IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

#1 COURT SQUARE, SUITE 203 PARKERSBURG, WV 26101

IN RE: MINUTES OF MEETING HELD THURSDAY, MARCH 1, 2018

PRESENT: DAVID BLAIR COUCH, PRESIDENT ROBERT K. TEBAY, COMMISSIONER JAMES COLOMBO, COMMISSIONER

At 9:30 A.M., the County Commission of Wood County met in regular session. They signed purchase orders, invoices and other correspondence.

The County Commission, upon a motion duly made, seconded and passed, approved minutes of February 12, 15 and 22, 2018.

The Oath of Office for Chad Beaver was put on record on this date. Oath is attached to these minutes and shall be made a part thereof.

AGENDA AND DISCUSSION ITEMS

At 9:30 A.M., Robert Andrew Waters took his oath as a new Deputy Sheriff.

At 9:33 A.M., the County Commission approved the hiring of Andrew J. Padden as an E-911 Telecommunicator and Gina Bargeloh as a Sheriff's Tax Deputy.

At 9:36 A.M., the County Commission met with representatives from the law firm of Hill, Peterson, Carper, Bee and Dietzler. They discussed their services to represent the County Commission in the Opioid Lawsuit. Ed Hill stated their charge would be 25% plus expenses. Handout is attached to these minutes and shall be made a part thereof.

At 10:10 A.M., the County Commission met with representatives from Marc J. Bern & Partners in conjunction with the Ford Law Firm. They presented their proposal for representing the County Commission in the Opioid Lawsuit. Their charge would be a straight 25% fee. Handout is attached to these minutes and shall be made a part thereof.

At 11:11 A.M., the law firm of Pritt and Spanner scheduled for 10:00 A.M. failed to appear.

Emails with attachments from the Chafin Law Firm and Skinner Law Firm are attached to these minutes and shall be made a part thereof.

ORDERS APPROVED AND ATTACHED TO THESE MINUTES

A/1913, A/1912, A/1911, M/3873, M/3874, M/3875, M/3876, M/3877, M/3878, M/3879

Having no further scheduled appointments or business to attend to, the County Commission adjourned at 11:24 A.M.

APPROVED:

THE COUNTY COMMISSION-OF WOOD COUNTY

David Blair Couch, Presiden

Robert K. Tobay, Sommissioner

James Colombo, Commissioner

To listen to this meeting, please refer to DVD labeled March 1, 2018.

Wood County Commission Meeting Held March 1, 2018

Please Print

1. Jim Leich	
2. Harry Deitzles	
1. Jim Leach 2. Harry Deitzler 3. Anthony Majostro	
4. Sd / DD	
5.	
6.	
7.	Service
8.	
9.	
10.	Farance 1
11.	
12.	Yana
13.	
14.	
15.	
16.	
17.	
18.	-
19.	
20.	4-1-4-1



Wood County Commission Agenda

3/01/2018 1 Court Square, Suite 203 Parkersburg, WV 26101

9:30 A.M.	Robert Andrew Waters — Take Oath as a Deputy Sheriff	
	Consider appointing James E. Colombo to the E-911 Advisory Board	
	Consider Request to Hire — Andrew J. Paden as a E-911 Telecommunicator - \$29,034.72/yr	
	Consider Request to Hire – Gina Bargeloh as a Tax Deputy - \$23,750.00/yr	
10:00 A.M.	Discuss opioid lawsuit representation	Pritt & Spanner
10:30 A.M.	Discuss opioid lawsuit representation	Lisa Ford, Ford Law
	Administrator's Report	Marty Seufer, County Administrator
	County Commission Reports	

Discussion, Review and Approval of expenditures and disbursements identified on Exhibit 1, hereto attached

Correspondence for this meeting will be available for public review during regular office hours in Room 205 of the Wood County Courthouse two (2) days prior to the meeting

Exhibit 1

Discussion, Review and Approval of the following items may be included during this meeting and are available for public inspection in the Office of the County Administrator two days prior to this meeting.

Budget revisions

Purchase orders and requisitions

Revisions, reimbursement requests, resolutions and correspondence for grants

Grant disbursements to other entities

Invoices for expenditures to be paid

Reimbursements for travel expenses

Bid specifications and procedures for bids previously authorized by the Commission

Monthly Hotel Occupancy Tax Collection disbursements

Disbursements for previously approved Innovative Programming Grants

Tax refunds, exonerations, impropers and consolidations

Probate items, including settlements, petitions and Fiduciary Commissioner reports

General Fund disbursements to entities

Funding requests from local organizations by written form

Payroll modification as submitted by elected officials

Marty Seufer

From:

Stephen Skinner <sskinner@skinnerfirm.com>

Sent:

Wednesday, February 28, 2018 5:44 PM

To:

Marty Seufer

Subject:

Opioid suit representation

Mr. Seufer,

Thank you for the inquiry about the potential representation of the Wood County Commission in the national opioid litigation. We think that Wood county would probably be a better served with a law firm that is closer to you. Thank you for thinking of us.

Best,

Stephen Skinner

Stephen G. Skinner
SKINNER LAW FIRM
115 E. Washington St.
Charles Town, WV 25414

304.725.7029

sskinner@skinnerfirm.com



WOOD COUNTY OPIOID LITIGATION

Background

Prescription opioids include brand-name drugs such as OxyContin and Percocet and generics such as oxycodone and hydrocodone, all of which are powerful narcotic painkillers. Opioids (prescription and illegal) are frequently abused because they are incredibly addictive. Opioid medications bind to the areas of the brain that control pain and emotions, driving up the levels of the feel-good hormone dopamine in the brain's reward areas and producing intense feelings of euphoria. As the brain becomes used to those feelings, it often takes more and more of the drug to produce the same levels of pain relief and feeling, which can lead to dependence and addiction.

Historically, opioids were only used to treat short-term acute pain or for end-of-life care because they were considered too addictive and debilitating for long term use. By the late 1990s and continuing to the present, however, drug companies began an aggressive marketing scheme designed to persuade doctors, patients, and the general public that opioids can and should be used for long-term, chronic pain—a much larger group of patients. The campaign was successful for the industry, but disastrous for the public. Today, millions of people nationwide have a substance abuse disorder that started with prescription pain relievers. According to the National Institute of Health, about 80% of all new heroin users began with using prescription opioids.

In connection with this scheme, major drug distributors have duties under state and federal law to create systems to detect "suspicious orders" of controlled substances like opioids. Upon detection, the distributors are required to report any suspicious orders to authorities. The distributors failed in their duty to develop the requisite systems to detect suspicious orders. At one point, they were compelled by court orders to develop these systems, but then they failed to report the suspicious orders as required. The distributor defendants have admitted to this behavior in prosecutions conducted by the Department of Justice, working in coordination with state and local police agencies. The distributor's failure to observe their legal duties allowed the opioid epidemic to happen.

Opioids are the most widely-prescribed class of drugs, generating \$11 billion in revenue for drug companies in 2014 alone. Many patients become physically and psychologically dependent on these highly addictive drugs and, when they can no longer legitimately obtain opioids, often turn to the street market to buy prescription opioids or other illegal drugs such as heroin and fentanyl. Prescription opioids have been described as "the on-ramp to addiction." Reports indicate that the opioid epidemic has resulted in nearly 180,000 overdose deaths between 2000 and 2015 (more than three times the number of Americans who died in the Vietnam War). Yearly deaths caused by drug overdoses have surpassed the peak number of yearly deaths resulting from car crashes, HIV, or firearms.





The opioid crisis is a national crisis both in terms of the human costs (loss of lives and addiction) and in terms of economic costs. The White House's Council of Economic Advisers under the Trump Administration recently issued a report estimating that the economic cost of the opioid crisis in 2015 was \$504 billion, or 2.8% of GDP. Local governments have incurred and continue to incur the costs associated with fatal and non-fatal overdoses and with addiction.

West Virginia's Opioid Epidemic

West Virginia, like the rest of the nation, is in the midst of an opioid epidemic, but has suffered tremendously compared to other states. Some statistics:

- The state has led the nation in the rate of drug overdoses nearly every year in the past decade.
- Between 2007 and 2012, state residents and visitors to the state filled prescriptions for 780 Million doses of opioids, enough to provide 433 pills per state resident.
- Between 2012 and 2016, the state saw a 25% increase in the number of children in the foster care system.
- The rate of neonatal abstinence syndrome, a condition that occurs when babies are born addicted to drugs, quadrupled between 2007 and 2013.

Wood County's Opioid Epidemic

Wood County has been particularly victimized by the opioid epidemic. Estimates from the CDC show Wood County experienced an increase in opioid overdose deaths as high as 195% between 1999 and 2015. In 2016, the County experienced 45 drug overdose deaths, ranking fifth in the state. The problem continues unabated today, with the Wood County emergency response system receiving more than 360 overdose calls in 2017. Considering the population of the County is less than 100,000 people, the incidence rates are alarming for these figures.

In Wood County, 109.4 opioid prescriptions were written per 100 County residents in 2016, that is more than one opioid prescription for every man, woman, and child. By way of comparison, the national opioid prescribing rate in 2016 was 66.5 prescriptions per 100 persons and the 2016. Wood County's prescription rate, being higher than the figure countrywide, indicates that the current problem in Wood County is likely just the tip of the iceberg without immediate action.

Potential Defendants

As detailed above, the manufacturers and distributors bear responsibility for creating the opioid epidemic because they 1.) deceptively marketed opioid drugs as not carrying a risk of addiction in long-term use; 2.) failed to detect suspicious orders; and 3.) failed to report suspicious orders. We will file claims against these entities, but also the sales representatives whose knowingly false





statements when marketing opioids contributed greatly to the County's problem. We will not name individual physicians, the board of pharmacy, or anyone affiliated with the board of pharmacy. Recent federal court decisions did not find these parties necessary for purposes of remand and each present significant complications for litigation efficiency. Particularly regarding the Board of Pharmacy, a jury would certainly be reminded that any award against it would ultimately be paid for with tax dollars. Thirty-two specific defendants are listed below.

I. Manufacturers

- Purdue Pharma L.P.
- Purdue Pharma Inc.
- The Purdue Frederick Company, Inc.
- Teva Pharmaceuticals USA, Inc. ("Teva USA")
- Cephalon, Inc.
- Johnson & Johnson ("J&J")
- Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals")
- Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.
- Janssen Pharmaceutica, Inc.
- Endo Health Solutions Inc.
- Endo Pharmaceuticals, Inc.
- Allergan Plc f/k/a Actavis Plc
- Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.
- Watson Laboratories, Inc.
- Actavis LLC
- Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

II. Distributors

- McKesson Corporation
- Cardinal Health, Inc.
- AmerisourceBergen Drug Corporation
- Rite Aid of West Virginia, Inc.
- CVS Indiana L.L.C.
- Kroger Limited Partnership II
- Wal-Mart Stores East, LP
- Miami-Luken, Inc.

III. Sales Representatives





- Mark Radcliffe
- Mark Ross
- Jeff Waugh
- Carol DeBord
- Amanda Bias Hayes
- Doug Powers
- Patty Carnes

Litigation Strategy

Our team intends to litigate these claims in state court, outside the federal multidistrict litigation ("MDL"), because keeping the County's case in state court offers the best potential for a high recovery by the County. The citizens of the community should decide how much responsibility to impose on the defendants. Our strategy for keeping the case in State Court relies on a method already proven successful: we will sue the company's Sales Representatives in their individual capacities. Because they intentionally engaged in tortious behavior, they are personally liable under West Virginia law. Previously successful strategies may fail if implemented precisely as before, because the sales representatives named previously had ceased working for the company over a decade ago. We have conducted the intelligence necessary to name currently employed sales representatives.

Proposed causes of action include the following: (1) Fraud; (2) Unjust Enrichment; (3) Negligent Misrepresentation; (4) Public Nuisance; (5) Negligent Misrepresentation; (6) Negligence, including allegations of breaching duties specified by the Food, Drug, and Cosmetic Act and State/Federal Controlled Substances Laws to create a *prima facie* presumption of negligence; and (7) Constructive Fraud.

The litigation team will avoid filing Racketeer Influenced and Corrupt Organizations Act ("RICO"), civil conspiracy, and strict liability claims because they: (1) are not necessary for a successful outcome; (2) would require excessive resources to investigate and prove; (3) provide an opportunity for the defendants to confuse the jury; and (4) would extend the length of trial.

Remedies

Proposed damages include damages for past costs that have already been incurred by the County as a result of the opioid epidemic. The main categories of damages relate to healthcare, criminal justice, public services, and lost productivity/ revenue.





- *Healthcare* A biostatistician and/or an epidemiologist will be employed to review health coding data from sources of County health services to assess losses relating to rehabilitation, Neonatal Abstinence Syndrome, overdose, and addiction.
- Criminal Justice A crime statistician will be employed to assess the increased costs relating to policing, arrests, processing, judiciary, incarceration, and rehabilitation of the criminal population.
- *Public Services* A forensic accountant will need to review past budgets for any relevant changes in public services, which include costs relating to Child Welfare Expenses, coroner's office, and EMS/First Responders.
- Lost Productivity/Revenue An economist will be employed to assess opioid addiction's impact to the County budget due to lost productivity and tax revenue. The Trump Administration's Council of Economic Advisers determined that most cost estimates of the opioid epidemic underestimate the overall impact on public funds because they exclude an analysis of lost tax revenue, totaling between \$2 MM and \$5 MM over the life of one decedent. Wood County derives revenue from licenses, permits, tags, property taxes, alcoholic beverage taxes, charges for services, fines, and gas and oil severance taxes, that can no longer be collected upon overdose.

Proposed damages also include damages for future costs that the County needs to abate the opioid epidemic ravaging its community. Abatement involves enhancing and creating programs with law enforcement, the courts system, educational institutions, and healthcare/treatment providers to establish and expand public programs to educate and rehabilitate the community. High quality patient substance abuse rehabilitation costs \$25,000 or more per person with a year of regular follow-up care costing approximately \$25,000 more per person. We are currently waiting on information from a contact affiliated with the Betty Ford Foundation regarding a more accurate cost assessment. The National Institute on Drug Abuse, a federal organization, estimates that every \$1 spent on rehab saves as much as \$12 in criminal justice and healthcare costs.

Ultimately, solutions to the opioid epidemic cost money and resources are needed to create intervention programs, provide access to treatment, invest in prevention initiatives, and deal with the ripple effects of substance abuse disorders, overdose deaths, and drug-related criminal activity. Those responsible for the opioid epidemic should have to pay for these solutions, not already strained County budgets funded by taxpayers.





Our Litigation Team

Marc J. Bern & Partners LLP presents to you a well-financed and highly sophisticated legal team, seasoned in complex tort litigation, led by Marc J. Bern and Joseph Cappelli.

- Marc J. Bern, Founding Partner at Marc J. Bern & Partners LLP Mr. Bern has successfully recovered over \$3 Billion in complex tort claims against multinational entities across 40 years of practice. He has been appointed by Courts to the leadership of many complex tort litigations. His firm currently represents 20 Counties from Pennsylvania and South Carolina against the manufacturers and distributors of opioid medications.
- Joseph Cappelli Mr. Cappelli is a veteran trial attorney with a 25-year track record of success against notable trial attorneys, including Phil Beck (counsel for George Bush in Bush v. Gore). Mr. Cappelli is licensed in Pennsylvania and is admitted to multiple federal district courts throughout the country. He has personally handled cases in courtrooms in over twenty states and has significant appellate experience, contributing greatly to the improvement of industrial safety standards.
- R. Joseph Kramer Mr. Kramer is a partner at Marc J. Bern & Partners LLP specializing in complex litigation against multinational entities. Mr. Kramer brings extensive experience with e-discovery matters and has served on discovery committees in multiple complex litigations, with his work product directly contributing to a \$2.4 Billion settlement in the Actos Products Liability Litigation. He has an affinity for complex scientific issues, working closely with experts in many claims.
- Carmen A. De Gisi Ms. De Gisi is an associate attorney at Marc J. Bern & Partners LLP focusing on the litigation of complex litigation against large corporations. Mr. De Gisi has vital experience representing multinational defendants in litigation, which will be essential in responding to document requests from the manufacturers and distributors of opioids. He has led document review teams for the purposes of relevancy and privilege review in the production of discovery.
- Margaret Cordner Ms. Cordner is an associate attorney at Marc J. Bern & Partners LLP focusing on complex litigation against multinational entities. Ms. Cordner brings an excellent briefing ability, which she has successfully applied to multiple complex litigation issues in multi-jurisdictional settings.



IN THE CIRCUIT COURT OF WOOD COUNTY, WEST VIRGINIA

WOOD COUNTY COMMISSION,	*	
	*	Civil Action No.
Plaintiff,	*	
vs.	*	TITLES TOTAL TOTAL ARTESTS
RITE AID OF WEST VIRGINIA, INC.;	*	JURY TRIAL DEMANDD
PURDUE PHARMA L.P.; PURDUE	*	
PHARMA INC.; THE PURDUE	*	
FREDERICK COMPANY, INC.; TEVA	*	
PHARMACEUTICALS USA, INC.;	•	
CEPHALON, INC.; JOHNSON &	*	
JOHNSON; JANSSEN	*	
PHARMACEUTICALS, INC.; ORTHO-		
MCNEIL-JANSSEN PHARMACEUTICALS,	*	
INC N/K/A JANSSEN	*	
PHARMACEUTICALS, INC.; JANSSEN		
PHARMACEUTICA, INC. N/K/A JANSSEN	*	
PHARMACEUTICALS, INC.; ENDO	*	
HEALTH SOLUTIONS INC.; ENDO	*	
PHARMACEUTICALS, INC.; ALLERGAN	*	
PLC F/K/A ACTAVIS PLC; ACTAVIS, INC.	*	
F/K/A WATSON PHARMACEUTICALS,	*	
INC.; WATSON LABORATORIES, INC.;	^	
ACTAVIS LLC; ACTAVIS PHARMA, INC.	*	
F/K/A WATSON PHARMA, INC.;	*	
MCKESSON CORPORATION; CARDINAL	••	
HEALTH, INC.; AMERISOURCEBERGEN	*	
CORPORATION; CVS INDIANA L.L.C.;	*	
KROGER LIMITED PARTNERSHIP II;		
WAL-MART STORES EAST, LP; MIAMI-	*	
LUKEN, INC.; MARK RADCLIFFE; MARK	*	
ROSS; JEFF WAUGH; CAROL DeBORD;		
AMANDA BIAS HAYES; DOUG POWERS;	*	
and PATTY CARNES,	*	
Defendants.	*	

COMPLAINT

Plaintiff, Wood County Commission, West Virginia ("Plaintiff" or "Wood County" or "the County"), by and through the undersigned attorneys, upon personal knowledge as to its own acts and beliefs, and upon information and belief as to all matters based upon the investigation of counsel, for its Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company; Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc.; Janssen Pharmaceutical, Inc. n/k/a/ Janssen Pharmaceuticals; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; (collectively, "Manufacturers" or "Defendants"); McKesson Corporation; Cardinal Health, Inc.; Rite Aid of West Virginia, Inc.; AmerisourceBergen Corporation; Kroger Limited Partnership II; CVS Indiana, L.L.C.; Wal-Mart Stores East, LP; Miami-Luken, Inc.; (collectively, "Distributor Defendants") or "Defendants"); Mark Radcliffe; Mark Ross; Jeff Waugh; Carol DeBord; Amanda Bias Hayes; Doug Powers; and Patty Carnes (collectively, "Sales Representative Defendants") alleges as follows:

INTRODUCTION

- 1. Plaintiff spends millions of dollars each year to provide or pay for the health care, pharmaceutical care, and other necessary services and programs on behalf of indigents and otherwise eligible residents, including payments for prescription opium-like painkillers ("opioids"), which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.
 - 2. Plaintiff not only provides a wide range of other services on behalf of its residents,

including services for families and children, public assistance, and law enforcement, but also depends on the health and productivity of its workforce to generate tax revenue.

- 3. Opioids include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. These drugs are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and, therefore, are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.
- 4. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. Opioids are approved by the FDA for use in the management of moderate to severe pain and their use is typically appropriate for a few days or more. For example, doctors traditionally used opioids to treat acute pain for severe bodily trauma (e.g., gunshot wounds and post-surgical pain). Patients experiencing extreme levels of pain from cancer have also received opioids to make the end of their life as pain free as possible. Defendants, however, have manufactured, promoted, and marketed opioids for the long-term management of chronic pain (e.g., low back pain, knee pain, and neck pain) by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.
- 5. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction. Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.
- 6. Defendants knew that, barring exceptional circumstances, opioids are too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer

 $^{^1}$ Diagnostic and Statistical Manual of Mental Disorders (5 $^{\mbox{th}}$ ed. 2013) ("DSM-V").

("chronic pain").

- 7. Defendants knew that, with prolonged use, the effectiveness of opioids wanes over time, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.²
- 8. Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized.
- 9. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.
- 10. Despite the foregoing knowledge, to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.
- 11. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s, became more aggressive in or about 2006, and continues to the present.
- 12. Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients.
 - 13. Defendants, individually and collectively, knowing that long-term opioid use

² See, e.g., Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Current Status, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, patients, governmental units, and others by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

- 14. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled.³ In 2010, 254 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month. Also in that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).⁴ While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.⁵ By 2014, nearly two million Americans either abused or were dependent on opioids.⁶
- 15. Defendants' campaign has been extremely profitable. In 2012 alone, opioids generated \$8 billion in revenue for drug companies. Of that amount, \$3.1 billion went to Purdue for its OxyContin sales. 8
- 16. Defendants' marketing campaign has been extremely harmful to Americans, including the citizens of and visitors to Wood County, West Virginia. Nationwide, overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half

CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed September 19, 2017) (internal footnotes omitted).
 M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010,

⁵¹⁽¹⁰⁾ Med. Care 870-78 (2013).

⁵ L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).

⁶ CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed September 19, 2017).

⁷ B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

⁸ K. Eban, Purdue Pharma's Painful Medicine, Fortune Magazine (Nov. 9, 2011).

a million people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose.

- 17. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers. ¹⁰ Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders. ¹¹
- 18. Opioid addiction and overdoses have reached epidemic levels over the past decade.

 On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country." 12
- 19. In 2016, approximately 64,000 people died from drug overdoses in the United States, more than the peak yearly death tolls from car crashes, HIV deaths, or gun deaths. Sixty-six percent of the drug overdose deaths in 2016 involved opioids, with the total deaths involving opioids taking more lives than breast cancer. The total overdose deaths in 2016 were 10,000 more than in 2015. The graph below shows the trend relating to overdose deaths since 2000: 15

⁹ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, supra.

¹⁰ Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

¹¹ J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) Addiction 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) Journal of Addictive Diseases 185 (2011).

