

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE**

METROPOLITAN GOVERNMENT OF NASHVILLE  
AND DAVIDSON COUNTY, TENNESSEE,

Plaintiff,

vs.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.;  
THE PURDUE FREDERICK COMPANY, INC.;  
CEPHALON, INC.; TEVA PHARMACEUTICAL  
INDUSTRIES, LTD.; TEVA PHARMACEUTICALS  
USA, INC.; JOHNSON & JOHNSON; JANSSEN  
PHARMACEUTICALS, INC.; ORTHO-MCNEIL-  
JANSSEN PHARMACEUTICALS, INC. n/k/a  
JANSSEN PHARMACEUTICALS, INC.; JANSSEN  
PHARMACEUTICA, INC. n/k/a JANSSEN  
PHARMACEUTICALS, INC.; NORAMCO, INC.;  
ENDO HEALTH SOLUTIONS INC.; ENDO  
PHARMACEUTICALS INC.; MALLINCKRODT  
PLC; MALLINCKRODT LLC; ALLERGAN PLC  
f/k/a ACTAVIS PLC; WATSON  
PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;  
WATSON LABORATORIES, INC.; ACTAVIS, LLC;  
ACTAVIS PHARMA, INC. f/k/a WATSON  
PHARMA, INC.; INSYS THERAPEUTICS INC.;  
AMERISOURCEBERGEN DRUG CORPORATION;  
CARDINAL HEALTH, INC.; and MCKESSON  
CORPORATION,

Defendants.

Case No.

**COMPLAINT AND JURY  
TRIAL DEMANDED**

Plaintiff, METROPOLITAN GOVERNMENT OF NASHVILLE AND DAVIDSON COUNTY, TENNESSEE (“Nashville,” “Davidson County,” “County” or “Plaintiff”), brings this lawsuit against prescription opioid manufacturers and distributors to recover taxpayer money and resources spent to combat the opioid epidemic wreaking havoc on the Nashville community. Nashville is the center of the music and healthcare industries. Like many other cities and counties in Tennessee and across the nation, though, Nashville is battling an opioid crisis whose hallmarks are addiction and death. So far this year, well over 200 Nashville residents have died due to opioid overdoses.

Defendants in this lawsuit caused the epidemic. Defendants violated the law by falsely promoting highly addictive opioids as safe and necessary, while concealing the true risks of the drugs. Defendants also conspired to manufacture and distribute millions of doses of highly addictive opioids, knowing that they were being trafficked and used for illicit purposes, and recklessly disregarded their devastating effect on the taxpayers and government of Nashville. As a result of the conspiracy, Nashville taxpayers have spent tens of millions of dollars and countless resources to fight the opioid crisis and deal with its effects on their community.

Accordingly, to protect the families of Nashville and to recover lost resources, Nashville brings this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Mallinckrodt Plc, Mallinckrodt LLC, Allergan PLC f/k/a Actavis PLS, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC,

Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., Insys Therapeutics, Inc., (“Manufacturer Defendants”), AmerisourceBergen Drug Corporation; Cardinal Health, Inc., and McKesson Corporation (“Distributor Defendants”) (collectively “Defendants”). Based upon personal knowledge, information, belief, and investigation of counsel, Nashville specifically alleges:

### **INTRODUCTION**

1. Opioids are estimated to kill upwards of 100 Americans per day, and cost health services providers billions of dollars per year both in payments for unnecessary and harmful prescriptions of the drugs themselves and the costs of treating the diseases and injuries they cause.

2. Accidental drug overdose deaths, of which at least two-thirds are opioid-related overdoses, are the leading cause of death for Americans under the age of 50.

3. Accidental drug overdose deaths, predominantly from opioids, exceed the number of deaths caused by car wrecks or guns.

4. The economic burden caused by opioid abuse in the United States is approximately \$78.5<sup>1</sup> billion, including lost productivity and increased social services, health insurance costs, increased criminal justice presence and strain on judicial resources, and substance abuse treatment and rehabilitation.

5. Opioid manufacturing and distributing companies systematically and repeatedly disregarded the safety of their customers and the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

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<sup>1</sup> *CDC Foundation’s New Business Pulse Focuses on Opioid Overdose Epidemic*, Centers for Disease Control and Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html>.

6. Corporate greed and callous indifference to known, serious potential for human suffering have caused this public health crisis. Defendants helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in this country.

7. For too long, the public at large has been forced to contend with the deadly aftermath of the proliferation of opioids in society. Those responsible should be required to internalize the costs with which they have burdened society.

8. Defendants' marketing scheme — and not any medical breakthrough — rationalized prescribing opioids for chronic pain and opened the floodgates for opioid use and abuse.

9. Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of “pseudoaddiction” and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction. Conversely, Defendants 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 good scientific evidence to support Defendants' claims.

10. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages.

11. Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as “key opinion leaders” (“KOLs”) and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, Continuing Medical Education (“CME”) programs, medical conferences and seminars, and scientific articles. Working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

12. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant’s misrepresentations has been confirmed by the U.S. Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.

13. Defendants’ efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation’s physicians in August 2016, the then-U.S. Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of

[whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.”<sup>2</sup>

14. This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale, and a population of patients physically and psychologically dependent on them. When those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

### **JURISDICTION AND VENUE**

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 based on the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, et seq. (“RICO”).

16. In addition, federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332, in that in each of the constituent actions there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds \$75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

17. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of Tennessee, purposefully directed their actions toward Tennessee, consensually submitted to the jurisdiction of Tennessee when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Tennessee necessary to constitutionally permit the Court to exercise jurisdiction.

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<sup>2</sup> Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at <http://turnthetiderx.org/>.

18. Venue is proper in this District under 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gives rise to the claim of relief in this District. Moreover, Plaintiff Nashville is located in this District, and a substantial part of property that is the subject of this action is situated in this District.

### **PARTIES**

#### **A. Nashville**

19. Nashville, Tennessee, is the capital and most populous city of Tennessee. It is a consolidated city municipality within Davidson County, which includes six smaller municipalities. Nashville's population is roughly 700,000 people, according to 2015 U.S. Census Bureau statistics. However, the Nashville metropolitan area, which includes Nashville and several surrounding counties include a population of roughly 1.8 million people.

20. Megan Barry is the duly elected Mayor and executive of Nashville, which is governed by a Mayor and a City Council consisting of 40 members.

21. David Briley is the Vice Mayor of Nashville and presides over the City Council.

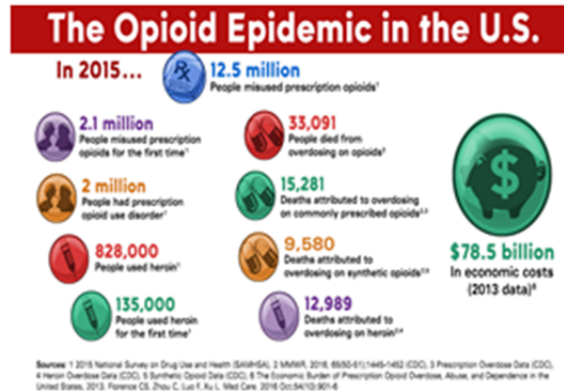
22. Nashville has the authority under the laws of the State of Tennessee to bring this lawsuit.

