earn extraordinary returns, and several segments in the United States pharmaceutical distribution system are highly concentrated.[99]

253. With this kind of monopolistic structure, the top three PBMs have almost exclusive control over the dissemination of opioids. In concert with drug manufacturers who give them rebates as an incentive,[100] they choose which drugs will be on a health insurance company's formulary, thus determining which drugs will be covered. If an insurance plan does not cover a drug, that drug will not enter the marketplace to be abused.

254. People with chronic pain are at the mercy of PBMs, yet PBMs make it more difficult to get pain medication that is less addictive and easier to get opioids, because opioids are generally cheaper than non-opioid alternatives. According to a study by the New York Times and ProPublica

[96] John Breslin, *Health care experts call for more transparency into PBMs*, PATIENTDAILY, Dec. 20, 2017, https://patientdaily.com/stories/511298841-health-care-experts-call-for-more-transparency-into-pbms

[97] Lydia Ramsey and Skye Gould, *A huge pharma middleman just lost its biggest customer — and it shows how drug pricing really works*, BUSINESS INSIDER, Apr. 25, 2017, http://www.businessinsider.com/express-scripts-esrx-anthem-not-renewing-pbm-2017-4

[98] Health Policy Brief, *supra* note 29.

[99] Neeraj Sood, Tiffany Shih, Karen Van Nuys, Dana Goldman, *Follow the Money: The Flow of Funds In the Pharmaceutical Distribution System*, HEALTH AFFAIRS, Jun. 13, 2017, https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/

[100] Health Policy Brief, *supra* note 29.

of 35.7 million people on Medicare prescription drug plans, in the second quarter of 2017 only one-third of them had access to pain medication less addictive than opioids.[101]

255. Even when they were asked to limit accessibility to opioids, PBMs refused. The seeds of the opioid epidemic were sown with early overprescription of OxyContin. In 2001, when officials in the West Virginia state employee health plan tried to get Purdue, which manufactured OxyContin, to require pre-authorization, Purdue refused.[102] Using the financial quid pro quo it had with the state's PBM, it paid Merck Medco (now Express Scripts) to prevent insurers from limiting access to the drug:

> The strategy to pay Merck Medco extended to other big pharmacy benefit managers and to many other states, according to a former Purdue official responsible for ensuring favorable treatment for OxyContin. The payments were in the form of "rebates" paid by Purdue to the companies. In return, the pharmacy benefit managers agreed to make the drug available without prior authorization and with low copayments.
>
> "That was a national contract," Bernadette Katsur, the former Purdue official, who negotiated contracts with pharmacy benefit managers, said in an interview. "We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or whether it has prior authorization. We like to keep prior authorization off of any drug."[103]

256. PBMs are "driving patients to opioids, away from abuse-deterrent form (ADF) and less addictive forms of opiates through formulary and pricing strategies."[104]

257. Not only do PBMs place roadblocks in the way of limiting excessive opioid prescriptions, they also make it more difficult to obtain Abuse Deterrent Formula (ADF) opioids.

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[101] Thomas and Ornstein, *supra* note 16.

[102] David Armstrong, *Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic*, STAT, Oct. 26, 2016, https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/

[103] *Id*.

[104] Charles L. Bennett MD PhD MPP, *Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses*, COLLABRX, Dec. 27, 2017, http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctor-illnesses/

These pills are more difficult to physically alter (crushing to snort or dissolving to inject) and therefore are less prone to abuse.[105] The three major PBMs carry at most 3 of the 10 FDA approved ADF opioids, while CVS Caremark, which has nearly 90 million members, carries none.[106] A study by Tufts CSSD found that ninety-six percent (96%) of all prescription opioids were non-ADF in 2015.[107]

258. This denial was endorsed by the Institute for Clinical and Economic Review, a private organization funded in part by some of the largest health plans and PBMs, that claimed that ADF opioids provided neither financial or societal benefits, even though they were given data showing that ADF OxyContin could prevent 4,300 cases of abuse and save $300 million over a five-year period.[108]

> ICER ignored research that demonstrated abuse deterrent Oxy reduced abuse by 20 percent and reduced the average daily dose of OxyContin from 80mg to 60mg. Perhaps even more important, it reduced sharing and selling of the drug for getting high ("diversion") by nearly 90 percent. The diversion of generic painkillers is responsible for as many as 63 percent of fatal prescription drug overdoses. ICER consciously decided to ignore the human cost of this deadly behavior.
>
> What the ICER report ignores entirely is that one of the factors driving abuse and addiction is the inappropriate use of generic opioids for conditions that have non-opioid, on-label options. Fifty-two percent of patients diagnosed with osteoarthritis receive an opioid pain medicine as first-line treatment, as do 43 percent of patients diagnosed with fibromyalgia and 42 percent of patients with diabetic peripheral neuropathy.[109]

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[105] Pitts, *supra* note 17.

[106] Bennett, *supra* note 104.

[107] Pitts, *supra* note 17.

[108] Robert Goldberg & Peter Pitts, *ICER Perpetuates the Opioid Crisis, Morning Consult*, MORNING CONSULT, May 11, 2017, https://morningconsult.com/opinions/icer-perpetuates-opioid-crisis/

[109] *Id*.

259. What is inconceivable is that PBMs, while making it easy to obtain generic highly addictive opioids, make it ***harder*** to obtain ***treatment***. The NY Times/ProPublica study found that insurers have erected more hurdles to approving addiction treatments than for the addictive substances themselves.[110] Only after being subject to much public pressure and congressional investigations did some insurers remove the barriers to addiction treatment.

260. A 2008 study by the Mayo Clinic[111] found that patients who were weaned off opioids and followed a non-drug treatment experienced less pain than when they were on opioids and had improved functioning. Some plans cover these costs but other do not.[112]

261. The efforts to artificially increase the number of opioids prescriptions, implemented by PBMs, directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and ***has increased in parallel with [opioid] overdoses.***"[113] Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[114] The PBMs' role in increasing prescriptions played an enormous role in the current opioid epidemic.