¹² FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed September 19, 2017).

Katz, Josh, The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years, https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html (published September 2, 2017, accessed October 27, 2017).

¹⁴ Kounang, Nadia, *Opioids now kill more people than breast cancer*, http://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html (accessed December 29, 2017).

¹⁵ Katz, Josh, The First County of Fentanyl Deaths in 2016: Up 540% in Three Years, Supra.

Total U.S. drug deaths

Around
60,000 deaths per year

60,000 deaths per year

died from drug overdoses in the U.S. in 2016

Peak car crash deaths (1972)

Peak H.I.V. deaths (1995)

Peak gun deaths (1993)



- 20. Despite the record profits being generated from their efforts, Defendants' marketing campaign has failed to achieve any material health care benefits. Since 1999, there has been no overall change in the amount of pain that Americans report.¹⁶
- 21. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by

¹⁶ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

pharmaceutical companies."¹⁷ As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

- 22. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the United States, including in West Virginia and Wood County. Consequently, public health and safety throughout the United States, including Wood County, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.
- 23. West Virginia has the highest rate of drug overdose deaths in the United States. West Virginia had 36.3 drug overdose deaths per 100,000 people in 2011, nearly triple the U.S. rate (13.2/100,000). Prescription drugs opioids and benzodiazepines in particular are major drivers of the drug overdose deaths in West Virginia. Opioid-prescribing rates in West Virginia are among the highest in the country. In 2012, West Virginia providers wrote 137.6 opioid pain reliever prescriptions per 100 people, the third highest prescribing rate in the country and far above the U.S. rate (82.5/100). 19

America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed September 19, 2017) (emphasis added).

According to the CDC, when prescription medicines are obtained or used illegally, it is called "drug diversion."

19 Centers for Disease Control and Prevention, CDC awards over \$1 Million to West Virginia to address prescription drug overdose prevention, https://www.cdc.gov/injury/pressroom/pressreleases/2014/pressrelease_pdo-wvirginia.html (August 14, 2014).

- 24. In 2014, West Virginia again had the highest drug overdose death rate in the United States (35.5 deaths per 100,000 people). It topped the unfortunate list in 2015 as well with 41.5 deaths per 100,000 people.
- 25. For over a decade, the state has been at the top, if not led the nation, in prescription drug overdose deaths. Fatal drug overdoses continue to rise in West Virginia and its overdose death rate far outpaces any other state in the country. In 2016, 818 West Virginians died of drug overdoses, four times as many as died in 2001 and a 13 percent increase over 2015.²⁰
- During the past several years, drug wholesalers, such as the Distributor Defendants named herein, have flooded West Virginia with 780 million hydrocodone and oxycodone pills. With approximately 1.84 million residents, this works out to an average of 433 pain pills per resident of the state. At the height of the pill shipments to West Virginia, there were other warning signs the prescription opioid epidemic was growing. During this time, drug wholesalers were shipping a declining number of 5 milligram oxycodone pills (the drug's lowest and most common dose), and at the same time, a dramatic increase in stronger doses. Between 2007 and 2012, the number of 30 milligram OxyContin tablets increased six-fold, the number of 15 milligram OxyContin pills tripled and the number 10 milligram OxyContin doses nearly doubled.
- 27. Over the past several years, West Virginia has seen a rise in the number of children in foster care. From 2012 2016, more than a thousand additional children were introduced into the system, bringing the total to 5,182 a 24% increase according to the West Virginia

Associated Press, Overdose Deaths Continue to Rise in West Virginia, https://www.usnews.com/news/best-states/west-virginia/articles/2017-03-07/overdose-deaths-continue-to-rise-in-west-virginia (published March 7, 2017)

9 of 115

Department of Human Services. About 42 percent of these children were removed from their homes due to family drug abuse.

- 28. During this period of time, three of the Distributor Defendants, McKesson Corporation, Cardinal Health, and AmerisourceBergen Corporation, made \$17 billion dollars by sending 523 million opioids pain killers to West Virginia between 2007 and 2012.²¹ These three distributors supplied more than half of all the opioids sold in West Virginia alone. Largely in part to the opioid market, Defendant McKesson has grown into the fifth largest corporation in America
- 29. In West Virginia, the abuse of opioids has also harmed children and infants. Neonatal Abstinence Syndrome ("NAS") is a condition where babies are born addicted to drugs. The incidence of NAS quadrupled between 2007 and 2013 from roughly 7.74 infants per 1,000 hospital births to 31.57 per 1,000, which would amount to 1,974 infants in 2013. Between 2000 and 2013, the incidence rate has increased over 5,000% from .5 per 1,000 births in 2000. The National Institute on Drug Abuse, a federal government research institute, determined that the average hospital cost for a newborn with NAS is \$66,700, compared to \$3,500 for the typical newborn. After birth, children born into families struggling with opioid addiction or who fall into opioid addiction frequently end up in the foster care system.
- 30. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts in West Virginia have migrated to heroin. Roughly 80% of heroin users previously used

²¹ Eyre, Eric, Charleston Gasette-Mail, *Drug firms poured 780M painkiller into WV amid rise of overdoses*, https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html (published December 17, 2016)

²² Stabler PhD, Meagan E., Journal of Rural Health, Neonatal Abstinence Syndrome in West Virginia Sub-State Regions, 2007-2013 The Post and Courier. (February 16, 2016).

²³ Centers for Disease Control and Prevention, *Incidence of Neonatal Abstinence Syndrome - 28 States, 1999-2013*, https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm (August 12, 2016).

National Institute on Drug Abuse, Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome, (accessed October 25, 2017).

prescription opioids.

- 31. Wood County has not been an exception to the suffering caused by the opioid epidemic. 109.4 opioid prescriptions were written per 100 Wood County residents in 2016, that is more than one opioid prescription for every man, woman, and child residing in Wood County. 25 Estimates from the CDC show Wood County experienced an opioid overdose death increase of as much as 195% between 1999 and 2015. 26 From a historical perspective, between 2001 and 2005, the county is in the second highest category for overall Opioid-related overdose deaths within West Virginia, with between 128 and 246 deaths occurring during that timeframe. 27 In 2016, the County experienced 45 drug overdose deaths, ranking 5th in the state. 28 The problem continues, with the Wood County emergency response system receiving more than 360 overdose calls in 2017. 29 Considering the population of the County is less than 100,000 people, the incidence rates are alarming for these figures.
- 32. With an increase in opioid use, a concomitant increase in drug-related crime activity has been seen within the County as well. United States Senator Joe Manchin recently supported a coalition of local law enforcement agencies asking that Wood County be designated a High Intensity Drug Trafficking Area (HIDTA). It would allow the county to receive additional federal funding. The additional funding is needed because of the County's proximity to other state lines

470411383.html (published January 29, 2018, updated January 29, 2018)

²⁹ *Id*.

²⁵ Centers for Disease Control and Prevention, U.S. County Prescribing Rates, https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (2016)

²⁶ CDC, Drug Poisoning Mortality by County: United States, https://data.cdc.gov/NCHS/NCHS-Drug-Poisoning-Mortality-by-County-United-Sta/pbkm-d27e/data (accessed October 9, 2017, updated August 28, 2017).

West VA Dept. of Health & Human Resources Bureau for Public Health, West Virginia Drug Overdose Deaths Historical Overview 2001-2015, http://dhhr.wv.gov/oeps/disease/ob/documents/opioid/wv-drug-overdoses-2001 2015.pdf (published August 17, 2017)

Lewis, Brandon, Wood County 911 Center Reports more than 360 overdose calls in 2017, http://www.thenewscenter.tv/content/news/Drug-overdose-deaths-decline-in-Wood-County-in-2017-

and multiple interstates, West Virginia and local law enforcement agencies have already committed resources to respond to Wood County's drug trafficking problem.³⁰

- 33. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.
- Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*,: (1) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment to infants born with opioid-related medical conditions; (4) costs associated with law enforcement and public safety relating to the opioid epidemic; (5) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered, directly by the Plaintiff. In sum, Plaintiff seeks to retrieve the costs it needed to spend on efforts to clean up the disastrous epidemic caused by Defendants, which has infected nearly every aspect of civic life, and the cost required to repair the damage

³⁰ Joe Manchin, Manchin Calls for Designation of Wood County as High Intensity Drug Trafficking Area, https://www.manchin.senate.gov/newsroom/press-releases/manchin-calls-for-designation-of-wood-county-as-high-intensity-drug-trafficking-area (May 9, 2017).

moving forward.

35. Plaintiff also seeks the means to abate the Defendants' wrongful and/or unlawful conduct creating this public health crisis.

JURISDICTION AND VENUE

- 36. The Court has subject matter jurisdiction over the claims made by Plaintiff pursuant to Article VIII, Section 6 of the West Virginia Constitution and W. Va. Code § 51-2-2.
- 37. Plaintiff, Wood County Commission, is a public corporation which may sue and plead in its own name. W. Va. Code. § 7-1-1(a) [2008]. Plaintiff is a "political subdivision" and is neither an agency nor an agent of the State of West Virginia. W. Va. Code § 29-12A-3(c) [1986]; W. Va. Code § 14-2-3 [1967]; *Kucera v. City of Wheeling*, 153 W. Va. 531, 170 S.E.2d 217 (1969).
- 38. A county commission only has powers expressly conferred by the West Virginia Constitution and our State Legislature, or powers reasonably and necessarily implied for the exercise of those expressed powers. Berkeley Cty. Comm'n v. Shiley, 170 W. Va. 684, 685–86, 295 S.E.2d 924, 926 (1982) (citing State ex rel. County Court of Cabell County v. Arthur, 150 W.Va. 293, 145 S.E.2d 34, Syl. Pt. 1 [1965]). The Wood County Commission is vested with the power of all superintendence and administration of the internal police and fiscal affairs of Wyoming County. W. Va. Code § 7-1-3 [1999].
- 39. The Wood County Commission is "authorized to enact ordinances, issue orders and take other appropriate and necessary actions for the elimination of hazards to public health and safety and to abate or cause to be abated anything which the commission determines to be a public nuisance." W. Va. Code § 7-1-3kk [2002].
- 40. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality has created a serious public health and safety crisis and is a public nuisance, and that the

diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

- 41. Venue is proper in Wood County pursuant to W.Va. Code § 56-1-1 because, *inter alia*, Defendants deliberately and regularly transact business in Wood County, West Virginia and Plaintiffs' causes of action arose in Marshall County, West Virginia.
- 42. This Court has personal jurisdiction over Defendants because they conduct business in West Virginia and Wood County; purposefully direct or directed their negligent and injurious actions toward West Virginia and Wood County; consensually submitted to the jurisdiction of West Virginia when obtaining a manufacturer or distributor license; have headquartered in West Virginia; have taken actions within Plaintiff's jurisdictional boundaries that have foreseeably caused injury to Plaintiff; and/or have the requisite minimum contacts with West Virginia and Wood County necessary to constitutionally permit the Court to exercise jurisdiction.
- 43. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

PARTIES

- 44. Wood County is a County in West Virginia with a population of approximately 86,956 residents as of the 2010 census. Plaintiff has a duty to provide a wide range of services to its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.
- 45. Plaintiff brings this action on its own behalf. By incurring the costs and expenses and in making the payments it has made on behalf of its employees, residents, and visitors, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

- 46. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of the State of Delaware with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.
- 47. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.
- 48. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.
- 49. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Wood County, including OxyContin (Oxycodone hydrochloride extended release), MS Contin (Morphine sulfate extended release), Dilaudid (Hydromorphone hydrochloride), Dilaudid-HP (Hydromorphone hydrochloride), Butrans (Byrenorpine), Hysingla ER (Hyrdrocodone bitrate), and Targiniq ER (Oxycdone hydrochloride and Naloxone hydrochloride), all of which except Butrans are Schedule II.³¹
- 50. 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 four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analysis drugs (i.e., painkillers).

³¹ Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. Of the Purdue drugs listed above, Butrans is the only Schedule III drug.

- 51. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation with its United States Headquarters located at 1090 Horsham Road, North Wales, Pennsylvania 19454.
- 52. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters at 1090 Horsham Road, North Wales, Pennsylvania 19454. In 2011, Teva Ltd. acquired Cephalon, Inc.
- 53. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally and in Wood County, including Actiq (Fentanyl citrate) and Fentora (Fentanyl citrate tablet), both Schedule II drugs.
- 54. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Wood County.
- 55. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its headquarters located at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933.
- 56. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560 and is a wholly owned subsidiary of J&J.
- 57. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.
- 58. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation that registered its headquarters with 16 of 115

the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560.

- 59. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation that registered its headquarters with the Pennsylvania Department of State at 1125 Bear Harbor Road, Titusville, New Jersey, 08560.
- 60. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.
- 61. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Wood County, including Duragesic (Fentanyl), Nucynta (Tapentadol), and Nucynta ER (Tapentadol extended release), all of which are Schedule 2 drugs.³²
- 62. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.
- 63. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania 19355.
- 64. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its headquarters at 1400 Atwater Drive, Malvern, Pennsylvania.
- 65. EHS and EPI (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Wood County, including Opana ER (Oxymorphone hydrochloride extended release), Opana (Oxymorphone hydrochloride), Percodan (Oxymorphone hydrochloride and aspirin), and Percocet (Oxymorphone hydrochloride and acetaminophen).

³² Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

- 66. Opioids make up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.
- 67. Allergan PLC is a public limited liability company incorporated in Ireland with its principal place of business at Clonshaugh Business & Technology Park, Coolock, Dublin 17. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in March 2015.
- 68. Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in January 2013. Actavis, Inc.'s headquarters are located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.
- 69. Watson Laboratories, Inc. is a Nevada corporation with its headquarters at 132 Business Center Drive, Corona, California and is a wholly owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).
- 70. Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and was formerly known as Watson Pharma, Inc.
- 71. Actavis LLC is a Delaware limited liability company with its headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.
- 72. Each of the defendants in ¶ 66-70 are owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC

exercises control over these marketing and sales efforts; profits from the sale of Allergan/Actavis products; and ultimately benefits from them (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.").

- 73. Actavis manufactures, promotes, distributes, and sells the branded opioids Kadian (morphine sulfate extended release) and Norco nationally and within Wood County. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.
- 74. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters at One Post Street, San Francisco, California, 94104.
- 75. McKesson promotes, distributes, and sells opioids manufactured by Manufacturers across the country and, upon information and belief, within West Virginia and Wood County to pharmacies and institutional providers. It had a net income over \$1.5 Billion in 2015.
- 76. Defendant Cardinal Health Inc. ("Cardinal") is an Ohio Corporation with its headquarters at 7000 Cardinal Place, Dublin, Ohio, 43017.
- 77. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including, on information and belief, West Virginia and Wood County.
- 78. Defendant Rite Aid of West Virginia, Inc., ("Rite Aid") was incorporated in West Virginia in 1971 and has various locations throughout West Virginia, including within Wood County, and acts as a subsidiary of Rite Aid Corporation.

- 79. Defendant Rite Aid distributes opioids to consumers within West Virginia and Wood County.
- 80. Defendant CVS Indiana, L.L.C. ("CVS") is an Indiana corporation with its principal place of business at Woonsocket, Rhode Island. Defendant CVS is registered to do business in West Virginia and distributes opioids to consumers within West Virginia and Wood County.
- 81. Defendant Kroger Limited Partnership II ("Kroger") is an Ohio Limited Partnership with its principal place of business in Columbus, Ohio. Kroger is registered to do business in West Virginia and distributes opioids to consumers within West Virginia and Wood County.
- 82. Defendant Wal-Mart Stores East LP ("Wal-Mart") is a Delaware Corporation with its principle place of business in Bentonville, Arkansas, doing business as Wal-Mart Pharmacy Warehouse #46. Wal-Mart is registered to do business in West Virginia and distributes opioids to consumers within West Virginia and Wood County.
- 83. Defendant Miami-Luken, Inc. is an Ohio Corporation with its principal office located in Springboro, Ohio. Miami-Luken is registered to do business in West Virginia and distributes opioids to consumers within West Virginia and Wood County.
- 84. Upon information and belief, Defendant AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware Corporation with its headquarters at 1300 Morris Drive, Chesterbrook, Pennsylvania, 19087.
- 85. Defendant Amerisource does substantial business as a pharmaceutical distributor to retail pharmacies and institutional providers in the State of West Virginia and Wood County.
 - 86. Three of the Distributor Defendants, Cardinal, Amerisource, and McKesson are

three of the largest opioid distributors in Wood County.

- Defendants, and others similarly situated, which caused the opioid epidemic plaguing Spartanburg County. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). All potential Distributor Defendants conceal and prevent their discovery of necessary information to confirm their identities. Neither the DEA³³ nor the wholesale distributors³⁴ will voluntarily disclose the data necessary to identify with specificity the transactions which will for the evidentiary basis for naming all Distributor Defendants responsible.
- 88. Defendant Mark Radcliffe is a resident and citizen of West Virginia. At all relevant times, Defendant Radcliffe was a sales detail person and/or district manager in West Virginia and/or a management employee for Defendant Purdue.
- 89. Upon information and belief, Mark Ross is a resident and citizen of West Virginia.

 At all times material herein, Defendant Ross was a sales detail person for Defendant Purdue.
- 90. Upon information and belief, Jeff Waugh is a resident and citizen of West Virginia.

 At all times material herein, Defendant Waugh was a sales detail person for Defendant Purdue.
 - 91. Upon information and belief, Carol DeBord is a resident and citizen of West

³³ See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), Madel v. USDOJ, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

³⁴ See Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, Madel v. USDOJ, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

Virginia. At all times material herein, Defendant DeBord was a sales detail person for Defendant Purdue.

- 92. Upon information and belief, Amanda Bias Hayes is a resident and citizen of West Virginia. At all times material herein, Defendant Bias Hayes was a sales detail person for Defendant Purdue.
- 93. Upon information and belief, Doug Powers is a resident and citizen of West Virginia. At all times material herein, Defendant Powers was a sales detail person for Defendant Purdue.
- 94. Upon information and belief, Patty Carnes is a resident and citizen of West Virginia. At all times material herein, Defendant Carnes was a sales detail person for Defendant Purdue.

GENERAL FACTUAL ALLEGATIONS

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

- 95. The pain-relieving properties of opium have been recognized for millennia. Likewise, the magnitude of opium's potential for abuse and addiction has been well-known for ages and has led to its strict regulation world-wide. Opioids, similar to the illegal drugs opium and heroin, are substances that act on opioid receptors to produce morphine-like effects.
- 96. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain, particularly on the battlefield, and they were popularly used in a wide variety of commercial products such as pain elixirs, cough suppressants, and beverages. By 1900, an estimated 300,000

people were addicted to opioids in the United States,³⁵ and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

- 97. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.
- 98. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids: Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed a tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.
- 99. In 1986, Dr. Russel Portenoy, M.D., who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."³⁶
 - 100. Writing in 1994, Dr. Russel Portenoy, described the prevailing attitudes regarding

³⁵ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

³⁶ R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.³⁷

According to Dr. Russel Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain." 38

101. For all the reasons outlined by Dr. Russel Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them."³⁹

102. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety,

³⁷ R. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Current Status, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

³⁹ J. Loeser. Five crises in pain management, Pain Clinical Updates. 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety? 6 J. Pain Research 513, 514 (2013)).

nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

- 103. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed, up to and including doses that are "frighteningly high." At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.
- 104. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.
- 105. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.
- 106. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids,

⁴⁰ M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate." The FDA required that, going forward, opioid makers of long-acting formulations clearly communicate these risks in their labels.

107. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.⁴²

108. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants in the 1990s when their deceptive marketing began.

B. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS

109. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have intentionally failed to disclose the substantial scientific evidence demonstrating that chronic opioid therapy actually worsens patients' health.

http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed September 19, 2017).

⁴¹ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013) (emphasis in original).

⁴² FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at

- 110. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function on a long-term basis. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use.
- 111. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.⁴³
- 112. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.
- 113. Although opioids may work acceptably well during a limited, short period of time, long-term usage results in marked declines in patient's ability to function, their general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.⁴⁴
- 114. The foregoing is true both generally and for specific pain-related conditions. Studies of the long-term use of opioids for chronic lower back pain have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not permit patients to return to work or

⁴³ A. Furlan et al., Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan, 307(9) J. Am. Med. Ass'n 940 (2012).

⁴⁴ See A. Rubenstein, Are we making pain patients worse? Sonoma Medicine (Fall 2009).

physical activity. This failure is due in part to addiction and other side effects.

115. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other, non-opioid medications.

C. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

- 116. Prior to the Defendants' marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used on a short-term, temporary basis in order to treat acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those limited instances, the risks of addiction are considered low or of little significance.
- 117. By its very nature, the market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell their opioid products for both short term pain relief and for the treatment of long-term, chronic pain, they could achieve blockbuster levels of sales while exponentially increasing their profits. Further, Defendants recognized that the elevated risk of addiction associated with the long-term use of their highly-addictive, opioid products virtually guarantee that their blockbuster profits would continue indefinitely.
 - 118. Defendants knew that to increase their profits from the sale of opioids they would

need to convince doctors and patients that long-term opioid therapy was safe and effective. In other words, Defendants needed to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

- 119. Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors such as Plaintiff.
- 120. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort and pervert medical and public perception of existing scientific data.
- 121. As explained more fully herein, Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses ("CMEs"), and other "educational" materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but patently false "consensus" supporting the long-term use of opioids.

D. DEFENDANTS USED "UNBRANDED" MARKETING TO EVADE REGULATIONS AND CONSUMER PROTECTION LAWS

122. Pharmaceutical companies' promotional activity can be branded or unbranded; unbranded marketing typically focuses on education regarding a particular disease state or treatment rather than promoting a specific drug product. By using unbranded marketing in its communications, drug companies avoid the extensive regulatory framework governing branded

communications.

123. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks. 45 The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of prescribing those drugs to their patients.

124. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places additional restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular." "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material. ⁴⁷ The term "accompanying" is interpreted broadly to include promotional materials – posters, websites, brochures, books, and the like – disseminated by or on behalf of the manufacturer of the drug. ⁴⁸ Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

125. Branded promotional materials for prescription drugs must be submitted to the FDA when they are first used or disseminated. If, upon review, the FDA determines that a drug's marketing materials are misleading, it can issue either an untitled letter or a warning letter. The

⁴⁵ 21 U.S.C. 352(a); 21 CFR 202.1(e)(6); 21 CFR 202.1(e)(3); 21 CFR 1.21(a)

^{46 21} U.S.C 352(f); 21 U.S.C. 352(g); U.S. v. Sullivan, 68 S.Ct. 331, 335 (1948)

⁴⁷ 21 U.S.C.A. § 321(m)

⁴⁸ Kordel v. U.S., 69 S. Ct. 106, 110 (1948)

FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

- 126. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Defendants intentionally avoided branded promotional materials for the express purpose of escaping regulatory review of their claims.
- 127. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated and unbranded marketing materials materials that generally promoted opioid use but did not name a specific opioid while doing so. Through these unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.
- 128. By acting through third parties, Defendants were able to give the false appearance that their messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. Further, as one physician adviser to Defendants noted, third-party documents had not only greater credibility, but also broader distribution, as doctors did not "push back" at having materials, for example, from the non-profit American Pain Foundation ("APF") on display in their offices, as they would with drug company pieces.
- 129. As part of their marketing scheme, Defendants spread and validated their deceptive messages through the following unbranded vehicles ("the Vehicles"): (i) so-called "key opinion leaders" (*i.e.*, Physicians who influence their peers' medical practice, including but not limited to prescribing behavior) ("KOLs"), who wrote favorable journal articles and delivered supportive CMEs; (ii) a body of biased and unsupported scientific literature, ghostwritten by Manufacturer

Defendants and published by KOLs; (iii) treatment guidelines ghostwritten by Manufacturer Defendants and published as a direct result of KOLs reputation and involvement with the publishing organizations, which were distributed within Wood County causing injury within the County; (iv) CMEs by KOLs, deliberately conducted within West Virginia, attended by Wood County physicians, causing tortious injury within the County; and (v) unbranded patient education materials disseminated within West Virginia and Wood County through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which were deliberately influenced by Defendant-controlled KOLs, exercising their influence both directly and indirectly because they served in leadership roles in these organizations.

- 130. Defendants disseminated many of their false, misleading, imbalanced and unsupported messages through the Vehicles because they appeared to uninformed observers to be independent. Through unbranded materials, Defendants presented information and instructions concerning opioids generally that were false and misleading.
- Vehicles, including the KOLs, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials all Defendants knew were false, misleading, unsubstantiated, unbalanced, and incomplete from the very outset of the message's "creation" by the purportedly independent KOLs. As described herein, Defendants' sales representatives distributed third-party marketing material to Defendants' target audience that was deceptive.
- 132. Defendants took an active role in writing, guiding, reviewing, and approving many of the misleading statements issued by third parties, including the KOLs' statements, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted

in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain. The process described in this paragraph is commonly referred to as "Ghostwriting."

133. The unbranded marketing materials that Defendants assisted in creating and distributing either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks. All of these unbranded marketing materials were promoted by the KOLs falsely from the very outset as independent statements. The KOLs' false promotion of independence provided the unbranded marketing materials utilized by Manufacturer Defendants the credibility required to fraudulently induce physicians within West Virginia and Wood County to prescribe opioids for chronic pain.

a. Manufacturer Defendants' Misuse of KOLs

- and sponsored by Manufacturer Defendants solely because they promoted the aggressive treatment of chronic pain with opioids in return for the payment of vast sums of money by the Manufacturer Defendants. Pro-opioid KOLs have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. These pro-opioid KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of opioid therapy for chronic pain. They have served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through the KOLs, each of whom accepted money to promote the false marketing claims of Defendants.
 - 135. In return for their successful pro-opioid advocacy, KOLs received money, prestige,

recognition, research funding, and avenues to publish. The more successful the KOLs' deceptive promotion of Opioids for Chronic Pain, the more they were able to receive from the Manufacturer Defendants.

- 136. Defendants cited and promoted the KOLs and studies or articles by the KOLs to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications of truly independent doctors critical of the use of chronic opioid therapy.
- 137. Defendants carefully vetted their KOLs to ensure that they would remain onmessage and supportive of the agenda to falsely promote Opioids as safe for the treatment of Chronic Pain. Defendants also kept close tabs on the content of the materials published by the KOLs, if not authoring, editing, and/or revising them in their entirety prior to publication.
- 138. In their promotion of the use of opioids to treat chronic pain, the KOLs knew that their statements were false and misleading, or they recklessly disregarded the truth in doing so, but they continued to publish their misstatements to benefit the Defendants.

b. Defendants' Corruption of Scientific Literature through KOLs

139. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants, instrumentally relying on KOLs, misled physicians, patients, and health care payors into believing that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

- 140. To accomplish their goal, Defendants sometimes through third-party consultants and/or front groups commissioned, edited, and arranged for the placement of favorable articles in academic journals authored by KOLs.
- 141. Defendants' plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants' marketing departments and with Defendants' marketing and public relations consultants, ultimately being published and promoted by KOLs.
- 142. In these materials, Defendants (and their KOL surrogates) often claimed to rely on "data on file" or presented posters, neither of which are subject to peer review. Still, Defendants presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.
- 143. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature and by KOLs, even when Defendants knew that the articles distorted the significance or meaning of the underlying study. Most notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"), in a manner that makes it appear that the item reported the results of a peer reviewed study. It also cited two CME programs sponsored by Endo where KOLs were presenters. Defendants and the KOLs acting on their behalf failed to reveal that this "article" was actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received

opioids:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center

Waltham, MA 02154

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

144. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain, making the data useless for any generalization regarding the safety or efficacy of opioids for treating chronic pain. Even aside from chronic pain treatment, the letter notes that when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were followed, for how long. None of these serious limitations were disclosed when Defendants and KOLs acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

- 145. Dr. Jick has complained that his letter has been distorted and misused as indeed it has.
- 146. Defendants not only created and promoted favorable studies in the literature through the paid efforts of KOLs but, in order to discredit or suppress negative information, funded studies and articles that targeted articles contradicting Defendants' claims or raising concerns about chronic opioid therapy. In order to do so, Defendants, often with the help of KOLs, used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.
- 147. Defendants' strategy—to create, fund, plant, and promote supportive literature for citation as pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted their claims—was flatly inconsistent with their legal obligations. Defendants' strategy was intended to alter, and did alter, prescribing and consumer patterns, including those in Wood County, by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

c. Defendants' Misuse of Treatment Guides

148. Treatment guidelines authored with KOLs' influence but under the direction and control of Manufacturer Defendants have been particularly important in securing acceptance for chronic opioid therapy. The guidelines are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

i, FSMB

- 149. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.
- opioids for the treatment of pain. The 1998 edition of the guidelines, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught that opioids were "essential" for the treatment of chronic pain, including as a first prescription option, rather than that opioids could be appropriate in limited cases after other treatments had failed. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Wood County.
- 151. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including those in Wood County.
- 152. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medical education (CME) activity for prescribers of opioid

medications."

- 153. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by a KOL named Dr. Scott Fishman, M.D. Dr. Fishman was frequently hired by a consulting firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.
- 154. Responsible Opioid Prescribing was a signature piece of Dr. Fishman's work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.
- 155. Defendants relied on 1998 Guidelines to convey the alarming message that "undertreatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

ii. AAPM/APS GUIDELINES

156. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding

from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁴⁹ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was a KOL named Dr. Russel Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

- 157. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, M.D., received support from Defendants Janssen, Cephalon, Endo, and Purdue.
- 158. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in Wood County during the relevant time period, and were and are available online.
- 159. Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

iii. GUIDELINES THAT DID NOT RECEIVE DEFENDANTS' SUPPORT

160. The extent of Defendants' influence on treatment guidelines is demonstrated by the

⁴⁹ Haddox J., et al., The Use of Opioids for the Treatment of Chronic Pain – A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 6(1) Pain Forum 77-79 (1997)

fact that independent guidelines (the authors of which did not accept drug company funding) reached very different conclusions.

- Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects." 50
- 162. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence."⁵¹
 - 163. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain,

⁵¹ American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids (2011).

⁵⁰ Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment, 15 Pain Physician (Special Issue) S1-S66; Part 2 – Guidance, 15 Pain Physician (Special Issue) S67-S116 (2012).

issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.⁵²

d. Defendants' Misuse of CMEs

education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. With the support of Defendants, the KOLs become highly respected in their fields. As a result, they typically teach CMEs. The program is thought to be an independent, objective reflection of these physicians' medical expertise. As a result, CMEs can be especially influential with doctors. In fact, the Defendants used KOL-taught CMEs in West Virginia to influence the prescribing habits of doctors within West Virginia and Wood County, ultimately inducing Wood County to provide health insurance for its workforce and treatment to its citizens that allowed the prescribing of opioids for chronic pain, ultimately costing lost revenue.

165. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants, through KOLs, aimed to reach general practitioners, whose broad area of

⁵² Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf (accessed September 19, 2017).

practice and lack of expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

166. Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

167. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter." ⁵³

Based Management of Persistent and Breakthrough Pain, with KOLs Dr. Christine A. Miaskowski, M.D., and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009. It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer or non-cancer related has limited utility," and recommended dispensing "rapid onset opioids" for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," Actiq, and "fentanyl buccal table," Fentora, including in patients with chronic non-cancer pain. Dr. Miaskoski disclosed in 2009, in connection

⁵³ Opinion 9.0115, Financial Relationships with Industry in CME, Am. Med. Ass'n (Nov. 2011).

⁵⁴ Fine, Perry, et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Pain Medicine News (2009), https://www.yumpu.com/en/document/yiew/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (accessed December 29, 2017).

with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speaker's bureau. 55 Dr. Fine also received funding from Cephalon for consulting services.

169. Wood County physicians attended or reviewed Defendants' sponsored CMEs during the relevant time period and were misled by them.

be patient-advocacy and professional organizations) like APF, AAPM and others, Defendants could rely upon instructors to deliver messages favorable to them, as these organizations were dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measure the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. Defendants' Misuse of Patient Education Materials and Front Groups

171. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats." ⁵⁶ Physicians are more likely to prescribe a drug if a patient specifically requests it, and physicians' willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not

⁵⁵ 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

⁵⁶ Kanika Johar, An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices, 76 Albany L. Rev. 299, 308 (2013).

approved.⁵⁷ Recognizing this phenomenon, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

172. Defendants entered into arrangements with numerous Front Groups (i.e., groups purporting to be patient-advocacy and professional organizations) to promote the prescription of opioids for the treatment of chronic pain. Each one of these Front Groups depends largely, if not exclusively, upon Defendants for significant funding and, in some cases, depend wholly upon Defendants' funding for their continued survival. In addition to generating Defendants' promotional materials and programs supporting chronic opioid therapy to be provided to doctors and patients, the Front Groups also assisted Defendants' marketing efforts by responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on the use of opioids to treat chronic pain. Defendants created a symbiotic relationship with the Front Groups whereby Defendants funded them in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages. In turn, the supportive messages drove prescriptions and profits for Defendants and ensured continued funding of the Front Groups.

i. AMERICAN PAIN FOUNDATION

173. The most prominent and effective of Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than \$10 million in funding from opioid

⁵⁷ In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it, compared with 1% of those making no specific request. J.B. McKinlay et al., Effects of Patient Medication Requests on Physician Prescribing Behavior, 52(2) Med. Care 294 (2014).

manufacturers from 2007 until it closed its doors in May 2012.

- 174. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain treatment and minimized their risks, specifically the risk of addiction. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to "educate" patients about their "right" to pain treatment with opioids. All of the programs and materials were intended to, and did, reach a national audience, including residents of Wood County.
- 175. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. APF board member, Dr. Portenoy, explained the lack of funding diversity was one of the biggest problems at APF.
- 176. While APF held itself out as an independent patient advocacy organization, it simultaneously engaged in grassroots lobbying against various legislative initiatives that might regulate the prescription of opioids and protect patients from the risks associated with the unnecessary prescription of highly addictive and ineffective drugs. In stark contrast to its stated purpose, APF functioned principally as an advocate for the interests of Defendants, not patients.
- 177. In practice, APF operated in close collaboration with Defendants. APF submitted grant proposals seeking to fund activities and publications suggested by Defendants. APF also assisted in marketing projects for Defendants.
- 178. The intimate relationship between APF and Defendants demonstrates APF's clear lack of independence in its finances, management, and mission, and its willingness to allow Defendants to control its activities and messages strongly indicates that each Defendant that provided it with funding was able to exercise editorial control over its publications.
 - 179. In May 2012, the U.S. Senate Finance Committee began looking into APF to 46 of 115

determine the links - financial and otherwise - between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF then "cease[d] to exist, effective immediately," proving the degree of its dependence upon Defendants' financing as well as their control over it.

ii. THE AMERICAN ACADEMY OF PAIN MEDICINE

180. The American Academy of Pain Medicine ("AAPM"), with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein, and sponsored and hosted CMEs essential to Defendants' deceptive marketing scheme.

181. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

182. The conferences sponsored by AAPM heavily emphasized CME sessions on

⁵⁸ William Heisel, USC Annenberg Center for Health Journalism, Antidote: Investigating Untold Health Stories, Journalists Bag a Big One: The American Pain Foundation, https://www.centerforhealthjournalism.org/blogs/2012/05/14/journalists-bag-big-one-american-pain-foundation (accessed September 19, 2017).

opioids: 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs, Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Lynn Webster, M.D. was elected president of AAPM while under a DEA investigation. Another past AAPM president, KOL Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."⁵⁹

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

E. DEFENDANTS ACTED THROUGH KOLS AND FRONT GROUPS TO CREATE, PROMOTE, AND CONTROL UNBRANDED MARKETING

- 184. Like the tobacco companies that engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the industry-funded and directed Front Groups and KOLs to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superior efficacy of opioids to treat chronic pain.
- 185. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Despite knowing that this information was false and misleading, Defendants, Front Groups, and KOLs disseminated these misrepresentations nationwide, including to Wood County prescribers and patients.
- 186. One Vehicle for Defendants' marketing collaboration was the Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where

⁵⁹ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed September 19, 2017).

multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

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

188. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients. ⁶⁰ This was critical because a REMS that went too far in narrowing the uses or benefits or in highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts and adversely affect profits. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, rather than undermine, their deceptive marketing of opioids for chronic pain treatment.

⁶⁰ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

F. DEFENDANTS' MISREPRESENTATIONS

- 189. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and payors in Wood County. These promotional messages were intended to and did encourage patients to request, doctors to prescribe, and payors to pay for chronic opioid therapy.
- 190. Recognizing that doctors are the gatekeepers for controlling access to prescription drugs, not surprisingly, Defendants focused the bulk of their marketing efforts and multi-million dollar budgets on the professional medical community. As a controlled substance with significant regulatory barriers limiting access, Defendants knew doctors would not prescribe opioids to patients with common chronic pain complaints unless doctors were convinced that opioids had real benefits and minimal risks. Accordingly, Defendants concealed from prescribers, patients, and the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Instead, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, Wood County doctors began prescribing opioids on a long-term basis to treat chronic pain, a treatment choice that most (if not all) never would have considered prior to Defendants' campaign.
 - 191. Drug company marketing materially impacts doctors' prescribing behavior. 61

⁶¹ See, e.g., P. Manchanda & P. 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); I. 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 a 34% decline in on-label use of promoted drugs); see also A. Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs. Evidence shows that doctors who would otherwise not have prescribed opioids were, in fact, induced by Defendants' deceptive marketing to prescribe opioids for chronic pain as a result of Defendants' deceptive marketing.

192. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, 88% of the practitioner respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities. These results are the direct consequence of Defendants' fraudulent marketing campaign.

193. As described in detail below, Defendants:

- Misrepresented the truth about how opioids lead to addiction;
- Misrepresented that opioids improve function;
- Misrepresented that addiction risk of opioids can be managed;
- Misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- Falsely claimed that withdrawal is simply managed;
- Misrepresented that increased doses pose no significant additional risks to patients;
- Falsely omitted or minimized the adverse effects of opioids and

⁶² Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

overstated the risks of alternative forms of pain treatment.

- 194. Defendants' misrepresentations were aimed at doctors, patients, and payors.
- 195. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.⁶³
 - a. Defendants, Acting Individually and Collectively, Misrepresented the Truth About How Use of Opioids Leads to Addiction.
- 196. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, and aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and persuaded them that opioid addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for chronic pain. As both an intended and foreseeable result, doctors in Wood County prescribed more opioids to more patients, thereby enriching Defendants.
- 197. Each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, despite the complete lack of supporting scientific evidence.
- 198. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide* for People Living with Pain (2007), which fraudulently claimed that addiction is rare and limited to extreme cases of unauthorized dose escalations, opioid prescription fraud, or theft.
 - 199. Similarly, Endo sponsored a website, www.painknowledge.com, through APF,

⁶³ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

which falsely claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician.

- 200. Additionally, Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that patients prescribed opioids for *genuine* pain will not become addicted, a claim which is both unsupported and known to be false.
- 201. Likewise, Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA and APF, which, as set forth in the excerpt below, described the fact that opioids are addictive as a "myth" and falsely asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

Coloid mytha Myth: Opioid medications are s Jerges an discous hack Many groups whose that colodo are raede addictive when need properly for the management of caronac paid. Myth: Opioids male: it harder to Fort When near concerns for apareprint conditions, epicids may make the constitution and starting Moth: Opened doses have to get ligger over their because the best reactor to their East United the united time cause of your pain zets worse (such as with cancer a arthritis) you will be bable remain on the same descor beed

Although the term "rarely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial. The language also implies that the long-term use of opioids presents minimal risk of addiction to patients if the opioids are properly prescribed by a physician, which is untrue. The guide states as a "fact" that "[m]any studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

202. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[1]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid

pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the rate is so low as to be immaterial.

- 203. For another example, Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which inaccurately claimed that less than 1% of children prescribed opioids would become addicted.⁶⁴ This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."
- 204. In addition, in the 1990s, Purdue amplified the pro-opioid message with promotional videos featuring Dr. Portnoy and other doctors in which it was claimed, "the likelihood that treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."⁶⁵
- 205. As yet another example from the industry, Actavis's strategy and pattern of deceptive marketing is similarly evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages described above—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Wood County.
- 206. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in

⁶⁴ In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.
65 Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604 (accessed September 19, 2017).

daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have necessitated increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to inform doctors, via its sales representatives, of the greater risks associated with opioids at high doses.

- 207. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers before that date. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]." Certain risks that the FDA noted were misrepresented include the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."
- 208. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the

AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients, regardless of past abuse histories, amongst other deceptive statements as described above.

209. Rather than honestly disclose the risk of addiction, Defendants attempted to portray those who were concerned about addiction as callously denying treatment to suffering patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables: they suggested that doctors who *failed* to treat their patients' chronic pains with opioids were failing their patients and risking professional discipline, while doctors who prescribed long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that "exaggerated" concerns about the risk of addiction resulted in patients' pain being under-treated while opioids were over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon claims that "[d]espite the great benefits of opioids, they are often underused." The APF publication funded by Purdue, *A Policymaker's Guide to Understanding Pain & Its Management*, laments that: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty in obtaining adequate care include . . . misconceptions about opioid addiction."

210. Let's Talk Pain, sponsored by APF, AAPM and Janssen, likewise warns, "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say, "[b]ecause of the potential for abusive and/or addictive behavior, many health care professionals have been reluctant to prescribe opioids for their patients.... This prescribing environment is one of many barriers that may contribute to the undertreatment of pain,

⁶⁶ This claim also appeared in a 2009 publication by APF, A Reporter's Guide.

a serious problem in the United States."

b. Defendants, Acting Individually and Collectively, Misrepresented that Opioids Improve Function

- 211. Defendants produced, sponsored, or controlled materials with the expectation that, by instructing patients and prescribers that opioids would improve patient functioning and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy for patients in the belief that lack of improvement in quality of life could be alleviated by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.
- 212. Although opioids may initially improve patients' function by providing pain relief in the short term, no controlled studies of the use of opioids beyond 12 weeks has ever shown that opioids improve patients' function in the long-term. On the contrary, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work. ⁶⁷ Despite this lack of evidence of improved function, and the existence of evidence to the contrary, Defendants consistently promoted opioids as capable of improving patients' function and quality of life without disclosing the lack of evidence for this claim.
- 213. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience." 68
 - 214. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007),

⁶⁷ Jeffrey Dersh, et al., Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders, 33(20) Spine 2219-27 (Sept. 15,2008).

⁶⁸ Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, King Pharmaceuticals, Re: NDA21-260 (March 24, 2008).

sponsored by drug companies including Cephalon, Endo and Purdue, deceptively taught that relief of pain in itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

- 215. Cephalon and Purdue sponsored the APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The Treatment Options guide notes that non-steroidal anti-inflammatory drugs (e.g., Aspirin or Ibuprofen) have greater risks with prolonged duration of use, but there was no similar warning for opioids. The APF distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report, and it is currently still available online.
- 216. Through the APF, Endo sponsored a website, painknowledge.com, which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as well as "improved function" as benefits of opioid therapy.
- 217. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) in conjunction with the AAPM, ACPA, and APF. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- 218. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.

Opioid myths

Myth: Oproid medications are absent addictive.

Fact: Many studies show that opioids are needy addictive when used properly for the management of chronic pain.

Myth: Oproids make it harder to function normally

Fact: When used correctly for appropriate conditions, opioids may make it reser for people to live normally.

Myth: Optoid doses have to get bigger over time because the body gets used to them.

Fact: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.

- 219. Janssen sponsored a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and American Society for Pain Management Nursing whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," falsely implying that her experience would be representative despite the lack of statistical support.
 - 220. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its

Management (2011), which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients," with the implication these studies presented claims of long-term improvement.

Because of their long history of use, the clinical profile of opioids has been very well characterized. Multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving:

- Daily function
- Psychological health
- Overall health-related quality of life for people with chronic pain¹²

The sole reference for the functional improvement claim 1.) noted the absence of long-term studies and 2.) actually stated, "For functional outcomes, the other analgesics were significantly more effective than were opioids."

- 221. Purdue sponsored and Janssen provided grants to APP to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning."
 - c. Defendants, Acting Individually and Collectively, Misrepresented that Addiction Risk can be Effectively Managed

- 222. Defendants each continue to maintain to this day that most patients can safely take opioids long-term for chronic pain relief without becoming addicted. Presumably to explain to doctors the high incidence of patient opioid addiction, Defendants have recently acknowledged that some patients could become addicted, but that doctors can effectively avoid or manage that risk by using screening tools or questionnaires. These tools, they claim, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) and allow doctors to more closely monitor patients at greater risk of addiction.
- 223. There are three fundamental flaws in Defendants' representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that the addiction risk screening tools currently available are reliable, effective, capable of being applied correctly and consistently, or invulnerable to patient manipulation. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through the screening tools can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients identified through such screening tools as "low risk" can take opioids long-term without significant danger of addiction.
- 224. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. An Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse-deterrent formulations on

outcomes related to overdose, addiction, abuse or misuse."⁶⁹ Furthermore, attempts to treat high-risk patients, like those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening tests are not proven to work in the real world, even when the most well-intentioned doctors were misled to employ them.⁷⁰

225. Defendants' misrepresentations regarding the risk of addiction from chronic opioid therapy were particularly dangerous because they were aimed at general practitioners or family doctors (collectively "GPs"), who treat many chronic conditions but lack the time and expertise to closely manage patients on opioids by reviewing urine screens, counting pills, or conducting detailed interviews to identify other signs or risks of addiction. One study conducted by pharmacy benefits manager Express Scripts concluded, after analyzing 2011–2012 narcotic prescription data of the type regularly used by Defendants to market their drugs, that only 385 of the more than half million prescribers of opioids during that time period were identified as pain specialists.⁷¹

226. In materials they produced, sponsored, or distributed, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Defendants' marketing scheme contemplated a "heads we win; tails we win" outcome: patients deemed low risk were to receive opioids on a long-term basis without enhanced monitoring, while patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring —

⁶⁹ The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain, Agency for Healthcare Res. & Quality (Sept. 19, 2014).

