IN THE CIRCUIT COURT FOR SULLIVAN COUNTY
AT KINGSPORT, TENNESSEE

BARRY STAUBUS, in his official capacity as the District Attorney General for the Second Judicial District,TN; TONY CLARK, in his official capacity as the District Attorney General for the First Judicial District, TN; DAN ARMSTRONG, in his official capacity as the District Attorney General for the Third Judicial District, TN; and BABY DOE, by and through his Guardian Ad Litem,	)	
Plaintiffs,	)	**JURY DEMAND**
	)	**Case No. _____**
v.	)	**Division**
PURDUE PHARMA, L.P.: PURUDE PHARMA, INC.: THE PURDUE FREDERICK COMPANY: MALLINCKRODT PLC; ENDO HEALTH SOLUTIONS, INC; ENDO PHARMACEUTICALS, INC; CENTER POINTE MEDICAL CLINIC, LLC; ELIZABETH ANN BOWERS CAMPBELL; and PAMELA MOORE,	)	
Defendants.	)	

COMPLAINT

I. INTRODUCTION

1. Like thousands of children born every year Plaintiff BABY DOE was born addicted to opioids. The first days of his life were spent in excruciating pain as doctors weaned him from his opioid addiction. Plaintiff BABY DOE's mother fell victim to an epidemic that has ravaged Tennessee, causing immense suffering to those born addicted to opioids and costing tens

of thousands of dollars to local governments forced to deal with the aftermath.

2. The opioid epidemic did not appear overnight. It is the result of a concerted effort among Defendants PURDUE PHARMA, L.P., PURDUE PHARMA INC., THE PURDUE FREDERICK COMPANY, MALLINCKRODT PLC, ENDO HEALTH SOLUTIONS INC., and ENDO PHARMACEUTICALS, INC. (collectively referred to herein as the "Manufacturer Defendants"), along with other opioid manufacturers, to mislead doctors and the public about the need for, and addictive nature of, opioid drugs. The Manufacturer Defendants spent years engaged in a fraudulent scheme to push their wares into a market of unsuspecting doctors and patients. When it became clear that entire regions of the country were being devastated by addiction to these drugs, the Manufacturer Defendants turned a blind eye to the problems and collected millions of dollars in ill-gotten profits. For their part, Defendants CENTER POINTE MEDICAL CLINIC, LLC, ELIZABETH ANN BOWERS CAMPBELL, and PAMELA MOORE contributed to the opioid epidemic by diverting and illegally selling opioids in upper East Tennessee.

3. BABY DOE is a victim of the opioid crisis. He was born addicted to opioids, diagnosed with Neonatal Abstinence Syndrome, and forced to endure a painful start to his life; crying excessively, arching his back, refusing to feed, and shaking. His mother, Mary Doe, did not start out as an addict. As a result of defendants' fraudulent scheme, Mary Doe's community in the Appalachian region of Tennessee was awash in opioids, fueling a dramatic increase in those exposed to and addicted to OxyContin, Roxicodone, Opana, and other opioids.

4. Like so many of her peers, Mary Doe began taking opioids recreationally, at a party or on the weekend; it didn't take long until the addiction took hold. She was taking the pills daily in order to stave off the withdrawal.

5. Then, in 2011, Mary Doe was involved in a serious automobile accident. She broke her ankle and legs and needed multiple surgeries to place pins in her legs and repair the damage. During that timeframe, Mary Doe was in extraordinary pain. To help alleviate her discomfort, her physician prescribed the opioid Lortab to her. He did not ask her any questions to screen for opioid dependence or abuse before prescribing this addictive opioid. She dutifully took her prescribed medication but, unbeknownst to her physician, she was taking it twice as often as her doctor prescribed. Out of medication, without a valid prescription, and needing to fuel her addiction, Mary Doe obtained oxycodone, OxyContin, and Roxicodone from others.

6. Oxycodone is a powerful type of opioid. It can be prescribed as oxycodone or more specifically branded by a company, such as OxyContin, Roxicodone, or Opana ER.

7. Hydrocodone is also a type of opioid. It can be prescribed as hydrocodone or more specifically branded by a company, such as Lortab or Vicodin.

8. Mary Doe had been fully addicted to opioids illegally for about 4 years when she discovered she was pregnant. But by the time she learned she was pregnant, it was too late to prevent Plaintiff BABY DOE's addiction; her unborn child was now addicted to opioids, too.

9. It is now beyond reasonable question that the Manufacturer Defendants' fraud caused Mary Doe and thousands of others in Tennessee to become addicted to opioids -- an addiction that, thanks to their fraudulent conduct, was all but certain to occur.

II. JURISDICTION AND VENUE

10. Jurisdiction is proper pursuant to Tenn. Code Ann. § 16-10-101, *et seq.*, and Tennessee's Drug Dealer Liability Act, Tenn. Code Ann. § 29-38-101, *et seq*. Plaintiff BABY DOE was born in Sullivan County, Tennessee, his mother made unlawful purchases of drugs produced by the Manufacturer Defendants in Tennessee. During both the time in which his

mother developed an addiction to opioids and while she was pregnant with BABY DOE, the Manufacturer Defendants directed their opioids to the Tennessee market.

11. Venue is proper pursuant to Tenn. Code Ann. § 20-4-101-102, because Plaintiff BABY DOE was born with Neonatal Abstinence Syndrome in Sullivan County, and District Attorney General BARRY STAUBUS is the prosecuting attorney for Sullivan County, Tennessee. BABY DOE's mother took opioids in Sullivan County that directly contributed to BABY DOE's Neonatal Abstinence Syndrome.

III. PARTIES

12. Plaintiff BARRY STAUBUS is the elected District Attorney General for the Second Judicial District. His district includes: Sullivan County, TN. He brings suit on behalf of Sullivan County pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-3-101.

13. Plaintiff TONY CLARK is the elected District Attorney General for the First Judicial District. His district includes: Carter County, TN; Johnson County, TN; Unicoi County, TN; and Washington County, TN. He brings suit on behalf of Carter County, Johnson County, Unicoi County, and Washington County pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-3-101.

14. Plaintiff DAN ARMSTONG is the elected District Attorney General for the Third Judicial District. His district includes: Greene County, TN; Hamblen County, TN; Hancock County, TN; and Hawkins County, TN. He brings suit on behalf of Greene County, Hamblen County, Hancock County, and Hawkins County pursuant to Tenn. Code Ann. §§ 29-38-106 and 29-3-101.

15. The counties of Tennessee's First Judicial District (Carter County, Johnson County, Unicoi County, and Washington County), Second Judicial District (Sullivan County), and

Third Judicial District (Greene County, Hamblen County, Hancock County, and Hawkins County) are collectively referred to herein as the "Opioid Epidemic Affected Counties." Plaintiffs BARRY STABUS, TONY CLARK, and DAN ARMSTRONG, who represent the counties in the judicial districts for which they are responsible, are collectively referred to herein as the "District Attorney Plaintiffs."

16. Plaintiff BABY DOE was born with Neonatal Abstinence Syndrome as a result of his exposure in utero to the illegal drugs oxycodone, OxyContin, and Roxicodone. This drug exposure provides him the right to sue for damages under the Drug Dealer Liability Act ("DDLA"), Tenn. Code Ann. § 29-38-106(a)(2), as well for statutory and common law nuisance.

17. Plaintiff BABY DOE brings this action by and through his court appointed Guardian Ad Litem, Rodney Rowlett. Mr. Rowlett was appointed Guardian Ad Litem by the appropriate juvenile court and is empowered to bring this suit. Legal Guardians of children exposed to illegal drugs in utero are authorized to bring this action under the Drug Dealer Liability Act. Tenn. Code Ann. § 29-38-106(a)(1).

18. Defendant PURDUE PHARMA, L.P., is a limited partnership organized under the laws of Delaware. Defendant PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and Defendant THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut. Defendants PURDUE PHARMA, L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY, INC. are referred to collectively as "Purdue." In Tennessee and nationally, Purdue is engaged in the manufacture, promotion, and distribution of opioids, including: (a) OxyContin (OxyContin hydrochloride extended release), a Schedule II

opioid agonist[1] tablet first approved in 1995 and marketed by Purdue for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." OxyContin was indicated, or legally approved, for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."; (b) MS OxyContin (morphine sulfate extended release), a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

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

20. Purdue transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Purdue hires employees to service the Tennessee market. For example, Purdue recently posted online that it was seeking a District Business Manager and a Territory Business Manager to operate out of Knoxville, Tennessee. Purdue also directs advertising and informational materials to impact Tennessee physicians and potential users of Purdue products.

21. PURDUE PHARMA L.P. can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, DE 19808. PURDUE PHARMA INC. can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 80 State Street, Albany, NY 12207. THE PURDUE FREDERICK

[1] An opioid *agonist* is a drug that activates certain opioid receptors in the brain. By contrast, an *antagonist* relieves pain by blocking the receptor.

COMPANY can be served through its registered agent: The Prentice-Hall Corporation System, Inc., 2711 Centerville Road, Suite 400, Wilmington, DE 19808.

22. Defendant MALLINCKRODT PLC ("Mallinckrodt") is an Irish public limited company with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey, TW18 3AG, UK.

23. In Tennessee and nationally, Mallinckrodt is engaged in the manufacture, promotion, and distribution of Roxicodone and Oxycodone among other drugs. Mallinckrodt transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Mallinckrodt hires employees to service the Tennessee market. For example, Mallinckrodt has recently advertised for the position of Regional Reimbursement Manager, Neurology, Tennessee/Ohio, to operate out of Cleveland, Ohio and Knoxville, Tennessee. Mallinckrodt also directs advertising and informational materials to impact Tennessee physicians and potential users of Mallinckrodt products. Upon information and belief, Mallinckrodt also maintains an office located at 1835 Nonconnah Blvd. # 153, Memphis, Tennessee.

24. Mallinckrodt can be served through its registered agent in the United States: CT Corporation System, 120 South Central Avenue, Suite 400, Clayton, MO 63105.

25. Defendant ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

26. 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. ENDO HEALTH SOLUTIONS INC. and ENDO

PHARMACEUTICALS INC. are referred to collectively as "Endo."

27. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Tennessee. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Tennessee, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

28. Endo transacts business in Tennessee, targeting the Tennessee market for its products, including the opioids at issue in this lawsuit. Endo hires employees to service the Tennessee market. For example, Endo recently posted online that it was seeking a District Sales Manager, Pain Management, to operate out of Memphis, Tennessee. Endo also directs advertising and informational materials to impact Tennessee physicians and potential users of Endo products. Upon information and belief, Endo also operates an office at 1910 Danielson Place, Memphis, Tennessee.

29. ENDO HEALTH SOLUTIONS INC. can be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. ENDO PHARMACEUTICALS INC. can be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

30. Defendant CENTER POINTE MEDICAL CLINIC, LLC ("CENTER POINTE") is a Tennessee Limited Liability Corporation. Its principal place of business is located at 2020 Brookside Drive, Suite 20, Kingsport, Tennessee 37660, which is in Sullivan County. It can be

served through its registered agent: Ina Kay Bone, 2020 Brookside Drive, Ste 20, Kingsport TN 37760. CENTER POINTE participates in the illegal drug market for opioids.

31. Defendant ELIZABETH ANN BOWERS CAMPBELL is a resident of Sullivan County, Tennessee. She may be served with process at 1390 Milligan Highway, Johnson City, TN 37601, which is located in Tennessee House District 6. She participated in the illegal drug market for opioids.

32. Defendant PAMELA MOORE is a resident of Hawkins County, Tennessee. She may be served with process at 230 Union Hollow Rd., Churchill, TN 37642. She participated in the illegal drug market for opioids.

33. Defendants CENTER POINTE, ELIZABETH ANN BOWERS CAMPBELL, PAMELA MOORE, and the Manufacturer Defendants are hereinafter collectively referred to as "Defendants."

IV. SCIENTIFIC BACKGROUND

A. Opioids have never been proven appropriate for chronic pain and other non-acute medical problems.

34. To understand the central role the Manufacturer Defendants played in the creation of the United States', Tennessee's, and the Opioid Epidemic Affected Counties' opioid crisis, one must understand that their marketing of opioids for chronic pain and other non-acute ailments, which created the current generation of opioid addicts, was based on fraud, and was entirely contrary to science. The scientific consensus that opioids are dangerous, highly addictive, and inappropriate for chronic pain – as opposed to cancer pain and pain associated with surgery and acute injuries – existed in the mid-1990s and has never been challenged in any meaningful way with new, valid scientific evidence.

35. The National Safety Council, a not for profit organization chartered by Congress to improve public health, has published a summary of research titled "Evidence for the Efficacy of Pain Medications."[2] The National Safety Council report concludes that "**[d]espite the widespread use of opioid medications to treat chronic pain, there is no significant evidence to support this practice**."[3]

36. Multiple researchers have found that "**no evidence exists to support long term use – longer than four months – of opioids to treat chronic pain**."[4]

37. A 2013 review of existing literature by Dr. Igor Kissin of the Department of Anesthesiology, Perioperative, and Pain Medicine at Brigham and Women's Hospital, Harvard Medical School, concluded that "**[n]ot a single randomized controlled trial with opioid treatment lasting [greater than] 3 months was found**."[5]

38. The same review found that "[a]ll studies with a duration of opioid treatment [greater than or equal to] 6 months were conducted without a proper control group."[6]

39. Dr. Kissin further concluded that "**[t]here is no strong evidence-based foundation for the conclusion that long-term opioid treatment of chronic malignant pain is effective**."[7]

B. <u>Opioids carry a high risk of addiction, serious medical problems, and death.</u>

40. Opioids have severe side effects, including: gastrointestinal bleeding, impaired recovery from injury or surgery, cognitive impairment, respiratory depression, endocrine

[2] Donald Teater, Nat'l Safety Counsel, *Evidence for the Efficacy of Pain Medications*, 3 (2014) [hereinafter *Evidence for Efficacy*].
[3] *Id.* at 6 (emphasis added).
[4] *Id.* (citing multiple publications).
[5] Igor Kissin, *Long-term Opioid Treatment of Chronic Nonmalignant Pain: Unproven Efficacy and Neglected Safety?*, 2013:6 J. Pain Research 513, 513 (2013), *available at* https://www.dovepress.com/long-term-opioid-treatment-of-chronic-nonmalignant-painnbspunproven-ef-peer-reviewed-article-JPR.
[6] *Id.*
[7] *Id.*

abnormalities, hyperalgesia (increased sensitivity to pain), increased risk of fractures and hospitalization for the elderly, addiction, and death.[8]

41. Research based on actual patient interviews has found that, **among patients who received four or more prescriptions in the prior year, 35% met the criteria for a lifetime opioid dependence and 25.8% met the criterial for current opioid dependence.**[9]

42. Dr. Wilson M. Compton, the Director and Deputy Director of the National Institute of Drug Abuse at the National Institute of Health, respectively, co-authored a 2006 study that concluded: "[t]hough the use of opioid analgesics for the treatment of acute pain appears to be generally benign, **long-term administration of opioids has been associated with clinically meaningful rates of abuse or addiction**."[10]

43. Consistent with this finding, a 2011 review of medical and pharmacy claims records revealed that two thirds of patients who took opioids daily for ninety days were still taking opioids five years later.[11]

44. Researchers evaluating opioids for treatment following lumbar disc herniation likewise found that giving such patients opioids had no effect on treatment outcome, but significantly increased their risk for long term opioid addiction.[12]

45. Dr. Mitchell H. Katz, current director of the Los Angeles County Health Agency, has described how patients with nonmalignant conditions can end up as drug addicts because of the prescribing of opioids:

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[8] Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications*, 2-6 (2014) [hereinafter *Side Effects*] (summarizing side effect data).
[9] Joseph A. Boscarino, *Opioid-Use Disorder Among Patients on Long-Term Opioid TherapyI*, 2015:6 Substance Abuse and Rehabilitation 87, 87-89 (2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/.
[10] Wilson M. Compton et al., *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81 Nat'l Inst. on Drug Abuse 103, 103-07 (2006).
[11] Bradley C. Martin et al., *Long-term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12) J. Gen. Intern. Med. 1450, 1450-57 (2011).
[12] Evidence for Efficacy, *supra* note 2, at 5 (citing Radcliff et al., *Does Opioid Pain Medication Use Affect the Outcome of Patients with Lumbar Disk Herniation?*, 38(14) The Spine J. E849, E849-60 (2013)).