262. There are steps the PBMs could take. They could make it easier to access other non-addictive forms of pain relief. They could require doctors to start treating pain first with non-opioid

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[110] Thomas and Ornstein, *supra* note 16.

[111] Available at https://www.ncbi.nlm.nih.gov/pubmed/18804915

[112] Barry Meier and Abby Goodnough, *New Ways To Treat Pain Meet Resistance*, THE NEW YORK TIMES, Jun. 22, 2016, https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html?mcubz=1,

[113] Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, MORBIDITY AND MORTALITY WKLY REP., Jan. 1, 2016, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (emphasis added)

[114] *Id*.

pain medications as recommended by the CDC and turn to opioids as a last resort. They could cover alternative, non-medication treatments for pain. They could make addiction treatment more accessible. They could make their pricing more transparent so everyone could see if they were being improperly influenced by manufacturers to make choices for financial, not medical reasons. No single actor is to blame for this epidemic, but PBMs have a unique role to play.

iii. Manufacturer and Distributor Defendants Violated their Requirements to Prevent Diversion and Report Suspicious Orders under the Controlled Substances Act, 21 U.S.C. § 801 et seq.

263. In addition to their common law duties, Manufacturer and Distributor Defendants are subject to the statutory requirements of the Controlled Substances Act, 21 U.S.C. § 801 et seq. (the "CSA"), and its implementing regulations. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572.

264. The opioid epidemic was further fueled by Defendants' failure to follow the specific mandates in the CSA requiring them to help ensure that highly addictive drugs are not diverted to illegal use. The brunt of the opioid epidemic could have been, and should have been, prevented if Defendants had fulfilled their duties set by statute and common law. Defendants, who operate at every level of the opioid supply chain, had an obligation and duty to act. They did not—and the country, including the Webb County, paid the price.

265. Recognizing that highly addictive drugs like opioids can be easily abused and diverted to the black market, Congress, in the Controlled Substances Act ("CSA") set forth two relevant controls on such drugs.

266. First, the DEA sets limits on the quantity of Schedule II controlled substances—such as opioids—that may be produced in the United States in any given year. *See* 21 U.S.C. § 826(a). 28 C.F.R. § 0.100. The DEA determines these quotas based on a variety of data including sales, production, inventories, and exports. The DEA can and does lower quotas as a means of addressing abuse and diversion.

267. Second, Congress anticipated that highly addictive prescription drugs like opioids could be abused and diverted to the black market. The CSA thus sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which manufacturers, wholesalers/distributors and retail pharmacies must register with the DEA. Every registrant, in turn, is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. 21 U.S.C. § 823(e). Specifically, every registrant—is required to "maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1)

268. In particular, the CSA and its implementing regulations require all registrants to (1) report suspicious orders of prescription opioids to the DEA, and (2) perform required due diligence prior to filling any suspicious orders. See 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b). A "suspicious order" is defined as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

269. In addition, the Code of Federal Regulations requires all registrants—including defendant manufacturers and wholesalers/ distributors—to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21. C.F.R. § 1301.74(b).

270. On information and belief, Defendants knowingly, recklessly, and/or negligently supplied suspicious quantities of prescription opioids to obviously suspicious physicians and

pharmacies in and around Webb County, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under Federal law.

271. Defendants' refusal to report and investigate suspicious orders had far-reaching effects. The DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, the DEA has cited the difficulty of determining an appropriate production level to ensuring that adequate quantities are available for legitimate medical use. That is because there are no direct measures available to establish legitimate medical need. The DEA's difficulty in setting production quotas was compounded by the fact that the Manufacturer and Distributor Defendants failed to report suspicious orders of opioids and failed to maintain effective controls against diversion. Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years

272. Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed in Webb County.

a. MANUFACTURER DEFENDANTS

273. Manufacturer Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823). They have not done so.

274. Upon information and belief, Manufacturer Defendants collected, tracked, and monitored extensive data concerning suspicious physicians and pharmacies, obtained from

Distributor Defendants who supplied the Manufacturer Defendants with distribution data in exchange for rebates or other consideration so Manufacturer Defendants could better drive.

275. In return for this payment, the distributor identified to the manufacturer the product, volume and the pharmacy to which it sold the product.

276. For example, IMS Health furnished Purdue and other Manufacturer Defendants with fine grained information about the prescribing habits of individual doctors and the ordering habits of individual pharmacies.

277. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion, but instead they utilized the data to understand which regions and which doctors to target through their sales force.

278. With the knowledge of improper diversion, Manufacturer Defendants could have but failed to report each instance of diversion to the DEA while rolling out marketing campaigns to churn its prescription opioid sales.

279. Indeed, upon information and belief, Manufacturer Defendants withheld from the DEA information about suspicious orders – and induced others to do the same – to obfuscate the extent of the opioid epidemic. Upon information and belief, Manufacturer Defendants knew that if they or the other defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels, and would refuse to increase the production quotas for opioids.

280. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law (21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1)), fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including

opioids, and for violating recordkeeping requirements.[115] Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report suspicious orders for controlled substances - orders that are unusual in their frequency, size, or other patterns. . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[116] Mallinckrodt agreed that its "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."[117]

281. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.[118] Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high

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

[116] *Id.* (internal quotation omitted).

[117] 2017 Mallinckrodt MOA at p. 2-3.