⁷⁰ M. Von Korff, et al., Long-term opioid therapy reconsidered, 15595, Annals Internal Med. 325 (Sept. 2011); L. Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part I – Evidence Assessment, 15 Pain Physician S1 (2012).

⁷¹ Express Scripts Lab, A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain (December 2014).

with those added visits, tests, and monitoring to be paid for or reimbursed by payors, including Plaintiff. This, of course, led to a "heads you lose; tails you lose" outcome for patients (all of whom are subjected to an unacceptable risk of addition) and for payors, including Plaintiff.

- 227. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which falsely reassured patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."
- 228. Endo paid for a 2007 supplement available for continuing education credit in the Journal of Family Practice written by a doctor who became a member of Endo's speaker's bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* created by KOL Dr. Webster and linked to Janssen or (b) the *Screener and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. Purdue sponsored a 2011 webinar taught by Dr. Webster, entitled *Managing Patient's Opioid Use: Balancing the Need and Risk.* This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths."
 - d. Defendants, Acting Individually and Collectively, Misled Physicians, Patients, and Payors Through the Use of the Term "Pseudoaddiction"
 - 229. Defendants instructed patients and prescribers that signs of addiction are actually the product of untreated pain, thereby causing doctors to prescribe ever more opioids despite signs that the patient was addicted. The word "pseudoaddiction" was concocted by KOL Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for

chronic pain by KOL Dr. Portenoy, who consulted for Defendants Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction" – as if patients could not experience both.

- 230. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.
- 231. Cephalon and Purdue sponsored the Federation of State Medical Boards' Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, which are in fact signs of genuine addiction, are all really signs of "pseudoaddiction."
- 232. Purdue did not mention that the author who concocted both the word and the phenomenon it purported to describe became a Purdue Vice President; nor did Purdue disclose the lack of scientific evidence to support the existence of "pseudoaddiction."
- 233. Purdue posted an unbranded pamphlet entitled Clinical Issues in Opioid Prescribing on its unbranded website, Partners Against Pain.com, in 2005, and upon information and belief circulated this pamphlet after 2007. The pamphlet listed conduct including "illicit drug use and deception" that it claimed was not evidence of true addiction but rather was indicative of "pseudoaddiction" caused by untreated pain. It also stated, "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is untreated Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief.

⁷² J. David Haddox & David E. Weissman, Opioid pseudoaddiction – an iatrogenic syndrome, 36(3) Pain 363 (Mar. 1989).

Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

e. Defendants, Acting Individually and Collectively, Claimed Withdrawal is Simply Managed

- 234. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical dependence is not the same as addiction and can be addressed, if and when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants failed to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—an adverse effect that also makes it less likely that patients will be able to stop using drugs.
- 235. In materials Defendants produced, sponsored, and/or controlled, Defendants made misrepresentations to persuade doctors and patients that withdrawal from their opioids was not a problem and they should not be hesitant about prescribing or using opioids. These claims were not supported by scientific evidence.
- 236. A CME sponsored by Endo entitled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering a patient's opioid dose by 10% to 20% per day for ten days. This claim was misleading because withdrawal in a patient already physically dependent would take longer than ten days—when it is even successful at all.⁷³
- 237. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose

⁷³ See Jane Ballantyne, New Addiction Criteria: Diagnostic Challenges Persist in Treating Pain with Opioids, 21(5) Pain Clinical Updates (Dec. 2013).

the significant hardships that often accompany cessation of use.

f. Defendants, Acting Individually and Collectively, Misrepresented that Increased Doses Pose no Significant Additional Risks

- 238. Defendants claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses.
- 239. In materials Defendants produced, sponsored or controlled, Defendants instructed patients and prescribers that patients could remain on the same dose indefinitely, assuaging doctors' concerns about starting patients on opioids or increasing their doses during treatment, or about discontinuing their patients' treatment as doses escalated. These claims were not supported by scientific evidence.
- 240. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide taught that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the true figure was closer to 3,200 at the time.⁷⁴
- 241. Cephalon sponsored a CME written by KOL Dr. Webster, *Optimizing Opioid*Treatment for Breakthrough Pain, offered by Medscape, LLC from September 28, 2007 through

⁷⁴ Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

- December 15, 2008. The CME taught that non-opioid analysis and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.
- 242. Endo sponsored a website, *painknowledge.com*, through APF, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," at which point further dose increases would not be required.
- 243. Endo distributed a patient education pamphlet edited by KOL Dr. Portenoy entitled Understanding Your Pain: Taking Oral Opioid Analgesics, which was published on Endo's website. In Q&A format, it asked, "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. ... You won't 'run out' of pain relief."
- 244. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dose escalations are "sometimes necessary," even indefinite ones, but did not disclose the risks from high-dose opioids. This publication is still available online.
- 245. Purdue sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME was edited by KOL Dr. Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.
 - g. Defendants, Acting Individually and Collectively, Deceptively Omitted or Minimized the Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment
- 246. In materials they produced, sponsored, or controlled, Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

None of these claims was supported by scientific evidence.

247. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Defendants routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;" hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.

248. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose when the figure is closer to 3,200.⁷⁹ *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

249. Endo sponsored a website, painknowledge.com, through APF, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects that omitted

⁷⁵ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA- 2012-P-0818 (Sept. 10, 2013).

⁷⁶ H.W. Daniell, Hypogonadism in men consuming sustained-action oral opioids, 3(5) J. Pain 377-84 (2001).

⁷⁷ Bernhard M. Kuschel, The risk of fall injury in relation to commonly prescribed medications among older people – a Swedish case-control study, Eur. J. Pub. H. (July 31, 2014).

⁷⁸ Karen H. Seal, Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan, 307(9) J. Am. Med. Ass'n 940- 47 (2012).

⁷⁹ Robert E. Tarone, et al., Nonselective Nonaspirin Nonsteroidal Anti-Inflammatory Drugs and Gastrointestinal Bleeding: Relative and Absolute Risk Estimates from Recent Epidemiologic Studies, 11 Am. J. of Therapeutics 17-25 (2004).

significant adverse effects including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

250. Janssen and Purdue sponsored and Endo provided grants to APF to distribute *Exit* Wounds (2009), which omits warnings of the risk of potentially fatal interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

251. As a result of Defendants' campaign of deception, promoting opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.⁸⁰

G. DEFENDANTS' PROMOTION OF THEIR BRANDED DRUGS WAS ALSO DECEPTIVE

252. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called "detailers" to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in Wood County. By establishing close relationships with doctors, Defendants

⁸⁰ M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care, 870-878 (2013). For back pain alone, the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined from 39.9% to 24.5% of these visits; and referrals to physical therapy remained steady. See also J. Mafi, et al., Worsening Trends in the Management and Treatment of Back Pain, 173(17) J. of the Am Med. Ass'n Internal Med. 1573, 1573 (2013).

were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

253. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors' prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including to doctors in Wood County.

H. DEFENDANTS KNEW THAT THEIR MARKETING OF CHRONIC OPIOID THERAPY WAS FALSE, UNFOUNDED, AND DANGEROUS AND WOULD HARM PLAINTIFF AND ITS RESIDENTS

- 254. Defendants made, promoted, and profited from their misrepresentations individually and collectively knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers.
- 255. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and payors to pay for their opioids for chronic pain.

disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

I. DEFENDANTS FRAUDULENTY CONCEALED THEIR MISREPRESENTATIONS

- 257. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.
- 258. Defendants disguised their own roles in the deceptive marketing by funding and working through Front Groups purporting to be patient advocacy and professional organizations and through paid KOLs. Defendants purposefully hid behind the assumed credibility of the front organizations and KOLs and relied on them to vouch for the accuracy and integrity of Defendants' false and misleading statements about opioid use for chronic pain. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and approving their content. Defendants exerted their considerable influence on these purportedly "educational" or "scientific" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not public.
- 259. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear these items

were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of materials they cited and offered them as evidence for propositions the materials did not support. The true lack of support for Defendants' deceptive messages was not apparent to the vast majority of the medical professionals who relied upon them in making treatment decisions. The false and misleading nature of Defendants' marketing was not known to, nor could it reasonably have been discovered by, Plaintiff or its residents.

- 260. Defendants also concealed their participation by extensively using the public relations companies they hired to work with Front Groups to produce and disseminate deceptive materials.
- 261. Defendants concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the existence of claims that Plaintiff now asserts. Plaintiff did not discover the existence and scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through the public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put them on notice of potential claims.
- J. DISTRIBUTOR DEFENDANTS INTENTIONALLY FAILED TO TAKE ANY ACTION TO STOP THE MISUSE OF OPIOIDS, IN VIOLATION OF STATE AND FEDERAL LAWS AND REGULATIONS
- 262. The Distributor Defendants purchased opioids from manufacturers, such as the named Manufacturer Defendants herein, and sold them to pharmacies throughout Wood County.
- 263. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Wood County.

- 264. West Virginia state law imposes a duty upon the Defendant Wholesale Distributors to provide effective controls and procedures to guard against theft and diversion of controlled substances. 15 CSR 2-4.2.1.
- 265. West Virginia state law imposes a duty upon the Defendant Wholesale Distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the West Virginia Board of Pharmacy of suspicious orders when discovered. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 15 CSR 2-4.4.
- 266. Federal regulations similarly impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).
- or orders deviating substantially from a normal pattern. See 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether an order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of

the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

- 268. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. See Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. Id.
- 269. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.⁸¹
- 270. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.⁸²
 - 271. As the DEA advised the Distributor Defendants in a letter to them dated September

⁸¹ See 1970 U.S.C.C.A.N. 4566, 4571-72.

⁸² Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, Masters Pharm., Inc. v. U.S. Drug Enf't Admin. (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. See generally HDA, About, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. See generally NACDS, Mission, https://www.nacds.org/about/mission/ (last visited Aug. 21, 2017).

27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." 83

272. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.⁸⁴

273. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

274. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007. 88 This letter reminds the Defendants of their statutory and regulatory duties to "maintain"

⁸³ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

⁸⁴ See Brief for HDMA and NACDS, supra, 2016 WL 1321983, at *4 ("[R]egulations... in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

⁸⁵ Rannazzisi Letter, supra, at 2.

⁸⁶ Id. at 1.

⁸⁷ Id. at 2.

⁸⁸ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., 76 of 115

effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system

U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

89 Id.

would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.⁹⁰

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious." ⁹¹

- 275. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society." 92
- 276. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution

⁹⁰ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), Supra.

⁹¹ See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), Supra.

⁹² See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., Cardinal Health, Inc., V. United States Dept. Justice, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *2 [hereinafter Brief of HDMA].

Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest. 93

- 277. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.
- 278. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.⁹⁴
- 279. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's community, is excessive for the medical need of the community

⁹³ Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

⁹⁴ See Rannazzisi Decl. ¶ 10, filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

and facially suspicious; some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.⁹⁵

- 280. Additionally, the Distributor Defendants' grossly negligent distribution to pharmacies outside the County also caused an influx of illicit diversion of opioids within Wood County.
- 281. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the state Board of Pharmacy.
- 282. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders that deviated substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants could foreseeably anticipate that opioids were likely to be diverted to Plaintiff's Community.
- 283. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse, and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.
- 284. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.
 - 285. The Distributor Defendants breached their duty to "design and operate a system to

⁹⁵ Masters Pharmaceuticals, Inc., 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the West Virginia Board of Pharmacy of suspicious orders when discovered, in violation of their duties under federal and state law.

- 286. The Distributor Defendants failed to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.⁹⁶
 - 287. The federal and state laws at issue here are public safety laws.
 - 288. The unlawful conduct by the Distributor Defendants is purposeful and intentional.
- 289. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.
- 290. The Distributor Defendants acted with actual malice, have consciously disregarded the rights and safety of other persons, and said actions have caused substantial harm.
- 291. The Distributor Defendants' repeated shipments of suspicious orders over an extended period, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.
- 292. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

⁹⁶ See Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

- 293. Distributor Defendants have refused to recognize any duty beyond reporting suspicious orders. In Masters Pharmaceuticals, the HDMA, a trade association run by the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:
 - a) The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."⁹⁷
 - b) The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."
 - c) The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."
 - d) The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties." 100
 - e) The Associations alleged (inaccurately) that "DEA's regulations [sensibly impose] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." ¹⁰¹

⁹⁷ Brief for HDMA and NACDS, supra, 2016 WL 1321983, at *4-5.

⁹⁸ Brief for HDMA and NACDS, supra, 2016 WL 1321983 at *8.

⁹⁹ *Id*. at *14

¹⁰⁰ Id. at *22

¹⁰¹ Id. at *24-25

- f) Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors which lack the patient information and the necessary medical expertise to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands." ¹⁰²
- 294. The positions taken by the trade groups is emblematic of the position taken by the Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs. 103
- 295. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218-219, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstances prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.
- 296. Wholesale Distributor McKesson was recently forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative

¹⁰² Id. at *26

¹⁰³ See Brief of HDMA, supra, 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." ¹⁰⁴

297. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)." McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers" including the McKesson Distribution Centers located in 12 different locations, any of which could have foreseeably caused the diversion of opioids into Wood County. Due to these violations, McKesson agreed that its authority to distribute controlled substances from these 12 facilities would be partially suspended. Due to distribute controlled substances from these 12 facilities would be partially suspended.

298. As punishment for its wrongdoing, McKesson agreed to pay a \$150 million fine

Department of Justice, Administrative Memorandum of Agreement, January 17, 2017, https://www.justice.gov/opa/press-release/file/928476/download, (accessed October 27, 2017).

¹⁰⁵ Department of Justice, Administrative Memorandum of Agreement at 4, Supra.

¹⁰⁰ Id.

¹⁰⁷ Id. at 6.

and suspend the sale of controlled substances from distribution centers in several states. 108

299. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA. 109 In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed in its obligations. 110 The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations." 111

300. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

301. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. 113

¹⁰⁸ Id. at 8.

¹⁰⁹ Id. at 4.

¹¹⁰ Id.

¹¹¹ *Id*

¹¹² U.S. Dep't of Justice, Evaluation and Inspections Div., Office of the Inspector Gen., *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf, (accessed October 27, 2017).

These actions include the following:

- a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an *Order to Show Cause* and *Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland

Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

- h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against facilities it owned in South Carolina, Florida, New York, and Washington.
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.
- 302. Defendant Rite Aid agreed that it failed to comply by State and Federal requirements after a pattern of failing to meet its duty was discovered by the Department of Justice. ¹¹⁴ In January 2009, Rite Aid Corporation and Subsidiaries agreed to pay \$5 million in civil penalties to resolve violations in eight states of the Controlled Substances Act. Nonetheless, Rite Aid continues to dispense opioids in quantities significantly higher than medically necessary to residents of Wood County.

¹¹⁴ Department of Justice, Rite Aid Corporation and Subsidiaries Agree to Pay \$5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (Published January 12, 2009).

303. Defendant CVS has paid over \$40 million in fines as the result of opioid prescription investigations by the DEA and the United States Department of Justice. Yet CVS continues to dispense opioids in quantities significantly higher than medically necessary to residents of Wood County. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the Department of Justice that its stores and pharmacists had been violating their duties under the Controlled Substances Act, by filling prescriptions with no legitimate medical purpose. CVS has settled similar cases with Florida, Oklahoma, Massachusetts, New Hampshire, and Rhode Island, for filling forged prescriptions for addictive painkillers and filling prescriptions with no legitimate medical purpose.

304. Operating within West Virginia and Wood County, the Distributor Defendants must have neglected their duties given that 109.4 retail prescriptions were dispensed per 100 residents. The total allows for one full prescription for each man, woman, and child within the County.

305. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any

Centers for Disease Control, U.S. County Prescribing https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html (2016)

Rates,

¹¹⁵ Press Release, Drug Enf't Admin., DEA Reaches \$8 million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances (Feb. 12, 2016.) https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled (Accessed February 20, 2018).

violations of law before a suspension order can be issued. 117

306. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

307. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity." Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results in favor of profits.

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

¹¹⁷ Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowedenforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13d7c704ef9fd9 story.html?utm term=.61697ec67e05; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post. Mar. 2017, https://www.washingtonpost.com/investigations/us-senator-calls-forinvestigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9a05d3c21f7cf story.html?utm term=.014176059151; Eric Eyre, DEA Agent: "We Had No Leadership" Flood of Pain Amid Pills,

http://www.100daysinappalachia.com/2017/02/22/dea-agent-no-leadership-west-virginia-amid-flood-pain-pills/, Charleston Gazette-Mail, Feb. 18, 2017, (all accessed October 27, 2017).

¹¹⁸ Lenny Bernstein et al., How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Wash. Post, Oct. 22, 2016, <a href="https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.6d9936e87c93, (accessed October 27, 2017).

¹¹⁹ Scott Higham et al., Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-

⁹⁴⁹c5893595e story.html?utm term=.0b845f727e2c, (accessed October 27, 2017).

McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

- 309. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.
- 310. Meanwhile, the opioid epidemic rages unabated in the nation, the State of West Virginia, and in Plaintiff's community.
- 311. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Wood County and elsewhere, harming Plaintiff.
- 312. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Wood County and elsewhere, causing diversion of opioid pain killers within Wood County.
- 313. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.
- 314. The sheer volume of the increase in opioid pain medications, including oxycodone, being distributed to retailers, should have put the Distributor Defendants on notice to investigate

and report such orders.

- 315. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Wood County and elsewhere.
- 316. Upon information and belief, the Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Wood County from 2007 to the present.
- 317. The Defendant Distributors knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Wood County.
- 318. The Defendant Distributors also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Wood County.
- 319. The Distributor Defendants made substantial profits from the opioids sold in Wood County and elsewhere.
- 320. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the residents of Wood County.
- 321. By the actions and inactions described above, the Distributor Defendants caused great harm to Wood County.
- 322. The Distributor Defendants have abandoned their duties imposed under federal and state law; taken advantage of a lack of DEA law enforcement; and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.
- K. DESPITE KNOWING ABOUT THE RISK OF ADDICTION, MISUSE, AND ABUSE TO THE COUNTY AND WEST VIRGINIA THE SALES REPRESENTATIVE DEFENDANTS MISREPRESENTED THE SAFETY OF OPIOIDS FOR TREATING CHRONIC PAIN TO THE MEDICAL COMMUNITY
- 323. At all relevant times, Defendant Radcliffe was a Purdue sales detail person and/or district manager in West Virginia and was responsible for the promotion, advertisement, sale,

marketing, and/or distribution of OxyContin in West Virginia, including to those who prescribed and/or consumed the drug in the County and across the state.

- 324. Defendant Radcliffe was a Purdue sales detail person and/or district manager in West Virginia who promoted, marketed, sold and/or distributed OxyContin in West Virginia, including to prescribers and consumers within the County and across the state.
- 325. At all relevant times, Defendants Ross, Waugh, DeBord, Bias Hayes, Powers, and Carnes were Purdue sales representatives who promoted, advertised, marketed, sold and/or distributed OxyContin in West Virginia, including prescribers and consumers within the County and across the state.
- 326. The Sales Representative Defendants owed a duty of care to Plaintiff in the marketing, advertising, sale, and promotion of Purdue's highly dangerous, addictive and abuse-prone OxyContin.
- 327. The Sales Representative Defendants owed a Plaintiffs a duty to use reasonable care because, *inter alia*, it was foreseeable, and in fact known to Defendant Radcliffe and the Sales Representative Defendants that their conduct would result in injuries and damages to and within the County.
- 328. The Sales Representative Defendants were aware that OxyContin posed a risk of harm to West Virginia and Wood County, including its risks relating to addiction, abuse, and diversion, all of which were occurring and ongoing in the County and across the state.
- 329. The Sales Representative Defendants had actual knowledge that the safety, efficacy, addictiveness, abuse and diversion potential of OxyContin was negligently and recklessly marketed, advertised, promoted, and sold.

- 330. The Sales Representative Defendants knew that OxyContin was highly susceptible to addiction, misuse, abuse and/or diversion and the risk for each of these factors bore a direct relationship to the amount and volume of opioids being prescribed within West Virginia and Wood County, and in fact that Oxycontin was being misused, abused and diverted across the country, including within Wood County and across West Virginia, for example:
 - a) The Sales Representative Defendants witnessed first-hand the devastating effects of OxyContin in and around West Virginia and Wood County that OxyContin was being regularly abused, misused, and diverted;
 - b) The Sales Representative Defendants were informed, alerted, questioned, and/or made aware by prescribers throughout West Virginia and Wood county that OxyContin was being abused, misused, and diverted and, on at least one occasion, that a family member of a prescriber within West Virginia had overdosed on OxyContin in West Virginia;
 - c) Memos from sales representatives within West Virginia and/or surrounding areas were distributed and/or discussed between Purdue employees and representatives, including Defendant Radcliffe, which contained "red flags" about OxyContin and detailed reports from prescribers that their patients were misusing, abusing, and diverting OxyContin;
 - d) The Weirton Daily Times, a local newspaper based in Hancock County and distributed within the surrounding counties published an article entitled "Too Much Heroin and Too Many OxyContins" which contained a warning from William Beatty, the head of the drug task force in Hancock County. In the article, Mr. Beatty warned that "[t]oo much heroin and too many OxyContins are hitting the streets in the Upper Ohio Valley... People can die very easily from either one." After the article's publication, two Purdue sales representatives visited the Weirton Daily Times and made copies of the article. Upon information and belief, the sales representatives that obtained the information worked for Defendant Radcliffe, at the direction of him, and reported this information to him, causing him to have actual knowledge of the abuse and diversion occurring in West Virginia; and,
 - e) Defendant Radcliffe was made aware of medical literature and studies that concluded OxyContin was more attractive to drug abusers compared to other prescription pain pills.