> A certain number of patients get better with NSAIDs [non-steroidal anti-inflammatory drugs, like Tylenol]…. For those still complaining of pain, you next prescribe a short-acting opioid with a relatively low potency, such as acetaminophen with codeine. …You tell them about the adverse effects of opioids and encourage them to use the lowest dose necessary. Not infrequently, at the next visit they tell you that the medicine works but that they are taking the pills more frequently than directed. At this point, you worry about liver damage from the acetaminophen and switch to a higher potency, longer acting agent. The patient returns for follow-up visits and tells you that the pills work but that they sometimes take an extra pill and could you please increase the number so they "don't run out before the next visit." Before you know it, the patient is on a high dose of an opioid, and you are unsure whether you have actually helped them. **What you know is you have committed yourself to endless negotiations about increasing doses, lost pill bottles, calls from emergency departments, worries that your patient is selling the drugs, and the possibility that one day, your patient will take too many pills, perhaps with alcohol, and overdose**.[13]

V. MATERIAL FACTS

A. Plaintiff BABY DOE is one victim of Tennessee's epidemic of Neonatal Abstinence Syndrome – a condition suffered by babies of mothers addicted to opioids.

46. On March 10, 2015, BABY DOE was born addicted to opioids at Holston Valley Regional Hospital, which is located in the Opioid Epidemic Affected Counties.

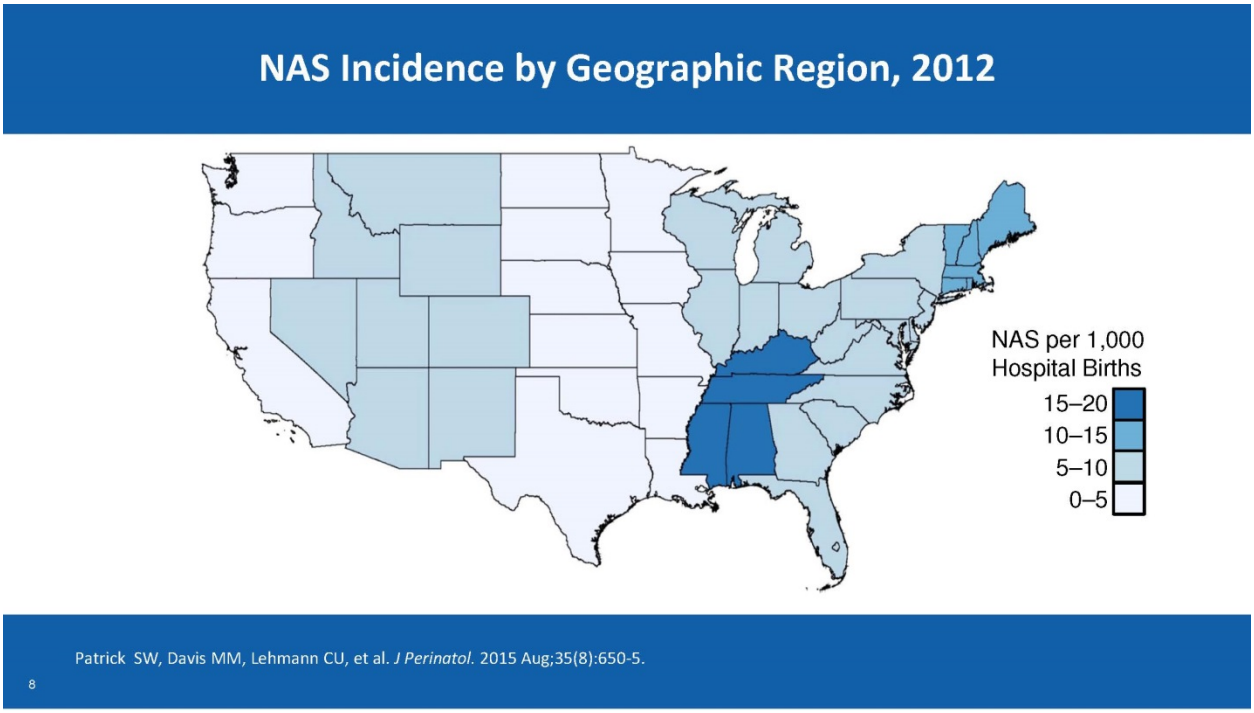
47. BABY DOE was diagnosed with Neonatal Abstinence Syndrome ("NAS"). NAS is a clinical diagnosis, and "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy."[14] BABY DOE spent his first days in the Neonatal Intensive Care Unit writhing in agony as he went through detoxification.

48. BABY DOE's experience is part of a nationwide epidemic of NAS that has its

[13] Mitchell H. Katz,, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170(16) Arch Intern. Med. 1422, 1422-24 (2010).
[14] Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) Pediatrics 547, 547-48 (2014), *available at* http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.

epicenter in upper east Tennessee. According to a report produced by Governor Bill Haslam's Opioid Abuse Working Group pursuant to 2015 Tenn. Pub. Acts Ch. 389 ("Governor's Working Group Report"), "**[t]he number of babies born with Neonatal Abstinence Syndrome (NAS) . . . increased tenfold from 2000 to 2010**."[15] Since 2010, the problem has only gotten worse.

49. As illustrated by the following map, researchers analyzing hospital discharge data have determined that Tennessee, along with its border states Kentucky, Alabama, and Mississippi, have the highest rates of NAS births in the nation.[16]



50. The percentage of pregnant women served by the Tennessee Department of Mental Health & Substance Abuse Services – 42.3% in 2012 – listing prescription opioids as their primary substance of abuse was over twice the percentage in the United States overall

[15] Opioid Abuse Reduction Act Working Group, Tenn. Dep't of Mental Health and Substance Abuse Services, *Working Group Report* 4 (2015) [hereinafter *Working Group Report*].
[16] Stephen W. Patrick et al., *Increasing Incidence of Neonatal Abstinence Syndrome: United States 2009-2012*, 35(8) J. Peronatol. 650, 650-55.

(18.4% in 2012).

51. NAS births in Tennessee are further concentrated in the counties of upper East Tennessee, which contains the Opioid Epidemic Affected Counties, with virtually every county in that region reporting between 12 and 60 NAS babies during a one year reporting period.[17]

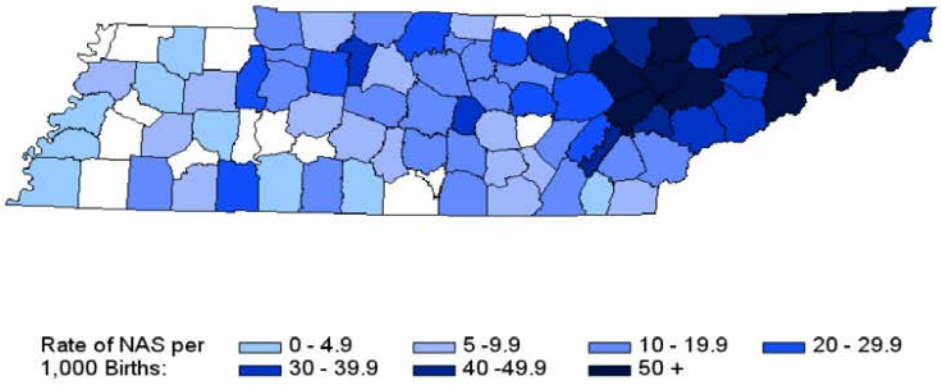


Figure 198. Incidence of NAS among TennCare recipients, 2014

Source: Bureau of TennCare Division of Health Care Finance and Administration (Provisional Data)

52. So prevalent is NAS in the Tri-Cities area that Niswonger Children's Hospital recently announced it is constructing a new Neonatal Intensive Care Unit simply to care for the influx of babies suffering from NAS. [18]

53. TennCare eligibility records establish that 24.3% of babies born with NAS in 2012 were placed in the Department of Children's Services' custody within one year of birth.[19]

B. <u>The Epidemic of neonatal abstinence syndrome babies is an outgrowth of the opioid explosion in Tennessee since the mid-1990's.</u>

54. Tennessee has the second highest statewide opioid prescription rate in the

[17] John Dreyzehner, Tenn. Dep't of Mental Health and Substance Anuse Services, *Governor's Public Safety Forum* 18 (2012), *available at* http://www.tn.gov/behavioral-health/article/data-briefs.
[18] Zack Vance, *Legislation Educating 'At-Risk' Mothers of Drug Dependent Babies Passes Committee*, johnsoncitypress.com, Apr. 7, 2017, www.johnsoncitypress.com/Government/2017 /04/07 /Legislation-educating-at-risk-mothers-of-drug-dependent-babies-passes-committee.
[19] Working Group Report, *supra* note 15, at 4.

nation.[20]

55. According to the Working Group Report, "[s]ince 1999, there has been no overall change in the amount of pain experienced by Americans, yet the number of prescriptions for opioids has quadrupled."[21]

56. In the past two decades, the rate of opioid prescribing in the United States has increased 600%.[22] The United States accounts for 4.6% of the world population but its citizens, by 2011, were consuming 80% of the world's opioid production.[23]

57. "Opioid overdoses, mainly from prescription drugs, are … the leading cause of the recent unexpected rise in the mortality rate of middle-aged white Americans, particularly women in rural areas, after decades of steady decline."[24]

58. Unintentional overdose deaths now account for more early deaths in Tennessee than automobile accidents, suicides, or homicides.[25]

59. Overdose deaths increased in Tennessee from 342 in 1999 to 1,451 in 2015, the last year for which overdoses have been calculated (2016 data is not yet available). [26] That represents more than a 400% increase.

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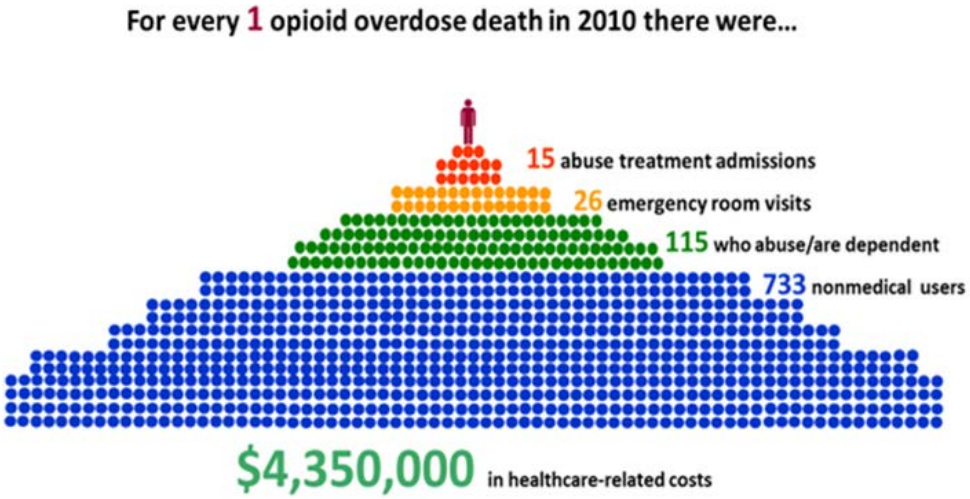
[20] Rodney L. Bragg, Assistant Commissioner, Tennessee Department of Mental Health and Substance Abuse Services, "Prescription Drug Epidemic in Tennessee," May 22, 2014 (citing CDC, MMWR weekly: Vital signs: overdose of prescription pain relievers – United States, 1999-2008).
[21] Working Group Report, *supra* note 15, at 3.
[22] Side Effects, *supra* note 8, at 2 (citing Leonard Paulozzi et al., Ctr. For Disease Control and Prevention, *CDC Grand Rounds: Prescription Drug Overdoses- A U.S. Epidemic, in* 61 Morbidity & Mortality Weekly Rept. 774, 774-76 (2012)).
[23] *Id.* (citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in Chronic Pain Patients: Assessment of Risk of Substance Misuse*, 14 Pain Physician J. 119, 120 (2011)).
[24] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: 'No One Was Doing Their Job'*, washingtonpost.com, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.
[25] Working Group Report, *supra* note 15, at 3 (citing Tenn. Dep't of Health Chronic Pain Guidelines).
[26] Tenn. Dep't of Health, *1,451 Tennesseans Die from Drug Overdoses in 2015*, tn.gov, Nov. 15, 2016, http://tn.gov/health/news/46773.

60. The vast majority of overdose deaths in Tennessee – nearly 72% in 2015 – involve opioids. [27]

61. Between 2005 and 2015, just one decade, unintentional overdose deaths in Tennessee increased over 250%.[28]

62. In Sullivan County alone, 35 persons died of overdoses in 2015. [29]

63. Opioid deaths represent the "tip of the iceberg" of the human and societal costs of the opioid epidemic:[30]



64. One tragedy caused by the explosion of opioids is the compounding rise in babies suffering from NAS.

65. The direct link between the Manufacturer Defendants' fraudulent campaign to flood America with opioids and the NAS baby crisis in Tennessee has been clearly stated by Tennessee's Commissioner of Health Dr. John Dreyzehner. In a 2015 presentation entitled

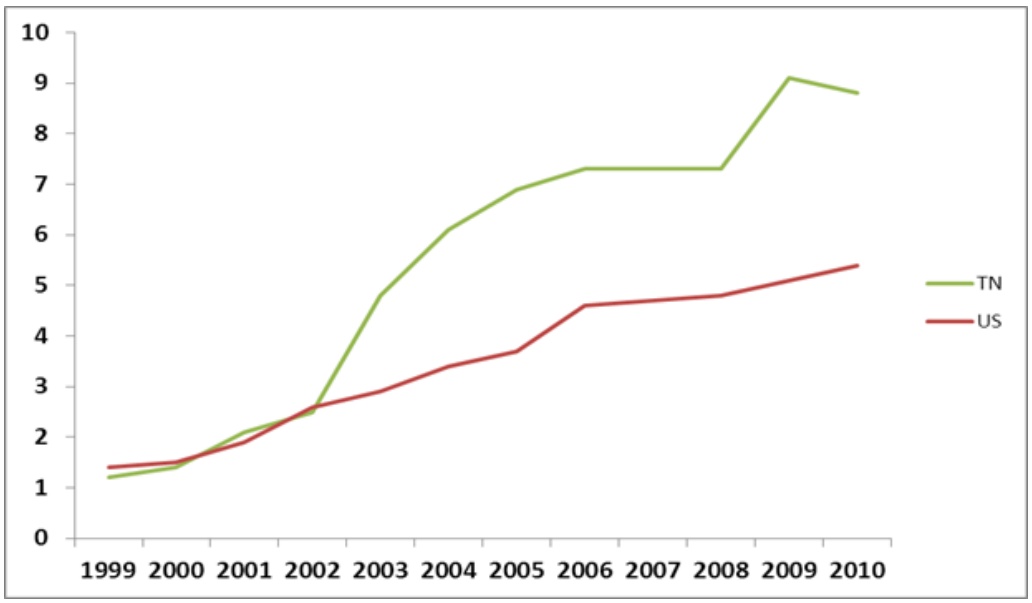
[27] *Id.*
[28] Working Group Report, *supra* note 15, at 3 (citing Tenn. Dep't of Health Chronic Pain Guidelines).
[29] Tenn. Dep't of Health, *supra* note 26.
[30] Benjamin Schachtman, 'Closer to Home' – The Cost of the Opioid Epidemic May be the Tip of the Iceberg, portcitydaily.com, Apr. 3, 2017 (attributing graphic chart to the N.C. Public Health Department). Available at: http://portcitydaily.com/2017/04/03/closer-to-home-the-cost-of-the-opioid-epidemic-may-be-the-tip-of-the-iceberg/.