[118] *See* Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, LOS ANGELES TIMES, Aug. 11, 2013, http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811

rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*,[119] Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

282. In 2016, the New York Attorney General found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.[120]

283. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it."[121] The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on

[119] *See* Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminal and addicts. What the drugmaker knew*, LOS ANGELES TIMES, Jul. 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/

[120] *See* NY Purdue Settlement, at 6-7, available at https://ag.ny.gov/pdfs/Purdue- AOD-Executed.pdf

[121] Glover and Girion, *supra* note 118.

information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

284. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the New York Attorney General found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

285. The New York Attorney General also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

286. On information and belief, the other Manufacturer Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

287. The Manufacturer Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Webb County's communities

b. DISTRIBUTOR DEFENDANTS

288. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Manufacturer Defendants are also legally required of the Distributor Defendants under federal law.

289. All opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to law enforcement downstream suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are indications of diversion.

290. Under the CSA, anyone authorized to handle controlled substances must track shipments their shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors' controlled substances and transactions, which are then used to identify diversion. Each person or entity that is registered to distribute controlled substances such as opioids must report each acquisition and distribution transaction to the DEA. See 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

291. Each registrant must also comply with the security requirements to prevent diversion set forth in 21 C.F.R. § 1301.71.

292. The DEA has provided guidance to distributors on how to combat opioid diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. On information and belief, the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the

percentage of controlled versus non-controlled purchases. On information and belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

293. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

294. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

295. Reporting an order as suspicious will not absolve a distributor of responsibility if the distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order, then filling said order with knowledge it may be suspicious constitutes a failure to maintain effective controls against diversion under 21 U.S.C. §§ 823 and 824.

296. On information and belief, the Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain,

distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

297. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

298. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

299. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[122] The DEA has repeatedly taken action to attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[123] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

> (a) In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

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[122] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industrycongress/?utm_term=.75e86f3574d3; Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* WASH. POST, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.3076e67a1a28

[123] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), available at https://oig.justice.gov/reports/2014/e1403.pdf (last accessed January 8, 2018)

(b) In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined $150,000,000.

(c) On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.

(d) On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

(e) On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

(f) On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.

(g) In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.[124]

(h) On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

(i) In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

(j) In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act.[125] On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to

[124] Lenny Bernstein and Scott Higham, *Cardinal Health fined $44 million for opioid reporting violations*, WASH. POST, Jan. 11, 2017, https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66

[125] Press Release, United States Dep't of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act

almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

(k) In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center in Florida amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.[126]

(l) In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

300. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

301. Once the DEA started to enforce suspensions of registrations to distribute controlled substances, rather than comply, manufacturers and defendants spent at least $102 million to undermine the DEA's ability to do so.

302. On February 19, 2014, acting at the behest of industry lobbyists, Representative Tom Marino introduced the "Ensuring Patient Access and Effective Drug Enforcement Act" as a supposed effort to define "imminent danger" in the 1970 act. A DEA memo noted that this bill would essentially destroy the agency's power to file an immediate suspension order of any suspicious drug shipments.

303. This bill required that the DEA show the company's actions had shown "substantial likelihood of an immediate threat," whether in death, serious bodily harm or drug abuse before a suspension order can be sought. It also gave drug companies the ability to submit "corrective action" plans before any penalties could be issued. The law essentially makes it impossible for the DEA to halt any suspicious narcotic shipments before opioids are diverted to the illegal black market.

[126] *AmerisourceBergen Plant license pulled*, BOSTON NEWS, Apr. 25, 2007, http://archive.boston.com/news/education/higher/articles/2007/04/25/amerisourcebergen_plant_license_pulled/

304. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid diversion created an enormous black market for prescription opioids, which market extended to Webb Count. Each Distributor Defendant knew or should have known that the opioids reaching Webb County were not being consumed for medical purposes and that the amount of opioids flowing to Webb County was far in excess of what could be consumed for medically necessary purposes.

305. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Webb County; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

306. It was reasonably foreseeable that the Distributor Defendants' conduct in flooding the market in and around Webb County with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

307. It is reasonably foreseeable that when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death.

308. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic faced by Webb County,

and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

309. The Distributor Defendants were aware of widespread prescription opioid abuse in and around Webb County, but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

310. The use of opioids by Webb County citizens who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, Webb County and its citizens would have avoided significant injury

311. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into Webb County.

312. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to Webb County showed an intentional or reckless disregard for the safety of Webb County and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of Webb County.

V. THE INAPPLICABILITY OF TEXAS' LIABILITY OF NONMANUFACTURING SELLERS STATUTE

313. The Texas Liability of Nonmanufacturing Sellers statute provides that "[a] seller that did not manufacture a product is not liable for harm caused to the claimant by the product" under certain circumstances. *See* Tex. Civ. Prac. & Rem. Code § 82.003. This limited immunity provision is inapplicable to the claims in the instant case because, *inter alia*, the claims brought in this lawsuit do not fall within the definition of a product liability action, because the claims brought

under this lawsuit are subject to one or more statutory exceptions to § 82.003, and because the immunity conferred in § 82.003 does not extend to illegal drug diversionary conduct.

VI. TOLLING OF THE STATUTE OF LIMITATIONS

314. Defendants' conduct has continued from the early 1990s through today, and is still ongoing. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

315. Defendants are equitably estopped from relying upon a statute of limitations defense. In Texas, the statute of limitations is tolled if, as occurred here, the defendant fraudulently concealed the existence of the claim. Only when the plaintiff discovers or could have discovered the claim through reasonable diligence does the clock start again.

316. Here, Defendants undertook efforts to purposefully conceal their unlawful conduct, by manipulating and distorting public information, knowledge, and facts; negligently and recklessly failing to make public or otherwise produce nonpublic information, over which the Defendants had exclusive possession, dominion, and control, that would have revealed the truth; and by deliberately and fraudulently concealing the truth.