- 331. The Sales Representative Defendants knew or should have known that OxyContin was unreasonably dangerous and highly addictive and highly susceptible to abuse and diversion, yet knowingly and negligently provided false and/or misleading information to prescribers within West Virginia, including Wood County and West Virginia, concerning the risk of addiction, abuse and diversion of OxyContin and of its relative safety.
- 332. The Sales Representative Defendants also represented to prescribers throughout West Virginia and Wood County that OxyContin was safe for use in chronic pain patients.
- 333. Upon information and belief, the Sales Representative Defendants purposefully or negligently caused the flooding of communities across West Virginia, including Wood County, with highly dangerous and addictive opioids knowing that these drugs were being misused, abused and diverted.
- 334. The Sales Representative Defendants knew or should have known that opioid addiction, abuse and/or diversion and their related consequences would injure and damage communities across the country including Wood County. As discussed herein, applicable West Virginia laws, and the industry standards applicable to the manufacture, advertising, labeling, distribution. and sale of opioid drugs exist to control addiction, abuse and/or diversion associated with these dangerous drugs. Moreover, the Sales Representative Defendants were aware their actions and the effects their actions were having in communities across the country, including Wood County. The escalating amounts of highly addictive drugs being prescribed and distributed, and the sheer volume of these prescription opioids, further alerted the Sales Representative Defendants that addiction was fueling increased addiction, abuse and diversion, and that legitimate medical purposes were not being served.

- 335. Despite this knowledge, and in direct disregard for the known and foreseeable harms to Plaintiffs, the Purdue Sales Representative Defendants negligently and recklessly breached their duty to Plaintiffs by, but not limited to:
 - a) Negligently and recklessly marketing, advertising, and promoting OxyContin in Wood County and surrounding areas;
 - b) Misrepresenting and misstating the addiction, abuse and/or diversion potential of OxyContin;
 - c) Overstating the benefits of chronic OxyContin therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;
 - d) Downplaying and/or ·obscuring OxyContin's serious risks and adverse outcomes, including the risk of addiction, abuse, diversion, overdose, and death;
 - e) Overstating OxyContin's superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;
 - f) Mischaracterizing the difficulty of withdrawal from OxyContin and the prevalence of withdrawal symptoms;
 - g) Marketing OxyContin for indications and benefits that were not supported by substantial evidence; and,
 - h) Misrepresenting to health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of misuse or abuse.
- 336. At all times material herein, the Sales Representative Defendants willingly and knowingly participated in Defendant Purdue's deceptive and misleading marketing scheme, were aware of its existence, and did nothing about it. The Purdue Sales Representative Defendants promoted, perpetuated, and furthered Purdue's deceptive and misleading marketing campaign by knowingly falsely promoting and marketing OxyContin as less addictive and less subject to abuse and diversion than other opioids.
- 337. The Purdue Sales Representative Defendants had a financial incentive to knowingly provide false information to prescribers within West Virginia and Wood County and their pay and continued employment depended on the volume of sales and prescriptions written within their

District and surrounding areas. Upon information and belief, the Sales Representative Defendants received extremely lucrative bonuses, trips, and other items of value as a result of their success in pushing OxyContin into the communities of West Virginia.

338. Defendant Radcliffe further trained his sales representatives to employ various tactics to evade physicians' questions regarding OxyContin's addictiveness and likelihood of addiction, misuse, abuse, and/or diversion and to misrepresent and conceal facts relating to OxyContin safety. By way of example, and not limitation, Defendant Radcliffe trained his sales representatives to be "Audible Ready" when questioned about street-abuse and to misrepresent OxyContin's addictiveness and likelihood of abuse, diversion, and misuse. In a memo to one of his sales representatives, Defendant Radcliffe wrote:

You continue to get hammered with pre-1990 attitudes about opioids. Dr. Steinberg shocked me! This Harvard trained physician and expert for medical cases said to you "Do you know how many days it takes to get addicted? Five and then they are addicted!" The pharmacist at Clark's informed us that they are doing "everything they can to slow it down (OxyContin)." Despite these relentless attacks, you've done a good job of remaining "Audible Ready" on the street abuse issue and not letting the "phobic" sell you. Distinguish between iatrogenic addiction (<1 % of patients) and substance abusers/diversion (about 10% of the population abuse something: weed; cocaine; heroin; alcohol; valium; etc.).

- 339. Upon information and belief, after receiving reports from prescribers and medical professionals that OxyContin was being abused and diverted in and around West Virginia, and that problems associated with OxyContin were metastasizing "like a cancer," Defendant Radcliffe instructed his sales team to ride out the controversy, ignore abuse reports, and "sell through it."
- 340. On information and belief, utilizing Purdue and the Manufacturer Defendant's deceptive marketing as further detailed herein, Defendant Waugh has sold opioids for Purdue in West Virginia since 1998; Conducts speaker programs attended by physicians from across the

state; received sales incentives trips in 2000, 2008, 2012, and 2016; is a district sales leader; and has trained other sales representatives.

- 341. Defendant Radcliffe and the Purdue Sales Representative Defendants knew their marketing and the information they and their sales team provided was a substantial factor in physicians, patients, and others prescribing, purchasing or using opioids in West Virginia and Wood County. In fact, within a year of being promoted to District Manager for West Virginia, Defendant Radcliffe's West Virginia district soared to Purdue's top rated District (up from No. 42 the previous years).
- 342. At all times material herein, prescribers and consumers within West Virginia and in Wood County relied upon the representations made by Defendant Radcliffe, the Purdue Sales Representative Defendants, and their sales team and their reliance was justified.
- 343. As stated herein, Defendant Radcliffe's and the Purdue Sales Representative Defendants' breach of duty bears a causal connection with and/or proximately resulted in the harm and damages to the Plaintiffs.
- 344. As a direct and proximate result of Defendant Radcliffe's and the Purdue Sales Representative Defendants' actions, as set forth herein, Plaintiffs have suffered and continue to suffer injury and damages, including but not Limited to, incurring excessive costs related to diagnosis, treatment, and cure of abuse and/or. addiction or risk of addiction to opioids; bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement associated with opioid addiction, abuse and diversion; and property damage.

FIRST CAUSE OF ACTION FRAUD (AGAINST ALL DEFENDANTS)

- 345. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 346. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:
 - The Manufacturer Defendants' and the Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
 - The Manufacturer Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
 - The Manufacturer Defendants' and the Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
 - The Manufacturer Defendants' and the Sales Representative Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
 - The Manufacturer Defendants' and the Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
 - The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible,

- "independent third party" appearance and allowing them to sidestep labeling regulations in violation of West Virginia and Federal law;
- The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and,
- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating West Virginia and Federal law by not reporting these doctors instead.
- 347. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

- 348. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.
- 349. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants' put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon (and were right to rely upon) Defendants' misrepresentations and omissions, as stated above.
- 350. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied upon (and were right to rely upon) the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.
- 351. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff had no knowledge of the Defendants' falsehoods and Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.
- 352. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

SECOND CAUSE OF ACTION UNJUST ENRICHMENT (AGAINST ALL DEFENDANTS)

- 353. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
 - 354. The doctrine of unjust enrichment is meant to prevent the wrongful retention of a 100 of 115

benefit in violation of good conscience and fundamental principles of justice and equity, or to prevent a double recovery. Unjust enrichment permits recovery of that amount the defendant has been unjustly enriched at the expense of the Plaintiff.

- 355. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint above, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.
- 356. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.
- 357. Defendants wrongdoing directly caused Plaintiff to suffer increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue, without receiving any of the purported benefits deceptively promoted by Defendants.
- 358. Defendants acts and practices alleged herein were motivated by a desire to retain and increase market share and profits, and were undertaken in bad faith.
- 359. Wood County has suffered injuries in paying for opioids, and the direct costs resulting from opioid use as a result of Defendants' unlawful conduct and are entitled to restitution or disgorgement.
- 360. Manufacturer Defendants and Sales Representative Defendants' have been unjustly enriched in the form of increased revenues and profits as a result of their deceptive marketing in violation of the laws of the state of West Virginia. Under equitable principles and due to its unjust enrichment, Defendants should be required to disgorge any profits, plus interest, that were obtained

as a result of its misrepresentations.

361. Distributor Defendants have been unjustly enriched in the form of increased revenues and profits as a result of their willful failure to design and implement a system to detect suspicious orders in violation of state and federal laws. Once such a system was designed, the Distributor Defendants continued being unjustly enriched by profiting from a willful failure to report suspicious orders once detected.

THIRD CAUSE OF ACTION NEGLIGENT MISREPRESENTATION (AGAINST ALL DEFENDANTS)

- 362. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 363. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:
 - The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
 - The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
 - The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
 - The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and law

- enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to sidestep labeling regulations in violation of West Virginia and Federal law;
- The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and,

- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating West Virginia and Federal law by not reporting these doctors instead.
- 364. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.
- 365. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiff.
- 366. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.
- 367. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants' put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions, as stated above.
- 368. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.
- 369. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services,

law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.

370. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

FOURTH CAUSE OF ACTION PUBLIC NUISANCE (AGAINST ALL DEFENDANTS)

- 371. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 372. Defendants, through the actions described in this Complaint, have created, or were a substantial factor in creating, a public nuisance by unreasonably interfering with a right common to the general public that worked to hurt, inconvenience, or damage and interfere with the enjoyment of life or property.
- 373. The County of Wood and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience. The interference of this right resulted from Defendants' illegal and deceptive marketing and distribution of opioids.
- 374. Defendants, individually and acting through their employees and agents, and in concert with each other, made unreasonable and/or unlawful use of their financial resources in an improper, indecent, and unwarranted fashion to wage a massive campaign of misrepresentations and omissions of facts, negligence, and violation of state laws material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:
 - The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using 105 of 115

- addictive opioids;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to sidestep labeling regulations in violation of West Virginia and Federal law;
- The Manufacturer Defendants' and Sales Representative Defendants' endorsing and/or assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the

- distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and,
- The Distributor Defendants' holding themselves out as law-abiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating West Virginia and Federal law by not reporting these doctors instead.
- 375. The activities of Defendants that created a public nuisance worked as an obstruction or injury to Wood County and its residents, producing a material annoyance, inconvenience, discomfort, and/or hurt on the County and its residents by causing them to suffer actual damages directly caused by Defendants' deceptive, negligent, and/or unlawful behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.
- 376. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.
- 377. At all times relevant to the Complaint, Defendants exercised control over the instrumentalities constituting the nuisance, Defendants' actions were a substantial factor creating the public nuisance, and the public nuisance was foreseeable to Defendants. Without Defendants'

actions, opioid use would not have become so widespread in Wood County, and the opioid epidemic that now exists would have been averted or would be much less severe.

FIFTH CAUSE OF ACTION CONSTRUCTIVE FRAUD (AGAINST ALL DEFENDANTS)

- 378. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 379. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above, including:
 - The Manufacturer Defendants' and Sales Representative Defendants' marketing of opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
 - The Manufacturer Defendants' and Sales Representative Defendants' creating, sponsoring, and/or assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
 - The Manufacturer Defendants' and Sales Representative Defendants' disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
 - The Manufacturer Defendants' and Sales Representative Defendants' distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
 - The Manufacturer Defendants' and Sales Representative Defendants' sponsoring, directly distributing, and/or assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids

versus NSAIDs:

- The Manufacturer Defendants' providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to sidestep labeling regulations in violation of West Virginia and Federal law:
- The Manufacturer Defendants' and Sales Representative Defendants' endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' developing and/or disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- The Manufacturer Defendants' and Sales Representative Defendants' assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- The Manufacturer Defendants' and Sales Representative Defendants' creating, endorsing, and/or supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- The Manufacturer Defendants' and Sales Representative Defendants' exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- The Manufacturer Defendants' and Sales Representative Defendants' making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing; and,
- The Distributor Defendants' holding themselves out as lawabiding distributors but instead withholding from law enforcement the names of prescribers they knew to be facilitating the diversion and over-prescribing of their products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs Defendants knew would reach these same prescribers, violating West Virginia and Federal law by not

reporting these doctors instead.

- 380. Defendants should have known at the time that they made their misrepresentations and omissions that they were false.
- 381. Defendants should have, at the least, investigated the truth or falsity of their representations to Plaintiff.
- 382. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.
- 383. Given the incredible resources the Manufacturer Defendants and Sales Representative Defendants put into crafting their misrepresentations to pervade nearly every source of trusted medical information, Plaintiff and its residents reasonably relied upon (and had the right to rely on) the Defendants' misrepresentations and omissions, as stated above.
- 384. Given the infinitely better-resourced and highly sophisticated nature of the Distributor Defendants' practices, and their intimate knowledge of state and federal legal requirements, Plaintiff and its residents reasonably relied on (and had the right to rely on) the Distributor Defendants to uphold its legal requirements and not commit intentional, material omissions to law enforcement for the sake of its own profits.
- 385. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff had no knowledge of the Defendants' falsehoods and Plaintiff and its residents suffered actual pecuniary damage directly caused by Defendants' deceptive behavior resulting in increased expenditures on public healthcare services, law enforcement, the justice system, child and family services as well as lost productivity and lost tax revenue.
- 386. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of

punitive damages in an amount to be determined by the jury at the trial of the matter.

SIXTH CAUSE OF ACTION NEGLIGENCE (AGAINST ALL DEFENDANTS)

- 387. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.
- 388. All defendants have a duty to behave in a reasonable manner to avoid causing harm to Plaintiff and others similarly situated.
- 389. The Federal Food, Drug, and Cosmetic Act ("FDCA") places restrictions on branded marketing. It prohibits the sale, in interstate commerce, of drugs that are "misbranded." A drug is "misbranded" if the label is false or misleading "in any particular." "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material. Furthermore, the FDCA specifies that drug advertisements must include a true statement of information and an advertisement fails to satisfy this requirement if it is:
 - a) "false or misleading with respect to side effects, contraindications, or effectiveness" 122; or,
 - b) "Contains a representation or suggestion that a drugs is safer than it has been demonstrated to be by substantial evidence or substantial experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." 123
 - 390. The Manufacturer Defendants and Sales Representative Defendants' breached their

^{120 21} U.S.C 352(a)

¹²¹ 21 U.S.C.A. § 321(m)

^{122 21} CFR 202.1(e)(5)(i)

^{123 21} CFR 202.1(e)(6)(iv)

duties within Wood County and West Virginia, including those specified by the FDCA when:

- marketing opioid drugs as safe and effective for the long-term treatment of chronic pain conditions when they were not, for the purpose of deceiving physicians into using addictive opioids;
- creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Defendants' own unbranded publications and on internet sites Defendants operated that were marketed to and accessible by consumers;
- distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse; indicating that screening tools effectively prevent addiction; and that abuse-deterrent opioids reduce tampering and abuse;
- sponsoring, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- providing significant financial support to pro-opioid KOL doctors and Front Groups so they would make deceptive statements concerning the use of opioids to treat chronic pain while maintaining a more credible, "independent third party" appearance and allowing them to side-step labeling regulations in violation of West Virginia and Federal law;
- endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- developing and disseminating misleading scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly

- educating them on new pain standards; and,
- making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.
- 391. West Virginia State Law at 15 CSR 2-4.4 and Federal law at 21 CFR § 1301.74(b) impose a non-delegable duty upon the Distributor Defendants to "design and operate a system to disclose . . . suspicious orders of controlled substances. The [Distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [Distributor]. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." The stated purpose of the statutory scheme is to reduce the widespread diversion of controlled substances, like opioids, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. 125
- 392. The Distributor Defendants breached their duties within Wood County and West Virginia, including as provided by state and federal law, and in many cases have admitted such breach, by:
 - Failing to design and operate a system to disclose suspicious orders of opioids;
 - Once compelled to design and operate a system to disclose suspicious orders of opioids, failing to report suspicious orders as required; and,
 - Failing to avoid filling suspicious orders that were ultimately diverted.
- 393. All of the aforementioned statutory provisions are designed to protect both individuals and the community-at-large, like Plaintiff Wood County and the State of West Virginia, from the addictive properties of opioids and the damages caused by opioid addiction,

^{124 21} CFR § 1301.74(b)

¹²⁵ 1970 U.S.C.C.A.N. 4566, 4571-72

which includes the current opioid epidemic caused by Defendants that Plaintiff is forced to cope with and ameliorate by use of public funds.

- 394. As a direct and a proximate result of Defendants' acts and omissions that breached their legal duties of care, Defendants and their agents have caused Plaintiff to suffer damages by (among other things) incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, the County has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, law enforcement services, first responder services, and child and family services for County Residents and using County resources in relation to opioid use and abuse. Additionally, the County has suffered lost productivity from its workforce, thereby losing much needed tax revenue.
- 395. The Defendants' acts are willful and wanton. In addition to actual damages, the Plaintiff is entitled to a reasonable amount of punitive damages in an amount to be determined by the jury at the trial of the matter.

PRAYER FOR RELIEF

WHEREFORE Plaintiff demands judgment against Defendants, jointly and severally, awarding Plaintiff:

- i. Compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- ii. Damages, costs, and reasonable attorney's fees;
- iii. A reasonable amount of punitive damages to be determined by the jury at the trial of the matter;
- iv. Interest, costs, and disbursements;
- v. An injunction forcing Defendants to abate the opioid epidemic ravaging West Virginia and Wood County, enjoining the Defendants from marketing opioids as a.) safe for use in chronic pain patients; b.) carrying a low risk of addiction in long term use; and c.) needed in patients

exhibiting signs of "pseudoaddiction."

vi. Such other and further relief as this Court deems just and proper.

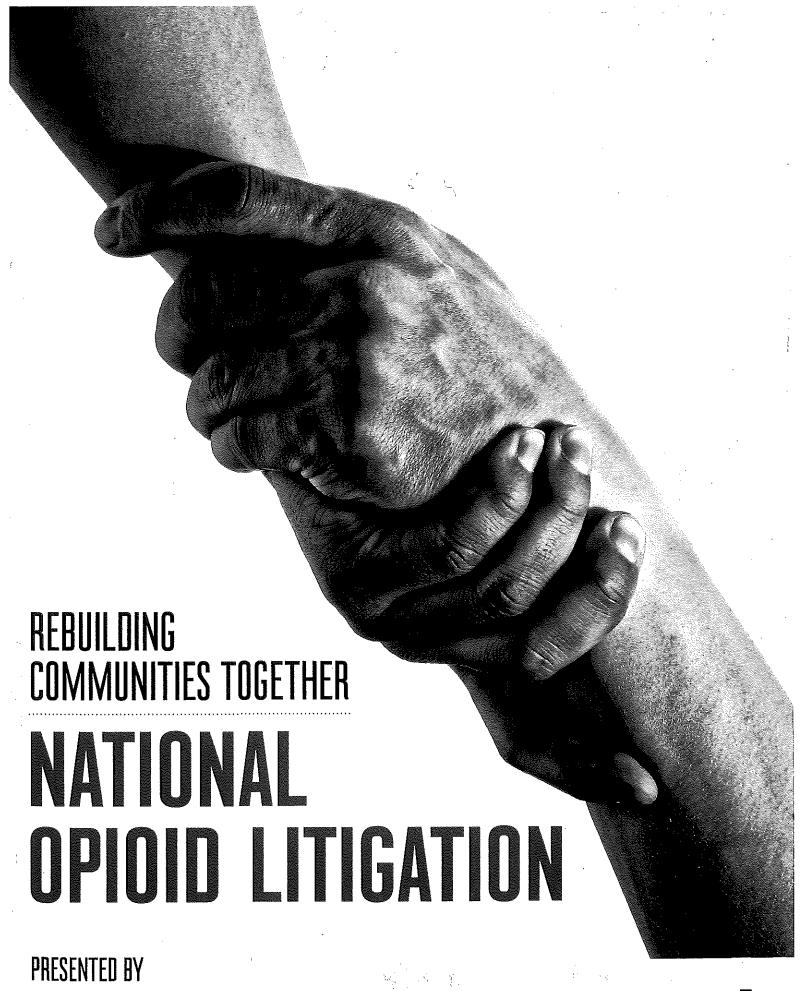
Dated: February 28, 2018

Respectfully Submitted,

-and-

/s/ Joseph Cappelli (Pro Hac Vice Pending)
/s/ Carmen De Gisi (Pro Hac Vice Pending)
/s/ R. Joseph Kramer (Pro Hac Vice Pending)
/s/ Marc J. Bern (Pro Hac Vice Pending)
MARC J. BERN & PARTNERS LLP
60 E. 42nd Street, Suite 950
New York, NY 10165
(800) 529-5432
opioidlitigation@bernllp.com

Attorneys for Plaintiff











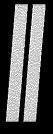




Our country is in the midst of a public health crisis stemming from a flood of opioids pouring into our cities and counties. These opioids are destroying our families, taking the lives of our loved ones, and sapping tax dollars and resources from our communities.

This opioid epidemic has been fueled by the greed of the corporate elite which includes drug manufacturers and distributors. Despite being required by federal and state law to detect and report "suspicious" orders of opioids they **chose not** to comply.

This has to stop. These companies need to be held accountable. We can help.



IN 2016 THERE WERE **OVER 42,249 DEATHS**INVOLVING PRESCRIPTION OPIOIDS – THIS IS 5X HIGHER THAN IN 1999

www.cdc.gov/drugoverdose/epidemic/index.html

ABOUT OUR LEGAL TEAM

We are unlike any other firm or attorney group. As opposed to some firms who are attempting to pursue this litigation on their own, we have formed a consortium comprised of some of the preeminent trial firms in the country that specialize in pharmaceutical litigation.

This Consortium was not cobbled together to fight a single battle. Recognizing that the target defendants are some of the richest corporations in the country we are prepared to go the distance and hold them accountable.

We are leaders in opioid litigation having filed some of the first cases in the country and having cases already working through the courts. Currently representing more than 200 governmental entities, our Consortium has filed more opioid cases across the country than any other group and is currently representing clients in more than ten states. Throughout this process, our firms have worked together seamlessly and successfully.

All six firms in our legal team are nationally recognized litigation firms that have built a reputation on their ability and willingness to litigate to verdict complex disputes against some of the world's largest companies. Large cases and powerful defendants are nothing new to us. We have fought and won cases against giants such as Big Tobacco, BP, Bayer, Merck, and DuPont to name just a few.

Whether large or small, we are committed to representing local governments - cities, towns, and counties and ensuring that they each are justly compensated for the public health crisis and costs imposed on them by the manufacturers and distributors of opioids.













MULTI-DISTRICT LITIGATION (MDL)

In December 2017, the cases brought against opioid manufacturers and distributors were consolidated in front of Judge Dan Polster in the Northern District of Ohio into a multi-district litigation ("MDL"). The MDL process permits the temporary transfer of civil lawsuits to one district court for pretrial consideration and/or consolidation. This creates efficiency and consistency by reducing the risk of contrary legal opinions and by allowing for coordinated discovery.