"Neonatal Abstinence Syndrome: A Tennessee Perspective," Commissioner Dreyzehner addressed **"the Substance Abuse Epidemic and resulting NAS epidemic."**[31]

66. In his NAS presentation, Commissioner Dreyzehner identified the obvious link between opioid sales and opioid related health problems, noting "the incredible correlation between sales and supply and availability [of opioids] and opioid related deaths and opioid treatment admissions."[32]

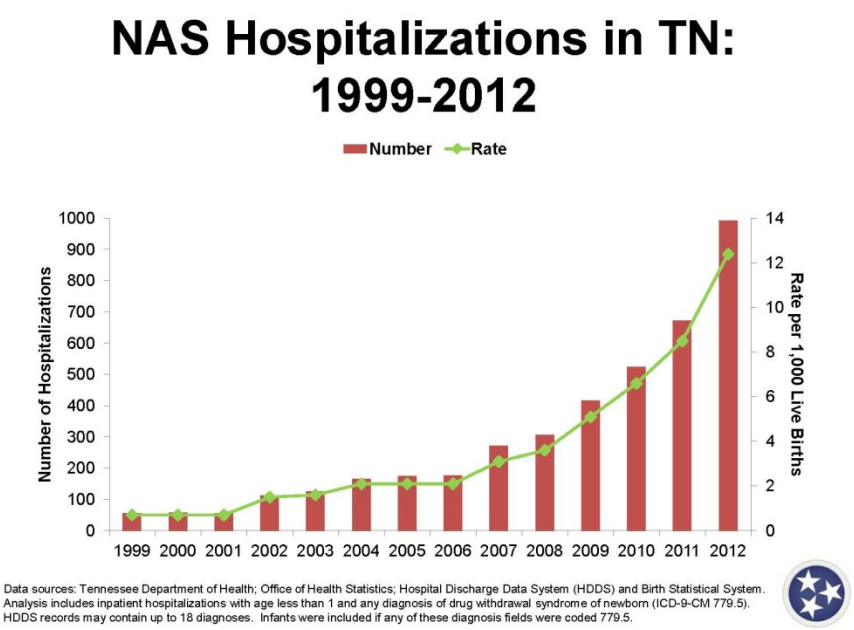
67. The following two charts from the Tennessee Health Department show the close correlation between skyrocketing Tennessee opioid overdoses and the increase in Tennessee babies suffering from NAS:

Rates of Opioid-Related Overdose Death (rate per 100,000 population)
Tennessee and United States, 1999-2010



Source: Tennessee Department of Health – Vital Statistics.

[31] National DEC, "Neonatal Abstinence Syndrome A Tennessee Perspective," Vimeo, May 4, 2015. Available at: https://vimeo.com/126839454.
[32] *Id.*



68. As Dr. Stephen Loyd, Medical Director of the Tennessee Department of Mental Health and Substance Abuse Services, recently testified before the Tennessee House of Representatives' Opioid Task Force ("House Opioid Task Force"): "[m]arketing of opioids as having a low addictive potential when used for the treatment of chronic pain" resulted in "opioids prescribed more freely by practitioners," and, in turn, an "increase in number of babies born drug dependent."[33]

C. Tennessee's opioid crisis is no accident: it is the result of a conspiracy the Manufacturer Defendants and other opioid manufacturers to fraudulently convince physicians that opioids carried a low risk of addiction and were therefore appropriate for non-acute problems like chronic pain.

Purdue set out to end medical providers' long-standing fear of providing opioids.

69. As stated by Commissioner Dreyzehner, "**in the 1990's, MD's started prescribing opioids in large volume to treat [nonmalignant] pain which has caused an opioid addiction problem**."[34] Douglas Varney, Commissioner of the Tennessee Department of

[33] House Opioid Task Force, February 23, 2017.
[34] Working Group Report, *supra* note 15, at attachment 2.

Mental Health, speaking at a meeting of the Governor's Working Group, similarly concluded that **"[b]asically we are dealing with the fallout from the medical profession overprescribing opioids."**

70. Up until the mid-1990s, physicians prescribed opioids primarily to cancer patients and persons recovering from surgery. Fearful of the addictive qualities of opioids, physicians would not generally prescribe them for long term chronic pain. As detailed in a review of the development of the opioid crisis published in the 2015 Annual Review of Public Health, "**[p]rior to the introduction of OxyContin [by Purdue in 1995], many physicians were reluctant to prescribe OPRs [opioid pain relievers] on a long-term basis for common chronic conditions because of their concerns about addiction, tolerance, and physiological dependence**."[35]

71. Purdue's own research confirmed the mid-1990s consensus of medical providers regarding the dangers of opioids. According to the Agreed Statement of Facts signed by Purdue in connection with its 2007 guilty plea to federal criminal charges for misbranding OxyContin: "During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain… **'[t]he biggest negative of [OxyContin] was the abuse potential**.'"[36]

72. As Purdue prepared to introduce OxyContin to the U.S. market, including Tennessee, it carefully evaluated physicians' concerns about the risks of addiction associated with opioids and embarked on a highly successful, fraudulent campaign to convince physicians that OxyContin created minimal risk of addiction. As Purdue's efforts demonstrated success in

[35] Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Ann. Rev. Pub. Health 559, 562. (2015).
[36] Information as to Purdue Frederick Co., Inc., U.S.A v. Purdue Frederick Co., Inc., No. 1:07-cr-00029 W.D. Va. May 10, 2007, ECF No. 5-2 at ¶19 (alteration in original).

the form of rapid increases in opioid prescribing, Mallinckrodt and Endo, and other opioid manufacturers joined Purdue in its fraudulent scheme.

Purdue's aggressive marketing of OxyContin fueled ever-increasing, and excessive, demand for the drug.

73. From the outset of its nationwide OxyContin marketing campaign, Purdue "aggressively" promoted the drug to physicians both inside and outside of Tennessee for non-cancer pain conditions that can be caused by arthritis, injuries, and chronic diseases.[37] Essential to this marketing strategy was Purdue's claim, which it later conceded to be fraudulent, that OxyContin rarely gave rise to addiction, a risk Purdue downplayed as likely in "less than one percent of patients."[38]

74. Purdue's promotion of OxyContin for the treatment of non-cancer-related pain contributed to a "nearly tenfold" increase in OxyContin prescriptions for non-cancer-related pain, from about 670,000 prescriptions in 1997 to about 6.2 million prescriptions in 2002.[39]

75. Purdue's marketing for OxyContin was bolstered by the bold claim that the drug was "the first and only 12-hour OxyContin pain medicine."[40] In a 1996 press release, Purdue touted: "Unlike short-acting pain medications, which must be taken every 3 to 6 hours – often on an 'as needed' basis – OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night."[41] That same press release included a "Background" section, which proclaimed that the "fear of addiction" to opioids was "exaggerated" and "largely

[37] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221, 222 (2009) [hereinafter *Van Zee*] (quoting Purdue's 1999 OxyContin Marketing Plan); *see also* U.S. Gov't Accounting Office, Report to Cong. Requesters, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 17 (2003) [hereinafter OxyContin Abuse and Diversion].
[38] OxyContin Abuse and Diversio, at 28.
[39] *Id.* at 18.
[40] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain (May 31, 1996), *available at* https://assets.documentcloud.org/documents/2815975/Pressreleaseversionone.pdf; *see also* Minutes from the OxyContin Launch Team Meeting (Mar. 31, 1995), *available at* http://documents.latimes.com/oxycontin-launch-1995/.
[41] *Id.*

unfounded."[42]

76. When it introduced OxyContin, Purdue had no meaningful evidence that supported its core claim that the drug's addiction risk was minimal. It later admitted that this claim was fraudulent.[43]

77. Purdue also had extensive evidence that its "12-hour relief" claims were false. This was critical because patients who could not get 12-hour relief would supplement their dosage, thereby increasing their risk of addition.[44]

78. Even before OxyContin went on the market, Purdue's clinical trials showed many patients were not getting 12 hours of relief from a single dose. The first clinical study of OxyContin – which was designed and paid for by Purdue, and overseen by Purdue scientists – occurred in 1989 and involved women recuperating from abdominal and gynecological surgery at two hospitals in Puerto Rico. In that study, 90 women were given a single dose of OxyContin while other patients were given short-acting painkillers or placebos. More than a third of women given OxyContin started complaining of pain after just eight hours, and about half required more medication before the 12-hour mark.[45]

79. The results of the 1989 study were not unique. Dr. Daniel Brookoff, a Tennessee pain specialist whom Purdue selected to field-test OxyContin, ran into similar issues. In a 1995 clinical study completed as part of the Food and Drug Administration ("FDA") approval process, Dr. Brookoff eventually moved 8 of 15 chronic pain patients to 8-hour dosing because they were not getting adequate relief taking the drug twice a day.[46]

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[42] *Id.*
[43] Clay Duda, *On the Front Lines of Knoxville's Battle Against Opiate Addiction*, knoxvillemercury.com, June 1, 2016, http://www.knoxmercury.com/2016/06/01/front-lines-knoxvilles-battle-opiate-addiction/.
[44] Harriet Ryan et al., *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, latimes.com, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.
[45] *Id.* (citing original documents from the study).
[46] *Id.*

80. Purdue nevertheless launched an extensive campaign to market and promote the drug using an expanded sales force and multiple promotional approaches to encourage physicians, including primary care specialists, to prescribe OxyContin as an initial opioid treatment for non-cancer pain.[47] This campaign was nationwide and directed at medical providers and potential consumers in Tennessee, among other states.

81. Utilizing marketing data, Purdue and its sales representatives pushed the false narrative that OxyContin, because of its time-release formulation, posed a lower threat of abuse and addiction to patients than traditional, shorter-acting painkillers like Percocet or Vicodin.[48]

82. To this end, Purdue used a series of deceptive videos and journal advertisements. For example, in 1998, Purdue distributed 15,000 copies of an OxyContin marketing video to physicians without submitting it to the FDA for review, as required under the Federal Food Drug and Cosmetic Act ("FD&C Act").[49] In the Purdue video, entitled *I Got My Life Back: Patients in Pain Tell Their Story*, a physician **"stated that opioid analgesics have been shown to cause addiction in less than 1 percent of patients."[50] That statement, according to the FDA, "has not been substantiated."[51]**

83. In 2000, Purdue submitted a different promotional video to the FDA, this one entitled *I Got My Life Back: A Two Year Follow up of Patients in Pain*.[52] **The FDA found that Purdue's video "appeared to make unsubstantiated claims regarding OxyContin's effects on patients' quality of life and ability to perform daily activities and minimized the risks**

[47] OxyContin Abuse and Diversion at 16-24, *supra* note 37.
[48] Press Release, U.S. Attorney's Office W.D. Va., *The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin: Will Pay Over $600 Million* (May 10, 2007), *available at* https://health.mil/Reference-Center/Publications/2007/05/10/The-Purdue-Frederick-Company-Inc-and-Top-Executives-Plead-Guilty. [hereinafter WV Press Release]
[49] OxyContin Abuse and Diversion at 27, *supra* note 37.
[50] *Id.*at 28.
[51] *Id*
[52] *Id.*

associated with the drug."[53] Ignoring the FDA's concerns, Purdue distributed 12,000 copies of the videos to physicians.[54]

84. Purdue also employed false or misleading medical journal advertisements that, as determined by the FDA, violated the FD&C Act. Notably, in January 2003, the FDA issued a stern warning letter to Purdue in response to two ads the company ran in the Journal of the American Medical Association, a prestigious publication distributed to physicians in Tennessee and throughout the United States:

> **Your journal advertisements omit and minimize the serious safety risks associated with OxyContin, and promote it for uses beyond which have been proven safe and effective.** Specifically, your journal advertisements fail to present in the body of the advertisements any information from the boxed warning in the approved product labeling (PI) for OxyContin regarding the potentially fatal risks associated with the use of OxyContin and the abuse liability of OxyContin, which is a Schedule II controlled substance, and make unsubstantiated efficacy claims promoting the use of OxyContin for pain relief. Your journal advertisements also understate the minimal safety information that is presented. **Your advertisements thus grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks associated with OxyContin, thereby potentially leading to prescribing of the product based on inadequate consideration of risk.** In addition, your journal advertisements fail to present in the body of the advertisements critical information regarding limitations on the indicated use of OxyContin, thereby promoting OxyContin for a much broader range of patients with pain than are appropriate for the drug. **The combination in these advertisements of suggesting such a broad use of this drug to treat pain without disclosing the potential for abuse with the drug and the serious, potentially fatal risks associated with its use, is especially egregious and alarming in its potential impact on the public health.**[55]

85. The message that the FDA deemed "egregious and alarming"- that OxyContin

[53] *Id.*
[54] *Id.*
[55] Letter from Thomas W. Abrams, FDA, Dir. of Drug Mktg. Adver. And Commc'n, to Michael Friedman, Exec. Dir. Purdue Pharma, L.P. (Jan. 17, 2003), *available at* http://wayback.archive-it.org/7993/20170112065652/http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM168946.pdf.

posed little rise of addiction and was thus appropriate for chronic non-cancer pain - was critical to Purdue's sales and central to Purdue's marketing efforts directed at prescribing physicians in Tennessee and throughout the United States. Purdue aggressively sought to influence physicians prescribing habits by inviting them to all-expenses-paid conferences. From 1996 to 2000, Purdue conducted more than 40 national pain management and speaker training conferences at resorts in Florida and Arizona.[56] Before that practice was discontinued, more than 5,000 physicians, pharmacists, and nurse practitioners from Tennessee and elsewhere attended Purdue's conferences, where they were recruited and trained for Purdue's national speaker bureau.[57]

86. Beginning in 1996, Purdue hired 318 sales representatives to implement its OxyContin marketing campaign.[58] By 2000, the number of sales representatives directly employed by Purdue had risen to 562, and Purdue added a Hospital Specialty Division which employed another 109 sales representatives.[59] At that time, the 671 Purdue sales representatives had a total physician call list of approximately 33,400 to 44,500 physicians.[60]

87. Purdue had a lucrative bonus system which incentivized its sales representatives to increase sales of OxyContin in their respective territories. In 2001, in addition to the average sales representative's annual salary of $55,000, annual bonuses averaged $71,500, with a range of $15,000 to nearly $240,000.[61] Purdue paid approximately $40 million in bonuses tied to OxyContin sales in 2001.[62]