23. Nashville is at the center of a rising opioid epidemic in the United States.

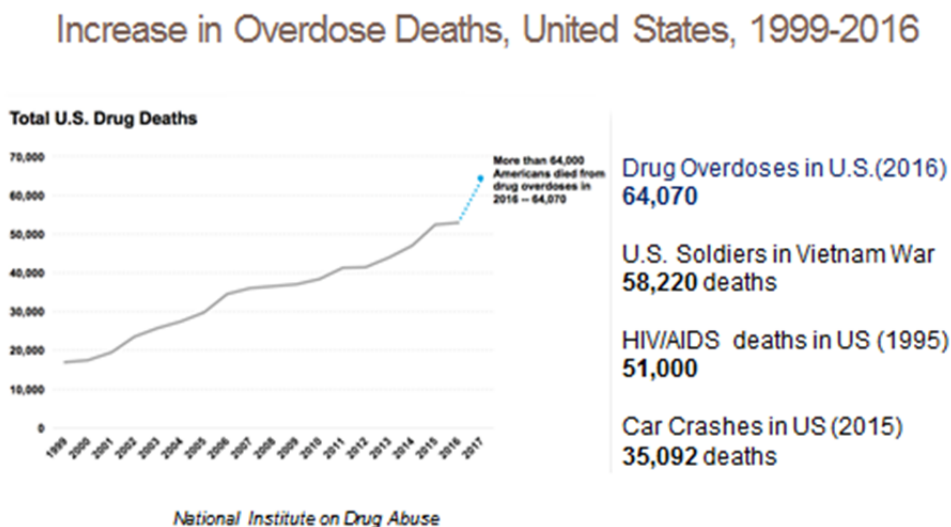
24. The slide below sets forth some of the national costs of the opioid epidemic in the United States, including nearly \$80 billion in costs nationally in 2015; 12.5 million people misusing prescription opioids and more than 33,000 deaths from overdoses on opioids in 2015 alone. The number of deaths due to opioids has increased each year thereafter.

## Opioids in the United States

- 37.8% of US adults used prescription pain killers in 2015
  - Prescriptions for opioids and deaths have quadrupled in the past 15 years
  - At least 50% of opioid overdoses involve prescriptions



25. The number of deaths have continues to increase at an alarming rate in recent years as the slide below sets forth:

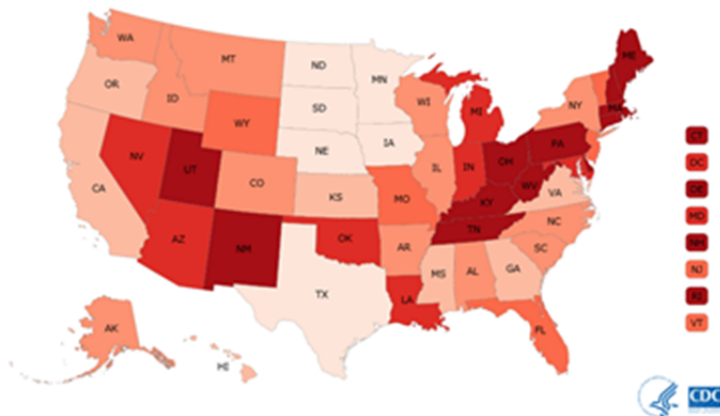




26. Tennessee has the third highest levels of prescriptions for opioids in the United States. While prescriptions are slightly declining, adverse health outcomes such as overdoses and Neonatal Abstinence Syndrome (“NAS”) and mortality rates are not declining.

27. There were 1,631 overdose deaths in Tennessee in 2016:

### Overdose Deaths – United States, 2016

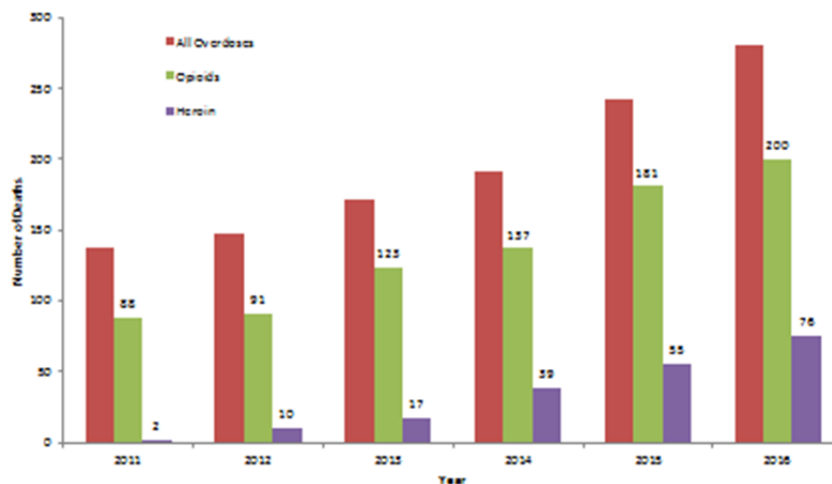


There were 1,631 overdose deaths in Tennessee in 2016



28. The number of deaths from opioid and heroin overdoses in Nashville has increased dramatically in recent years as the chart below shows:

## Overdose Deaths in Davidson County, 2011 - 2016



Around 70% of all overdoses in Davidson County involve at least one opioid  
2016: 84 homicides;

29. In 2016, around 70 percent of all overdoses in Nashville involved at least one opioid and 84 homicides involved opioids.

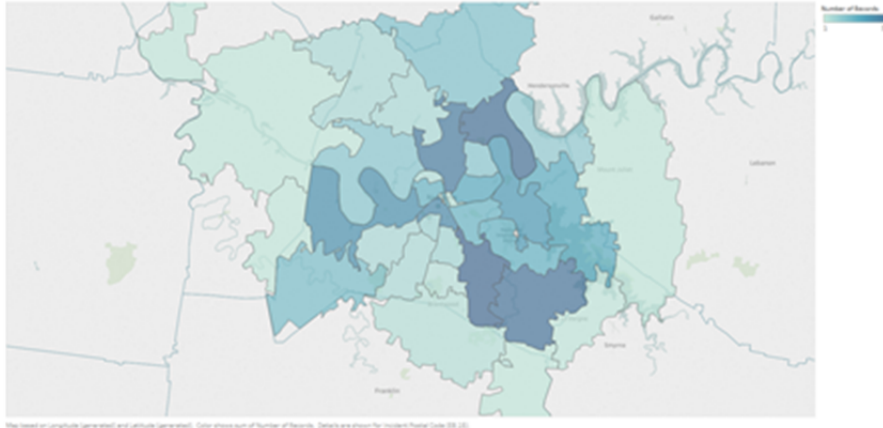
30. Nashville has created a working group to address and stem the increasing opioid epidemic through, among other responses: tracking the problem; educating the public and instituting prevention programs; helping families living with addiction issues; treating addiction; and developing a city-wide response to the epidemic.

31. Nashville has incurred staggering costs and a loss of resources attempting to curb the epidemic, impacting virtually every branch of city departments from emergency services to the courts to care facilities, clinics, prisons and the police department.

32. Nashville emergency services track where the most frequent opioid emergency overdose transport calls occur as shown in one slide below:

## Emergency Transports for Suspect Overdose by Zip Code, 2016

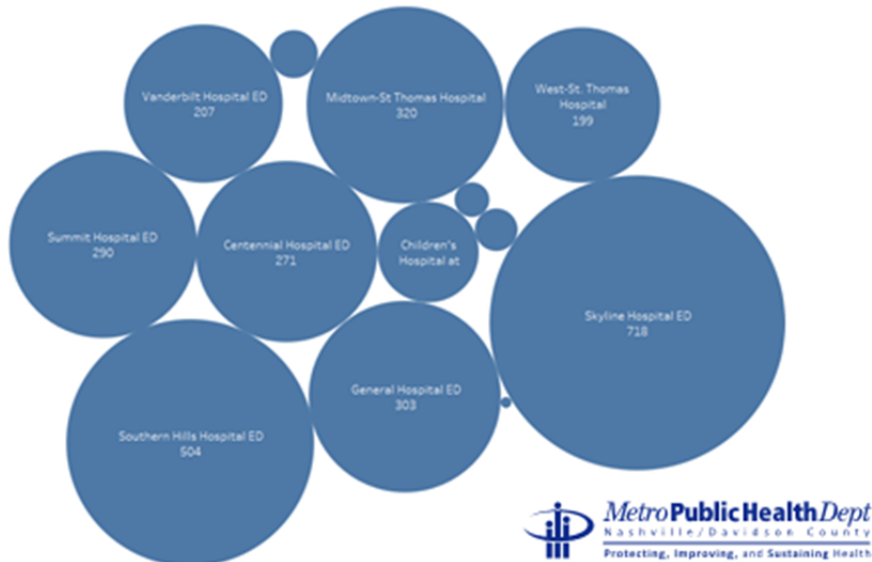
2016 Incident Zipcodes Where Overdose Was Primary Impression



Most impacted Zip Codes: 37013, 37115, 37207, and 37211

33. The slide below shows which hospitals then treat the overdose cases:

## Overdose EMS Runs by Hospital



34. According to the Centers for Disease Controls, in 2016 there were 85 prescriptions per every 100 men, women and children. In years prior, that number was, at time, over 100 prescriptions per 100 people.