317. Defendants had in their possession and control reports that those treated with opioids in clinical trials exhibited behaviors indicating that the Manufacturer Defendants' opioids were addictive; data suggesting or proving that large amounts of opioids were being diverted from legitimate, legal channels and used for medical treatment; and information that specific doctors and pharmacies were engaged in an illegal pattern of conduct that was designed to provide, in exchange for monies, opioids to persons who did not suffer from FDA approved indications.

318. Defendants purposely concealed their wrongful conduct, including by assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse. The Defendants were aware of the falsity of their misrepresentations because they were aware of their own history of conduct which included repeated breaches of such duties.

319. Manufacturer Defendants also misrepresented the impact of their behavior by providing the public with false information about opioids and have continued to use Front Groups and third parties to minimize the risks of Defendants' conduct.

320. PBM Defendants fraudulently hid their financial relationship with Manufacturer Defendants, making it impossible for Webb County to discover the PBM Defendants' role in promoting opioids through reasonable diligence.

321. Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

322. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.[127] As a result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a distributor's license was raised.

323. Because the Defendants concealed the facts surrounding the opioid epidemic, Webb County did not know of the existence or scope of the Defendants' misconduct, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

[127] *See* Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, WASH. POST, Oct. 15, 2017, https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3

324. Defendants intended that their false statements and omissions be relied upon.

325. Defendants knew of their wrongful acts and had material information pertinent to their discovery, but concealed that information from the public, including Webb County. Only Defendants knew of their widespread misinformation campaign and of their repeated, intentional failures to prevent opioid diversion.

326. Defendants cannot claim prejudice due to a late filing because this suit was filed upon discovering the facts essential to the claim. Indeed, the full existence, extent, and damage of the opioid crisis and those responsible, including the PBMs, have only recently come to light.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

327. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

328. Texas law prohibits the maintenance of a public nuisance. Under common law, a public nuisance may result from intentional conduct, negligent conduct, or conduct that is unusually hazardous, abnormal, or out of place considering the surroundings. A public nuisance adversely impacts an entire community or a significant portion of the public. Therefore, a cause of action for public nuisance exists where a defendant's abnormally hazardous conduct negatively affects the community at large. "The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Webb County as well as the adverse social and environmental outcomes associated with widespread and/or illegal opioid use.

329. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to the County and its residents as described herein.

330. The Manufacturer Defendants knew or should have known that their promotion of opioid use would create a public nuisance:

(a) Manufacturer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Webb;

(b) Manufacturer Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management;

(c) Manufacturer Defendants misrepresented the benefits of opioids for chronic pain and fraudulently concealed, misrepresented, and omitted the serious adverse effects of opioids, including the addictive nature of the drugs;

(d) Manufacturer Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community would suffer as a result.

331. The Manufacturer Defendants' actions were a substantial factor in making opioids widely available and widely used. The Manufacturer Defendants' actions were a substantial factor in doctors and patients not accurately assessing and weighing the risks and benefits of opioids for chronic pain. Without the Manufacturer Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.

332. The Manufacturer Defendants also knowingly, intentionally, recklessly, and/or negligently funneled massive quantities of prescription opioids to physicians and other prescribers who they knew or should have known wrote suspicious prescriptions and/or wrote prescriptions for known abusers of prescription opioids.

333. The Manufacturer Defendants knowingly, intentionally, recklessly, and/or negligently disseminated prescription opioids to distributors who they knew or should have known failed to implement effective controls and procedures to guard against theft, diversion, and abuse of prescription opioids.

334. The Manufacturer Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" known for providing opioids to known drug abusers, and known drug dealers, knowing that such opioids would be illegally trafficked and abused.

335. The Manufacturer Defendants knowingly and intentionally financially incentivized the PBM Defendants to place their opioids on the PBMs formularies irrespective of medical necessity, resulting in widespread and unnecessary overuse.

336. The Distributor Defendants' nuisance-causing activities include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of prescription opioids, and failing to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

337. The Distributor Defendants also knowingly and intentionally enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" known for providing opioids to known drug abusers, and known drug dealers, knowing that such opioids would be illegally trafficked and abused.

338. The PBM Defendants knowingly and intentionally chose to include opioids on their formularies that were more addictive to users because they generated greater profits. This failure led directly to the increased likelihood of addiction.

339. The PBM Defendants knowingly and intentionally chose to include opioids that were easier to misuse (for example, by crushing them into powder and mixing them with liquid in order to inject them) instead of Abuse Deterrent Formulations ("ADFs") which tended to be more expensive. This choice directly led to the ease with which the pills could be misused.

340. The PBM Defendants knowingly and intentionally made it more expensive or more difficult to obtain knowingly efficacious non-opioid medications for pain. This led directly to the increased sale and use of opioids.

341. The PBM Defendants knowingly and intentionally chose not to include certain medications that would prevent overdoses or made them more difficult or expensive to obtain.

342. The PBM Defendants chose not to cover or provide less coverage for drug treatment.

343. The PBM Defendants knowingly and intentionally created their formularies to ensure that an excessive number of pills were made available to users for use and abuse.

344. The public nuisance created by Defendants endangers the health and safety of the County's residents.

345. The public nuisance created by Defendants' actions has caused and continues to cause significant harm to the community that includes but is not limited to:

(a) Opioid-related drug overdose deaths;

(b) The disease of opioid addiction and other diseases related to long-term opioid use;

(c) Infants born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

(d) Other child abuse and neglect resulting from opioid abuse;

(e) Crime associated with illegal drug use and opioid sales;

(f) Unemployment resulting from an inability to work while addicted to opioids;

(g) Blight, vagrancy, property damage, and property crime.

346. Defendants' actions created a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them. The result of Defendants'

actions is not only an explosion of prescription opioids on the black market, but also a marked increase in the availability of heroin and synthetic opioids.

347. The diversion of opioids into the secondary, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the County.

348. Adults and children in Webb County who have never taken opioids have also suffered the costs of the Defendants' public nuisance. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

349. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which could be used to benefit the public at large in the County.

350. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in the Manufacturer Defendants' dissemination of false "scientific" facts and advice in their pursuit of increased profits. There is no legitimate societal interest in the Distributor Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in the PBM Defendants promoting and reimbursing for pills that are more addictive and easier to divert purely for financial reasons by giving such drugs prime position on their formularies.

351. At all times, the Manufacturer Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. The Manufacturer Defendants and PBM Defendants also had the power to shut off the supply of illicit opioids into the County.

352. The Distributor Defendants possessed the right and ability to control the nuisance-causing outflow of prescription opioids to pharmacy locations and other points of sale into the County.

353. The PBM Defendants had the power to minimize the sale and use of less effective, more addictive and more divertible opioids. They could have prohibited doctors from prescribing opioids for non-chronic pain when other non-opioid options were available. They could have responded favorably to direct requests from governmental payors attempting to control opioid flow. They could have made it easier for patients to access less addictive, less dangerous drugs.

354. As a direct and proximate result of the public nuisance, the County has sustained (and continues to sustain) harm by spending a substantial amount of money trying to fix the societal harms caused by the Defendants' nuisance-causing activity, including, but not limited to, the costs of hospital services, healthcare, emergency medical services, social services, prevention, treatment, intervention and law enforcement as set forth more fully above in Section IV, B.

355. Defendants should be required to pay the expenses the County incurred or will incur in the future to fully abate the nuisance.

SECOND CAUSE OF ACTION
NEGLIGENCE PER SE
(AGAINST MANUFACTURER AND DISTRIBUTOR DEFENDANTS)

356. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

357. As set forth herein, the Manufacturer and Distributor Defendants failed to perform their statutory and regulatory obligations under the CSA and Texas Controlled Substances Act, Tex. Health & Safety Code § 481.001 *et seq*., which was enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

358. Defendants failed to maintain effective controls against diversion as required under 21 C.F.R. § 1301.74(b).

359. Defendants failed to report suspicious orders to law enforcement and perform due diligence prior to filling orders.

360. Defendants failed to design and operate a system to disclose suspicious orders of controlled substances.

361. Together, these requirements were intended to prevent opioid use and diversion.

362. The Manufacturer and Distributor Defendants also violated the Texas Controlled Substances Act by knowingly diverting opioids for unlawful use. Tex. Health & Safety Code § 481.1285(b)(2).

363. The Defendants' failure to comply with these requirements caused precisely the type of harm that the requirements were intended to prevent.

364. As a proximate result of these failures, pills flooded the system causing the County to incur excessive costs related to responding to the opioid crisis. These costs include, but are not limited to, increased policing, medical, fire, and court services, lost tax revenues, and lost communal benefits of the County's limited and diverted resources.

365. These injuries are a direct and proximate result of the Manufacturer and Distributor Defendants' conduct, and Webb County should be awarded civil penalties pursuant to the CSA and § 481.1191 of the Texas Controlled Substances Act.

THIRD CAUSE OF ACTION
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

366. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

367. Defendants have a duty to Webb County to employ a reasonable standard of care in the sale, distribution, dispensing, reimbursement and promotion of prescription opioids. This includes a duty to not create a foreseeable risk of harm to others.

368. Defendants breached this duty by failing to take any action to prevent or reduce the unnecessary, non-medical or criminal use of opioids. Collectively, and individually, Defendants made prescription opioids available to the marketplace with the knowledge that they were likely being used for non-medical purposes and/or posed an inherent danger to patients who were using opioids for chronic pain.

369. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

370. Defendants placed their profit motives above their legal duty and enabled, encouraged and caused the over-prescribing and distribution of opioids.

371. All Defendants knew of the highly addictive nature of prescription opioids and knew of the high likelihood of foreseeable harm to patients and communities from prescription opioid addiction and diversion. Defendants breached their duties when they failed to act with reasonable care to prevent the diversion of prescription opioids.

372. A negligent and/or intentional violation of the Defendants' duties poses distinctive and significant dangers to the County and its residents, including epidemic levels of addiction and the diversion of opioids for illegitimate purposes.

373. As a proximate result of the failure to prevent the over prescription and excessive distribution of opioids, the Defendants have caused the County to incur excessive costs related to responding to the opioid crisis. These costs include but are not limited to, increased policing, medical, fire, and court services, lost tax revenues, and lost communal benefits of the County's limited and diverted resources.

FOURTH CAUSE OF ACTION
GROSS NEGLIGENCE
(AGAINST ALL DEFENDANTS)

374. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

375. Defendants' scheme to optimize profits regardless of the effect on Webb County was done intentionally.

376. Defendants' failure to take any action to prevent or reduce the unnecessary, non-medical, or criminal use of opioids was grossly negligent and done with conscious indifference or disregard for the rights and safety of others in a reckless, wanton, willful, or grossly negligent manner that had a great probability of causing substantial harm.

377. At every stage, Defendants knew or should have known that their conduct would create an unreasonable risk of physical harm to others, including Webb County and its residents, and should be held liable in punitive and exemplary damages to the County.

FIFTH CAUSE OF ACTION
FRAUD
(AGAINST MANUFACTURER DEFENDANTS)

378. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

379. As set forth herein, Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material

to the County and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

380. Defendants intentionally made inaccurate representations regarding the adverse medical conditions associated with the use of opioids.

381. Defendants knew or reasonably should have known that the representations made to the County regarding the risks of opioids were false or incomplete and misrepresented material facts regarding the use of opioids for chronic pain.

382. Defendants willfully, knowingly, and deceptively withheld material facts regarding the risks and side effects associated with opioids from Webb County, healthcare providers, and consumers.

383. The County and its residents reasonably relied on the representations made by Defendants, which caused the County, through its programs, departments, and agencies, to spend County funds responding to the opioid crisis.