[56] OxyContin Abuse and Diversion at 22, *supra* note 37.
[57] *Id.*
[58] *Id.*
[59] *Id.* at 19-20.
[60] *Id.* at 20.
[61] *Id.*
[62] *Id.*

88. Purdue also entered into a co-promotion agreement with Abbott Laboratories ("Abbott"), through which Abbott provided an additional 300 sales representatives per year from 1996 through 2002.[63] The sales representatives from the two companies closely coordinated their efforts, met regularly to strategize, and shared marketing materials.[64] Internal Abbott and Purdue memos, as well as sales documents and marketing materials, show that Abbott sales representatives were instructed to downplay the threat of addiction with OxyContin and make other claims to doctors that had no scientific basis.[65] For example, in one internal Abbott memo – which listed ideas to help sales personnel increase OxyContin's share of pain-pill prescriptions written by orthopedic surgeons – Abbott told its sales representatives to highlight the "less abuse/addiction potential" of the drug, which could be taken just twice a day because of its time-release formulation.[66]

89. The more Abbott generated in OxyContin sales, the higher the reward for the company. Under the agreement with Purdue, Abbott received 25 percent of all net sales, up to $10 million, for prescriptions written by doctors its sales reps called on, and 30 percent of sales above $10 million.[67] Accordingly, similar to Purdue, Abbott heavily incentivized its sales staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers.[68]

90. One of the "critical foundations" of Purdue and Abbott's marketing for OxyContin was the use of sophisticated marketing data to influence physicians' prescribing habits.[69] By compiling prescriber profiles on individual physicians, the co-promoters were able to identify the highest and lowest prescribers of particular drugs in a single zip code, county,

[63] *Id.* at 19-20.
[64] David Armstrong, *Secret trove reveals bold 'crusade' to make OxyContin a blockbuster*, STAT News, September 22, 2106.
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] Van Zee at 222, *supra* note 37.

state, or the entire country.[70] Purdue and Abbott then targeted the highest, and in some cases least discriminate, prescribers of opioids across the country.[71]

91. Purdue and Abbott spent hundreds of millions of dollars promoting OxyContin through their respective sales forces because they understand that their representatives' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits, and face-to-face detailing has the highest influence on intent to prescribe.[72] Purdue and Abbott could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers, whom they targeted for detailing and who responded by prescribing more OxyContin. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.[73] Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.[74]

92. As part of its direct marketing campaign, Purdue distributed several types of branded promotional items to health care professionals.[75] Among the items were OxyContin fishing hats, stuffed plush toys, music compact discs (entitled "Get in the Swing With OxyContin"), and pens containing a pullout conversion chart showing physicians how to

[70] *Id.*
[71] *Id.*
[72] Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in 34% decline in on-label use of promoted drugs); *see also* Van Zee at 222, *supra* note 37 (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).
[73] David Armstrong, *Secret trove reveals bold 'crusade' to make OxyContin a blockbuster*, STAT News, September 22, 2106.
[74] *Id.*
[75] OxyContin Abuse and Diversion at 25, *supra* note 37.

calculate the dosage to convert a patient to OxyContin from other opioid pain relievers.[76] **According to the U.S. Drug Enforcement Agency ("DEA"), the "use of such branded promotional items for a Schedule II opioid [was] unprecedented… and indicates Purdue's aggressive, excessive, and inappropriate marketing of their product, OxyContin."[77]**

93. Akin to practices employed by street drug dealers, Purdue also gave away its addictive product to first-time users. "For the first time in marketing any of its products, Purdue used a patient starter coupon program for OxyContin to provide patients with a free limited-time prescription."[78] Under this program, Purdue's sales representatives distributed coupons to physicians who, in turn, decided whether to offer one to a patient, and then the patient could redeem a free prescription through a participating pharmacy. Approximately 34,000 coupons had been redeemed nationally when the program was terminated following the July 2001 OxyContin label change.

94. In conjunction with its direct marketing efforts, Purdue began an innovative indirect-marketing campaign for OxyContin. Because FDA regulations prohibit direct-to-consumer advertising of narcotics, Purdue decided to concentrate on "nonbranded education," which would market the concept of pain relief to consumers. To this end, in 1997, the company launched the "Partners Against Pain" website available to consumers in Tennessee and throughout the United States.[79] Through a variety of articles, studies, and polls, the "Partners Against Pain" website "promoted three ideas to doctors and patients: that pain was much more widespread than had previously been thought; that it was treatable; and that in many cases it

[76] *Id.*
[77] *Id.*56.
[78] *Id.* at 23.
[79] *Id.* at 23-24.

could, and should, be treated with opioids."[80]

95. Purdue also used paid third parties to give its marketing claims a perception of scientific legitimacy. To this end, as explained in a recently published history of the opioid crisis, "Purdue provided financial support to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, pain patient groups, and other organizations. In turn, these groups all advocated for more aggressive identification and treatment of pain, especially use of OPRs [opioids]."[81]

96. "To overcome what they claimed to be 'opiophobia,' physician-spokespersons for opioid manufacturers published papers and gave lectures in which they claimed that the medical community had been confusing addiction with 'physical dependence.' They described addiction as rare and completely distinct from so called 'physical dependence,' which was said to be clinically unimportant. They cited studies with serious methodological flaws to highlight the entirely false claim that the risk of addiction was less than 1%."[82]

97. For example, in 1996, the American Pain Society and the American Academy of Pain Medicine – who were funded in part by the Manufacturer Defendants - issued a "consensus statement" that "suggested that opioids were safe and effective for chronic, noncancer pain and that the risk of addiction was low."[83]

98. The co-authors of the Consensus Statement were David Joranson, MSSW, then founder and distinguished scientist of the Pain and Policy Studies Group at the University of Wisconsin School of Medicine and Public Health, and J. David Haddox, MD. Between 2000 and 2010, Joranson's Pain and Policy Studies Group received approximately $1.6 million in grants

[80] Paul Tough, *The Alchemy of OxyContin*, nytimes.com, July 29, 2001, http://www.nytimes.com/2001/07/29/magazine/the-alchemy-of-oxycontin.html.
[81] Kolodny, *supra* note 35, at 562.
[82] *Id.*
[83] John Fauber, *Academics Profit by Making the Case for Opioid Painkillers*, abcnews.go.com, Apr. 4, 2011, abcnews.go.com/Health/academics-profit-making-case-opioid-painkillers/story?id= 13284493.

from Purdue.[84] As detailed in an investigative series in the Milwaukee Journal Sentinel, the group became a consistent cheerleader for the widespread prescriptions of opioids. When he co-authored the Consensus Statement, Dr. Haddox was a paid speaker for Purdue. He was hired by Purdue in 1999 and has continued to be a Purdue executive ever since.[85]

99. Purdue further bolstered its fraudulent efforts with legislation in Tennessee and elsewhere as a part of national lobbying effort to promote opioids to chronic pain. In Tennessee, "legislators passed the Intractable Pain Treatment Act in 2001, a law requiring doctors to either prescribe opiates for pain or provide patients with a list of places they could get the drugs, including pain clinics."[86] "When it was repealed in 2015, Sen. Janice Bowling, R-Tullahoma, said the original bill had been 'well-intentioned,' but was largely 'based on intentional misinformation' provided by Purdue at the time."[87] "With 11 minutes of deliberation, the Tennessee General Assembly passed what Purdue was telling states to do," said Bowling, who was not in the legislature in 2001, but later researched the bill. "The patient became the prescriber, if you will."[88]

Purdue's 2007 guilty plea for lying about OxyContin,
and its continued marketing of the drug.

100. **In 2007, Purdue and its three top executives were indicted and forced to plead guilty to wide ranging fraud in falsely promoting OxyContin as non-addictive and appropriate for chronic pain.** Purdue's extensive fraud during the first two decades of its OxyContin campaign are thus an uncontroversial matter of public record admitted by the

[84] *Id.*
[85] *Id.*
[86] Duda, *supra* note 43.
[87] *Id.*
[88] Rich Lord, *In 2001, Tennessee Gave Pain Physicians Green Light to Prescribe Opioids Without Repercussions*, postgazette.com, May 25, 2016, http://www.post-gazette.com/news/nation/2016/05/26/In-2001-Tennessee-gave-pain-physicians-green-light-to-prescribe-opioids-without-repercussions/stories/201605250148 (quoting State Senator Janice Bowing).

company.

101. As United States Attorney John L. Brownlee explained in a 2007 news release: "**Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal**."[89]

102. As part of its 2007 felony guilty plea for misbranding OxyContin as less addictive and appropriate for chronic pain, Purdue admitted that:

> **Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subjective to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:**
>
> [t]rained Purdue sales representatives and told some health care providers that it was more difficult to extract the OxyContin from an oxycodone tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton onto a syringe;
>
> [t]old Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids,[which the company knew was not true]; …
>
> [s]ponsored training that taught Purdue sales supervisors that OxyContin had fewer 'peak and trough' blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids, [which the company knew was not true];
>
> [falsely] [t]old certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> [falsely] [t]old certain health care providers that OxyContin did not cause a 'buzz' or euphoria, caused less euphoria, had less addiction potential, had less abuse

[89] WV Press Release, *surpa* note 48 (quoting U.S. Attorney John Brownlee).

> potential, was less likely to be diverted than immediate-release opioids, and could be used to 'weed out' addicts and drug seekers.[90]

103. As Purdue admitted in its 2007 guilty plea, these claims about OxyContin were entirely fraudulent. Nevertheless, for over 20 years they had been at the center of an unprecedented multi-million-dollar marketing campaign designed to convince physicians to disregard their longstanding unwillingness to prescribe opioids for any medical conditions other than late stage cancer and other acute, or short-term, conditions.

104. Under the plea agreement, Purdue also agreed to pay $600 million in criminal and civil penalties —one of the largest settlements in history for a drug company's marketing misconduct.[91]

105. At the same time Purdue's president, top lawyer, and medical director pled guilty as individuals to criminal misbranding[92] and agreed to pay a total of $34.5 million in fines.[93]

106. Under the plea agreement, Purdue also entered into a Corporate Integrity Agreement ("CIA") with the United States Department of Health and Human Services – Office of Inspector General ("HHS-OIG").[94] As part of the CIA, Purdue agreed to refrain from deceptively marketing OxyContin, to train its employees regarding compliance with the CIA, and to report its compliance (both independently and through an independent review organization) to the HHS-OIG.[95]

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[91] *U.S. v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, 571-72 (W.D. Va. 2007).
[91] *U.S. v. Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569, 571-72 (W.D. Va. 2007).
[92] "Misbranding" is a broad statute that makes it a crime to mislabel a drug, fraudulently promote it or market it for an unapproved use.
[93] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, nytimes.com, May 10, 2007, http://www.nytimes.com/2007/05/10/business/11drug-web.html.
[94] Information, *supra* note 36 at 5-5.
[95] *Id.*

Even after its guilty plea, Purdue continued its
false and misleading marketing practices, added by the other Manufacturer Defendants

107. Despite its guilty plea, Purdue has continued to deceptively market opioids, feeding the opioid addiction crisis set in motion by its fraudulent advertising. As a result, sales of OxyContin were not only unhindered by the guilty plea – they continued to grow. OxyContin yielded $3.1 billion in revenue for Purdue in 2010, which was nearly four times its 2006 sales of $800 million.[96] Endo and Mallinckrodt joined in this effort.

108. Purdue continued to aggressively push the same false narrative for which it had been criminally prosecuted – that, to quote its statement of facts accompanying its guilty plea, "OxyContin was less addictive, less subject to abuse" than traditional opioids, and therefore appropriate for treatment of long term chronic pain.

109. To evade scrutiny, Purdue continued to use third parties – with which it was closely tied financially – to convey its pro-OxyContin message.

110. In addition to using front groups, Purdue masked its effort to continue the promotion of widespread opioid prescribing by presenting the decision to use opioids for chronic pain not as a highly risky practice with no scientific support – the truth – but rather as a complex determination that required extensive analysis of each individual patient. There was no scientific basis for this position, which effectively justified continued widespread opioid prescribing for virtually any patient, thereby allowing Purdue's fraudulent marketing campaign to continue after 2007, as if the guilty plea had not occurred.

111. For example, in December 2009, medical education materials paid for by opioid manufacturers, including Endo and Purdue (1) reiterated Purdue's core fraudulent claim that "addiction is rare in patients who become psychologically dependent on opioids while using

[96] Katherin Eban, *OxyContin: Purdue Pharma's Painful Medicine*, Fortune.com, Nov. 9, 2011, http://fortune.com /2011/11/09/oxycontin-purdue-pharmas-painful-medicine/.

them for pain control," (2) emphasized the need to individually evaluate each patient "as clinical trials [rejecting opioid treatment]are not designed to identify the best treatment regimen in a given situation to manage chronic pain," and (3) urged use of opioids even for patients engaging in "aberrant behaviors" while setting the following extreme standard to be used to identify individual patients with addiction problems: "a patient exhibiting egregious behaviors that persist, despite repeated warnings and that require significant time and resources to manage, is likely to have a problem with abuse and possibly addiction." The materials further stated that "[a]n opioid trial is the only way a clinician can determine the efficacy and tolerability of a particular agent in a particular person" – in other words, the only way to rule out opioids for any given chronic pain patient was to give opioids a try. Not one of these assertions has ever been supported by science. Though "expired," the materials are still available on the Internet today.[97]

112. In the same vein, Purdue-funded key opinion leader Dr. Russell Portenoy, speaking on Good Morning America in 2010, stated categorically that "[a]ddiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted." As detailed in the scientific background section of this complaint, Dr. Portenoy's bold assertion was directly contrary to the scientific evidence. Dr. Portenoy, who himself is facing lawsuits for his work as a Purdue-paid opioid pitchman, has now conceded that this promotion of opioids for chronic pain was "clearly the wrong thing to do." He is on record

[97] Anderson et al, "Opioid Prescribing: Clinical Tools and Risk Management Strategies, available at https://mn.gov/boards/assets/Opioid_Prsecibing_Clinical_Tools_ and_Risk_Management_Strategies.pdf_tcm21-366993.pdf

stating: "I gave innumerable lectures in the late 1980s and 90's about addition that weren't true."[98] But the damage has long since been done.

113. Another opioid pitchman, Dr. Lynn Webster, in 2010 disclosed serving on Purdue's Medical Advisory Board. During the period of 2013 through 2015, Dr. Lynn Webster was the principle researcher on over $9 million in contracts with pharmaceutical companies, including Mallinckrodt. Dr. Lynn Wesbster created a webinar out of a presentation he gave in Las Vegas, Nevada on September 22, 2011. In the Webinar, which remained available on the Internet on June 12, 2017, Webster promoted "Single-entity opioids (oxycodone, fentanyl)" for treatment of chronic pain.[99] The seminar was, according to Dr. Webster, funded by a "generous education grant" from Purdue.