35. Nashville estimates that more than 200 deaths in 2017 in the county were due to overdoses, many of which were opioid-related.

36. Nashville has been harmed by being required to spend increasing amounts of money and resources to combat the increasing opioid epidemic over the past decade, including but not limited to:

- a. Medication costs for employees and retirees;
- b. Health insurance premiums paid on behalf of employees and retirees;
- c. Addiction treatment for employees and retirees;
- d. Costs related to absenteeism due to addiction in the workforce;
- e. Overdose- and addiction-related medical and hospital costs for employees and retirees;
- f. Overdose-related emergency room services for indigent members of the community and jail inmates;
- g. Detoxification, substance abuse treatment, and certain related medical care for jail inmates;
- h. Incarceration costs for opioid-related crimes;
- i. Emergency ambulance, fire, and police services associated with opioid arrests and overdose calls;
- j. Drug court and related judicial expenditures;

k. Medical examiner and burial costs associated with overdoses and related medical conditions; and

l. Homelessness services and mental health services related to opioid addiction.

37. Nashville has expended taxpayers' resources to deal with each of the aforementioned situations caused by the opioid epidemic, as well as many others.

**B. Manufacturer Defendants**

**1. Purdue and Associated Companies**

38. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. It is owned principally by parties and descendants of Mortimer and Raymond Sackler.

39. Defendant Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

40. Defendant The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

41. At all relevant times, Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company, Inc. (collectively, "Purdue Pharma") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids throughout the United States.

**2. Cephalon and Associated Companies**

42. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

43. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals Ltd. acquired Cephalon

in October 2011, and Cephalon Inc. became a wholly owned subsidiary of Teva Pharmaceuticals Ltd.

44. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in North Wales, Pennsylvania and is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. in Pennsylvania.

45. Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, “Cephalon”) are in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

### **3. Janssen and Associated Companies**

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

47. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson.

48. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc.

49. Defendant Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of Johnson & Johnson until July 2016. Noramco, Inc. is or had been part of Johnson & Johnson’s opium processing by making active pharmaceutical ingredients (“APIs”) for opioid painkillers.

50. 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.

51. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

52. Johnson & Johnson is the only company that owns over 10% of Janssen Pharmaceuticals stock. J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

53. Johnson & Johnson, Janssen Pharmaceuticals, Inc., Noramco, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

#### **4. Endo and Associated Companies**

54. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

55. 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.

56. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, "Endo") are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

57. Endo also is or has been in the business of manufacturing, selling, promoting, and/or distributing generic opioids through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

**5. Mallinckrodt and Associated Companies**

58. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom and maintains a U.S. headquarters in St. Louis, Missouri.

59. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, Plc. Mallinckrodt, Plc and Mallinckrodt, LLC (collectively, “Mallinckrodt”) are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids throughout the United States.

**6. Allergan and Associated Companies**

60. Defendant Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland.

61. Defendant Actavis Plc acquired Defendant Allergan Plc in March 2015, however the combined company changed its name to Allergan Plc in June 2015.

62. Defendant Watson Pharmaceuticals, Inc. had acquired Defendant Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then changed the name to Actavis Plc in October 2013.

63. 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.).

64. 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.



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

66. Each of these defendants is owned by Defendant Allergan Plc, which uses them to market and sell its drugs in the United States.

67. Defendant Allergan Plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan Plc, Actavis Plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. (collectively, “Allergan”) are or have been in the business of manufacturing, selling, promoting, and/or distributing both brand name and generic opioids throughout the United States.

**7. Insys**

68. Insys Therapeutics, Inc. (“Insys”) is a Delaware company with its principal place of business in Chandler, Arizona. Insys is or has been in the business of manufacturing, selling, promoting, and/or distributing fentanyl-based cancer spray Subsys.

**C. Distributor Defendants**

**1. AmerisourceBergen**

69. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania. AmerisourceBergen is the second largest pharmaceutical distributor in North America.

70. 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.”

## **2. Cardinal Health**

71. Defendant Cardinal Health, Inc. (“Cardinal Health”) is an Ohio Corporation with its principal place of business in Dublin, Ohio. In 2016, Cardinal Health generated revenues of \$121.5 billion.

72. Cardinal Health is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. Additionally, in December 2013, Cardinal Health formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal Health has, at all relevant times, distributed opioids nationwide.

## **3. McKesson**

73. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with its principal place of business located in San Francisco, California.

74. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America.

75. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 Billion.

76. 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.”

77. According to the 2017 Annual Report, McKesson “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”

78. McKesson is the largest pharmaceutical distributor in the United States.

79. McKesson has more than 40,000 customers nationally.

80. Collectively, McKesson, AmerisourceBergen, and Cardinal Health account for 85 percent of the drug shipments in the United States. These companies together collect about \$400 billion in annual revenue.

**D. Defendants' Agents**

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

**BACKGROUND**

**A. The History of Opioids and Addiction**

82. The synthetic opioids manufactured and distributed by Defendants are related to the opium poppy, whose pain-relieving properties and dangerous qualities have been recognized for millennia.

83. The opium poppy was a well-known symbol of the Roman Civilization, which signified both sleep and death. The Romans used opium not only as a medicine but also as a poison.<sup>3</sup>

84. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain on

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<sup>3</sup> Martin Booth, *Opium: A History*, 20 (Simon & Schuster Ltd. 1996).

the battlefield. They were also used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages.

85. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.<sup>4</sup>

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

87. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

88. Opioids include brand-name drugs and generics like oxycodone and hydrocodone. They are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.

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<sup>4</sup> Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol, No. 43 (2005).

89. Since passage of the Controlled Substances Act (“CSA”) in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety.

90. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

91. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, and marketed opioids for the management of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

92. The synthetic opioid fentanyl has been a driving force behind the nation’s opioid epidemic, killing tens of thousands of Americans in overdoses. Two states are now pushing to use the drug’s powerful properties to execute prisoners on death row.<sup>5</sup>

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<sup>5</sup> William Wan & Mark Berman, *States to try new ways of executing prisoners. Their latest idea? Opioids.*, Wash. Post (Dec. 9, 2017), [https://www.washingtonpost.com/national/health-science/states-choose-new-ways-to-execute-prisoners-their-latest-idea-opioids/2017/12/09/3eb9bafa-d539-11e7-95bf-df7c19270879\\_story.html?utm\\_term=.c37d8e3e76b3](https://www.washingtonpost.com/national/health-science/states-choose-new-ways-to-execute-prisoners-their-latest-idea-opioids/2017/12/09/3eb9bafa-d539-11e7-95bf-df7c19270879_story.html?utm_term=.c37d8e3e76b3)

93. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.<sup>6</sup>

94. The CDC estimates that approximately three out of four new heroin addicts in the United States started by abusing prescription opioids.<sup>7</sup>

95. According to the CDC, opioids are responsible for the majority of drug overdoses today.<sup>8</sup> Additionally, opioid overdose have quadrupled nationally since 1999.<sup>9</sup>

96. The youngest members of society have also been affected by the opioid crisis. Eighty-seven children died of opioid intoxication in 2015, according to the Centers for Disease Control and Prevention, up from just 16 in 1999. Toddlers and young children are increasingly being found unconscious or dead after consuming an adult's drugs, and there has been a surge of opioid-dependent newborns.

97. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders.<sup>10</sup> Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

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<sup>6</sup> Rudd et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015, 65 Morbidity & Mortality Wkly. Rep. 1445, 1450 (2016).