OUR TEAM HOLDS FIVE KEY LEADERSHIP POSITIONS IN THE MDL

Our legal team led the way toward the creation of the MDL, in the best interests of our clients. The benefits to our clients include consistency in the legal rulings and opinions of the presiding judge, an efficient and coordinated discovery process, and lower costs by preventing redundant and repetitive efforts from being made at the county's expense.

FOUR THINGS THAT SEPARATE OUR CONSORTIUM FROM OTHER FIRMS AND GROUPS:

1. Pioneers of the Wholesale Distributor Litigation

Our Consortium was the first to pursue litigation against the wholesale distributors on behalf of municipalities and filed the motion seeking formation of an MDL proceeding on behalf of the other public entity clients we represent.

Being the first to litigate these cases on behalf of counties and cities also means we have the most experience developing crucial evidence and litigating the common arguments being made by defendants. We have already conducted an in-depth investigation into the facts giving rise to potential liability of the opioid manufactures and distributors and are already engaged in focus groups and mock trials to test trial strategy and defenses.

2. Our MDL Leadership

The six national law firms that comprise our legal team are considered giants in the MDL world and between them have been actively involved in most every major mass tort litigation since the days of asbestos. Between our six firms we have 28 lawyers across the country currently working full-time on this project, with an additional 200 attorneys and hundreds of support staff at our disposal.

This experience, combined with our extensive client list, our opioid litigation experience, and our stature within the MDL community has led to us receiving five of the twenty-two leadership roles on the Opioid MDL including Co-Lead Counsel (Paul Farrell, Greene Ketchum), Co-Liaison Counsel (Troy Rafferty, Levin Papantonio), and three Plaintiff's' Executive Committee positions (Peter Mougey, Levin Papantonio; Roland Tellis, Baron & Budd; Mike Fuller, McHugh Fuller). This is an incredible benefit to our clients, ensuring that their community's cries for help are heard.

3. Former DEA and Exclusive Preeminent Witnesses

60 Minutes has aired several exposes that have highlighted the nefarious conduct of the pharmaceutical distributors and featured interviews of former DEA agents that have been retained by our Consortium under agreements that they testify exclusively for our group. (The Whistleblower, Redemption, 10/15/17).

Additionally, we have retained many of the country's preeminent experts in the fields of addiction medicine, pain management, epidemiology, public health, urban and rural blight, the economics of addiction, and others (e.g. Presidents of Medical Schools, Universities, and Pharmacy Schools, as well as the heads of several governmental agencies), many of whom have published extensively on the subject of the opioid epidemic. These experts will help determine the amount needed to implement a strategic plan that will compensate your community for past and ongoing damages.

4. Experienced Trial Lawyers

The members of our Consortium are all trial law firms with unmatched experience in pharmaceutical litigation. Unlike many firms, we are staffed, experienced, and able to take our clients' cases to trial, if the need arises. No matter the case, no matter the client, we will do what's best for each of them, whether that's taking the case to trial or negotiating a settlement.

OUR LEGAL TEAM WAS NOT CREATED MPLY TO WIN A SMALL BAT

we have created a team, a partnership, that is made to win the war, and it is a war that must be waged on the opioid crisis and those that fuel it and profit from it. We must hold the perpetrators of this crisis accountable and begin to rebuild our communities that have been ravaged by these drugs.

AN INDUSTRY CREATED **EPIDEMIC**

The manufacturers and distributors of prescription opioids have created this opioid epidemic by generating a population that is physically and psychologically dependent on opioids (the demand) and conspiring to provide floods of prescription opioids which are not medically necessary and will ultimately become available for illicit use or sale (the supply).

These manufacturers and distributors have been repeatedly investigated and sanctioned by regulators for abdicating their legal duties. For example, within the last several years alone, the largest opioid distributors in the nation, as well as certain manufacturers, have been fined hundreds of millions of dollars for their failure to report suspicious orders to the DEA and prevent diversion of these dangerous drugs. Many of these same defendants have been subject to prior litigation by states and counties arising out of the prescription opioid crisis.

However, the fines and prior litigation have not stopped the flood of opioids into our communities and have provided little - if any - relief to our communities.

For years, the distributors and manufacturers of prescription opioids have failed to report or halt suspicious orders, while funneling millions of pills into our communities.

MANUFACTURERS AND DISTRIBUTORS ARE RESPONSIBLE THEY KNEW!

WHO ARE THE MANUFACTURERS?

- Purdue Pharma
- Endo Health Solutions
- Janssen Pharmaceuticals
- Mallinckrodt
- Cephalon
- Actavis
- · Insys Therapeutics
- Teva Pharmaceuticals

WHAT DO THEY MANUFACTURE?

- Oxycodone
- Hydrocodone
- Fentanyl

WHO ARE THE DISTRIBUTORS?

The "Big Three"

- McKesson Corporation
- Cardinal Health
- · AmerisourceBergen Drug Corp.

OTHER WHOLESALE DISTRIBUTORS

- Miami-Luken
- Masters Pharmaceuticals

PHARMACY DISTRIBUTORS

- Wal-Mart
- CVS
- Walgreens
- Rite Aid

OPIOID DISTRIBUTION SYSTEM THE DISTRIBUTORS' AND MANUFACTURERS' RESPONSIBILITY TO

PREVENT DIVERSION

To understand why these companies are liable for the epidemic that is crippling our country, it is helpful to know how the system of drug distribution is designed to work.

1970 CONTROLLED SUBSTANCES ACT (CSA)

Congress enacted this law to create a "closed system" for the distribution of controlled substances and designed to prevent diversion of legally produced substances into illicit markets. This act stripped the manufacturers of the ability to sell directly to retailers and created a link in the distribution chain between Big Pharma and pharmacies.

With this act, distributors and manufacturers became legally bound to identify, investigate, and report suspicious orders of opioids to authorities. These distributors and manufacturers have access to nonpublic data showing the volume and pattern of opioid sales nationwide and have a legal duty to spot and report red flags in the distribution chain to authorities and to halt suspicious orders before shipment.

These pharmaceutical companies are supposed to serve as the gatekeepers - the watch dogs - for preventing opioid abuse. However, for years, the distributors and manufacturers of prescription opioids have failed to report or halt suspicious orders, while continuously funneling millions of pills into communities.

Distributors and manufacturers of opioids systematically and fraudulently violated their statutory duties to prevent diversion of their drugs and to notify the DEA of suspicious orders. Through their scheme, the distributors and manufacturers of opioids repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the manufacturers and distributors allowed hundreds of millions of pills to enter the illicit market, allowing them to generate obscene profits.

THE DISTRIBUTOR

The pharmaceutical distributors are the first line of defense and are supposed to play the role of "beat cops" in preventing the flow of controlled substances to illegitimate uses that can lead to abuse, addiction and blight.

Distributors are legally required to be on alert for suspicious orders by pharmacies - such as unusual size, frequency, or pattern - and to report these to the relevant authorities to be investigated.













Rather than controlling the flow of pills and alerting authorities to suspicious orders, the distributors have chosen to abuse their privileged position, lining their pockets by shipping massive quantities of drugs to pharmacies and dispensaries. They have breached the very industry standards they helped enact and that has led to our present-day epidemic.

McKesson, Cardinal, and their distributor cronies admit that they are the gatekeepers for preventing opioid abuse, stating: "distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances... and reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach." The distributors make this admission in the Industry Compliance Guidelines they themselves created to comply with legal mandates - and then wholly ignored.

Federal and state laws give cities and counties the means to hold these distributors accountable for their actions and to stop the influx of these powerful drugs.



In January 2017, McKesson, the largest drug distributor in the nation, was fined a record \$150 million by the federal government for its blatant failure to report suspicious orders in violation of federal law. Cardinal Health, another member of the "Big Three" drug distributors, was fined \$44 million for its own failures to report suspicious narcotic orders to the DEA.

THE MANUFACTURER

Manufacturers of controlled substances are under the same legal obligations as distributors to prevent drug diversion and are also required to notify DEA of suspicious orders. But they don't.

In July of 2017, the DEA for the first time sanctioned an opioid manufacturer for failing to report suspicious opioid orders. Pursuant to a memorandum of understanding between manufacturer Mallinckrodt and the DEA, Mallinckrodt paid a \$35 million civil penalty for violating federal laws that mandate suspicious order reporting.

CHARGEBACK SYSTEM/SCHEME

Mallinckrodt was caught operating what is known in the industry as a "chargeback" system. Mallinckrodt sold opioids to a wholesale distributor at a higher than usual price, and then offered the distributor a substantial rebate in exchange for the distributor's downstream customer sales information or "chargeback data". This chargeback data allows manufacturers, like Mallinckrodt, to obtain knowledge of suspicious opioid orders.

The "chargeback" system is not unique to Mallinckrodt. An investigation performed by our Consortium has discovered that this practice is widespread throughout the industry, and that manufacturers have embraced shipping suspicious orders of opioids as an integral part of their business model. Therefore, manufacturers of opioids such as Purdue Pharma, Teva, Endo, Cephalon, and Janssen may also be liable for opioid-related damages.

FALSE AND DECEPTIVE MARKETING CLAIMS

Before the 1990s, generally accepted standards dictated that patients should only use opioids short-term for acute pain. The use of opioids for chronic pain was discouraged or even prohibited due to evidence of patients developing a tolerance to opioids which lead to the serious risk of addiction and other side effects.

WE BELIEVE THAT MANUFACTURERS KNEW THEIR DRUGS WERE ADDICTIVE, BUT AGGRESSIVELY MARKETED THEM FOR THE TREATMENT OF CHRONIC PAIN THROUGH DIRECT AND INDIRECT MARKETING.

In spite of this evidence, opioid manufacturers have conducted, and continue to conduct, marketing campaigns designed to decrease the fear of prescribing opioids and to encourage and persuade doctors and patients that opioids can and should be used for chronic pain. This resulted in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids.

Manufacturers have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though no scientifically reliable evidence to support the manufacturers' claims existed.

WHERE ARE THEY MAKING THESE CLAIMS? THEY'RE NOT JUST SELLING ADDICTION OUIETLY IN A DOCTOR'S OFFICE OR AT A MEDICAL CONFERENCE THEY'RE IN YOUR LIVING ROOM, ON YOUR COMPUTER, AND IN YOUR MAIL THEY'RE EVERYWHERE YOU ARE.

These manufacturers spend MILLIONS OF DOLLARS ON PROMOTIONAL **ACTIVITIES AND MATERIALS**

that falsely deny or trivialize the risks of opioids while

ERSTATING THE BENEFITS of using them for chronic pain.

Manufacturers' false representations include:

- downplayed the serious risk of addiction,
- 2. created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that doctors should treat the signs of addiction with more opioids,
- 3. exaggerated the effectiveness of screening tools to prevent addiction,
- 4. claimed that it is easy to manage opioid dependence and withdrawal,
- denied the risks of higher opioid dosages, and
- exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

CAUSES OF ACTION

The conduct outlined above showing the conduct of manufacturers and distributors of opioids supports several claims for damages. We propose filing lawsuits based on public nuisance, false marketing, RICO, and negligence, among other claims. Through these claims we will demand that the mega-corporations who caused this epidemic fund the clean-up efforts.

PUBLIC NUISANCE

Manufacturers and distributors of opioids have created an epidemic within our cities and counties and we will demand that they fund the abatement of this nuisance.

FALSE AND FRAUDULENT MARKETING

Manufacturers of opioids may be held liable for their false and fraudulent marketing activities that have directly led to and exacerbated the opioid epidemic. Claims here include negligent misrepresentation, civil conspiracy, fraud and fraudulent misrepresentation.

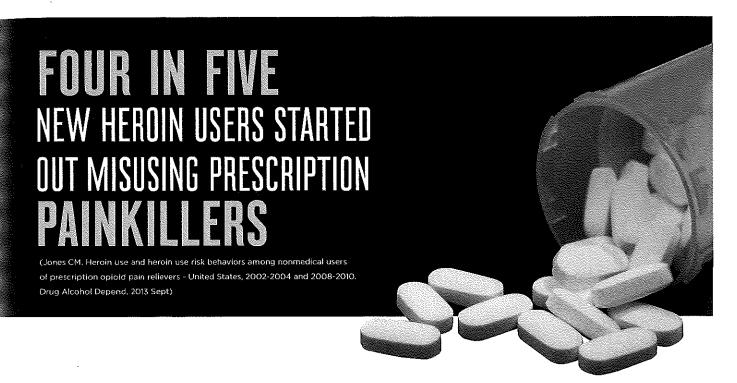
RICO (RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT)

Additionally, as more information becomes available on the distribution methods of opioid distributors and manufacturers, it becomes clearer that these entities were working hand-in-hand to maximize their profits at the expense of the health and well-being of American citizens. The federal RICO statute is the perfect tool to hold them accountable for the harm they have caused.

NEGLIGENCE

Finally, distributors and manufacturers also face liability for negligence. Federal regulations require distributors and manufacturers of opioids to be on the lookout for, detect, and report suspicious orders of opioids. Distributors and manufacturers violated industry standards of care by breaching their duty to identify and report suspicious opioid orders to the DEA or other relevant state agencies.

There is no doubt that these violations directly contributed to the opioid epidemic that is running rampant across the nation, and without question, substantial damages have been incurred by cities and counties. These costs should be borne by the negligent distributor and manufacturer defendants.



POTENTIALLY RECOVERABLE DAMAGES

The companies' known violations of these laws give rise to strong claims for significant equitable and monetary relief. Potentially recoverable damages may include:

- 1. Money wrongfully paid for opioids through government-payor programs including employee insurance,
- 2. costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from oploid-related addiction or disease, including overdoses and deaths,
- 3. costs for providing treatment, counseling, rehabilitation services,

- 4. costs for providing treatment of infants born with opioid-related medical conditions,
- 5. costs for providing welfare or protective services for children whose parents suffer from opioidrelated disability or incapacitation, and
- 6. costs directly associated with law enforcement and public safety relating to the opioid epidemic. Local governments may also be entitled to injunctive relief to prevent further unlawful distribution of these drugs.

DAMAGE MODEL WHAT IS RECOVERABLE FOR LOCAL GOVERNMENTS?

Our Consortium recommends pursuing a damage model that is aggressive, expansive, and encompasses both retrospective and prospective aspects. Our team of experts will help identify the impact of this crisis on your community.

A successful outcome would include action to address and end the current opioid crisis in addition to compensating your community for its past and ongoing damages resulting from defendants' conduct that caused the current opioid epidemic.

While they are not exact equivalents, good examples of the type of outcomes which we believe would be successful and achievable may be found in the tobacco and the California lead paint litigation. In both cases, governmental entities were awarded damages as well as ongoing relief to combat what was recognized to be a continuing crisis. Members of our Legal Team were instrumental in the tobacco litigation. The tobacco defendants continue to pay damages on an annual basis, totaling over \$200 billion, and the California lead paint defendants have been ordered to fund an abatement fund estimated to be \$600 million to \$1.15 billion in ten California counties and cities, based on the same public nuisance theory at the heart of our Legal Team's proposed case strategy.

Retrospectively, our lawsuit will seek to recover the funds that your community has already spent addressing the crisis. This will include funds spent on obvious and direct expenses, including:

- · EMS and other first responders
- Drugs such as Naloxone (Narcan)
- Medical Examiner expenses
- Public Hospital expenses
- Increased law enforcement expenses

- · Drug courts
- Increased jailing expenses
- Substance abuse programs
 (including education, prevention, and treatment)
- Increased expenses due to Child Welfare and Dependency docket associated with child welfare.

Prospectively, our lawsuit will ask (and then answer at trial) the question:

"What will it take to put your community and its citizens back into the position it was in before the opioid crisis began – how much will it cost to clean up the mess?"

There is no doubt that the target defendants in this litigation have created a public nuisance within your community and we will demand that these defendants foot the bill for abating that nuisance.

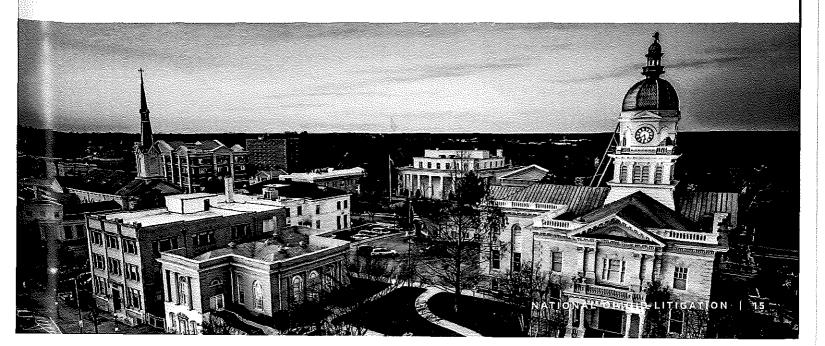
Our Consortium generally envisions an abatement fund covering three broad areas.

First, we believe funding for education is essential. It is important that we get into the school systems and ensure that children understand that the pills in their parent's cupboards are just as dangerous as a heroin needle. They also need to understand that if a needle goes into their arm one time, it won't be the last.

Second, funding is needed to support law enforcement and jailing so that the community can stay safe while your community works to addressing this crisis.

NO UP-FRONT COSTS
OUR CONSORTIUM WILL FRONT
ALL COSTS OF THE LITIGATION.
OUR CLIENTS PAY NO FEE
UNLESS WE RECOVER.

Third, and likely most importantly, to truly have a chance at rehabilitating the community funding is needed for healthcare and additional addiction recovery facilities that will help put an end to the cycle and plague of addiction. This will require extensive resources – and deservedly so.



SEVERITY OF THE OPIOID EPIDEMIC

Now that we know who and what created this epidemic, we need to understand how bad it is.

The Manufacturers' and Distributors' efforts have been wildly successful. Opioids are now the most prescribed class of drugs.

GLOBALLY, OPIOID SALES GENERATED \$11 BILLION IN REVENUE FOR DRUG COMPANIES IN 2010



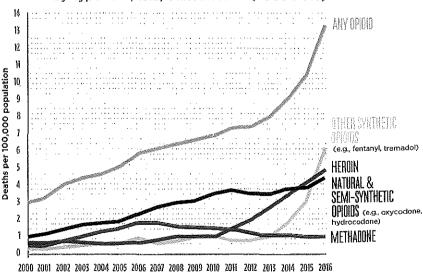
SALES IN THE UNITED STATES EXCEEDED \$8 BILLION IN REVENUE ANNUALLY SINCE 2009

In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain."

This epidemic has resulted in a flood of prescription opioids available for illicit use or sale and a population of patients physically and psychologically dependent on them. When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids, like heroin.

OVERDOSE DEATHS INVOLVING OPIOIDS

by Type of Opioid, United States (2000-2016)



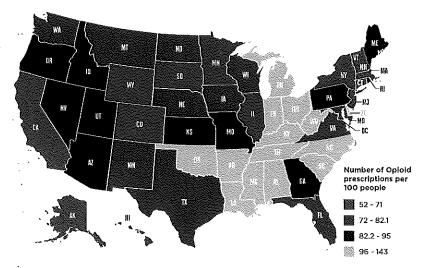
(CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER)



LIKE BIG TOBACCO, BIG PHARMA HAS ABSOLUTELY HAMMERED RURAL COMMUNITIES WITH A CONSTANT FLOOD OF OPIATES.

OPIOID PRESCRIBING

- We are experiencing the consequences of 25+ years of prescribing more opioids at higher doses.
- Between 1991 and 2016 sales of these prescription drugs have
- During 2015, an estimated 12,462,000 PERSONS aged 12 years or older in the U.S. misused prescription pain relievers in the past year.



(SOURCE: IMS, National Prescription Audit (NPA), 2012)

SOME STATES HAVE MORE OPIOID PRESCRIPTIONS PER PERSON THAN OTHERS BUT EVEN THE LOW AREAS HAVE OVER 50 PRESCRIPTIONS PER 100 PEOPLE.

DRUG ADDICTION AND OVERDOSE DEATHS

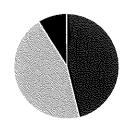
Prescription drug addicts are normal people. They're our neighbors, our children, our parents, our friends. The harsh reality is that anyone who takes prescription opioids can become addicted to them. In fact, as many as one in four patients receiving long-term opioid therapy in a primary care setting struggles with opioid addiction as a result. And once addicted, it can be hard to stop.

- Between 1999-2013 opioids claimed 175,000 lives and the sales of these prescription drugs have quadrupled.
- This pales in comparison to the 42,249 DEATHS IN 2016 ALONE.

This is 5x higher than in 1999 - and it continues to grow - destroying lives, families, and communities. (CDC, Prescription Drug Overdose data)

A HIGH COST TO **OUR COMMUNITIES**

In the United States, prescription opioid abuse costs are about \$55.7 billion annually. (CDC, Prescription Drug Overdose data)



\$26 BILLION WORKPLACE COSTS (e.g., lost productivity)

SZŐ BILLÍBB REATHCARE COSTS (e.g., abuse treatment)



MORE THAN 2.000

people are treated in emergency departments for misuse of opioids.

OUR LEGAL TEAM

Levin Papantonio | levinlaw.com

Levin Papantonio is a nationally recognized litigation firm that has built a reputation on its willingness to litigate to verdict complex disputes against some of the world's largest companies. The firm routinely litigates cases that require thousands of attorney hours and millions in expenses.

The firm pioneered the tobacco litigation and recent victories by Levin Papantonio attorneys in the nationwide DuPont C8 litigation helped bring a \$670 million settlement in February 2017.

Baron & Budd | baronandbudd.com

Baron & Budd, PC was founded in 1977 and has offices in Dallas, Austin, Baton Rouge, New Orleans, Los Angeles and San Diego. Baron & Budd is one of the largest and most accomplished plaintiffs' law firms in the country.

Greene Ketchum | greeneketchum.com

Greene, Ketchum, Farrell, Balley & Tweel LLP is considered one of the most experienced regional firms in the fields of medical malpractice and coal mining accidents. Greene Ketchum played a prominent role in the financing and litigation of thousands of asbestos cases over the past 30 years. Their skilled advocacy has returned millions of dollars in verdicts for their clients in both trial settings and settlements.

McHugh Fuller | mchughfuller.com

McHugh Fuller Law Group, established in 2006, is a trial firm that specializes in complex litigation and trials in the health and medical fields. The firm functions as an elite trial team made up of experienced litigators and legal writers.

The attorneys at McHugh Fuller have tried hundreds of cases, obtaining multi-million-dollar verdicts in courts throughout the country.

Hill Peterson | hpcbd.com

Founded in 1980, Hill, Peterson, Carper, Bee & Deitzler has extensive legal experience along with a broad network of resources to undertake a wide variety of complicated claims including, but not limited to Mass Torts and Class Action Litigation, Defective Drug Litigation, and Opioid Distribution Liability.