384. Webb County's healthcare providers and consumers were justified in their reliance on Defendants to educate them as to the risks and dangerous and potentially life-threatening side effects associated with opioid use.

385. As a proximate and legal result of Defendants' fraudulent misrepresentations, Webb County has suffered and will continue to suffer damages and is therefore entitled to recover for those damages.

386. Defendants' conduct was willful, wanton, and malicious and was directed at patients within the County.

387. The reprehensible nature of the Defendants' conduct further entitles the County to an award of punitive damages.

SIXTH CAUSE OF ACTION
CIVIL CONSPIRACY
(AGAINST ALL DEFENDANTS)

388. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

389. The Defendants agreed to engage in a campaign to flood the market with false and misleading information about the safety of prescription opioid use for the treatment of chronic pain, to evade controls on opioid diversion, to increase opioid quotas, and to promote their use through formulary placements, not requiring pre-authorization and not promoting less addictive alternatives.

390. The Defendants did so in an effort to profit off the increased sales of prescription opioids.

391. Each Defendant made false or misleading statements directly and through third parties to further the objectives of their conspiracy.

392. Webb County was directly and proximately harmed by the Defendants' civil conspiracy in an amount to be determined in this litigation.

SEVENTH CAUSE OF ACTION
VIOLATION OF THE DECEPTIVE TRADE PRACTICES –
CONSUMER PROTECTION ACT § 17.41 ET SEQ.
(AGAINST ALL DEFENDANTS)

393. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

394. The Texas Deceptive Trade Practices – Consumer Protection Act ("DTPA") is designed to protect consumers against false, misleading, and deceptive business practices. Tex. Bus. & Comm. Code § 17.44(a). Defendants' acts and omissions, as set forth herein, constitute false or misleading oral or written statements or other representations and omissions that

Defendants knowingly made in the regular course of their trade and in connection with the sale of their goods, which may have, tended to, or did deceive or mislead consumers and medical professionals. These acts and omissions therefore constitute unfair and deceptive trade practices in violation of § 17.44(a).

395. The DTPA specifically prohibits a person from representing that goods or services have "sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have." § 17.46(b)(5).

396. Moreover, "the term 'false, misleading, or deceptive acts or practices' includes, in the production, sale, distribution, or promotion of a synthetic substance that produces and is intended to produce an effect when consumed or ingested similar to, or in excess of, the effect of a controlled substance or controlled substance analogue, as those terms are defined by Section 481.002, Health and Safety Code: (A) making a deceptive representation or designation about the synthetic substance; or (B) causing confusion or misunderstanding as to the effects the synthetic substance causes when consumed or ingested." § 17.46(b)(31).

397. As alleged herein, each Manufacturer Defendants violated the DTPA by representing that opioids have uses or benefits in treating chronic, non-cancer pain that they do not have, and by misrepresenting the risks of addiction, overdose, and other negative effects that opioids pose.

398. Distributor Defendants violated the DTPA by making deceptive representations about using opioids to treat chronic pain and/or omitting or concealing material facts, and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Distributor Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

399. The PBM Defendants violated the DPTA by making deceptive representations about using opioids to treat chronic pain and/or omitting or concealing material facts, and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each PBM Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

400. Defendants engaged in the above-described acts and omissions intentionally and with knowledge that harm might result, and thus willfully violated the DTPA.

401. As a proximate result of Defendants' deceptive acts, Defendants have caused the County to incur excessive costs related to responding to the opioid crisis. These costs include but are not limited to, increased policing, medical, fire, and court services, lost tax revenues, and lost communal benefits of the County's limited and diverted resources.

402. Unless enjoined from doing so, Defendants will continue to violate the DTPA.

403. The County seeks reimbursement of all monies paid for Defendants' products by the County and its residents.

404. Because the Defendants willfully and knowingly violated the DTPA, the County is entitled to three times the damages it sustained by the Defendants and an order enjoining such acts. § 17.50(b)(1)-(2).

EIGHTH CAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

405. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

406. As an intended result of their intentional wrongful conduct as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the County and its residents.

407. Defendants were aware they were receiving this benefit.

408. Defendants' conduct was designed to bring about this benefit.

409. Defendants have been unjustly enriched in the form of profits because of their wrongful conduct.

410. As a matter of equity, Defendants should be required to disgorge their unjustly obtained profits from the County's purchases of opioids.

NINTH CAUSE OF ACTION
THE LANHAM ACT
U.S.C. § 1125(A)(1)(B)
(AGAINST MANUFACTURER DEFENDANTS)

411. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

412. The Lanham Act provides, in pertinent part: "Any person who, on or in connection with any good or services, or any container for goods, uses in commerce any word, terms, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which…in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act."[128]

413. As set forth herein, the Manufacturer Defendants committed repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in connection with the sale of goods and services.

[128] 15 U.S.C. § 1125(a)(1).

414. The Manufacturer Defendants engaged in a false and misleading advertising campaign designed to deceive doctors and the public into believing that opioids were safe for the treatment of chronic pain.

415. Webb County is a "person" for purposes of the civil remedy that the Lanham Act created.

416. Webb County is entitled to legal and equitable relief, including injunctive relief, disgorgement of profits, and damages in an amount to be determined in this litigation.

TENTH CAUSE OF ACTION
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO') 18 U.S.C § 1962(C) - RICO
(AGAINST ALL DEFENDANTS)

417. Webb County re-alleges and incorporates by reference each of the allegations contained in the preceding Paragraphs of this Complaint as though fully alleged herein.

418. This claim is brought against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961 et seq.

419. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity …" 18 U.S.C. § 1962(c).

420. Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, Defendants were "person[s]" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, a legal or beneficial interest in property.

421. The Defendants conducted and participated in the conduct of the opioid promotion enterprise described herein through a pattern of racketeering activity as defined in 18 U.S.C.