<sup>7</sup> Heroin Overdose Data, Ctrs. For Disease Control & Prevention, <https://www.cdc.gov/drugoverdose/data/heroin.html>

<sup>8</sup> *Id.*

<sup>9</sup> Drug Overdose Death Data, Ctrs. For Disease Control & Prevention, <https://www.cdc.gov/drugoverdose/data/statedeaths.html>. Drug deaths take a long time to certify, so this is the most recent available data. <https://www.cdc.gov/nchs/data/vsrr/report001.pdf>

<sup>10</sup> Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

**B. Prior Bad Acts**

98. Defendants have long known about the dangers of their opioid products, and the alarming quantities in which they were pouring into communities all across the country, because they have been sued, fined, and criminally convicted for failing to mitigate these problems.

99. For example, in 2007 Purdue settled criminal and civil charges against it for “misbranding” OxyContin. Purdue was forced to admit it illegally marketed and promoted OxyContin by claiming it was less addictive and less subject to abuse than other pain medications. Purdue agreed to pay nearly \$635 million in fines, and three of its executives pled guilty to federal criminal charges for misleading regulators, doctors, and patients about OxyContin’s risk of addiction and its potential to be abused. At the time, this was one of the largest settlements with a drug company for marketing misconduct.<sup>11</sup>

100. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, to design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.<sup>12</sup> The DEA also published suggested questions that distributor should ask prior to shipping controlled substances, in order to know their customers.

101. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade”

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<sup>11</sup> Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

<sup>12</sup> Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Sept. 27, 2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (Dec. 27, 2007); “Suggested Questions a Distributor should ask prior to Shipping Controlled Substances, *Dea*[diversion.usdoj.gov/](http://www.deadiversion.usdoj.gov/), U.S. Dept. of Justice, Drug Enforcement Administration; 1970 U.S.C.A.N. 4566 at 5490; *see also* Rannazzisi May 5, 2015 Testimony.

by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.” When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;

102. In 2008, McKesson agreed to pay \$13.3 million to settle the allegations and to strengthen its controls by implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids.

103. However, documents that have been recently unsealed show that five months after the 2008 settlement, the board’s audit committee was notified of “serious deficiencies” in its system to spot suspicious opioid shipments.<sup>13</sup>

104. Inspections of some of McKesson’s distribution facilities in 2013 found the company “did not fully implement or adhere to its own” compliance program. The findings forced McKesson to admit that it failed to report suspicious opioid shipments to the DEA and sign another settlement with DOJ that included tougher and verifiable compliance responsibilities, as well as a \$150 million fine.

105. In 2013, Cardinal paid a \$34 million fine for failing to report suspicious orders of controlled substances.

106. In 2015, the Indiana Department of Public Health determined that an HIV outbreak in Southeastern Indiana was linked to injection of the prescription painkiller Opana,<sup>14</sup>

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<sup>13</sup> Anders Melin & Jef Feeley, *McKesson Records Show Failed Opioid Oversight, Lawsuit Says*, Bloomberg (Dec. 8, 2017 10:34 A.M.), <https://www.bloomberg.com/news/articles/2017-12-08/mckesson-investor-claims-board-failed-oversight-duty-on-opioids>



the first documented HIV outbreak in the United States associated with injection of a prescription painkiller. After the outbreak, the FDA require “that Endo Pharmaceuticals remove [Opana ER] from the market.” The agency sought removal “based on its concern that the benefits of the drug may no longer outweigh its risks.”<sup>15</sup>

107. Two former CEOs of Insys have been charged in an indictment along with other former Insys executives and managers, who were initially charged in December 2016.<sup>16</sup> The indictment said that, beginning in 2012, Kapoor, Babich and others devised a scheme to pay speaker fees and other bribes to medical practitioners to prescribe Subsys and to defraud insurers into approving payment for it.

108. Federal charges have also been filed in several other states against other ex-Insys employees and medical practitioners who prescribed Subsys. Insys also faces lawsuits by attorneys general in Arizona and New Jersey. It previously paid \$9.45 million to resolve investigations by attorneys general in Oregon, New Hampshire, Illinois and Massachusetts.

109. In 2017, The Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.<sup>17</sup>

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<sup>14</sup>Press Release, State of Indiana Health Department, *available at* [http://www.in.gov/activecalendar/EventList.aspx?view=EventDetails&eventidn=210259&information\\_id=211489&type=&syndicate=syndicate](http://www.in.gov/activecalendar/EventList.aspx?view=EventDetails&eventidn=210259&information_id=211489&type=&syndicate=syndicate).

<sup>15</sup> CNN Wire, *FDA wants Opioid at Center of Scott County HIV Outbreak Pulled off Market*, Fox59.com (June 9, 2017 7:45 A.M.) <http://fox59.com/2017/06/09/fda-wants-opioid-at-center-of-scott-county-hiv-outbreak-pulled-off-market/>; Press Release, FDA Requests Removal of Opana ER for Risks Related to Abuse, *available at* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

<sup>16</sup>*Billionaire Insys Founder to Plead Not Guilty in Opioid Bribery Case*, Reuters (Nov. 16, 2017), <http://fortune.com/2017/11/16/insys-john-kapoor-opioid-case/>.

<sup>17</sup> Press Release, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to*

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**C. Opioid Crisis Today**

110. The epic scale of the crisis ravaging the country has gotten too big to ignore. What was once considered a problem only amongst the rural poor now touches every demographic group – including those with historically low rates of drug use.

111. The opioid epidemic is America's deadliest overdose crisis ever. The most recent CDC data, from 2015, show the opioid death toll exceeded 33,000 that year.

112. By comparison, more than 58,000 US soldiers died in the entire Vietnam War, nearly 55,000 Americans died of car crashes at the peak of such deaths in 1972, more than 43,000 died due to HIV/AIDS during that epidemic's peak in 1995, and nearly 40,000 died of guns during the peak of firearm deaths in 1993.<sup>18</sup>

113. Nevertheless, opioid sales overall totaled \$8.6 billion and continue to rise, according to data from Quintiles IMS Holdings Inc.<sup>19</sup>

**TOLLING AND FRAUDULENT CONCEALMENT**

114. Plaintiff continues to suffer harm from the unlawful actions by the Defendants.

115. 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 harm is not completed nor have all the damages been

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*Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations, available at <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.*

<sup>18</sup> German Lopez, Drug overdose deaths skyrocketed in 2016, Vox (Sept. 5, 2017 12:10 P.M.), <https://www.vox.com/policy-and-politics/2017/9/5/16255040/opioid-epidemic-overdose-death-2016>.

<sup>19</sup> Esme Deprez and Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes On the Opioid Industry*, Bloomberg (Oct. 5, 2017), <https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry>

incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

116. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including public officials in Tennessee and Nashville, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status and to continue generating profits. The Defendants affirmatively assured the public, including Nashville, that they are working to curb the opioid epidemic.

117. The Defendants not only have acknowledged that they understood their obligations under the law, but they further publicly affirmed their claim that their conduct was in compliance with those obligations.

118. The Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which would confirm the extent of their wrongful and illegal activities.

119. The Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Defendants invented the term “pseudoaddiction” and promoted it to an unsuspecting medical community. Defendants provided the medical community with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales.

120. The medical community, consumers, and Nashville were duped by the Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state and in Nashville.

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

122. Nashville's claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts and their wrongful acts, and the material information pertinent to their discovery, which Defendants concealed them from the Plaintiff. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its claims, as a result of Defendants' conduct.

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

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

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

## **CLAIMS FOR RELIEF**

### **FIRST CLAIM FOR RELIEF**

#### **RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS (RICO) (18 U.S.C. §1961, et. seq.)**

126. Plaintiff incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

127. Plaintiff brings this Count against all Defendants.

128. Defendants are persons within the meaning of 18 U.S.C. §1961(3) who conducted the affairs of the enterprises described below through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

129. Section 1962(c) of RICO 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 or collection of unlawful debt.” 18 U.S.C. §1962(c).