Hill Peterson's attorneys were awarded the prestigious Trial Lawyer of the Year award by Public Justice in 2005 for their work on the successful class action litigation Leach, et al. v. E. I. du Pont de Nemours and Company representing plaintiffs who suffered various cancers and other illnesses due to exposure through drinking water to the chemical ammonium perfluorooctanoate ("PFOA" or "C-8"), a chemical utilized in the manufacture of Teflon.

Powell & Majestro | powellmajestro.com

Founded in 2002, Powell & Majestro has been a premier resource for clients who want experienced, dynamic legal representation. The firm handles complex litigation including the representation of individuals and others who are victims of consumer fraud or are injured by defective products. Powell & Majestro attorneys are nationally recognized for their work in serious injury claims and have successfully tried numerous civil cases to verdict in state and federal courts.

OUR ATTORNEYS



Paul Farrell

Paul Farrell, Jr. is a trial lawyer and partner at Greene, Ketchum, Farrell, Bailey & Tweel LLP. Mr. Farrell filed the first cases in the country on behalf of public entities against the wholesale distributors of prescription opiates in southern West Virginia and is focusing his efforts to abate the nationwide opioid epidemic. His work has earned him a spot as co-lead counsel in the National Prescription Opiate Litigation MDL.

Mr. Farrell is recognized as a premier trial lawyer in the field of medical malpractice and appellate advocacy, making some thirty appearances before the West Virginia Supreme Court.

Mr. Farrell filed some of the first transvaginal mesh (TVM) cases in the country and served as liaison counsel on the executive committee for the 7 Pelvic Repair System Products Liability MDLs in Charleston, West Virginia. These MDLs consolidated 80,000 cases and resulted in several multi-million dollar jury verdicts. Mr. Farrell served as trial counsel for the TVM litigation, successfully trying two beliwether cases to verdicts in excess of \$20 million.



Burton LeBlanc

Baron & Budd shareholder Burton LeBlanc has successfully represented both individuals and governmental entities, including the States of Hawaii, Mississippi, Louisiana, and West Virginia in complex consumer fraud litigation. He was part of Baron & Budd's team that pursued litigation on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia, litigation which settled for \$177 million.

Mr. LeBlanc is a 2017 recipient of the Lifetime Achievement Honor from America's Top 100 Attorneys for his career dedicated to the protection of America's civil justice system. He was named as one of the top 75 plaintiff's attorneys in the United States by The American Lawyer in 2014 and has also been selected for inclusion in the Louisiana Super Lawyers® list from 2012 to the present.



Peter Mougey

Peter Mougev is a shareholder and the Chair of Levin Papantonio's Securities and Business Litigation department. Recognized as one of Florida's top 100 trial lawyers and a Florida Super Lawyer in securities litigation, Mr. Mougey has represented hundreds of municipalities and governmental entities. Mr. Mougey currently serves on the Plaintiff's Executive Committee in the National Prescription Opiate Litigation MDL.

In Mr. Mougey's securities and complex litigation practice, over the last five years, Mr. Mougey has represented many state, municipal, and institutional clients in litigation and arbitration, as well more than one thousand fraud victims in state and federal court and arbitrations across the country. He has recovered hundreds of millions of dollars on behalf of his clients.



Mike Fuller

Mike Fuller, of McHugh Fuller, has extensive experience in nursing home, medical malpractice and criminal prosecutions and trials. He has worked with a top national law firm and the Hillsborough County State Attorney's Office in Florida, and he has litigated and tried numerous cases to verdict in jurisdictions nationwide. Part of his educational process was spent working in the White House as an intern involved with Presidential Correspondence, providing a wealth of experience with citizens, legislators, and diplomats across the United States. Mr. Fuller currently serves on the Plaintiff's Executive Committee in the National Prescription Opiate Litigation MDL.



Troy Rafferty

Troy Rafferty is a shareholder at Levin, Papantonio. He litigates mass tort, pharmaceutical, and major personal injury cases throughout the country.

Mr. Rafferty has been appointed to handle some of the nation's largest pharmaceutical and mass tort cases. He has been appointed to serve on many Plaintiffs' Steering Committees including the national Vioxx Litigation which resulted in a \$4.7 billion settlement and the national Zyprexa Litigation which resulted in a \$700 million settlement. Mr. Rafferty was also one of the leading attorneys in the national Rezulin Litigation. He and his partner obtained a \$40 million judgement for a woman who took this diabetes drug. Mr. Rafferty has successfully tried numerous complex pharmaceutical cases throughout the country and currently serves as the Plaintiff's Co-Liaison Counsel in the National Prescription Opiate Litigation MDL.



Roland Tellis

Roland Tellis' practice at Baron & Budd focuses on complex, high-profile litigation, including consumer class actions, financial fraud, business torts, corporate misconduct, automobile defect, food labeling, false advertising, securities fraud, and environmental contamination.

He holds leadership roles in numerous multi-state, complex class action cases, including Bias v. Wells Fargo Bank, a certified nationwide RICO class action involving millions of mortgage loans that settled for more than \$50 million; In re: Volkswagen "Clean Diesel" Marketing, Sales Practices, and Products Liability Litigation, a multi-state class action in the process of settling with values and fines totaling in the billions of dollars, involving hundreds of thousands of vehicles equipped with "defeat devices" designed to evade emissions laws; and In re: Takata Airbag Products Liability Litigation, which has received preliminary approval for a settlement valued at \$553 million.

Mr. Tellis currently serves on the Plaintiff's Executive Committee in the National Prescription Opiate Litigation MDL.



James Peterson

James C. Peterson is a member/partner at Hill, Peterson, Carper, Bee & Deitzler, PLLC since 1983, focusing his legal practice on litigation of severe personal injury, medical/legal malpractice, product liability, insurance bad faith, mass tort/class action involving defective products, pharmaceuticals, and insurance issues.

He served as co-lead counsel for the settlement of the largest pharmaceutical class action litigation in the history of the State of West Virginia, involving the diet drug Fen-Phen.

Representative mass tort/class action includes cases against Purdue- Pharma, Inc., et al. (Oxycontin); VIOXX Products Liability Litigation (osteo-arthritic pain medication); and E. I. DuPont de Nemours and Company C-8 Personal Injury Litigation (representation of 3,500 plaintiffs who suffered various cancers and other illnesses due to exposure to C-8, a chemical used in the manufacture of Teflon, in public drinking water which brought a global settlement reached in 2017 for close to \$1 billion;

Settlements and verdicts handled on behalf of Hill & Peterson or on a co-counsel basis exceeds \$1.6 billion.



Anthony Majestro

Anthony Majestro, managing partner at Powell & Majestro, has a proven record of litigating matters of great complexity nationwide. Mr. Majestro concentrates his practice in prosecuting complex litigation, focusing on consumer fraud and defective products, including defective drugs and medical devices. In the course of his practice, Mr. Majestro has served as class counsel, lead counsel, liaison counsel and in leadership roles in a number of state and national class actions, mass torts, and other complex cases.

Mr. Majestro has successfully represented, or is currently representing, clients with injuries caused by Fen-Phen/ Redux, Paxil, Baycol, Propulsid, Oxycontin, Rezulin, Vioxx, hormone replacement drugs, pedicle screws, and breast implants. In addition, Mr. Majestro leads the firm's extensive consumer protection practice.

Marty Seufer

From:

Tish Chafin <tish@thechafinlawfirm.com>

Sent:

Wednesday, February 28, 2018 4:53 PM

To:

Marty Seufer

Cc: Subject: Letitia Chafin Proposal for Legal Representation

Attachments:

Wood County Proposal.pdf; Community Profile-Wood Cnty, WV.docx; Wood County

Presentation .pdf

Dear Marty:

I am attaching the following materials for presentation to the Wood County Commission:

- 1. A slide presentation;
- 2. Wood County Profile; and
- 3. Proposal for Legal Representation.

I regret that I cannot be there tomorrow to present the information in person however, I can be available by telephone to answer any questions you or the Commissioners may have regarding the materials. My cell phone number is 304-545-2554.

As we discussed, over 31 million pills were distributed to Wood County from 2007-2012. The distributors responsible were Rite Aid (distribution company), Cardinal, Amerisource Bergen, CVS Indiana (distribution company), McKesson, Walmart (distribution company) and Miami-Luken.

The manufacturers listed in the slide show would also be potential defendants along with the WV Board of Pharmacy.

Our litigation team was the first team to file a lawsuit against the distributors on behalf of a county (McDowell County) in West Virginia and in the Nation.

We would be honored to represent Wood County and hope that we are given the opportunity to be competitive if other proposals have different fee schedules.

Letitia Neese Chafin, Esq.

The Chafin Law Firm, PLLC

Post Office Box 1799

Williamson, WV 25661

P: (304) 235-2221

F: (304) 235-2777

tish@thechafinlawfirm.com

CONFIDENTIALITY NOTICE: This message is for the sole use of the intended recipient or recipients and may contain confidential and/or privileged information. Any unauthorized review, use, disclosure or distribution of the information contained therein is strictly prohibited. If you are not the intended recipient of this message, please contact the sender by reply e-mail and destroy all of the original message.

^{*}Admitted in West Virginia and Kentucky

Proposal for Legal Representation in Opioid Litigation

Wood County, West Virginia



H. Truman Chafin, Esq.*
Letitia Neese Chafin, Esq.*
*ADMITTED IN WEST VIRGINIA AND MENTUCKY

February 28, 2018

Via Email
Marty Seufer
Wood County Administrator
Wood County Commission
#1 Court Square
Parkersburg, West Virginia 26101

RE: Prescription Opioid Products Matter

RFP Submission

The Chafin Law Firm, PLLC in collaboration with Morgan & Morgan; the Bell Law Firm, PLLC; and the Troy Law Firm, PLLC proudly present this proposal in connection with the above referenced Request for Proposal. We stand ready, willing, and able to assist the Wood County Commission (WCC) with the continuing investigation and litigation against the manufacturers, distributors, and all other responsible entities and individuals who helped to create or fuel the opioid epidemic in West Virginia.

This proposal, like our approach to all such governmental actions, is founded upon a bedrock commitment of true collaboration and open transparency in order to ensure that the WCC controls the litigation and that our efforts are continually aligned with the objectives and best interests of the WCC. We currently represent over seventeen West Virginia cities and counties and remain committed to delivering justice to the people of West Virginia.

Like all counties in West Virginia, Wood County has been inundated with highly addictive opioid pills. From 2007-2012, over 23,870,370 Hydrocodone pills and over 7,258,240 Oxycodone pills were distributed in Wood County. Over 31,128,610 million opioid pills were distributed in your County in a six-year period. With a population of approximately 86,000, that equates to 361 opioid pills for every man, woman and child in Wood County.

There is not a more professional, committed, and capable team than the one assembled herein. Once selected, we will use our significant successful experience and subject matter expertise to

deliver a result that both makes Wood County whole and deters future violators from similar conduct moving forward. In closing, we applaud the WCC's commitment to this vital matter of

public health, as well as his leadership in seeking the best available legal team to handle this matter to conclusion.

Sincerely,

Letitia Neese Chafin

FIRM HISTORY

This proposal incorporates the impressive strength and resources of four widely respected law firms: Morgan & Morgan, The Chafin Law Firm, The Bell Law Firm, and the Troy Law Firm. Responses throughout this proposal will refer to our collaboration as "Team", unless individual firm responses are more appropriate. As more fully detailed throughout, our firms stand tall among our competition and boast incredible successes in our respective histories. While many law firms can propose to represent the WCC in this important matter, no one firm can bring to bear the combined experience, expertise, reputation, resources, and gravitas that our Team possesses. Led by an unparalleled roster of experienced plaintiff attorneys, our Team stands ready to assist the WCC in holding opioid manufacturers, distributors, and all other responsible parties, accountable for their conduct.

I. Morgan & Morgan

Founded thirty years ago, Morgan & Morgan is the largest exclusively plaintiff contingency fee law firm in the world. While growing every day, we currently employ 365 lawyers and 2,45 support staff throughout 40 offices in 11 states as well as Canada and Amsterdam. Our firm motto and guiding principle, is "For the People". Akin to a collection of private attorneys general, each member of our firm proudly stands on this foundation for our representation in every case for every client.

As the largest plaintiff-only firm in America, our client base stretches across the entire United States, though it is concentrated in the southeastern United States. Each year, tens of thousands of people entrust Morgan & Morgan to represent them in legal matters ranging from personal injury and workers compensation, to class actions and medical malpractice, just to name a few.

One of the unique characteristics of Morgan & Morgan is our emphasis on actually trying cases. John Morgan's sincere belief is that in order to obtain the best results for all clients, every lawyer in the firm must regularly draw a line in the sand and enter the courtroom arena to adjudicate our client's claims before a jury of their peers. As a result of this philosophy, our firm has the distinction of conducting more jury trials in civil cases over the last five years than any other law firm in America.

Within the last ten years, Morgan & Morgan developed three distinct practice groups within the firm in order to expand its mission and reach. The Consumer Protection Group was created in order best serve clients who are impacted by violations of traditional consumer protection statutes and rules such as the Fair Debt Collection Practices Act, Fair Credit Reporting Act, Telephone Consumer Protection Act, and others.

Morgan & Morgan also established the Complex Litigation Group to handle multi-party complex civil matters such as class actions, mass torts, qui tams, environmental and governmental actions. This group draws on the expertise of 20 dedicated trial attorneys supported by 18 highly skilled paralegals, 25 support staff, four investigators, and state of-the-art technology. While this group is primarily based in Tampa, Florida, Complex Litigation Group attorneys and support staff are located in Jacksonville, Ft. Myers, Ft. Lauderdale, Brooklyn, New Orleans, Southern California, and elsewhere.

The attorneys who make up this group have impressive diverse backgrounds including litigators from top 50 defense firms, senior government counselors, elected officials, and named partners from highly successful plaintiff firms. An indication of the success of this group lies in the number of appointments to Plaintiff Steering Committee and leadership positions within class and mass litigation and the staggering dollar value of recoveries in cases since its inception, all of which are contained in the below responses. By way of initial example, Morgan & Morgan served as the co-lead in the In re: Black Farmers Discrimination Litigation, filed in the District of Columbia wherein we successfully negotiated a \$1.2b settlement.

More recently, the firm created the Government Action Group led by James Young, former Special Counsel to the Florida Attorney General, and including other qualified lawyers knowledgeable in representing governmental entities such as Greg Stumbo, or who have dedicated their professional lives to the pursuit of public justice such as Robert Kennedy Jr. It is our strong belief that former government attorneys, unbound by the constraints of civil service and limited state budgets, are uniquely qualified to represent governmental entities.

II. The Chafin Law Firm

The Chafin Law Firm is a small, specialized practice in the heart of the West Virginia coalfields. Collectively our attorneys have over 75 years experience in personal injury litigation and have

generated over \$150 million in verdicts and settlements for our clients. We specialize in major coal truck accidents, serious workplace injuries and other serious accidents.

Senator H. Truman Chafin is the founding partner of The Chafin Law Firm, PLLC – West Virginia's longest serving senate majority leader and a distinguished and prominent West Virginia and Kentucky attorney. Letitia Neese Chafin is the managing partner of The Chafin Law Firm, and is a distinguished graduate of the West Virginia University College of Law, and has been counsel for clients who have obtained some of the largest verdicts in the State of West Virginia.

III. The Bell Law Firm

In 1993, Harry founded The Bell Law Firm, PLLC, which is recognized as one of West Virginia's leading complex litigation firms that represents both individuals and businesses in class action, MDL, and medical malpractice cases. The firm and its attorneys are also highly regarded for their work with nursing home abuse and neglect cases.

As a proud native of Charleston, West Virginia, Harry F. Bell, Jr. has dedicated his time to practicing law in West Virginia for over 33 years. He has been recognized as a Super Lawyer® by Super Lawyers Magazine, and has been named by The American Trial Lawyer Association as one of the Top 100 Civil Trial Lawyers® in West Virginia.

Harry has participated in nearly one hundred trials, and he has spoken nationally at various seminars, including Mass Torts Made Perfect, The Combined South Carolina Judiciary and South Carolina Bar Annual Meeting, and the West Virginia State Bar Association. He also presented the topic, "MDL Exit Strategies" before the Louisiana State Bar Association's 10th Annual Class Action/Mass Tort Symposium.

IV. Troy Law Firm

With over two decades of professional practice, the Troy Law Firm has assisted numerous clients throughout West Virginia in litigation, mediation, and arbitration, to help obtain millions of dollars in verdicts and settlements. No matter how complicated the case, their goal remains to provide high-quality service aimed at seeking results.

The firm's founder, Mark Troy, holds an AV Distinguished® Rating by Martindale-Hubbell®,

the most recognized attorney rating service in the country. This peer rating is based upon the comments of more than 20 attorneys and up to 4 judges in the community. Mr. Troy also received Martindale-Hubbell's® "Premier" Client Review Rating, which is the highest recognition given based upon the comments of his clients in such areas as skill, client communications, responsiveness, and quality of service.

WEST VIRGINIA REPRESENTATION

Our team currently represents 17 counties and municipalities in West Virginia. We filed the very first West Virginia lawsuit against drug wholesalers on behalf of local governments and we have filed eight such actions since that time, with several more pending.

LOCAL GOVERNMENTS CURRENTLY REPRESENTED:

- McDowell County
- TOWN OF KERMIT
- LINCOLN COUNTY
- Webster County
- TOWN OF GILBERT
- TOWN OF HAMLIN
- TOWN OF WEST HAMLIN
- BARBOUR COUNTY
- Mercer County
- MINGO COUNTY
- TAYLOR COUNTY
- MASON COUNTY
- TOWN OF ADDISON (F/K/A CITY OF WEBSTER SPRINGS)
- CITY OF WELCH
- TOWN OF CHAPMANVILLE
- CITY OF WILLIAMSON
- CLAY COUNTY

AND LAWRENCE COUNTY KENTUCKY

MEET OUR TEAM

To be truly successful, the WCC needs a team of lawyers with government enforcement experience, subject matter expertise, a proven record of high-stakes trial victories, along with sufficient size and scale to stand toe-to-toe with some of the world's largest companies. There is but one team that meets each of these requirements; ours.

James Young, Esq.

While serving as Special Counsel in the Florida Attorney General's office, James Young headed up consumer protection enforcement for North Florida and helped design task force protocols for statewide enforcement of Fair Debt Collection Practices Act violators, personally prosecuting a case which resulted in the largest judgment against a debt collector at the time. (State of Florida v. Ellis Crosby & Associates) James has lectured on consumer protection topics for the last 10 years and served as guest professor to the Consumer Law Clinic at Florida Coastal School of Law from 2009-2012.

James was also part of a team of lawyers retained by the Eastern Band of Cherokee and Cherokee Nation to represent them in consumer protection claims against Volkswagen and Bosch relating to the emissions scandal of 2016. The tribal claims were resolved via an agreement to create a trust fund of \$50 million for mitigation of environmental impact.

After a successful career as Special Counsel to the Florida Attorney General's office, James Young joined the firm's complex litigation unit focusing on qui tam whistleblower cases nationwide. He handles government actions as well. Mr. Young has broad experience and is nationally known in the areas of consumer protection, health fraud, and pharmaceutical litigation. He has served in leadership positions in numerous multistate Attorney General investigations including starting and co-leading the largest consumer protection drug settlement to date, In Re Risperdal. He was appointed co-lead of the government plaintiffs group in the Vioxx Multi-District Litigation and has served as lead of several litigation subcommittees.

Mr. Young and has recently been appointed to the Plaintiffs' Executive Committee (PEC) in the current Prescription Opiate Multi-District Litigation (MDL: 2804).

John Yanchunis, Esq.

John has handled a diverse size of complex consumer and commercial disputes, and for the last 13 years he had focused his practice on consumer class action litigation and false claims. He has served as co-lead counsel in the successful prosecution of the two largest class action cases in the

United States, Fresco vs. Automotive Directions, Inc., Case No. 03-61063-JEM et al; and Fresco vs. R.L. Polk Case 0:07-cv-60695-JEM (Southern District of Florida), and served as lead, co-lead or class counsel in numerous other consumer class actions, including:

John was selected by the Chief Financial Officer for the state of Florida to serve as lead counsel for the Florida Department of Financial Services and the Florida Department of Insurance Regulation (the insurance regulators of Florida) in their investigations of the insurance industry on issues concerning possible antitrust activity and other possible unlawful activities regarding the payment of undisclosed compensation to insurance brokers. John served as lead regulator counsel and worked with a core group of state attorneys general from the National Association of Attorneys General, which were selected to conduct the investigations.

John served as co-lead counsel in the successful resolution of the following privacy, non-data-breach class actions: Davis v. Bank of America, No. 05-cv-80806 (S.D. Fla.) (\$10 million common fund), Kehoe v. Fidelity Federal Bank and Trust, No. 03-cv-80593 (S.D. Fla.) (\$50 million common fund), and Pino v. Warranty Acceptance Corporation, No. 05-cv-61576 (S.D. Fla.).

John served as co-lead counsel in the MDL case In re The Home Depot, Inc. Customer Data Security Data Breach Litigation, No. 1:14-md-02583-TWT (N.D. Ga.) (consumer class cases) which was settled for \$ 19.5 million,

John is a member of the Executive Committee in the MDL data breach case against the Office of Personnel Management, In re: U.S. Office of Personnel Management Data Security Breach Litigation, 1:15-mc-01394-ABJ (D.C.), a case involving the loss of approximately 18 million present and former federal employees' information), and the Executive Committee in Ortiz v. UCLA Health System, No. BC589327 (Cal. Sup. Ct. Los Angeles Cnty.); and class counsel in Diaz v. Intuit, Inc., No. 5:15-cv-1778-EJD (C.D. Cal.), McDowell v. CGI Group, Inc., No. 1:15-cv-01157-GK (D.D.C.) and Walters v Kimpton Hotel & Restaurant Group, LLC, No. 3:16-cv-05387 (N.D. Cal.).

Gregory Stumbo, Esq.

In January 2009, nearly a year after starting his second tenure in the Kentucky House of Representatives, Gregory D. Stumbo was elected House Speaker by his legislative colleagues, an honor he received again in 2011 and 2013. He has spent more than 30 years in public service, beginning when he became Floyd County's state representative in 1980. He became House Majority Floor Leader five years later, making him the youngest state legislator in the nation to hold that title. By 2003, when he was elected as Kentucky's Attorney General, he had

accumulated 19 years in House leadership, giving him the longest uninterrupted service ever by a Kentuckian.