114. In 2016 and 2017, Webster also produced and distributed a 57-minute documentary, "The Painful Truth," which continues to promote the use of opioids to treat chronic non-cancer pain. "The Painful Truth" tries to excuse Dr. Webster's role in unleashing America's opioid addiction crises by featuring chronic pain patients expressing their fears about losing access to opioids.[100]

115. The 2010 annual report of the Manufacturer Defendants-funded American Pain Foundation ("APF"), which has been described by the President of Physicians Responsible Opioid Prescribing as "a front for opioid manufacturers,"[101] carefully documents the scope of the Manufacturer Defendants' fraudulent enterprise. This 2010 report details thousands of pro-opioid advertisements, public statements, letters, Facebook Posts, and similar communications. For

[98] Thomas Catan & Evan Perez, *A Pain Champion has Second Thoughts*, wsj.com, Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[99] See generally Emerging Solutions, http://emergingsolutionsinpain.com/ (last visited June 12, 2017).
[100] David Armstrong, *TV Documentary on Pain Treatment Funded by Doctor with Industry Ties*, statnews.com, Mar. 24, 2017, https://www.statnews.com/2017/03/24/pain-documentary-public-television/.
[101] Charles Ornstein and Tracy Weber, *Patient Advocacy Group Funded by Success of Painkiller Drugs, Probe Fins*, washingtonpost.com, Dec. 23, 2011. Available at: https://www.washingtonpost.com/national/health-science-/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html.

example, the report states: "Through online, print, radio, and television outlets, APF's local and national media outreach efforts secured 1,600 media stories on pain in 2010 – an increase of 1,255% from 2009. Reaching more than 600 million people with important pain-related messages, APF spokespeople and advocates provided education, information and assistance to people with pain and combated the negative stereotypes and stigmas associated with pain."[102]

116. In October 2011, the APF published a Policymaker's Guide "to help meet the informational needs of busy policymakers and their staff members." **The Policymaker's Guide included a list of "some common misconceptions about pain" including the "misperception" that "[u]se of strong pain medication leads to addiction."** The Policymaker's Guide further concluded that: "Unfortunately, too many Americans are not getting the pain care they need and deserve" and noted, among "common reasons for difficulty in obtaining adequate care," "[c]oncerns among providers about providing pain medications for chronic pain, and fears of scrutiny by regulators or law enforcement."[103]

117. To this day, Purdue publishes an OxyContin website for physicians promoting OxyContin for patients with chronic pain – even those with a history of substance abuse. The site provides an example of a person suffering "sciatic nerve pain" with a history of substance abuse and states: "Risks are increased in patients with personal or family history of substance abuse … [t]he potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as OxyContin."[104]

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[102] American Pain Fund 2010 Annual Report. Available at: https://archive.org/stream/277604-apf-2010-annual-report/277604-apf-2010-annual-report_djvu.txt.
[103] American Pain Foundation, *A Policymaker's Guide to Understanding Pain & Its Management* (rev. Oct., 2011), *available at* http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[104] About OxyContin. Available at: http://www.purduepharma.com/healthcare-professionals/products/oxycontin/ (last visited June 12, 2017).

118. These are not isolated statements, but just a select few representative examples of fraudulent pro-opioid communications that formed part of a vast, multi-year fraud designed to fuel the improper marketing of opioids following Purdue's guilty plea by misrepresenting addiction risks and fraudulently promoting the entirely unscientific practice of using opioids for non-acute long term chronic pain.

119. The net effect of the Manufacturer Defendants' pro-opioid communications effort has been to continue the broad dissemination of the very lies for which Purdue pled guilty in 2007 up through this very day, thereby ensuring that the continuous flow of opioids to east Tennessee and communities throughout the United States such as the Opioid Epidemic Affected Counties continued without interruption.

120. Speaking before the House Opioid Task Force in 2017, Dr. Michael Baron of the Tennessee Board of Medical Examiners summed up the cumulative effect of the opioid manufacturers' multi-year fraud:

> We came out with what I call 'Generation O.' A whole generation of physicians that were taught it's ok to prescribe opiates, that they're safe, and that it's what the patient wants. But we bypassed evidence-based medicine. The whole medical system was hijacked by industry and really greed.
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> ***
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> The triggers of the opioid epidemic were really the pharmaceutical industry and pain experts that were on the payroll of the pharmaceutical industry. And they preached that opioids are safe and effective for chronic, non-cancer pain, the risk of addiction is rare, and opioid therapy can be easily discontinued, all of which is nonsense. [105]

Purdue profited from the abuse and diversion of OxyContin.

121. The high availability of OxyContin correlated with increased addiction, abuse, and diversion (a term used to describe the redistribution of prescription drugs for illegal uses),

[105] House Opioid Task Force, February 23, 2017.

and by 2004 OxyContin had become a leading drug of abuse in the United States.[106]

122. The increasing rates of addiction and abuse sustained OxyContin's remarkable commercial success.[107] As the DEA has explained, OxyContin abusers learned how to simply crush the controlled-release tablet and swallow, inhale, or inject the high-potency opioid for an intense morphine-like high.[108] Purdue was well aware of this risk of diversion and abuse in this manner as early as 1995, because the company's own testing demonstrated that 68% of the oxycodone could be extracted from an OxyContin tablet when crushed.[109]

123. In a November 2003 letter to the General Accounting Office ("GAO"), the DEA provided the following explanation of the causes and factors relating to the diversion of OxyContin:

> **The DEA has previously stated that the company's [i.e. Purdue's] aggressive methods, calculated fueling of demand and the grasp for major market share very much exacerbated OxyContin's widespread abuse and diversion.** While Purdue highlights its funding of pain-related educational programs and websites and its partnership with various organizations, the fact remains that Purdue's efforts – which may be viewed as self-serving public relations damage control – would not have been necessary had Purdue not initially marketed its product aggressively and excessively. **Contributing to the abuse and diversion problem (and the product's excessive availability) is the fact that in promoting this drug to practitioners, Purdue deliberately minimized the abuse risk associated with OxyContin** . . . . The claim in Purdue's "educational" video for physicians that opioid analgesics cause addiction in less than one percent of patients is not only unsubstantiated but also dangerous because it misleads prescribers.[110]

[106] Van Zee, *supra* note 37, at 221..
[107] *Id.* at 223.
[108] Drug Enforcement Administration, Office of Diversion Control, Action Plan to Prevent the Diversion and Abuse of OxyContin, https://web.archive.org/web/20080512200957/https://www.deadiversion.usdoj.gov/drugs_concern/OxyContin/abuse_oxy.htm (accessed May 4, 2017) [hereinafter *DEA OxyContin Action Plan*].
[109] Information, *supra* note 36; *see also* Van Zee at 223, *supra* note 37.
[110] *Id.*, at 56.

124. In addition to DEA reports, the U.S. Department of Justice's ("DOJ") yearly drug market analysis of the Appalachia High Intensity Drug Trafficking Area ("Appalachia HIDTA"), which includes 29 counties in Tennessee, and more specifically, the Opioid Epidemic Affected Counties, provides an overview of opioid-related abuse and diversion in and around Tennessee.[111] As the DOJ explained in its 2009 drug market analysis:

> The diversion, distribution, and abuse of controlled prescription drugs (CPDs) such as OxyContin (oxycodone), Vicodin (hydrocodone), and Valium (diazepam), are significant threats in the Appalachia HIDTA region. Traffickers and abusers illicitly obtain CPDs through traditional diversion methods (primarily doctor-shopping, theft, forged prescriptions, and unscrupulous physicians and pharmacists working alone or in association). Prescription drug traffickers and abusers increasingly circumvent law enforcement efforts to prevent CPD diversion in the region by obtaining drugs in Florida, Pennsylvania, and Tennessee.[112]

125. The DOJ's drug market analyses of the Appalachia HIDTA for the years 2008 through 2011 detail a steady rise in the availability and law enforcement seizures of oxycodone (primarily OxyContin) in the Tennessee illegal drug market: 1,069 dosage units of oxycodone seized in Tennessee in 2007;[113] 2,679 dosage units of oxycodone seized in Tennessee in 2008;[114] 3,016 dosage units of oxycodone seized in Tennessee in 2009;[115] and 4,142 dosage units of oxycodone seized in Tennessee in 2010.[116]

126. More recently, a 2013 article in the L.A. Times revealed that, since at least 2002, Purdue has maintained a database of 1,800 doctors suspected of recklessly prescribing the

[111] U.S. Dep't of Justice, *Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis*, 1-2 (June 2007) (explaining that the AHIDTA region "has a combined population of approximately 2.5 million" and "Knoxville, Tennessee, is the largest metropolitan area").
[112] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 2 (Mar. 2009).
[113] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 4 (June 2008).
[114] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 4 (March 2009).
[115] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 3 (May 2010).
[116] U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, Drug Market Analysis, 11 (Sept. 2011).

company's pills to addicts and drug dealers.[117] Purdue refers to the confidential list as "Region Zero" in internal documents.[118] In all but a few cases, Purdue did not alert law enforcement or medical authorities to the doctors on its list, many of whom were prolific prescribers of OxyContin.[119]

127. The example of Dr. Elanor Santiago, one of the physicians on Purdue's "Region Zero" list, provides a stunning display of the causal relationship between the prescription market and diverted market for OxyContin, as well as Purdue's willful and knowing decision to profit from the diversion problem.

128. Beginning in the summer of 2008, Dr. Santiago, an elderly physician, ran the Lake Medical "clinic" (set up by an ex-con and his business partner) out of office space on a seedy block near MacArthur Park in Los Angeles.[120] Dr. Santiago immediately began prescribing OxyContin in extraordinary quantities. In a single week in September 2008, she issued orders for 1,500 pills, more than entire pharmacies sold in a month. In October, it was 11,000 pills. By December, she had prescribed more than 73,000, with a street value of nearly $6 million. Purdue tracked the surge in prescriptions, and eventually sent Michele Ringler, the district sales manager for Los Angeles, to check out the clinic as part of the company's investigation. When Ringler and one of her sales reps arrived, they found a building that looked abandoned, according to company emails recounting the visit. Inside, the hallways were strewn with trash and lined with a crowd of men who looked like they "just got out of L.A. County jail." Feeling uncomfortable, Ringler and the rep left without speaking to Dr. Santiago. When a Purdue

[117] Scott Glover & Lisa Girion, *OxyContin Maker Closely Guards Its List of Suspect Doctors*, latimes.com, Aug. 11, 2013, http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811.
[118] *Id.*
[119] *Id.* (noting that Purdue purportedly alerted law enforcement or medical regulators to 154 of the suspected prescribers – about 8% of those in its database).
[120] Harriet Ryan et al., *More than 1 million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, latimes.com, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

security committee met in Stamford in December 2008, less than five months after Lake Medical opened, Dr. Santiago was under review, according to internal records and interviews. The panel, comprised of three company lawyers, could have reported Dr. Santiago to the DEA. Instead it opted to add her name to the "Region Zero" list of physicians suspected of recklessly prescribing OxyContin to addicts or dealers. As Purdue's investigation of the clinic continued, the company eventually concluded that Lake Medical was working with a corrupt pharmacy in Huntington Park to obtain large quantities of OxyContin. In a September 1, 2009 email Purdue district sales manager Ringler sent to company officials, she referred to the Lake Medical clinic and corrupt pharmacy as "an organized drug ring," and suggested that Purdue contact the DEA. Nevertheless, 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.[121]

129. Dr. Santiago's case is just one of many that demonstrate that Purdue did not use its database of suspected physicians to reduce OxyContin abuse, to rein in dangerous physicians, or to stop the unlawful distribution of opioids. Instead, Purdue knowingly aided criminal activity in order to maximize its own profits.

130. Purdue knowingly entered and participated in the marketing of illegal drugs in the Opioid Epidemic Affected Counties. Purdue is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. Tennessee doctors in 2015 wrote more than 7.8 million opioid prescriptions — or 1.18 for every man, woman and child, placing Tennessee number 2 in the nation among all States for the number of opioid prescriptions per capita according to IMS Health data. By contrast, California with its population of 38.8 million people

[121] *Id.*

only had 0.48 prescriptions per capita in 2015. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. As reported by Commissioner of Health Dreyzehner in 2016 his presentation "Neonatal Abstinence Syndrome, a Tennessee Perspective," 51 hydrocodone pills and 113.5 oxycodone pills were prescribed for every Tennessean during the period covered by that report. The same report details the dramatic, multi-fold increase in opioid prescriptions since 1999, in the absence of any meaningful increase in patients experiencing chronic pain.

131. Purdue has knowledge of the fact that such inflated prescribing levels necessarily reflect illegal prescribing and diversion of opioids. Purdue presented before the Governor's Working Group on or about September 11, 2015. At that presentation, Purdue conceded that "[t]he abuse of prescription opioid analgesics in the US is a significant public health problem," conceded that "OxyContin … is subject to misuse, addiction, and criminal diversion," and conceded that even after the creation of abuse-resistant OxyContin, "abuse by these routes [injection and nasal], as well as the oral route, is still possible."

132. Purdue also gained knowledge of its participation in the illegal drug market in the Opioid Epidemic Affected Counties through its knowledge of suspect and/or fraudulent OxyContin prescriptions and massive diversion of OxyContin based on, among other things, Purdue's own internal prescription tracking system and investigation, as well as notifications from pharmacies within Tennessee.

133. Purdue also presented a study of OxyContin abuse in rural Kentucky which showed that oral abuse of OxyContin and Oxycodone increased following the introduction of the abuse-resistant drugs. With full knowledge of the diversion risk, Purdue flooded the market without safeguards and ignored evidence of diversion where it was plain. As detailed elsewhere

in this Complaint, Purdue further made misrepresentations regarding the properties of opioids, thereby knowingly causing illegal over-prescribing and giving rise to the addicts that require diversion to feed their habits.

134. Purdue further knowingly participated in the illegal drug market in Tennessee and elsewhere promoting the abuse-deterrent properties of OxyContin, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other fraudulent conduct detailed in this Complaint. Those actions were designed to expand Purdue's market for opioids by inducing the medical community to overprescribe those drugs.

135. On information and belief, Purdue also knowingly participated in the illegal drug market in the Opioid Epidemic Affected Counties by supplying suspicious quantities of OxyContin to suspect physicians and pharmacies in the Opioid Epidemic Affected Counties, without disclosing suspicious orders as required by applicable regulations (including 21 U.S.C. § 823 and 21 C.F.R. 1301.74(b)), and otherwise circumventing Purdue's obligations under, for example, its own OxyContin Abuse and Diversion Detection Program.

Similar to Purdue, Endo profited from abuse of its opioid painkiller, Opana ER

136. Endo's Opana ER was first approved by the FDA in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

137. From the very beginning of its marketing efforts for Opana ER, Endo disseminated false and misleading statements which drove sales of the drug, including, but not limited to:

- creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- providing needed financial support to pro-opioid pain organizations -- including over $5 million to the APF, the organization responsible for many of the most egregious opioid-related misrepresentations -- that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- creating and disseminating misleading statements concerning the risk of addiction, the misleading concept of pseudoaddiction, and misleading claims that long-term treatment of opioids improves function;
- creating, sponsoring, and/or assisting in the dissemination of advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse.[122]

138. To convince doctors and patients that opioids are safe, Endo deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction.

139. Endo's efforts to minimize the risk of addiction from taking opioids long-term are evident in the contrast between its unbranded marketing materials, which dramatically understate or deny the risk of addiction, and branded materials, which include stronger addiction warnings taken from the Opana ER label:

Pain: Opioid Therapy (2009)	**Living with Someone with Chronic Pain (2009)**	**Opana ER Advertisement (2011 – 2013)**
National Institute on Pain Control publication funded by Endo	Unbranded patient education material created by Endo	Branded Endo advertisement
"People who take opioids **as prescribed usually do not become addicted**."	"Most health care providers who treat people with pain agree that **most people do not develop an addiction problem."**	"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

[122] *See, e.g., In re: Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228 at 6, March 2016. Available at: https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals. [Hereinafter "NY AOG Settlement"].