#### **Relevant Enterprises**

130. The term “enterprise” includes “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). The definition of “enterprise” in Section 1961(4) includes both legitimate and illegitimate enterprises.

131. Defendants engaged in two relevant illegal enterprises in violation of these statutes: the Opioids Promotion Enterprise and the Opioids Diversion Enterprise.

132. The Opioids Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOL’s; as well as external and other as yet

unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioids Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. §1961(3) and acted to enable Defendants to fraudulently market Opioids as scientifically proven as safe and effective. The Opioids Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioids Promotion Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to ensure the prescription opioids for chronic pain. Each of these entities, including the Defendants, is a “person” distinct from the Opioids Promotion Enterprise.

133. The Opioids Diversion Enterprise is an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed by each of them. In particular, each of the Defendants was associated with, and conducted or participated in, the affairs of the enterprise, whose purpose was to engage in the unlawful sales of opioids, deceive the public and federal and state regulators into believing that the Defendants were faithfully fulfilling their statutory obligations. The Defendants’ scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the Defendants’ fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue, while Plaintiff suffered injury caused by the reasonably foreseeable consequences of the opioid epidemic. As explained in detail below, the Defendants’ misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

134. Members of the Opioid Diversion Enterprise, finding it impossible to legally achieve their ever-increasing sales ambitions, systematically and fraudulently violated their

statutory duty 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. As discussed in detail below, through the Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate enormous profits.

135. Alternatively, the Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

136. The Defendants are members, participants, and/or sponsors of the HDA and utilized the HDA to conduct the Opioid Diversion RICO Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

137. Each of the Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the Defendants.

138. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the Defendants exists separately from the HDA. Therefore, the HDA itself serves as a RICO enterprise.

139. The association-in-fact enterprises (Opioid Promotion Enterprise and Opioid Diversion Enterprise) and the legal enterprise (HDA) were each used by the Defendants to conduct the RICO Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises are pleaded in the alternative and are collectively referred to as the “RICO Enterprise.”

140. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.

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

142. At all relevant times, the RICO Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f)



functioned as a continuing unit. Each member of the RICO Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the RICO Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the Defendants would have a larger pool of prescription opioids from which to profit.

143. The RICO Enterprise also engaged in efforts to lobby against the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion.

144. Members of the Pain Care Forum ("PCF") and the HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees, and political parties. The PCF and its members spent significant funds on lobbying efforts while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

145. The RICO Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits

were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate, and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

146. The RICO Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

147. Within the RICO Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis.

148. These interpersonal relationships also formed the organization of the RICO Enterprise. The RICO Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

149. Each of the Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships, and continuing coordination of activities. The Defendants participated in the operation and management of the RICO Enterprise by directing its affairs, as described herein.

150. While the Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

151. The Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the PCF, the HDA, and through their contractual relationships.

152. The PCF has been described as a coalition of drugmakers, trade groups, and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

153. The Center for Public Integrity and the Associated Press obtained “internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF participants spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.

154. Not surprisingly, each of the Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF. In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Johnson & Johnson, Allergan, and Teva. Each Manufacturer Defendant worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.

155. The 2012 Meeting Schedule for the PCF is specific example of the Defendants’ interpersonal relationships. The meeting schedule indicates that meetings were generally held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis. Local members were encouraged to attend the monthly meetings in person.

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

157. Second, the HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants are members. And, the HDA and each of the Distributor Defendants sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

158. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.” The HDA and the Distributor Defendants used membership in the HDA as an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturer and Distributor Defendants.

159. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the Defendants. The manufacturer membership application must be signed by a “senior company executive,” and it requests that the

manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.

160. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, which promoted the Opioid Diversion Enterprise efforts, including lobbying and even development of chargebacks, including

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

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

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

d. Logistics Operation Committee: “This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information

systems, operational integration, resource management and quality improvement.” Participation in this committee includes distributors and manufacturer members.

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

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

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

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

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

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

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

163. Third, the Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and chargebacks to the Distributor Defendants for sales of prescription opioids. As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturer Defendants paid the Distributor Defendants rebates and/or chargebacks on their prescription opioid sales.

164. These contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, ship notices, acknowledgements, and invoices. The Manufacturer Defendants used this information to gather

high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

165. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opioids. Manufacturers likely negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and anti-diversion duties.

166. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants was in communication and cooperation.

167. According to articles published by the Center for Public Integrity and The Associated Press, the PCF has been lobbying on behalf of the Manufacturer and Distributor Defendants for more than a decade. And, from 2006 to 2016 the Distributor and Manufacturer Defendants worked together through the PCF to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA



has continued its work on behalf of Defendants, without interruption, since at least 2000, if not longer.

168. As described above, the Defendants began working together as early as 2006 through the PCF and the HDA to promote the common purpose of their enterprise.

169. Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

### **Defendants' Conduct**

170. During the time period alleged in this Complaint, the Defendants exerted control over, conducted and/or participated in the RICO Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

171. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

172. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

173. Defendants paid nearly \$800 million dollars to influence local, state, and federal governments through joint lobbying efforts as part of the PCF. The Defendants were all members of the PCF either directly or indirectly through the HDA. The lobbying efforts of the PCF and its

members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

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

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

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

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

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

number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, and these questionnaires put the recipients on notice of suspicious orders.

179. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of them despite their actual knowledge of drug diversion rings.

180. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders—all for failure to report suspicious orders.

181. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal governments' response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and to identify and report suspicious orders to the DEA.

182. The Defendants worked together to control the flow of information and influence state and federal governments and politicians to pass legislation that benefitted Defendants. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

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

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the PCF;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing [opioids]."
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

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

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

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

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

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

### **Pattern of Racketeering Activity**

184. The Defendants conducted and participated in the conduct of the RICO Enterprise 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); and 18 U.S.C. §1961(D) by the felonious manufacture, importation, receiving, concealment, buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

### **Mail and Wire Fraud**

185. The Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public, including Plaintiff, by knowingly conducting or participating in the conduct of the RICO Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

186. The Defendants committed, conspired to commit, and aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by the Defendants’ regular use of the facilities, services, distribution channels, and employees of the RICO Enterprise. The Defendants participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

187. The Defendants used, directed the use of, and caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

188. In devising and executing the illegal scheme, the Defendants devised and knowingly carried out a material scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of

executing the illegal scheme, the Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

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

a. Mail Fraud: The Defendants violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

190. The Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and facilitated Defendants' DEA registrations;

- e. Documents and communications that supported and facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. §827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. §823 and 21 C.F.R. §1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- l. Payments to Defendants' lobbyists through the Pain Care Forum;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

191. The Defendants, for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:



192. Defendants and The Drugs They Manufacture:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
<b>Purdue</b>	(1) Purdue Pharma, LP, (2) Purdue Pharma, Inc., (3) The Purdue Frederick Company	OxyContin	Oxycodone hydrochloride extended release	Schedule II
		MS Contin	Morphine sulfate extended release	Schedule II
		Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
		Butrans	Buprenorphine	Schedule III
		Hysingla ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride and naloxone	Schedule II
<b>Cephalon</b>	(1) Cephalon, Inc., (2) Teva Pharmaceutical Industries, Ltd., (3) Teva Pharmaceuticals USA, Inc.	Actiq	Fentanyl citrate	Schedule II
		Fentora	Fentanyl citrate	Schedule II
		Generic Oxycontin	Oxycodone hydrochloride	Schedule II
<b>Janssen</b>	(1) Johnson & Johnson; (2) Janssen Pharmaceuticals, Inc. (formerly (2a) Ortho-McNeil-Janssen Pharmaceuticals, Inc., formerly (2b) Janssen Pharmaceutica, Inc. Also, Johnson & Johnson owns >10% of Janssen Pharmaceuticals Stock and controls the sale and development of drugs and its profits inure to Johnson & Johnson's benefit); (3) Noramco, Inc.	Duragesic	Fentanyl	Schedule II
		Nucynta [Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015]	Tapentadol	Schedule II
		Nucynta ER	Tapentadol extended release	Schedule II