§1961(b), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); 18 U.S.C. § 1961(d) "fraud connected with … the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance … as defined in section 102 of the Controlled Substances Act"; and 19 U.S.C. § 1952 (entering goods into commerce using statement or omission that is materially false).

422. The opioid promotion enterprise described herein was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to increase the use of opioids and fraudulently sell and distribute as many opioids as possible by falsely marketing them as safe for treatment of chronic pain, suppressing evidence to the contrary, maintaining their placement on formularies to ensure reimbursement, limiting access to competing less-additive alternatives and improperly inducing physicians to prescribe opioids for chronic pain.

423. The opioid promotion enterprise described herein engaged in and affected interstate commerce because, inter alia, it marketed, promoted, sold, provided or reimbursed for opioids to thousands of individuals and entities throughout the United States.

424. Each of the Defendants either actively participated and/or aided and abetted in the pursuance of this common purpose. Each of the participants in the opioid promotion enterprise described herein received substantial revenue from the scheme, in the form of sales for Manufacturer Defendants, sales and kickbacks for Distributor Defendants who reached particular monthly goals, and rebates or other financial incentives for PBM Defendants who placed opioids in a preferred place on a formulary or otherwise made opioids available for improper use—all in an effort to maximize profits.

425. Under the present facts, each co-conspirator either (a) agreed to operate or manage the enterprise that did and does feloniously deal in controlled substances, an offense punishable under the laws of the United States, or (b) if a co-conspirator did not agree to operate or manage the enterprise, each co-conspirator knowingly agreed to facilitate others who did and do operate or manage the enterprise of felonious dealing in controlled substances, an offense punishable under the laws of the United States.

426. The Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues while benefitting from, encouraging, indirectly creating, contributing to, and maintaining an illegal secondary market for highly addictive and dangerous drugs. The predicate acts are not isolated events.

427. While Defendants participated in, and are members of, the enterprises described herein, they have an existence separate from the enterprises, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

428. In addition, finding it impossible to achieve their increasing sales ambitions through legal means, the Defendants systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders, allowing hundreds of millions of pills to enter the illicit market, which allowed the Defendants to derive and be unjustly enriched by obscene profits.

429. An association-in-fact enterprise existed between the Defendants, the purpose of which was to engage in the sale of opioids while deceiving the public and regulators into believing that the Defendants were faithfully fulfilling their obligations.

430. The Defendants operated as an association-in-fact to unlawfully increase sales and revenues in order to unlawfully increase the quotas set by the DEA, which in turn allowed them to collectively profit from distributing a greater pool of opioids each year. Each member of the Rico enterprise described herein participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits generated by the scheme.

431. The Defendants also engaged in lobbying efforts against the DEA's authority to investigate and hold responsible those who failed in their duty to prevent diversion. The Ensuring Patient Access and Effective Drug Enforcement Act was the result of an effort by the Defendants to reduce the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.

432. In order to achieve this goal, Defendants thwarted the ability of federal and state regulators to prevent diversion. As set forth herein, this unified scheme was furthered by (1) habitual noncompliance with federal and state law; (2) intensive lobbying of federal and state official to evade further regulation; and (3) increasing and/or maintaining high production quotas for their prescription opioids from which Defendants could profit for as long as possible.

433. The RICO enterprise described herein functioned by selling prescription opioids in interstate commerce in violation of the Defendants' legal obligations to maintain effective controls against opioid diversion.

434. Each Defendant communicated with other Defendants, shared information on a regular basis, and participated in joint lobbying efforts, trade industry organizations, contractual relationships, and other coordination of activities to effect the RICO Scheme. The contractual relationships included, on information and belief, rebates and/or chargebacks on opioid sales and security arrangements.

435. The Defendants refused to identify, investigate, or report suspicious orders despite their actual knowledge of drug diversion rings.

436. The Defendants worked together to ensure that opioid production quotas continued to increase, allowing them to generate more and more profits from the RICO enterprise described herein.

437. In addition to violating their statutory requirement to minimize diversion of opioids, as set forth herein, Defendants and their co-conspirators engaged in a coordinated conspiracy to deceive the American public and the medical profession about the efficacy and safety of opioids, including by minimizing the addictive qualities of opioids.

438. To effectuate their goal of maximizing the number of opioid users and their profits at all costs, Defendants engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the sale and distribution of the Defendants' opioids and to popularize the misunderstanding that opioids are effective for chronic pain and that the risk of addiction is low.

439. The formation, existence, and actions of the enterprise described herein were essential to the success of Defendants' campaign to increase and maintain profits from unlawful sales of opioids. The constituent members of the enterprise were aware that, unless they agreed to act and acted as an enterprise, their sales of prescription opioids would substantially decrease, and accordingly, the profits would substantially diminish.

440. Each of the Defendants, in concert with co-conspirators, created and maintained systematic links for a common purpose, i.e., to aid in marketing opioids as effective and safe for use by patients in moderate pain, while suppressing evidence to the contrary. Each of the participants in

the enterprise described herein received revenue, directly or indirectly, and/or otherwise benefitted from the scheme to promote opioids as safe and non-addictive.

441. At all relevant times, each Defendants was aware of the enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids. In fact, Distributor Defendants received kick-backs from Manufacturer Defendants if they reached particular monthly goals and PBM Defendants received rebates and other financial incentives to promote the Manufacturer Defendants' drugs to ensure they were widely sold.

442. Such revenue was exponentially greater than it would have been had opioids been marketed appropriately and the true efficacy and safety risks of prescription opioids disclosed.

443. The Manufacturer and PBM Defendants and their co-conspirators engaged in a conspiracy to increase the use of the least expensive, most addictive opioid by controlling the drugs' placement on the formulary. The PBM formularies are a critical piece of the enterprise described herein. The enterprise would not have succeeded absent the opioids' placement on the formulary. The formulary controlled which opioids were paid for, reimbursed, and covered by public and private pharmacy benefit plans.