140. Endo also falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and failed to disclose the greater risk of addiction with prolonged use of opioids. For example, Endo sponsored a facially unaffiliated website, Painknowledge.com, available in Tennessee and elsewhere, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." The website further promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Painknowledge.com was run by the National Institute on Pain Control ("NPIC"), an APF initiative, and Endo's involvement was not disclosed either on the website or by the NPIC or Endo. Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

141. *Exit Wounds*, a 2009 publication sponsored by Purdue and distributed by APF with grants from Endo, describes opioids as "under-used" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "*increase* your level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The book also asserts that "**denying a person opioid pain medications because he or she has a history of substance abuse or addiction is invalid and contrary to the guidelines for the prescription of opioids published by the U.S. Federation of State Medical Boards**." The U.S. Federation of State Medical Boards itself received support from the

Manufacturer Defendants during the time it created and published its guidelines for prescription of opioids.

142. Endo further sought to minimize the risk of abuse by misrepresenting Opana ER's susceptibility to tampering. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting. At that time, Endo asked the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, meaning that it was protected against manipulation that would allow users to snort or inject it. It also sought permission to withdraw its previous approval for Opana ER in favor of its newer, purportedly safer version.

143. While the product met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER. Nevertheless, as Endo has admitted, the company advertised, and advised its sales representatives, to market reformulated Opana ER fraudulently as the only oxymorphone extended release tablets that are "designed to be" crush resistant.

144. Endo continued to promote the purported abuse-deterrent properties of Opana ER despite the fact that Endo executives knew that both the original and reformulated Opana ER were being widely abused. In an internal Endo document from February 2013, an Endo consultant reported, after reviewing national data from substance abuse treatment facilities, that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant," and that there were reports of higher levels of abuse of reformulated Opana ER via injection.[123]

[123] NY AOG Settlement at 5.

145. Endo's misrepresentations regarding the properties of Opana ER, and failure to accurately describe the drug's risk of addiction, drew the attention of the Attorney General of the State of New York ("AOG"), who opened an investigation into the company's marketing practices.

146. In March 2016, the AOG and Endo reached an agreement ending the investigation. In connection with the 2016 settlement agreement, the AOG found there was no evidence to support Endo's claim – made on Endo's website, www.opana.com, and elsewhere – that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[124] Consistent with that finding, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York.[125]

147. In the 2016 settlement, Endo further agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant."[126] The AOG found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the CDC's "Guideline for Prescribing Opioids for Chronic Pain – United States, 2016" states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies, even when they work, "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."[127]

148. The 2016 settlement also addressed Endo's misleading use of the term "pseudoaddiction." As the AOG found:

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[124] *Id.* at 15.
[125] *Id.*
[126] *Id.* at 5-6.
[127] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, at 22, March 18, 2016. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

> Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction," a purported condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. The "pseudoaddiction" concept has never been empirically validated and in fact has been abandoned by some of its proponents. Endo's Vice President for Pharmacovigilance and Risk Management testified to OAG that he was not aware of any research validating the "pseudoaddiction" concept.[128]

149. Based on that finding, the 2016 settlement prohibits Endo from "us[ing] the term 'pseudoaddiction' in any training or marketing" in New York.[129]

150. Critically, the 2016 settlement highlighted Endo's failure to set up an effective system for identifying and reporting suspicious prescribing. To this end, the AOG found that Endo:

- failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing;
- paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and
- failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.[130]

151. Endo's misconduct is not limited to New York. Upon information and belief, in Tennessee, Endo and its sales representatives knowingly utilized the same false and misleading marketing practices for Opana ER, and falsely claimed that the risk of addiction to the drug was low, or even non-existent.

152. Upon information and belief, Endo also knowingly failed to institute internal procedures designed to identify potential abuse, diversion, and/or inappropriate prescribing of opioids in Tennessee and the Opioid Epidemic Affected Counties. As such, Endo bears

[128] NY AOG Settlement at 7.
[129] *Id.* at 15.
[130] *Id.* at 9-12.

responsibility for the rise of the opioid epidemic currently gripping the state and the Opioid Epidemic Affected Counties.

153. **The ongoing, and excessive, abuse of Opana ER reached such a critical level that, on June 8, 2017, the FDA took the unprecedented step of demanding that Endo permanently remove the drug from the marketplace**.[131] According to a FDA press release, the agency's "decision [was] based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation."[132] The FDA further stated that its decision to remove the opioid from the marketplace followed a March 2017 FDA advisory committee meeting where a group of independent experts voted that "the benefits of reformulated Opana ER no longer outweigh its risks."[133]

154. Endo knowingly entered and participated in the marketing of illegal drugs in the Opioid Epidemic Affected Counties. Endo is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. Tennessee doctors in 2015 wrote more than 7.8 million opioid prescriptions — or 1.18 for every man, woman and child, placing Tennessee number 2 in the nation among all States for the number of opioid prescriptions per capita according to IMS Health data. By contrast, California with its population of 38.8 million people only had 0.48 prescriptions per capita in 2015. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. As reported by Commissioner of Health Dreyzehner in 2016 his presentation Neonatal Abstinence Syndrome, a Tennessee Perspective, 51 hydrocodone pills and 113.5 oxycodone pills were prescribed every Tennessean

[131] FDA Press Release. *FDA requests removal of Opana ER for risks related to abuse*. June 8, 2017. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[132] *Id*.
[133] *Id*.

during the period covered by that report. The same report details the dramatic, multi-fold increase in opioid prescriptions since 1999 in the absence of any meaningful increase in patients experiencing chronic pain. Endo knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Endo's products.

155. Endo also gained knowledge of its participation in the illegal drug market in the Opioid Epidemic Affected Counties through its knowledge of reports detailing health complications resulting from injection of Opana. In October 2012, the CDC issued a health alert, saying a "cluster of at least 12 patients" (later raised to 15 victims) in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana. Furthermore, in 2014 a case study from the University of Tennessee School of Medicine described the University-based hospital's experience of a series of ten patients with characteristic clinical and laboratory findings of Thrombotic Microangiopathy (TMA) and documented recent history of illicit IV Opana ER use, including patients from Opioid Epidemic Affected Counties. Endo would eventually conduct an ethnographic study aimed at better understanding the causes of IV abuse in the Tennessee region, giving it further information and knowledge about the breadth of abuse due to illegally-obtained Opana. Endo further knowingly participated in the illegal drug market in Tennessee and elsewhere by promoting the abuse-deterrent properties of Opana, by deliberately and knowingly downplaying addiction risks associated with opioids and by the other fraudulent conduct detailed in this Complaint. Those actions were designed to expand Endo's market for opioids by inducing the medical community to overprescribe those drugs.

156. On information and belief, Endo also knowingly participated in the illegal drug market in the in the Opioid Epidemic Affected Counties by supplying suspicious quantities of its

products to suspect physicians and pharmacies in the Opioid Epidemic Affected Counties, without disclosing suspicious orders as required by applicable regulations (including 21 U.S.C. § 823 and 21 C.F.R. 1301.74(b)).

Mallinckrodt Pharmaceuticals' contributions to Tennessee's opioid crisis

157. Mallinckrodt has been a loyal solder in the effort to mislead the medical community and general public about the addiction risk posed by opioids and the corresponding lack of scientific support for using opioids for long term chronic pain.

158. For example, Mallinckrodt has funded many groups that have pushed the pro-opioid message, nationally and in Tennessee, such as the American Academy of Pain Management, the American Chronic Pain Association, and the Pain Action Alliance to implement a national strategy. [134]

159. Mallinckrodt also funded pro-opioid educational seminars directed at doctors in Tennessee and elsewhere in which the unscientific claim that opioids were safe and appropriate for long term chronic pain therapy was promoted.[135]

160. In 2011, to combat the opioid epidemic, the DEA began investigating Mallinckrodt, one of the nation's largest manufacturers of oxycodone. As a Washington Post article explained, "[i]t was the first time the DEA had targeted a manufacturer of opioids for alleged violations of laws designed to prevent diversion of legal narcotics to the black market. It would become the largest prescription-drug case the agency has pursued." [136] Relying on confidential government records and emails, the article further explained that the DEA and federal prosecutors had evidence Mallinckrodt "ignored its responsibility to report suspicious

[134] *See* Letter from Sen. Ron Wyden to Thomas E. Price, Sec. U.S. Department of Health and Human Services (May 5, 2017).
[135] *See, e.g.*, Dr. Lynn Webster, *Emerging Solutions Webinar* (Sept. 33, 2011), http://emergingsolutionsinpain.com/.
[136] Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, washingtonpost.com, April 2, 2017, https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.a0e6a4979116.

orders as 500 million of its pills ended up in Florida between 2008 and 2012 – 66 percent of all oxycodone sold in the state," and that "the company's lack of due diligence could have resulted in nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[137] As of April 2017, Mallinckrodt agreed to a tentative settlement of $35 million with the DEA to resolve all allegations of criminal wrongdoing.[138]

161. The Washington Post article highlighted Tennessee's connection to the DEA investigation. According to the article: "The first hint that Mallinckrodt might pose a problem for the DEA came not from Florida but from Tennessee. [¶] On July 7, 2009, members of a Tennessee drug task force in a sting operation seized several 100-tablet bottles of Mallinckrodt-made oxycodone. Task force agents alerted Mallinckrodt. The company's lot numbers were printed on the labels, allowing for easy tracking of the pills. [¶] Three days later, Mallinckrodt responded that the oxycodone had been prescribed by Barry Schultz, a doctor who ran a medical clinic in Delray Beach, Fla. The company said that one of its distributors, Sunrise Wholesale of Broward County, Fla., had sent 20,400 tablets of oxycodone to Schultz in the previous year."[139]

162. **The article went on to further explain the significance of the Tennessee sting operation: DEA learned that in the six weeks after the Tennessee task force alerted Mallinckrodt to the drugs found in the 2009 sting operation, the company had shipped another 2.1 million tablets of oxycodone to Sunrise, the Florida distributor.** The DEA also discovered that Sunrise, over an 11-month period, had sent at least 92,400 tablets to Schultz, the Delray Beach doctor who prescribed the pills found in Tennessee. In one day, he had prescribed 1,000 tablets to one patient.[140]

[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *Id.*

163. At the time, the street value of oxycodone was $30 a tablet. The Mallinckrodt drugs that Sunrise sent to Schultz (after Mallinckrodt was notified of the Tennessee sting) were worth nearly $2.8 million on the street, prosecutors said.[141]

164. In an internal document sent to Mallinckrodt, the DEA stated: "When Mallinckrodt continued to distribute oxycodone to Sunrise for such purposes, and continued to pay incentives in the form of chargebacks for the product sales to Barry Schultz, Mallinckrodt was diverting oxycodone" [142]

165. Mallinckrodt knowingly entered and participated in the marketing of illegal drugs in the Opioid Epidemic Affected Counties. Mallinckrodt is aware of the extraordinary volume of opioid prescriptions in Tennessee in relation to other states. Tennessee doctors in 2015 wrote more than 7.8 million opioid prescriptions — or 1.18 for every man, woman and child, placing Tennessee number 2 in the nation among all States for the number of opioid prescriptions per capita according to IMS Health data. By contrast, California with its population of 38.8 million people only had 0.48 prescriptions per capita in 2015. As reported by the CDC, Tennessee's oxycodone prescription rate is twenty-two times that of Minnesota's. As reported by Commissioner of Health Dreyzehner in 2016 his presentation Neonatal Abstinence Syndrome, a Tennessee Perspective, 51 hydrocodone pills and 113.5 oxycodone pills were prescribed every Tennessean during the period covered by that report. The same report details the dramatic, multi-fold increase in opioid prescriptions since 1999 in the absence of any meaningful increase in patients experiencing chronic pain. Mallinckrodt knew that such inflated prescribing necessarily reflects improper prescribing and diversion of opioids, including Endo's products.

[141] *Id.*
[142] *Id.*

166. Mallinckrodt further knowingly participated in the illegal drug market in Tennessee and elsewhere by knowingly shirking its responsibility to detect and investigate suspicious orders, for which it was cited by the DEA, by deliberately and knowingly downplaying addiction risks associated with opioids and through the other knowing, fraudulent actions detailed in this Complaint. Those actions were designed to expand Mallinckrodt's market for opioids by inducing the medical community to overprescribe those drugs.

167. On information and belief, Mallinckrodt also knowingly participated in the illegal drug market in the in the Opioid Epidemic Affected Counties by supplying suspicious quantities of its products to suspect physicians and pharmacies in the Opioid Epidemic Affected Counties, without disclosing suspicious orders as required by applicable regulations (including 21 U.S.C. § 823 and 21 C.F.R. 1301.74(b)).

168. Purdue's, Endo's and Mallinckrodt's fraudulent promotion of opioids gave rise to and fueled the illegal drug market that existed in the Opioid Epidemic Affected Counties during all periods relevant to this suit. As noted in testimony before the House Opioid Task Force, the effect of Purdue's Endo's and Mallinckrodt's fraudulent conduct was to create a "generation O" among prescribing physicians, who were provided fraudulent information leading them to prescribe opioids for non-acute conditions without fear of addicting their patients. Each company's misrepresentations regarding the risks of opioids and actions taken to push opioids through aggressive marketing of their collective fraudulent message contributed to the market for both illegally prescribed opioids and for diverted opioids (and heroin for those addicts who could no longer obtain or afford prescription opioids). Each of the Manufacturer Defendants' actions benefitted the other Manufacturer Defendants by spreading the fraudulent message that opioids bore minimal addiction risk and were therefore appropriate for long term chronic conditions and

by creating legions of opioid addicts desperate to obtain opioids from any manufacturer's line. The dramatic rise in opioid prescriptions, and associated overdoses, NAS births and other related health problems since the commencement of the Manufacturer Defendants' fraudulent campaign in the mid-1990's shows the scope of the illegal drug market created by those defendants.

D. The Manufacturer Defendants' marketing campaign has given rise to a market for street heroin distributed to addicts who can no longer obtain prescription opioids or afford diverted opioids available on the black market.