Defendant Group Name	Company Names  (wholly owned subsidiary of Johnson & Johnson).	Drugs		
		Drug Name	Chemical Name	CSA Schedule
Endo	(1) Endo Health Solutions Inc., (2) Endo Pharmaceuticals Inc., (3) Qualitest Pharmaceuticals, Inc. (wholly-owned subsidiary of Endo)	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
		Opana	Oxymorphone hydrochloride	Schedule II
		Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
Mallinckrodt	(1) Mallinckrodt PLC; (2) Mallinckrodt, LLC (wholly-owned subsidiary of Mallinckrodt PLC)	Exalgo	Hydromorphone hydrochloride	Schedule II
		Roxicodone	Oxycodone hydrochloride	Schedule II
Allergan	(1) Allergan Plc, (2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc, (5) Actavis, Inc., (6) Watson Pharmaceuticals, Inc., (7) Watson Laboratories, Inc., (8) Watson Pharma, Inc.	Kadian	Morphine sulfate	Schedule II
		Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II
		Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II
Insys	Insys Therapeutics, Inc.	Subsys	Fentanyl	Schedule II

193. The Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

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

195. Defendants also utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

196. The Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

197. Several Defendants also entered into various Corporate Integrity Agreements with various entities, including the Office of Inspector General and the United States Department of Health and Human Services, that required the Defendants annually to certify in writing that the Defendants had implemented effective compliance programs and were otherwise in compliance with laws and regulations regarding, among other things, the manufacture and distribution of opioids. Defendants submitted through the mail and wires certifications that were false and misleading, in furtherance of the Opioid Diversion RICO Enterprise's operation and goals, including false and misleading certifications required annually under the following:

a. Section V. of the Deferred Prosecution Agreement entered in *United States of America v. Endo Pharmaceuticals, Inc.*, No. 1:14-CR-00066-MAD, ECF No. 2 (N.D.N.Y. Feb. 21, 2014)

b. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Endo Pharmaceuticals, Inc. (fully executed on Feb. 21, 2014);

c. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Johnson & Johnson (fully executed on Oct. 31, 2013); and

d. Section III of the Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Purdue Pharma, L.P. (fully executed on May 8, 2007).

198. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

199. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of

communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

200. The Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. §1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the Defendants.

201. The Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§1341 and 1343 offenses.

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

203. 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 and distributing prescription opioids.

204. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

205. 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 from the sale of their highly

addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

206. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to its operations through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the RICO Enterprise and in furtherance of its fraudulent scheme.

207. The pattern of racketeering activity and the RICO Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the RICO Enterprise.

208. The pattern of racketeering activity is continuing as of the date of this Complaint and will continue into the future unless enjoined by this Court.

209. Many of the precise dates of the Defendants' criminal actions have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the RICO Enterprise alleged herein depended upon secrecy.

210. Each instance of racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and Plaintiff. Defendants calculated and intentionally crafted the RICO Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on Plaintiff, or the community. In designing and implementing the scheme, at all times Defendants knew that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding

Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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

212. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

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

214. The Defendants conducted and participated in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

215. The Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

216. Each of the Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

217. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

218. The Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and omitted material information from reports, records, and other documents required to be filed with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

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

220. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious



orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles yet failed to alert the DEA. The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking “Shouldn’t the DEA be contacted about this?” and adding that she felt “very certain this is an organized drug ring.” Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, “Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals.”

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

222. These examples reflect the Defendants’ pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. §1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants. For example:

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

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center for failure to maintain effective controls against diversion of hydrocodone;

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

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

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

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

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

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

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

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

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

Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

224. The pattern of racketeering activity is continuing as of the date of this Complaint and will likely continue into the future unless enjoined by this Court. Many of the precise dates of Defendants' unlawful actions were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the RICO Enterprise depended upon the secrecy of the participants in that enterprise.

225. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiff, its insureds, and its community. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

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

227. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

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

### **RICO Damages**

229. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injuries because Plaintiff paid for costs associated with the opioid epidemic. These harms are ongoing.

230. Plaintiff's injuries, were, and are being, proximately caused by Defendants' racketeering activities. But for the Defendants' conduct, Plaintiff would not have paid the exorbitant costs and expenditures required as a result of the epidemic affecting Nashville.

231. Plaintiff has injuries that were directly caused by the Defendants' racketeering activities.

232. Plaintiff seeks all legal and equitable relief as allowed by law, including actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

### **SECOND CLAIM FOR RELIEF** **RICO CONSPIRACY**

**(18 U.S.C. § 1962(d))**

233. Plaintiff incorporates and re-alleges each of the paragraphs above as though fully set forth herein.

234. Plaintiff brings this claim against all Defendants. At all relevant times, the Defendants were associated with the RICO Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the RICO Enterprise through a pattern of racketeering activity. Under

Section 1962(d) it is unlawful for “any person to conspire to violate” Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

235. Defendants conspired to violate Section 1962(c), as alleged more fully in Count 1, by conducting the affairs of the RICO Enterprise through a pattern of racketeering activity, as incorporated by reference herein.

**THIRD CLAIM FOR RELIEF**  
**COMMON LAW PUBLIC NUISANCE**  
**(Tennessee Common Law)**

236. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

237. Under Tennessee common law, a “public nuisance” is defined as any “condition of things which is prejudicial to health, comfort, safety, property, sense of decency or morals of the citizens at large, resulting either from an act not warranted by law, or from neglect of a duty imposed by law.” *State ex. rel. Swann v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975).

238. A common law nuisance “extends to everything that endangers life or health, gives offense to the senses, violates the laws of decency, or obstructs the reasonable or comfortable use of property.” *Id.*

239. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Nashville for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

240. 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 Nashville and its residents.

241. The nuisance includes the over-saturation, unlawful availability, and abuse of opioids as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

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

243. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Nashville.

244. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

245. 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.

246. Defendants knew or should have known that their promotion would lead to addiction and other adverse consequences and that the larger community, including places such as Nashville, would suffer as a result.

247. The Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without the 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, including in Nashville.

248. Defendants' nuisance-causing activities include selling, and/or facilitating the illegal sale of, prescription opioids from premises in and around Nashville to unintended users in the community, including people at risk of overdose and criminals.

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

250. The Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including so-called “pill mills” and other dealers.

251. The Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including through alleged “pill mills” as well as other drug dealers, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

252. The public nuisance created by Defendants endangers the health and safety of the Nashville and its residents.

253. The public nuisance created by Defendants has caused, and continues to cause, significant harm to, and the expenditure of taxpayer dollars by Nashville, including, but not limited to the following:

a. The staggering rates of opioid use among adults in Nashville has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Nashville.

b. Infants have been born addicted to opioids due to pre-natal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. The Defendants’ success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for illicit use and fueled a new wave of addiction, abuse, and injury. The Defendants’ scheme created a new secondary market for opioids – providing both the supply of narcotics to sell and the demand of addicts to buy them.



d. The diversion of opioids into the secondary, illicit market 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 Nashville.

e. Adults and children in Nashville 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. All these problems harm Nashville by diminishing Nashville's revenues and forcing it to make increased expenditures.

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

255. 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 Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Defendants' dissemination of false "scientific" facts and advice.

256. At all times, the 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 surrounding Nashville. The Defendants had the power to shut off the supply of illicit opioids into the County. The 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

257. As a direct and proximate result of the public nuisance, Nashville has sustained 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, costs of hospital services, healthcare, child services, judicial services, incarceration, medical examinations, burials, and law enforcement.

258. Defendants should be required to pay the expenses the Nashville has incurred or will incur in the future to fully abate the nuisance.

**FOURTH CLAIM FOR RELIEF**  
**STATUTORY PUBLIC NUISANCE**  
**(Tenn. Code Ann. § 29-3-101, *et seq.*)**

259. Plaintiff incorporates all preceding and subsequent paragraphs by reference.

260. Under Tennessee statutory law, “[a]ny person who uses, occupies, establishes or conducts a nuisance, or aids or abets therein, and the owner, agent or lessee of any interest in any such nuisance, together with the persons employed in or in control of any such nuisance by any such owner, agent or lessee, is guilty of maintaining a nuisance and such nuisance shall be abated as provided hereinafter.” Tenn. Code Ann. § 29-3-101(b).