444. Defendants' fraudulent scheme consisted of, inter alia: exacerbating the opioid crisis by choosing drugs to put on their formularies that provided the largest profit to themselves, regardless of the addictive quality of the drug and whether there was an alternative available.

445. The PBM and Manufacturer Defendants coordinated to ensure that the PBM Defendants got the maximum profit at the expense of patients.

446. The persons engaged in the enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities.

447. All participants of the enterprise described herein were aware of Defendants' control over the activities of the enterprise in promoting opioids for use in every situation in which a patient is in pain. Furthermore, each part of the enterprise benefited from the existence of the other parts.

448. The enterprise described herein is engaged in interstate commerce, or its activities affect interstate commerce, because Defendants marketed, promoted, sold, or provided opioids to thousands of individuals and entities throughout the United States, including promotion of opioid sales between or among residents of different states, and/or physically transporting drugs or promotional materials across state lines.

449. The Defendants' predicate acts of racketeering, 18 U.S.C. § 1961(1) include, but are not limited to:

(a) Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. Mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell, promote, distribute and reimburse the opioids by means of false pretenses, misrepresentations, promises, omissions and the operation of the PBM formularies; and

(b) Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to deceptively market, sell, promote, reimburse, distribute the opioids by means of false pretenses, misrepresentations, promises, omissions and the operation of the PBM formularies.

450. The Defendants' use of the mails and wires include, but are not limited to:

(a) representations that they would comply with their duty to (1) design and operate a system to disclose to the registrant suspicious orders of controlled substances, and (2) disclose the results of such a program to resolve concerns about overprescription and diversion of opioids;

(b) communications with and among the enterprise participants that misrepresented the safety and risks of opioid drugs amongst themselves and others;

(c) communications with Plaintiff, inducing payments for opioids by misrepresenting the safety and risks of opioids;

(d) receiving the proceeds in the course of and resulting from Defendants' improper scheme;

(e) transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Opioid Promotion Enterprise.

(f) suppressed and destroyed records of suspicious orders to hide evidence of overprescription and diversion

(g) negotiations concerning opioid formulary placement, opioid alternatives, prior authorization requirements, rebates and other incentives and arrangements between Manufacturer Defendants and PBMs.

451. The Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme, and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing, promoting, and distributing prescription opioids.

452. Many of the precise dates of the Defendants' criminal actions are not known and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the unified scheme alleged herein depended upon secrecy and, towards that end, Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal and scheme, Defendants likely committed thousands, if not millions, of predicate acts of racketeering activity.

453. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other, had a similar purpose, involved the same or similar participants and methods of commission, and have similar results affecting similar victims, including Plaintiff, Webb County. These acts pose a threat of continued racketeering activity and constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

454. These acts were conducted pursuant to an understanding and agreement, whether explicit or implicit, that each member would participate to facilitate and further the purpose of the Defendants' enterprise, which was to maximize profits by manufacturing, distributing, and selling as many opioid pills as possible.

455. As a result of Defendants' racketeering activity, Webb County has been injured in their business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs. But for the conduct of the enterprise's affairs, Webb County would not have sustained damages.

456. The opioid promotion enterprise described herein largely created, encouraged, contributed to, and maintained an illegal secondary market for opioids.

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

458. Defendants' violations of 18 U.S.C. §1962(c) have directly and proximately caused injuries and damages to Webb County and the public who are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. §1964(c).

ELEVENTH CAUSE OF ACTION
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C § 1962(D) - RICO CONSPIRACY
(AGAINST ALL DEFENDANTS)

459. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth.

460. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

461. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the opioid promotion enterprise described herein through a pattern of racketeering activity.

462. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff of money.

463. The nature of the above-described Defendants' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § l962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity.

464. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § l962(c), Webb County has been and continues to be injured in its business or property as set forth more fully above.

465. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

(a) Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

(b) Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

466. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and, upon information and belief, will continue into the future unless enjoined by this Court.

467. Webb County has been injured in its property by reason of these violations in that Webb County has paid hundreds of millions of dollars for opioid drugs, the treatment related to the misuse, addiction and/or overdose of opioids, and the abatement of the societal harms that

opioid addiction and misuse have caused that they would not have paid had Defendants not conspired to violate 18 U.S.C. § 1962(c).

468. Injuries suffered by Plaintiff were directly and proximately caused by Defendants' racketeering activity as described above.

469. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiff for compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays:

1. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

2. That Defendants be enjoined from, directly or indirectly, through any third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Texas law;

3. That Plaintiff recover all measures of damage, including punitive and exemplary damages, allowable under law, and the judgment be entered against Defendants in favor of Plaintiff;

4. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law;

5. That Defendants be ordered to abate the public nuisance that they caused and that they be ordered to reimburse Plaintiff for the amount of damages sustained by the Plaintiff as a result of Defendants' breaches of statutory and common law as described more fully in this Complaint;

6. Punitive damages against the Defendants, including, but not limited to, punitive damages for those acts or omissions which resulted in the Defendants, or any one of them, being convicted of a felony under state or federal law, and which acts or omissions caused the Plaintiff's damages or injuries;

7. An award of restitution from the Defendants, and an order requiring disgorgement of all profits, benefits and other compensation obtained by the Defendants;

8. An order of abatement and permanent injunction against all Defendants prohibiting them from flooding the Texas markets, specifically Webb County, with illegal opioids; and

9. Such other and further relief as the Court deems just and proper.

THIS IS THE FIRST REQUEST FOR INJUNCTIVE RELIEF.

[signature page follows]

Date: January 25, 2018

Respectfully submitted,

THE CICALA LAW FIRM PLLC

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