169. Another important feature of the opioid epidemic is the relationship between opioid pain reliever use and heroin use. According to the federal government's National Survey on Drug Use and Health, four out of five heroin addictions begin with opioid prescription pain relievers.[143]

170. On November 13, 2015, E. Douglas Varney, Commissioner of the Tennessee Department of Mental Health, issued a message detailing the recent rise of heroin abuse in Tennessee.[144] In the message, Varney explained that, as the state "forged efforts to reduce availability of opioid based pain remedies, in the shadows, heroin arrived on the scene. It arrived like a tidal wave in Tennessee. It's a far more potent form of opioids, cheaper, more dangerous and more lethal."[145] Varney referenced data from multiple sources showing heroin, and heroin-related criminal activity, sharply on the rise, and said: "I'm saddened to see our friends and

[143] Pradip K. Muhuri et al., Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States* (August 2013), *available at* http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.
[144] TN Dep't of Mental Health and Substance Abuse Services, *Message from Commissioner E. Douglas Varney on Heroin's Grip in our Cities and Suburbs* (Nov. 13, 2015), *available at* https://www.tn.gov/ behavioral-health/news/20176.
[145] *Id.*

neighbors that have been struggling with opioid addiction now transitioning to heroin which is coming from the criminal underground street dealer."[146]

171. In a December 2016 publication of the Tennessee Medical Association entitled "No Easy Fix: Tennessee's Doctors Take on The Opioid Abuse Epidemic," Dr. Roland W. Gray described the opioid epidemic as the "worst and deadliest drug epidemic in our nation's history."[147] He went on to say that "[t]here's good news in that we are prescribing significantly fewer opiates in Tennessee; the bad news is they are being replaced by a heroin epidemic. Tennesseans are rapidly turning to those drugs – they're available on the street and are cheaper and far more powerful than prescription opiates."[148]

172. According to the Tennessee Department of Health, heroin-associated overdose deaths are also on the rise, increasing from 147 in 2014 to 205 in 2015.[149]

173. Commissioner Dreyzehner has determined that "[t]here is a direct correlation between opioid addiction and heroin use."[150]

174. As set forth in a September 2016 report by the Tennessee Department of Mental Health and Substance Abuse Services, people with prior treatment admissions, people who inject opioids, people age 25-34, and people who started opioid use after age 18 are all at increased risk for switching from prescription opioids to heroin.[151]

E. <u>The Opioid Epidemic Affected Counties have been at the epicenter of the opioid crisis caused by the opioid manufacturers' fraudulent campaign.</u>

175. The District Attorney Plaintiffs' judicial districts are located in upper east

[146] *Id.*
[147] Roland W. Gray, *The Good News/Bad News About Tennessee's Opioid Epidemic*, 109 Tenn. Med.. 4, 23 (2016), *available at* https://www.tnmed.org/Documents/TennMed-Qtr4-05FINAL.pdf.
[148] *Id.*
[149] Tennessee Dep't of Health, *supra* note 27.
[150] Working Group Report, *supra* note 15, at attachment 2.
[151] K. Edwards, Tennessee Department of Mental Health & Substance Abuse Services, *Turning the Curve on Opioid and Heroin Abuse in Tennessee*, 14 (September 14, 2016).

Tennessee in the heart of Appalachia.

176. Police, medical personnel, and prosecuting attorneys in the Opioid Epidemic Affected Counties generally refer to OxyContin, Roxicodone, and Opana ER by the umbrella term "oxycodone," in reference to the active opioid ingredient in documents related to opioid criminal investigations.

SULLIVAN COUNTY / SECOND JUDICIAL DISTRICT

177. Plaintiff BARRY STAUBUS is the elected District Attorney for the Second Judicial District of Tennessee. The Second Judicial District includes Sullivan County.

178. According to the 2010 census, Sullivan County, TN has a population of 156,823.

179. Sullivan County is made up of approximately 429 square miles. [152]

180. The median household income is $39, 957.[153]

181. 15.9% of residents of Sullivan County live below the poverty line.[154]

182. Sullivan County has the highest rate of opioid addiction in Tennessee.[155]

183. The Sullivan County District Attorneys' Office has an annual budget of $4,367,000. The budget includes funding for 16 attorneys and 4 investigators in the district attorney office.

184. The Sullivan County District Attorney's Office expends thousands of hours and tens of thousands of dollars every year prosecuting crimes that are a result of Sullivan County's opioid crisis.

185. In 2013, 64.7% of autopsied deaths in Sullivan County directly involved opioids.

186. In 2014, 68.2% of autopsied deaths in Sullivan County directly involved opioids.

[152] All from United States010 Census (2010).
[153] *Id.*
[154] *Id.*
[155] Tenn. Dep't. of Health, *supra* note 29. Available at: https://www.tn.gov/health/article/nas-update-archive.

187. In 2015, 71.3% of autopsied deaths in Sullivan County directly involved opioids.

188. In 2016, at least 106 of autopsied deaths in Sullivan County directly involved opioids.

189. Plaintiff BARRY STAUBUS prosecutes thousands of people for committing crimes every year.

190. The Sullivan County District Attorney prosecutes hundreds of opioid related misdemeanor cases every year, causing a great financial burden on the Office of the District Attorney General.

191. The Sullivan County District Attorney also prosecutes felony drug cases related to opioids.

192. From January 1, 2016 to April 1, 2017, the Sullivan County District Attorney prosecuted at least 24 people for 52 felony charges of sale, possession with intent to sell or delivery of opioids.

193. The Sullivan County District Attorney has prosecuted an untold number of felony cases related to opioid addiction, separate and apart from the felony charges that specify the illegal drug as "Oxy."

THIRD JUDICIAL DISTRICT

194. Plaintiff DAN ARMSTRONG is the elected District Attorney for the Third Judicial District of Tennessee. The Third Judicial District includes Greene County, Hamblen County, Hancock County, and Hawkins County.

195. The District Attorney's office for the Third Judicial District has an annual budget of $2,689,600.00. The budget includeS funding for 12 attorneys and 3 investigators in the District Attorney's office.

196. The District Attorney's office for the Third Judicial District expends thousands of hours and tens of thousands of dollars every year prosecuting crimes that are a result of the opioid crisis.

Greene County

197. According the 2010 census, Greene County, TN has a population of 68,576.

198. The median household income is $35,196.00.[156]

199. 20.5% of residents of Greene County live below the poverty line.[157]

Hamblen County

200. According the 2010 census, Hamblen County, TN has a population of 62,999.

201. The median household income is $37,617.00.[158]

202. 21.3 % of residents of Hamblen County live below the poverty line.[159]

Hancock County

203. According the 2010 census, Hancock County, TN has a population of 6,642.

204. The median household income is $26,898.00.[160]

205. 27.7% of residents of Hancock County live below the poverty line.[161]

Hawkins County

206. According the 2010 census, Hawkins County, TN has a population of 56,595.

207. The median household income is $36,927.00.[162]

208. 19.1% of residents of Hawkins County live below the poverty line.[163]

[156] United States Census (2010).
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.*
[161] *Id.*
[162] *Id.*
[163] *Id.*

209. In 2015, 19% of autopsied deaths in the Third Judicial District were opioid involved deaths.

210. In 2016, 24% of autopsied deaths were opioid involved deaths.

211. In 2016, Plaintiff DAN ARMSTRONG's office prosecuted 371 cases involving Schedule II and Schedule III drugs, the majority of which were opioid-related.

212. As of June 9, 2017, Plaintiff DAN ARMSTRONG's office has prosecuted 132 cases involving Schedule II and Schedule III drugs, the majority of which were opioid-related.

FIRST JUDICIAL DISTRICT

213. Plaintiff TONY CLARK is the elected District Attorney for the First Judicial District of Tennessee. The First Judicial District includes Carter County, Johnson County, Unicoi County, and Washington County.

214. The District Attorney's office for the First Judicial District has an annual budget of $3,103,400.00 The budget included funding for 15 attorneys and 1 investigator in the District Attorney's office.

215. The District Attorney's office for the First Judicial District expends thousands of hours and tens of thousands of dollars every year prosecuting crimes that are a result of the opioid crisis.

Carter County

216. According the 2010 census, Carter County, TN has a population of 56,941.

217. The median household income is $33,213.00.[164]

218. 23.6% of residents of Carter County live below the poverty line.[165]

Johnson County

[164] United States Census (2010).
[165] *Id.*

219. According the 2010 census, Johnson County, TN has a population of 18,017.

220. The median household income is $30,763.00.[166]

221. 25.6% of residents of Johnson County live below the poverty line.[167]

Unicoi County

222. According the 2010 census, Unicoi County, TN has a population of 18,069.

223. The median household income is $33,210.00.[168]

224. 22.5% of residents of Unicoi County live below the poverty line.

Washington County

225. According the 2010 census, Washington County, TN has a population of 125,317.

226. The median household income is $42,817.00.[169]

227. 18.1% of residents of Washington County live below the poverty line.[170]

228. In 2014-2015, 104 deaths in the Third Judicial District were directly related to opioids. This number does not include cases where opioids were contributing factors such as vehicular homicide, etc.

229. In 2016, 79 deaths in the Third Judicial District were directly related to opioids.

230. From 2014-2016, CLARK'S office prosecuted 783 opioid cases. CLARK also prosecuted approximately 120 opioid related cases, such as attempting to obtain an opioid by fraud.

CENTER POINTE

231. Defendant CENTER POINTE is a clinic that is located in Sullivan County.

232. Defendant CENTER POINTE employs approximately five nurse practitioners.

[166] *Id.*
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *Id.*

233. Customers of Defendant CENTER POINTE are able to obtain prescriptions for opioids without a legitimate medical purpose.

234. Defendant CENTER POINTE prescribes opioids at a rate higher than typical medical clinics, and thereby knowingly participates in the illegal drug market in Tennessee.

235. Defendant CENTER POINTE prescribes in excess of 50,000 pills of hydrocodone and oxycodone per week.

236. Typical opioid prescriptions dispensed by this clinic are greater in quantity than is typical of other clinics.

237. It has been reported that prescriptions for 120 Lortab and 120 oxycodone for 30-day period for one individual is representative of the typical prescription coming from Defendant CENTER POINTE.

238. The vast majority of individuals obtaining opioids from Defendant CENTER POINTE pay in cash or use TennCare to fill their prescriptions.

239. Many of the prescription drugs obtained from Defendant CENTER POINTE are diverted to the illegal opioid drug market.

ELIZABETH ANN BOWERS CAMPBELL

240. Defendant ELIZABETH ANN BOWERS CAMPBELL ("CAMPBELL") admitted that on or about July 15, 2013, she began working as a medical assistant for Dr. Sheng Tchou, who owned and operated Appalachian Pain Rehab Associates in Johnson City, Tennessee.

241. Appalachian Pain Rehab Associates is located at 411 Princeton Road in Johnson City. Appalachian Pain Associates is located in Tennessee House District 6, as is Sit N Bull

restaurant (730 Gray Station Road), Poblanos (2697 Boones Creek Road), and the home address of Defendant CAMPBELL.

242. While working at Appalachian Pain Associates, Defendant CAMPBELL became addicted to hydrocodone. After learning that her co-worker had been forging and calling in fraudulent prescriptions for herself and others, Defendant CAMPBELL, too, began utilizing Dr. Tchou's DEA number to call in fraudulent prescriptions for herself and others. Defendant CAMPBELL through her actions knowingly participated in the illegal drug market in Tennessee.

243. As part of a conspiracy with at least three others, from approximately January 3, 2014 until approximately June 28, 2014, Defendant CAMPBELL and others conspired to distribute and possess with the intent to distribute numerous controlled substances, including: 4,620 dose units of hydrocodone, 720 dose units of oxycodone, among others.

244. Defendant CAMPBELL was criminally charged in the U.S. District Court for the Eastern District of Tennessee with Conspiracy to Distribute Hydrocodone and Carisoprodol in 2015.

245. On August 25, 2015, Defendant CAMPBELL pled guilty to Conspiracy to Distribute and Possess with Intent to Distribute Hydrocodone, Conspiracy to Distribute and Possess with Intent to Distribute Carisoprodol, and Acquiring or Obtaining Possession of Controlled Substances by Misrepresentation, Fraud, Forgery, Deception, or Subterfuge.

246. On March 28, 2016, Defendant CAMPBELL was sentenced to four years of probation, ten days of incarceration.

PAMELA AND GREGORY MOORE

247. Defendant PAMELA MOORE is married to Gregory Harold Moore, who has pled guilty to Conspiracy to Distribute and Posses with the Intent to Distribute Hydrocodone,

Oxycodone, Oxymorphone, and Methamphetamine; Possession of the Firearm in furtherance of a Drug Trafficking Crime; and Conspiracy to threaten and attempt to engage in conduct which would cause bodily injury with the intent to retaliate against a witness. Gregory Harold Moore admitted that he sold Lortab, Roxicodone, and oxycodone pills – approximately 20-50 pills a week.

248. Defendant PAMELA MOORE admitted that she was aware that Gregory Moore had been selling pills from their residence and his workshop located at 1996 Carters Valley Road, Surgoinsville, Tennessee.

249. After he was arrested, Gregory Moore enlisted the help of his wife to spread the word all around Hawkins County that their operation had been compromised by an informant. He also told her that when the police searched their home, they missed finding many of the pills. Gregory Moore told his wife, Defendant PAMELA MOORE, where the drugs were hidden, how many pills there were, what they were worth, and who to contact about them. Defendant PAMELA MOORE admitted to police that she met with co-conspirators about paying off the drug debt and/or coming to get the drugs that were hidden on her property. Defendant PAMELA MOORE through her actions knowingly participated in the illegal drug market in Tennessee.

250. On August 26, 2015, after monitoring the jail calls between Defendant PAMELA MOORE and her husband, the police obtained permission to search their home. During the search, the police recovered 711 combined oxycodone and oxymorphone pills and an additional quantity of methamphetamine. Specifically, they found: 330 (40 mg) oxymorphone pills, 9 (20 mg) oxymorphone pills, 13 (15 mg) oxymorphone pills, 2 (10 mg) oxymorphone pills, and 357 (30 mg) oxycodone pills.

251. Defendant PAMELA MOORE was charged criminally in the U.S. District Court for the Eastern District of Tennessee with Aiding and Abetting the Possession with the Intent to Distribute of Oxycodone and Oxymorphone in 2015 and Conspiracy to Threaten or Intimidate a Witness.

252. On April 29, 2016, Defendant PAMELA MOORE pled guilty to Conspiracy to Threaten or Intimidate a Witness.

253. On October 4, 2016, Defendant PAMELA MOORE was sentenced to 36 months of probation.

F. Plaintiff BABY DOE's mother became addicted as a result of the Manufacturer Defendants' fraudulent campaign and maintained her addiction with diverted opioids and street heroin marketed and available as a direct result of that campaign.

254. Mary Doe is from a typical middle-class family. She was born and raised in Sullivan County, Tennessee.

255. While in high school, Mary Doe, like many teenagers experimented with alcohol and marijuana. Mary Doe was also exposed to opioids in high school. Because of Defendants' fraudulent scheme, her high school and community were flooded with OxyContin and other opioids.

256. It was not long before she tried and then became addicted to oxycodone. She consumed a variety of opioids including, but not limited to, hydrocodone, OxyContin, Roxicodone, and Opana.

257. She managed to mask her addiction and hid it from her friends and family, but, eventually, her need for the drugs became too much for her to bear.

258. While working and attending beauty school, Mary Doe discovered and became addicted to Roxicodone and began feeding her opioid addiction with that brand of opioid as well.

259. Roxicodone is known by its street name, Roxy.

260. She bought Roxicodone and other opioids illegally from a woman from Gray, Tennessee, who obtained the opioids in Florida and Georgia, where she also sold them. The woman told Mary Doe that she would get the drugs through prescriptions she had for her husband and disabled daughter.

261. The woman seemed to have an unlimited supply and access to Roxicodone and other opioids. Mary Doe would meet her and others in Sullivan County to purchase the pills.

262. Mary Doe paid approximately $30.00 per pill.

263. Mary Doe bought illegal opioids in the parking lots of both Poblanos and Sit N Bull restaurants. Both places are located in Tennessee State House District 6, in Washington County.

264. From at least 2009, Mary Doe was taking opioids every single day. She was working solely to pay for her illegal drug habit.

265. In 2015, Mary Doe discovered she was pregnant. She had been using opioids during her pregnancy and was terrified to see a doctor.

266. She finally saw an obstetrician when she was approximately 5 months pregnant. The doctor explained that withdrawal from opioids could kill the fetus and that a new law required him to either report her to law enforcement for endangering the life of her unborn child or to insist that she receive drug treatment.

267. Mary Doe, not wanting to risk the death of her child, began a course of Subutex, a less powerful opioid, for the remainder of her pregnancy.