261. The term “nuisance” includes “[a]ny place in or upon which. . . [the] unlawful sale of any regulated legend drug, narcotic or other controlled substance . . . are carried on or permitted, and personal property, contents, furniture, fixtures, equipment and stock used in or in connection with the conducting and maintaining any such place for any such purposes.” *Id.* § 29-3-101 (a)(2)(A).

262. The nuisance statute further provides that, in an “order of abatement, the court may . . . assess costs of public services required to abate or manage the nuisance, including, but not limited to, law enforcement costs, if any, caused by the public nuisance.” *Id.* § 29-3-110.

263. 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 Nashville and their residents.

264. The public nuisance complained of herein includes the over-saturation, unlawful availability, and abuse of opioids in Nashville for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

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

a. Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of Nashville.

b. Defendants' actions created and expanded the market for opioids, promoting its wide use for pain management.

c. 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. 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.

266. The Defendants' actions were a substantial factor in opioids becoming widely available and widely used. Without the 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.

267. Defendants' nuisance-causing activities include selling, and/or facilitating the illegal sale of, prescription opioids from premises in and around Nashville to unintended users in Nashville, including people at risk of overdose and criminals.

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

269. The Defendants knowingly, intentionally, recklessly, and/or negligently disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including so-called "pill mills" and other dealers.

270. The Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including "pill mills" and other drug dealers, with actual knowledge, intent, and/or reckless or negligent disregard that such opioids would be illegally trafficked and abused.

271. The public nuisance created by Defendants endangers the health and safety of Nashville and its residents.

272. The public nuisance created by Defendants has caused, and continues to cause, significant harm and taxpayer dollars to Nashville including, but not limited to the following:

a. The staggering rates of opioid use among adults in Nashville has led to unnecessary opioid abuse, addiction, injuries, overdose, and deaths. It has also resulted in increased crime and property damage in Nashville.

b. Infants have been born addicted to opioids due to pre-natal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. The Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. The Defendants' scheme created a new secondary market for opioids - providing both the supply of narcotics to sell and the demand of addicts to buy them.

d. The diversion of opioids into the secondary, illicit market 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 Nashville.

e. Adults and children in Nashville 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. All these problems harm Nashville by leading to decreased revenues for Nashville and increased expenditures.

273. Public resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resource which could be used to benefit the public at large in Nashville. 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 Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Defendants' dissemination of false "scientific" facts and advice. Moreover, there is no legitimate societal interest to the diversion and/or illegal sale of prescription opioids.

274. At all times, the 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 surrounding Nashville. The Defendants had the power to shut off the supply of illicit opioids into Nashville. The 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.

275. As a direct and proximate result of the public nuisance, Nashville has sustained harms 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, costs of hospital services, healthcare, child services, and law enforcement.

276. Defendants should be required to pay the expenses Nashville has incurred or will incur in the future to fully abate the nuisance.

**FIFTH CLAIM FOR RELIEF**  
**TENNESSEE DRUG DEALER LIABILITY ACT**  
**(Tenn. Code Ann. § 29-38-101 *et seq*)**

277. Plaintiff incorporates all preceding paragraphs by reference.

278. Tennessee's DDLA, Tenn. Code Ann. § 29-38-101 *et seq.*, provides a civil remedy for "damages to persons in a community as a result of illegal drug use." Tenn. Code Ann. § 29-38-102.

279. Among the persons to whom the DDLA provides a remedy are "[a] ... ***governmental entity***, ... or other entity that funds a drug treatment program or employee assistance program for the individual drug user, or that otherwise expended money on behalf of the individual drug user." Tenn. Code Ann. § 29-38-106 (emphasis added).

280. One of the intents of the DDLA, among others, is "to shift, to the extent possible, the cost of damage cause by the existence of the illegal drug market in a community to those who illegally profit from that market." Tenn. Code Ann. § 29-38-102.

281. Plaintiff is a governmental entity that funds drug treatment and assistance programs for individual drug users in the Nashville, and otherwise expended significant sums of money as a result of the illegal distribution of opioids in Nashville.

282. The DDLA makes anyone who “knowingly participates in the illegal drug market within this state ... liable for civil damages.” Tenn. Code Ann. § 29-38-105(a).

283. “A person may recover damages under [the DDLA] ... for injury resulting from an individual’s use of an illegal drug.” Tenn. Code Ann. § 29-38-105(b).

284. Under Tennessee criminal laws, such as Tenn. Code Ann § 39-17-417 and Tenn. Code Ann § 39-17-418, hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, Opana, Lortab and other opioids are illegal drugs if possessed, sold, and distributed without a valid prescription.

285. The DDLA imposes liability on those who directly participate in the distribution of an illegal drug that causes damages. Damages may be recovered under the DDLA from a “person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by the individual drug user.” Tenn. Code Ann. § 29-38-106(5)(b)(1 ).

286. The DDLA also imposes market liability on those who participate in the unlawful distribution of drugs in the area where illegal drugs cause damages. Damages may be recovered under the DDLA from a “person who knowingly participated in the illegal drug market, if (A) [t]he place of illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant; (B) the defendant’s participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and (C) [t]he

defendant participated in the illegal drug market at any time during the individual user's period of illegal drug use." Tenn. Code Ann. § 29-38-106(5)(b)(2)(A)-(C).

287. For purposes of the DDLA, an "'individual drug user' means the individual whose illegal drug use is the basis of an action brought under [that statute]," Tenn. Code Ann. § 29-38-104(4).

288. Residents of Nashville who acquired hydrocodone, oxycodone, oxymorphone, Roxicodone, OxyContin, and/or Opana from unlicensed drug dealers illegally distributing the prescription opioids in Nashville are "individual drug user[s]" under the DDLA.

289. Those purchases of hydrocodone, oxycodone, oxymorphone, OxyContin, Roxicodone and/or Opana were illegal in that they were made without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).

290. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached Nashville during all times relevant to this complaint. For purposes of the DDLA, Defendants' "illegal drug market target community" is the entire state of Tennessee, because Defendants participated in the illegal drug market by distributing 4 ounces or more of a "specified illegal drug." Tenn. Code Ann §§ 29-38-104(8), 29-38-109(4). As noted by the Tennessee Department of Health in a 2015 presentation, the Tennessee market for hydrocodone and oxycodone pills comprised of 51 hydrocodone pills and 21 oxycodone pills for every Tennessean. Commissioner of Health Dreyzehner noted that 50% of mothers of NAS babies obtained their pills, in whole or in part, from diverted pills (28.7% solely from diverted drugs). Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg and contains at least 10 mg of opioid, there can be no question that each of the Manufacturer Defendants far exceeded the four-ounce level.



291. The Manufacturer Defendants knowingly failed to implement effective controls and procedures in their supply chains to guard against theft, diversion, and abuse of prescription opioids, and failed to adequately design and operate a system to detect, halt, and report suspicious orders of prescription opioids.

292. As a result, the Manufacturer Defendants knowingly disseminated massive quantities of prescription opioids for distribution to Nashville, including “pill mills,” and other drug dealers.

293. The Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including “pill mills” as well as and other drug dealers, knowing that such opioids would be illegally trafficked and abused.

294. The diversion of prescription opioids into the secondary, criminal market and the increase in the number of individuals who abuse or are addicted to opioids has place unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of Nashville.

295. Having knowingly participated in the illegal distribution of hydrocodone, oxycodone, oxymorphone, OxyContin, Roxicodone, and/or Opana, the drugs purchased or obtained by residents of Nashville in the “place of illegal drug activity,” Defendants are liable to Plaintiff Nashville under the DDLA even for damages caused by opioids in Nashville that were acquired from distribution channels in which Defendants were a market participant.