268. Treatment of opioid-addicted pregnant women with Subutex is a known method for handling addicted mothers.

269. On March 10, 2015, Mary Doe delivered BABY DOE via cesarean section at Holston Valley Hospital.

270. Plaintiff BABY DOE was diagnosed with NAS and was transferred to the Neonatal Intensive Care Unit where he remained for 14 days.

271. Plaintiff BABY DOE arched his back, refused to eat, and cried uncontrollably as he was weaned from his addiction with controlled doses of Morphine.

272. Plaintiff BABY DOE continues to suffer from numerous health and learning disabilities to this day.

G. Plaintiff BABY DOE is one of thousands of innocent infants victimized by the Manufacturer Defendants' campaign.[171]

273. In 2015, 12.1 of every 1,000 babies were born with NAS in Tennessee.

274. In 2015, 42.9 of every 1,000 babies were born with NAS in North East Tennessee.

275. In 2015, 47.0 of every 1,000 babies were born with NAS in Sullivan County, Tennessee.

276. In 2016, 12.2 of every 1,000 babies were born with NAS in Tennessee.

277. In 2016, 58.6 of every 1,000 babies were born with NAS in North East Tennessee.

278. In 2016, 50.5 of every 1,000 babies were born with NAS in Sullivan County, Tennessee.

279. As of April 1, 2017, 10.1 of every 1,000 babies were born with NAS in Tennessee.

280. As of April 1, 2017, 41.6 of every 1,000 babies were born with NAS in North East Tennessee.

[171] The TN Department of Health has tracked statistics related to babies with NAS from which the following statistical data has been gathered. https://www.tn.gov/health/article/nas-update-archive

281. As of April 1, 2017, 47.9 of every 1,000 babies were born with NAS in Sullivan County, Tennessee.

282. For decades to come, the police departments, schools, district attorneys' offices, hospitals, doctors, insurance companies, TennCare, and the taxpayers of the State of Tennessee and the Opioid Epidemic Affected Counties, will bare the financial burden of the Defendants' campaign to addict America to opioids.

VI. CLAIMS

283. Tennessee's Healthcare Liability Act does not apply to this DDLA action or any other claims made in this lawsuit. Without conceding that Tennessee's Healthcare Liability Act applies to any claim brought in this action, or that a certificate is required under the Tennessee Healthcare Liability Act for any claim brought in this action, and pled in the alternative, to the extent necessary, Plaintiffs have complied with the certificate of good faith requirement of the Tennessee Healthcare Liability Act, Tenn. Code Ann. § 29-26-101, *et seq*, which has been interpreted as a jurisdictional requirement. Pursuant to Tenn. Code Ann. § 29-26-122(a), a Certificate of Good Faith signed by the undersigned counsel is included as Exhibit A and incorporated herein by reference.

COUNT I:

TENNESSEE DRUG DEALER LIABILITY ACT

(Brought on behalf of Plaintiff BABY DOE)

284. Plaintiffs incorporate all preceding and subsequent paragraphs by reference.

285. Tennessee's Drug Dealer Liability Act ("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.

286. Among the persons to whom the DDLA provides a remedy are "infants injured as a result of exposure to drugs in utero." Tenn. Code Ann. § 29-38-102.

287. The Tennessee General Assembly has codified its deep concern for infants exposed to drugs, stating that "[d]rug babies, who are clearly the most innocent and vulnerable of those affected by illegal drug use, are often the most physically and mentally damaged due to the existence of an illegal drug market in a community. For many of these babies, the only hope is extensive medical and psychological treatment, physical therapy, and special education. All of these potential remedies are expensive. **These babies, through their legal guardians and through court appointed guardians ad litem, should be able to recover damages from those in the community who have entered and participated in the marketing of types of illegal drugs that have caused their injuries**." Tenn. Code Ann. § 29-38-103(7)(emphasis supplied).

288. Plaintiff BABY DOE has been exposed to the illegal drugs oxycodone, OxyContin, and Roxicodone in utero because of his mother's addiction to, purchase, and use of those illegal drugs. That exposure provides him the right to sue for damages under the DDLA. Tenn. Code Ann. § 29-38-106(a)(2).

289. 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).

290. "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).

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

292. 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).

293. 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).

294. 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).

295. Mary Doe, mother of Plaintiff BABY DOE, was an "individual drug user" who acquired oxycodone, OxyContin and Roxicodone during her pregnancy from local unlicensed drug dealers for the black-market price of $30-$120 per pill.

296. Mary Doe's purchases of oxycodone, OxyContin, and Roxicodone were illegal in that they were made without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).

297. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached the Opioid Epidemic Affected Counties 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 113.5 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.

298. 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.

299. As a result, the Manufacturer Defendants knowingly disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including "pill mills" such as CENTER POINTE.

300. The Manufacturer Defendants also enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including CENTER POINTE and other "pill mills" as well as CAMPBELL, PAMELA MOORE, and other drug dealers, knowing that such opioids would be illegally trafficked and abused.

301. During her pregnancy with BABY DOE, Mary Doe bought Oxycodone, OxyContin and Roxicodone in Washington County, Tennessee, which is within the 6th state

house legislative district and used the drugs throughout Washington and Sullivan counties. Under the DDLA, that legislative district is a "place of illegal drug activity." Tenn. Code Ann. § 29-38-104(11).

302. Having illegally distributed oxycodone, OxyContin, and Roxicodone, the drugs used by Mary Doe in the "place of illegal drug activity" where Mary Doe consumed them during her pregnancy, and participated in that illegal distribution during Mary Doe's pregnancy, Defendants are liable to Plaintiff BABY DOE under the DDLA even for damages caused by opioids that were acquired from distribution channels in which Defendants were a market participant.

COUNT II:

TENNESSEE DRUG DEALER LIABILITY ACT

(Brought on behalf of Plaintiffs BARRY STAUBUS, TONY CLARK,

and DAN ARMSTRONG)

303. Plaintiffs incorporate all preceding paragraphs by reference.

304. 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.

305. Among the persons to whom the DDLA provides a remedy are "[a] medical facility, insurer, governmental entity, employer, 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."

306. Plaintiffs BARRY STAUBUS, TONY CLARK, and DAN ARMSTRONG all represent governmental entities that fund drug treatment and employee assistance programs for

individual drug users in the Opioid Epidemic Affected Counties, and otherwise expended significant sums of money as a result of the illegal distribution of opioids in the Opioid Epidemic Affected Counties.

307. Plaintiffs BARRY STAUBUS, TONY CLARK and DAN ARMSTRONG proceed pursuant to their authority under Tenn. Code Ann. 20-38-116, which authorizes actions by district attorneys on behalf of political subdivisions of the state, including the Opioid Epidemic Affected Counties.

308. 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).

309. "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).

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

311. 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).

312. 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).

313. 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).

314. Residents of the Opioid Epidemic Affected Counties who acquired oxycodone, Roxicodone, OxyContin, and/or Opana from unlicensed drug dealers illegally distributing the prescription opioids in the Opioid Epidemic Affected Counties are "individual drug user[s]" under the DDLA.

315. Those purchases of oxycodone, 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).

316. Defendants knowingly participated in the manufacture and/or distribution of prescription opioids that reached the Opioid Epidemic Affected Counties 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 113.5 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.

317. 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.

318. As a result, the Manufacturer Defendants knowingly disseminated massive quantities of prescription opioids to suspect physicians and pharmacies and into the black market, including "pill mills" such as CENTER POINTE.

319. The Manufacturer Defendants also knowingly enabled and/or failed to prevent the illegal diversion of prescription opioids into the black market, including CENTER POINTE and other "pill mills" as well as CAMPBELL, PAMELA MOORE, and other drug dealers, knowing that such opioids would be illegally trafficked and abused.

320. 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 the Opioid Epidemic Affected Counties.

321. Having knowingly participated in the illegal distribution of oxycodone, OxyContin, Roxicodone, and/or Opana, the drugs purchased by residents of the Opioid Epidemic Affected Counties in the "place of illegal drug activity," Defendants are liable to Plaintiffs BARRY STAUBUS, TONY CLARK, and DAN ARMSTRONG under the DDLA even for damages caused by opioids in the Opioid Epidemic Affected Counties that were acquired from distribution channels in which Defendants were a market participant.

COUNT III:

PUBLIC NUISANCE (Tennessee Common Law)

322. Plaintiffs incorporate all preceding and subsequent paragraphs by reference.

323. 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). 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 comportable use of property." *Id.*

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

325. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to the Opioid Epidemic Affected Counties and their residents.

326. The nuisance includes the over-saturation, unlawful availability, and abuse of opioids in the Opioid Epidemic Affected Counties for non-medical purposes, as well as the adverse social and environmental outcomes associated with widespread illegal opioid use.

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

a. Manufacturer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of the Opioid Epidemic Affected Counties.

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

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

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

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

329. Defendants' nuisance-causing activities include illegally selling, or facilitating the illegal sale of, prescription opioids from premises in and around the Opioid Epidemic Affected Counties to unintended users in the Opioid Epidemic Affected Counties – including people at risk of overdose and criminals.

330. The Manufacturer 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.

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

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

333. The public nuisance created by Defendants endangers the health and safety of the Opioid Epidemic Affected Counties and their residents.

334. The public nuisance created by Defendants has caused, and continues to cause, significant harm to the Opioid Epidemic Affected Counties including, but not limited to:

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

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

c. The Manufacturer 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 Manufacturer

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, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the Opioid Epidemic Affected Counties.

e. Adults and children in the Opioid Epidemic Affected Counties 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.

335. 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 the Opioid Epidemic Affected Counties

336. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in the Manufacturer Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer Defendants' dissemination of false "scientific" facts and advice. Moreover, there is no legitimate societal interest to CENTER POINTE, CAMPBELL, and PAMELA MOORE's diversion and/or illegal sale of prescription opioids.

337. At all times, the Manufacturer 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 Opioid Epidemic Affected Counties. The Manufacturer Defendants had the power to shut off the supply of illicit opioids into the Opioid Epidemic Affected Counties. The Manufacturer Defendants had the power to stop providing false information to the market about the dangers of opioids and the highly addictive nature of their opioid products. Moreover, CENTER POINTE, CAMPBELL, and PAMELA MOORE could, at any time, stop diverting and/or illegally selling prescription opioids. As a direct and proximate result of the public nuisance, the Opioid Epidemic Affected Counties have 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, and law enforcement.

338. Defendants should be required to pay the expenses the Opioid Epidemic Affected Counties have incurred or will incur in the future to fully abate the nuisance.

COUNT IV:

PUBLIC NUISANCE (Tenn. Code Ann. § 29-3-101, *et seq.*)

339. Plaintiffs incorporate all preceding and subsequent paragraphs by reference.

340. 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).

341. 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).

342. 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.

343. Defendants manufactured, sold, promoted, and/or distributed prescription opioids in a manner that created, or participated in creating, a public nuisance that is harmful and injurious to the Opioid Epidemic Affected Counties and their residents.

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

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

a. Manufacturer Defendants have engaged in massive production, promotion, and distribution of opioids for use by the residents of the Opioid Epidemic Affected Counties.

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

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

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

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

347. Defendants' nuisance-causing activities include illegally selling, or facilitating the illegal sale of, prescription opioids from premises in and around the Opioid Epidemic Affected Counties to unintended users in the Opioid Epidemic Affected Counties – including people at risk of overdose and criminals.

348. The Manufacturer 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.

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

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

351. The public nuisance created by Defendants endangers the health and safety of the Opioid Epidemic Affected Counties and their residents.

352. The public nuisance created by Defendants has caused, and continues to cause, significant harm to the Opioid Epidemic Affected Counties including, but not limited to:

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

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

c. The Manufacturer 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 Manufacturer 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, criminal market by Defendants and the increase in the number of individuals who abuse or are addicted to opioids has placed

unnecessary and excessive demands on the medical, public health, law enforcement, and financial resources of the Opioid Epidemic Affected Counties.

e. Adults and children in the Opioid Epidemic Affected Counties 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.

353. 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 the Opioid Epidemic Affected Counties

354. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimate societal interest in the Manufacturer Defendants failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer Defendants' dissemination of false "scientific" facts and advice. Moreover, there is no legitimate societal interest to CENTER POINTE, CAMPBELL, and PAMELA MOORE's diversion and/or illegal sale of prescription opioids.

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information to the market about the dangers of opioids and the highly addictive nature of their opioid products. Moreover, CENTER POINTE, CAMPBELL, and PAMELA MOORE could, at any time, stop diverting and/or illegally selling prescription opioids. As a direct and proximate result of the public nuisance, the Opioid Epidemic Affected Counties have 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, and law enforcement.

356. Defendants should be required to pay the expenses the Opioid Epidemic Affected Counties have incurred or will incur in the future to fully abate the nuisance.

VII. CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

357. Plaintiffs incorporate all preceding and subsequent paragraphs by reference.

358. Plaintiffs seek a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that the caps on personal injury and punitive damages set forth in Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are an unconstitutional deprivation of the right to trial by jury set forth in Article I, Section 6, of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate, and violate the provisions of Article XI, Section 16, of the Constitution of the State of Tennessee which absolutely precludes the Legislature from exercising any legislative power to remove or restrict the right of juries in civil cases to determine damages.

359. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiffs' non-

economic damages are purportedly capped at $750,000, and their ability to recover punitive damages is capped at twice the compensatory damages up to a maximum of $500,000.

360. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiffs' constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6, of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17, of the Tennessee Constitution, which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16, of the Tennessee Constitution which indicates that the rights of citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever . . . and shall forever remain inviolate."

361. Therefore, Plaintiffs request a declaration that the statutory caps are unconstitutional, void *ab initio*, and of no force and effect.

362. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiffs are challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

363. The requirements of Tenn. Code Ann. § 29-26-121 have been satisfied

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment as follows:

1. Against the Defendants and in favor of the Plaintiffs for the amount of damages

sustained by the Plaintiffs as a result of Defendants' breaches of statutory and common law as described more fully in this Complaint;

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

3. Under the DDLA, "[e]conomic damages, including, but not limited to: the cost of treatment and rehabilitation, medical expenses, loss of economic or educational potential, loss of productivity, absenteeism, support expenses, accidents or injury, and any other pecuniary loss proximately caused by the illegal drug use" described in this Complaint. Tenn. Code Ann. § 29-38-106(c)(1). In this case, in addition to these expenses, the Opioid Epidemic Affected Counties have incurred numerous structural costs, including, but not limited to, increased healthcare costs, the cost of increased police services, and the cost of increased incarceration services.

4. Under the DDLA, "[n]on-economic damages, including, but not limited to, physical and emotional pain, suffering, physical impairment, emotional distress, mental anguish, disfigurement, loss of enjoyment, loss of companionship, services and consortium and other nonpecuniary losses proximately caused by an individual's use of an illegal drug." Tenn. Code Ann. § 29-38-106(c)(2).

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

6. Under the DDLA, Plaintiffs are entitled to recover awards from all Defendants, including but not limited to the costs and disbursements of this action, reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses as provided by the common fund doctrine

and other applicable law pursuant to Tenn. Code Ann. §29-38-106(c)(3) (4)-(5).

7. An order of abatement and permanent injunction against all Defendants prohibiting them from flooding the Tennessee markets, specifically the First, Second, and Third Judicial Districts, with illegal opioids.

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

This is the First Request for Injunctive Relief.

Filed on this the _____ day of June, 2017.

Respectfully submitted,

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