**SIXTH CLAIM FOR RELIEF**  
**NEGLIGENCE**

296. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

297. To prevail on a negligence claim, a plaintiff must establish (1) a duty of care owed by the defendant to the plaintiff; (2) conduct by the defendant falling below the standard of care amounting to a breach of that duty; (3) an injury or loss; (4) causation in fact; and (5) proximate or legal cause. *Naifeh v. Valley Forge Life Ins. Co.*, 204 S.W.3d 758, 771 (Tenn. 2006).

298. Each Defendant had an obligation and duty to exercise reasonable care in the manufacturing, marketing and distribution of highly dangerous opioid drugs in and around Nashville.

299. Each Defendant owed a duty to Nashville, and to the public health and safety in Nashville, because the injuries and harms to the county were foreseeable, and in fact were foreseen by each Defendant.

300. Defendants breached this duty by failing to take any action to prevent or reduce the improper manufacture, marketing as well as distribution of the opioid drugs.

301. Reasonably prudent wholesale drug manufactures, marketers and distributors would have anticipated the scourge of opioid addiction that would wreak havoc on communities, including Nashville. Defendants were repeatedly warned by law enforcement. The escalating amounts of addictive drugs flowing through Defendants' businesses and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling the increased consumption and that legitimate medical purposes were not being served.

302. Defendants marketed opioids in an improper manner by: overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use; trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death;

overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms; marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

303. It was Defendants' marketing — and not any medical breakthrough — that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

304. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

305. Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

306. Defendants knew or should have known that opioids were unreasonably dangerous and were likely to cause addiction.

307. Defendants' marketing was a factor in physicians, patients, and others to prescribe or purchase opioids.

308. As a direct and proximate result of Defendants' negligence, the County has suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for County residents and using County resources in relation to opioid use and abuse.

309. As a proximate result, Defendants and their agents have caused Nashville to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, and the County has borne the massive costs of these illnesses, deaths and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for County residents and expend County resources in relation to opioid use and abuse.

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

311. Defendants were negligent in not disclosing to Nashville suspicious orders for opioids pursuant to the requirements of the Controlled Substances Act as well as Tennessee State law.

312. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

313. Defendants are in a class of a limited number of parties that can legally manufacture and distribute opioids, which places it in a position of great trust by the County.

314. The trust placed in Defendants by Nashville through the license to manufacture and distribute opioids in Nashville creates a duty on behalf of Defendants to prevent diversion of the medications it supplies for illegal purposes.

315. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the County and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

316. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

317. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during manufacture and distribution.

318. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

319. Defendants acted intentionally and with actual malice and reckless disregard for Nashville and its residents and taxpayers.

320. Defendants are in exclusive control of the management of the opioids they manufacture, market, and distribute in Nashville.

321. Nashville is without fault and the injuries to the County and its residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the manufacture and distribution of opioids.

322. Plaintiff is entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

**SEVENTH CLAIM FOR RELIEF**  
**UNJUST ENRICHMENT**

323. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

324. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the opioid epidemic.

325. For years, Nashville has conferred a benefit on Defendants by attempting to address all aspects of the opioid epidemic, including but not limited to, supplying emergency care and treatment to opioid users and their families; education , counseling and therapy to opioid users; police protection and law enforcement as a result of opioid users; abatement of nuisances; and other efforts to address and curb the increasing epidemic, all of which conferred a benefit on Defendants, which continued to have more customers and a market in Nashville for profiteering.

326. Nashville and its residents expected that Defendants had provided all of the necessary and accurate information regarding the risks associated with Defendants' drugs and had not misrepresented any material facts regarding those risks.

327. Defendants appreciated the benefits conferred upon them by Nashville.

328. Defendants appreciated the profits and other benefits conferred upon them by Nashville under such circumstances that it would be inequitable for Defendants to retain the benefit without payment of the value thereof.

329. The benefits conferred upon Defendants by Nashville were unjust.

330. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of Plaintiff.

331. In equity and good conscience, it would be unjust and inequitable to permit defendants to enrich themselves at the expense of Plaintiff and its residents.

332. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and provide restitution to Plaintiff.

**EIGHTH CLAIM FOR RELIEF**  
**VIOLATION OF TENNESSEE CONSUMER PROTECTION ACT**  
**Tenn. Code Ann. § 47-18-101, *et seq.***

333. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

334. For purposes of the Tennessee Consumer Protection Act (“TCPA”), Nashville is a “consumer” and “person,” as defined in Tenn. Code Ann. § 47-18-103(2) and (13), which made opioid-related purchases, including paying money for goods and services, from Defendants. Nashville has authority to bring this claim pursuant to Tenn. Code Ann. § 47-18-103(2) and (13), and § 47-18-109.

335. In connection with the sale, promotion, marketing, and distribution of opioids to Nashville, directly or indirectly, Defendants’ violated the TCPA in at least the following ways:

- a. Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another in violation of Tenn. Code Ann. § 47-18-104(b)(5); and
- b. Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another in violation of Tenn. Code Ann. § 47-18-104(b)(7);

336. Defendants’ acts and/or practices caused actual harm to Nashville, including financial loss.

337. Nashville has been injured as a result of Defendants' acts and/or practices.

338. Defendants' conduct was and continues to be willful and knowing.

339. Nashville has suffered an ascertainable loss of money or property and/or other things of value as a result of the use or employment by Defendants of an unfair or deceptive act or practice described in Tenn. Code Ann. §47-18-104(b).

340. Nashville is entitled to recover its damages caused by Defendants' violation of the TCPA in an amount to be determined at trial, including treble damages if the court finds that the use or employment of the unfair or deceptive act or practice was a willful or knowing violation of the TCPA, as well as attorneys' fees.

341. Nashville also seeks injunctive relief pursuant to Tenn. Code Ann. §47-18-109.

**NINTH CLAIM FOR RELIEF**  
**CIVIL CONSPIRACY**

342. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

343. Defendants engaged in (1) a common design between two or more persons, (2) to accomplish by concerted action an unlawful purpose, or a lawful purpose by unlawful means, (3) an overt act in furtherance of the conspiracy, and (4) resulting injury to Nashville.

344. Defendants engaged in one or more unlawful activities to further the conspiracy. The objects of the conspiracy were racketeering, nuisance, negligence, fraud, misrepresentation, violation of the Tennessee Consumer Protection Act, and other unlawful conduct as described above in this Complaint. Defendants knew that these objects were unlawful and would be accomplished by unlawful means such as fraud, misrepresentations, and omissions.

345. Defendants had a meeting of the minds on the object of or course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this



conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Nashville and its residents.

346. As described above, Defendants committed multiple unlawful and overt acts to further the object or course of action for this conspiracy as described above.

347. These unlawful acts proximately caused the damages suffered by Nashville. Accordingly, Plaintiff is entitled to recover its actual damages

348. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore jointly and severally liable for the damages flowing from the conspiracy.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays that the Court:

- A. Enter judgment against Defendants jointly and severally and in favor of Plaintiff;
- B. Award damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- C. Award actual and triple the actual damages Nashville sustained as a result of the Defendants' violations of the Racketeer Influenced and Corrupt Organization Act ("RICO");
- D. Award pre-judgment and post-judgment interest as provided by law, and award such interest at the highest legal rate;
- E. Enter an order of abatement and permanent injunction against all Defendants prohibiting them from engaging in the unlawful conduct detailed herein, including over-promotion and over-supply of opioids in and around Nashville;
- F. Enter an order requiring Defendants to fund an "abatement fund" for the purpose of abating the opioid nuisances;
- G. Award Plaintiff the costs of suit, including reasonable attorneys' fees as provided by law, including the Tennessee Consumer Protection Act;

H. Require Defendants to disgorge their unjustly acquired profits and other monetary benefits resulting from their unlawful conduct, and provide restitution to Plaintiff;

I. Award treble damages and injunctive relief pursuant to the Tennessee Consumer Protection Act; and

J. Award such further and additional relief as the Court may deem just and proper under the circumstances.

**JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38, Nashville demands a trial by jury on all issues so triable.

Dated: December 22, 2017

/s/ Mark P. Chalos

/s/ Kenneth S. Byrd

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