As Attorney General, Greg Stumbo cracked down on internet pharmacies shipping illegal narcotics into Kentucky, and he also ran a series of successful child-predator stings across Kentucky, one of which was featured on the NBC series "To Catch a Predator."

Before he began serving as Attorney General, he played key roles in several other landmark laws. He sponsored the legislation creating the Kentucky Lottery and the Kentucky Education Reform Act, and in 2002 his legislation streamlining the state's solid-waste system helped close landfills and clean up open dumps and litter along public roads. In 1999, his environmental work earned him the Kentucky Environmental Quality Commission's prestigious Earth Day award.

Patrick Barthle, Esq.

Patrick Barthle attended the University of Florida where he was admitted to the Honors Program and graduated, cum laude, with a double major in History and Criminology. While at UF, Patrick was inducted into the Phi Beta Kappa Honor Society and served as President of the Catholic Student Center.

Thereafter, Mr. Barthle attended Washington and Lee University School of Law, where he graduated summa cum laude, was a Lead Articles Editor for the Wash. & Lee Law Review, a member of the Order of the Coif and the Phi Delta Phi Legal Honor Society, and President of the W&L Law Families student organization.

Before joining Morgan & Morgan, he worked at one of the country's largest law firms, Greenberg Traurig, LLP, and then served as a judicial law clerk for two years to the Honorable Mary S. Scriven, United States District Judge, Middle District of Florida. Mr. Barthle now practices in Morgan & Morgan's Complex Litigation Group where he focuses on consumer class action litigation.

David Reign

David is the former Assistant Special Agent In Charge of the Tampa FBI Field office, with nearly 25 years of investigative experience. He has investigated and managed some of the FBI's most complex white-collar crime cases, with an emphasis on health care fraud, public corruption and financial crimes.

As Assistant Special Agent In Charge in Tampa, he was responsible for the criminal and administrative branches of the office and managed high-profile domestic and foreign terrorism matters. While working with the FBI, David spoke to investigators, analysts and government

attorneys internationally about mortgage and accounting fraud, healthcare fraud and drug interdiction programs. He briefed law enforcement officials at Scotland Yard and the City of London Police on economic crimes, and spoke in Lisbon, Portugal to a joint interagency task force focused on international drug trafficking.

As Deputy Chief of the Enron Task Force, he led a team of investigators and analysts in the successful investigation and prosecution of several executives of the Enron Corporation. He received the Attorney General's Award for Exceptional Service for his work on the Enron matter.

During his tenure in Tampa, David also planned and managed security matters for major events, including the 2012 Republican National Convention and the 2003 Super Bowl. David often briefed the Director of the FBI and the Attorney General on significant matters, and has testified in front of the Senate Select Committee on Intelligence.

Lee Walters

Former FBI Supervisory Special Agent Lee Walters has more than 24 years of experience conducting investigations for the FBI, including several years in the top-secret TacOps-Electronic Access Group. He worked on a variety of white-collar crime matters including healthcare and bank fraud, public corruption, and violations of the Foreign Corrupt Practices Act.

Lee was the lead investigator in a two-year undercover operation, Operation Broken Star, which led to the conviction of 7 rogue Chicago police officers and for which he was awarded the Chicagoland Chamber of Commerce Excellence in Law Enforcement Award. He was also one of the first agents assigned to the Whitewater investigation of Bill & Hillary Clinton.

While at the FBI, Lee was one of a handful of agents trained on how to defeat any alarm system or electronic access technology manufactured to date. Prior to his assignment with TacOps, Lee was a certified Technically Trained Agent (TTA) and served in the Chicago and Little Rock offices of the FBI wiretapping phones, planting tracking and listening devices, installing hidden cameras, and other technologies in support of major investigations. His work on one such operation helped solve a 15-year old murder mystery.

Lee spent 23 years as a Firearms Instructor and Defensive Tactics Instructor and 14 years in the Special Weapons & Tactics (SWAT) program as an Observer/Sniper. He was deployed as a SWAT member to the Branch Davidian siege in Waco, Texas, during the Los Angeles riots after the Rodney King verdict, and participated in numerous other high-risk operations.

Lee was also a member of the FBI's Art Crime Team (ACT), a team of twelve special agents trained to conduct art crime investigations, and has spoken at length about the team and their efforts to combat art crime in all of its many forms. He also spent several years as the team leader of a surveillance squad and was involved in numerous arrests, car chases and operations involving all types of criminal activity the FBI investigates.

Sarah Foster, Esq.

Sarah Foster was recruited to join Morgan & Morgan's Government Action Group in Jacksonville, Florida. Sarah brings a wealth of experience in e-Discovery and litigating at a large insurance defense firm.

Rebecca Lowrance, Esq.

A lawyer by training, Rebecca heads up research analytics for the Government Action Group, where she reviews and analyzes public health and government budget datasets in order to build advanced damages models and supervise experts.

H. Truman Chafin, Esq.

H. Truman Chafin, one of the most trusted and experienced political leaders in West Virginia, was first elected to the State Senate in 1982. A Marshall University graduate, Chafin received his law degree from Michigan State University and served as a judge in Williamson where he was past president of the Mingo County Bar Association and the Mingo County Commission. Chafin was also elected to the West Virginia State Democratic Executive Committee and served as a delegate to the 1996 and 2000 Democratic National Conventions.

Truman Chafin is the only state senator to serve on both the Senate Finance Committee and the Senate Judiciary Committee, and served as Vice Chairman of the Senate Rules Committee. He served as the Majority Leader for the 69th, 70th, 72nd, 73rd, 74th, 75th, 76th, 77th, 78th, and 79th Legislatures. Currently Chafin serves as a member of the West Virginia Bar Association and the Mingo County Bar Association, the Trial Lawyers of America, Pi Kappa Alpha, LOOM, BPOE, and is a Scottish Rite Mason. Chafin is also a charter member of the Governor's Judicial Advisory Committee.

Letitia N. Chafin, Esq.

Letitia Neese Chafin is the managing partner at The Chafin Law Firm. She graduated cum laude from Marshall University and received her J. D. from West Virginia University, Order of the Barristers. Chafin has worked at the firm since graduating from law school and is licensed in both West Virginia and Kentucky. She is also certified to practice before the United States Supreme Court, the Fourth Circuit; and the United States Federal Court, Southern District of West Virginia. Chafin has argued cases before the Supreme Court of Appeals in West Virginia and the Kentucky Supreme Court of Appeals.

Chafin is the immediate Past President of the West Virginia State Bar Association (2010-2011), where she has also served on the Board of Governors and is an Ex Officio member of the Judicial Advisory Committee. She is currently serving her second term on the Marshall University Board of Governors, and is Chairperson of the Academic & Student Affairs Committee. Chafin also serves on the Education Alliance Board and the Children's Home Society Board, and is an Elder of the Presbyterian Church, Charleston.

Mark E. Troy, Esq.

Mark Troy has served clients throughout West Virginia for more than twenty-three years and is now in his second year of serving clients in Kentucky. Mr. Troy's practice is focused on personal injury, medical malpractice, product defect and, of course, litigation against opioid distributors and manufacturers. Mr. Troy has obtained one of the largest plaintiff's verdicts in the U.S. District Court for the Southern District of West Virginia in a case stemming from the corporate conversion of clients, product designs and other items, and his lawsuit against opioid wholesale distributors, filed on behalf of the McDowell County Commission, was one of the first of its kind in the country.

Mr. Troy, the founder and managing member of Troy Law Firm, PLLC, holds an AV Distinguished® Rating by Martindale-Hubbell®, the highest rating available from the most recognized attorney rating service in the country. This peer rating is based upon the comments of more than 20 attorneys and up to 4 judges in the community. Mr. Troy also received Martindale-Hubbell's® "Premier" Client Review Rating, which is the highest recognition given based upon the comments of his clients in such areas as skill, client communications, responsiveness, and quality of service. Mr. Troy also maintains an AVVO rating of "10.0 Superb," AVVO's highest rating available, in the areas of Car Accidents, Defective Products and Medical Malpractice, and he has been recognized as one of West Virginia's "10 Best Firms" in Client Satisfaction by the American Institute of Personal Injury Attorneys for the past four years.

Harry F. Bell, Jr., Esq.

As a proud West Virginia native, Harry F. Bell, Jr. has dedicated his time to practicing law in West Virginia for over 33 years. He has been recognized as a Super Lawyer® by Super Lawyers Magazine, and has been named by The American Trial Lawyer Association as one of the Top 100 Civil Trial Lawyers® in West Virginia.

Throughout his career, Harry has been involved in numerous successful class action litigations. He served as Liaison and Co-lead Counsel in the Digitek product liability case (2:08-md-01968), and he served on the Plaintiffs Steering Committee (PSC) during the Comcast Anti-Trust litigation (09-md-02034-AB).

Additionally, Harry served on the PSC and the Plaintiffs' Co-liaison Counsel for several noteworthy pelvic repair system product liability cases, including American Medical Systems (2:12-md-02325), Boston Scientific Corp. (2:12-md-02326), C. R. Bard Inc. (2:10-md-02187), Ethicon Inc. (2:12-md-02327), and Coloplast Corp. (2:12-md-02387). He has also served in various capacities as special master and mediator appointed by state and federal courts in West Virginia.

Additional Staff & Resources

The very nature of a multi-district investigation and litigation connects to multiple cities outside of West Virginia and throughout the United States. As such, we are fully prepared to utilize the entire inventory of Morgan & Morgan's 36 offices as well as the significant local West Virginia resources provided by The Chafin Law Firm, The Bell Law Firm, and the Troy Law Firm. Attorneys and staff in these offices are essentially on stand-by and all members of our Team are willing to commit all resources needed to handle this matter.

Simply put, we have fought and won similar wars before. Without question, the defendants will rely upon legions of hourly counsel filing every conceivable motion in an attempt to muddy the waters and slow down the pace of the proceedings. Countering their approach, we will use the full depth and breadth of our Team to respond in kind in order to hold their feet to the fire. To succeed, a local presence in and familiarity with West Virginia is of utmost importance.

The attorneys and staff chosen to collaborate on this proposal were specifically selected for their relevant work experience and distinctive skill sets. Indeed, the team assembled was compiled for

a singular purpose, to represent the local governments in holding the parties responsible for the opioid epidemic accountable.

Resumes for all relevant attorneys and staff are included in Exhibit 1.

PROPOSED FEE SCHEDULE

Our Team will diligently fight for the recovery of damages from the pharmaceutical manufacturers, distributors, and any other party responsible for flooding Upshur County with prescription pills. The tortious, willful, wanton, and reckless misconduct of Big Pharma has fueled prescription drug-related crime, the prescription overdose rate, prescription drug addiction and abuse, and otherwise directly and indirectly cost your county and other West Virginia cities and counties to incur millions, if not hundreds of millions of dollars in continuing damage.

Proposed Fee Schedule

The following fee proposal reflects the terms under which our Team is willing to undertake legal representation of the WCC in connection with the above referenced RFP.

We will only be compensated for attorney fees related to legal services rendered in a contingency matter if a recovery is obtained for you. The attorney fees to be paid to us will be twenty-five (25%) of any recovery received on the WCC's behalf, whether recovery occurs by way of award, order, or judgment or through compromise or settlement before trial and preparation, and before any costs and expenses are deducted.

If the Team is unable to obtain a recovery, it will seek no attorney's fees for the legal services rendered to WCC, and in no instance will any costs or fees incurred relative to the representation be paid out of the client's general fund or other resources that were not generated as a result of the litigation. In the event the lawsuit is successful, the WCC will reimburse all costs and expenses incurred in the course of the Team's institution and prosecution of the current claims, unless such costs are ordered or agreed to be paid by the parties or entities against whom the claims will be made.

Our Team shall advance any and all costs and expenses incurred in relation to the current legal matter. As authorized by the WCC, the Team will incur such costs and expenses as it deems necessary for prosecution of this matter and on any matter the Team deems appropriate. Again, if our Team is not able to obtain recovery, it will not seek cost or expense reimbursement from the WCC.

We stand ready to assist the WCC in holding all parties responsible for creating or fueling the opioid epidemic. We welcome the opportunity to further elaborate on our experience and qualifications, as well as our overall strategy during an oral presentation at a time of your choosing.

With best regards,

H. Truman Chafin
WV BAR NO. 684
Letitia N. Chafin
WV BAR NO. 7207
THE CHAFIN LAW FIRM, PLLC
P.O. Box 1799
Williamson, WV 25661
Phone: 304 235 2221

Phone: 304-235-2221 Fax: 304-235-2777

Email: truman@thechafinlawfirm.com Email: tish@thechafinlawfirm.com

Mark E. Troy, Esq. WV Bar No.: 6678 Troy Law Firm, PLLC 222 Capitol Street, Suite 200A Charleston, WV 25301 Email: mark@troylawwv.com Phone 304-345-1122

Harry F. Bell, Jr., Esq. WV Bar No.: 297 THE BELL LAW FIRM, PLLC

P.O. Box 1723 30 Capitol St. Charleston, WV 25326-1723 Email: hfbell@belllaw.com Phone: 304-345-1700

James D. Young, Esq. Florida Bar No. 567507 jyoung@forthepeople.com MORGAN & MORGAN Government Action Group 76 S. Laura St., Suite 1100

John Yanchunis Florida Bar No. 324681 jyanchunis@forthepeople.com

Patrick Barthle
Florida Bar No. 99286
MORGAN & MORGAN
Litigation Group
201 N. Franklin St., 7th Floor
Tampa, FL 33602
(813) 223-5505

Community Profile Wood County, WV

I. Local Government to be Assessed:

Wood County, WV

II. Local Govt's in Wood County:

Cities

- Parkersburg (county seat)
- Vienna
- Williamstown

Town

North Hills

Census-designated places

- Blennerhassett
- Boaz
- Lubeck
- Mineralwells
- Washington
- Waverly

Unincorporated communities

- Belleville
- Bonnivale
- Cedar Grove
- Central
- Eli
- Dallison
- Davisville
- Deerwalk
- Fort Neal
- Kanawha
- New England
- Ogden
- Pettyville
- Rockport
- Slate
- Volcano
- Walker
- Wells Subdivision

III. Overview:

Wood County is West Virginia's fifth-most populous county. Its county seat is Parkersburg. The county was formed in 1798 from the western part of Harrison County and named for James Wood, governor of Virginia from 1796 to 1799. Wood County is part of the Parkersburg-Vienna, WV Metropolitan Statistical Area.

IV. Demographics (US Census Bureau):

a. 2016 Population Estimates: 85,643
b. Median Household Income: \$43,944
c. Persons in poverty, percent: 17.2 %

d. Educational Attainment: Percent high school graduate or higher: 89.6 %

e. Persons without health insurance, under age 65 years, percent: 6.7 %

f. Median Housing Value: \$ 109,100

g. Total Housing Units: 40,245h. Number of Companies: 6,122

i. Veterans: 7,207

V. News Articles:

Wood County Commission Discusses West Virginia Drug Abuse Problem (found at: http://www.newsandsentinel.com/news/local-news/2017/12/wood-county-commission-discusses-west-virginias-drug-abuse-problem/)

Last year, 884 West Virginians lost their lives due to overdose, resulting in the highest overdose death rate per capita in the nation, the DHHR reported in a press release. Preliminary analysis of overdose deaths in West Virginia in 2016 shows that seven out of 10 people who died had a prescription for a controlled substance filled within a year of their death, and two in five overdose victims had a prescription filled within 30 days prior to their death, the press release said.

Wood County Prosecutor Pat LefebureLefebure said many doctors don't have the resources to address drug abuse by expectant mothers. Most of what is available addresses the baby's health and not the mother's when the child is born, Lefebure said.

As the need for more drug treatment becomes apparent, so is the possibility for people and organizations to exploit it for monetary gain, commissioners said.

Wood County Sheriff Steve Stephens said the problem starts with people being prescribed opioids and becoming addicted. Even after they are weaned off of it, many still crave it and will look for other means to get that fix, which leads to heroin abuse and other drugs, he said.

VI. Opioid Use: (Source: http://opioid.amfar.org/WV)

Entity	Drug-related Deaths per 100,000 (2016)	Drug-related Deaths (2016)	Percent of people 12+ reporting drug dependence (2016)	Percent of population 12+ reporting non-medical use of pain relievers (2016)
United States	19.69	63,632	2.7	4.31
West Virginia	48.3	884	2.8	3.89
Wood County	53.7	46	2.56	3.82

VII. Prescribing Rates (Source: https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html)

Jurisdiction	Prescribing Rate Per 100 Persons (2006)	Prescribing Rate Per 100 Persons (2010)	Prescribing Rate Per 100 Persons (2016)
United States	72.4	81.2	66.5
West Virginia	129.9	143.1	96.0
Wood County	126.4	151.5	109.4

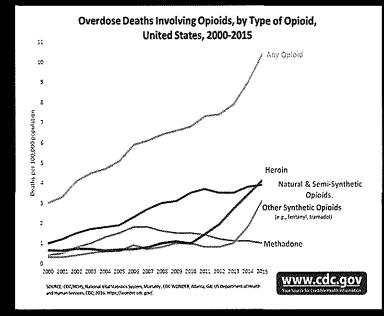
Opioid Litigation Proposal West Virginia Local Governments





THE OPIOID EPIDEMIC'S DEVASTATING TOLL





Opioids Come to West Virginia

West Virginia County Gets Drug-Trafficking Designation | West Virginia ...

https://www.usnews.com/.../west-virginia/.../west-virginia-county-gets-drug-traffickin... ▼
Sep 29, 2017 - (AP) — Federal authorities have designated West Virginia's Wood County as a high intensity drug trafficking area eligible for support for joint federal, state and local police ... West Virginia County Gets Drug-Trafficking Designation ... West Virginia is dealing with what authorities call an opioid addiction crisis.

Drug Distributors Shipped 20.8 Million Painkillers To West Virginia ... https://www.npr.org/.../drug-distributors-shipped-20-8-million-painkillers-to-west-virgin...

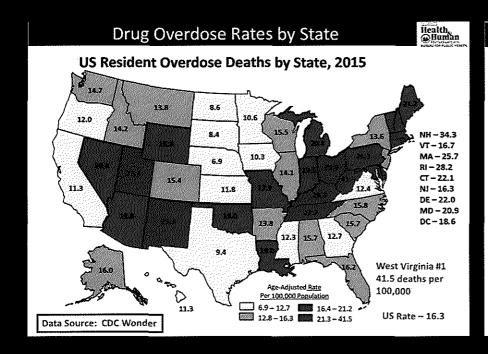
Jan 30. 2018 - The House committee's findings were first reported by Eric Eyre at Gazette-Mail, who won a Pulitzer Prize in April for his investigative reporting on how rural "pill mills" had fueled the West Virginia's opioid crisis. (The Gazette-Mail reported Monday that its owners were filing for Chapter 11 bankruptcy.).

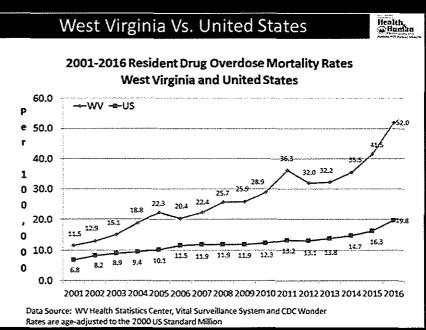




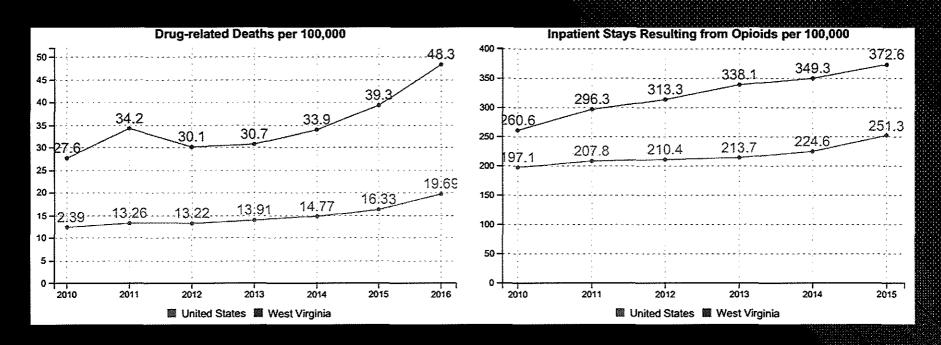
Drug companies submerged WV in opioids: One town of 3,000 got 21 ... https://arstechnica.com/.../drug-companies-submerged-wv-in-opioids-one-town-of-30... ▼
Drug companies submerged WV in opioids: One town of 3,000 got 21 million pills. The state has the highest rate of overdose deaths in the country. Beth Mole - 1/30/2018, 2:21 PM. Enlarge / WASHINGTON, DC - OCTOBER 25: Committee chairman Rep. Greg Walden (R-Ore.) questions witnesses during a House Energy ...

West Virginia has the highest rate of drug overdose mortality in the United States





In 2017, 884 West Virginians lost their lives due to overdose, resulting in the highest overdose death rate per capita in the nation



How did we get here?

- •Primary causation: Purdue Pharma's expansive strategy deployed in late 90's
- Secondary causes: follow-on manufacturers and unchecked growth by wholesalers
- Prescribers were also complicit, particularly KOLs and front groups.
- Adoption of the Fifth Vital Sign
- •DEA and State Boards of Pharmacy were asleep at the switch

Opioid Lawsuits Filed Nationwide

States, cities, counties and other public entities have filed more than 250 opioid-related lawsuits. The number is steadily increasing after creation of the MDL.



County and City Actions

- Every county and city has been affected by this epidemic
- •One of our clients, Welch, WV has one pharmacy and under 500 residents.
- •Over a 3 year period they received 9,000,000 opioid pills
- Their annual public safety budget was blown in two months

THE MDL

- → JPML granted MDL (MDL# 2804) on December 5, 2017
- → 250+ cases have been transferred to the Northern District of Ohio located in Cleveland with more filed/transfered every day.
- → Judge Dan A. Polster was appointed to preside over the MDL:
 - a. Harvard Law Alumni
 - b. Appointed by Clinton in 1997
 - c. Former DOJ and Assistant US Atty
 - d. Currently presiding over four opioid cases
 - e. Previous complex MDL experience: Gadolinium Contrast Dyes Products Liability Litigation (MDL #1909) and Oral Sodium Phosphate Solutions (MDL# 2066)

→ Next steps:

- a. Plaintiff Executive Committee (PEC) determination of leadership structure & roles
- b. Global settlement discussion



Judge Dan Aaron Polster

Career

- » U.S. District Judge, Northern Ohio (1998-present)
- » Assistant U.S. Attorney, Economic Crimes Division, Northern Ohio (1932-98)
- Trial Attorney, U.S. Department of Justice, Antitrust, Cleveland, Ohio (1976-82)

Notable Cases

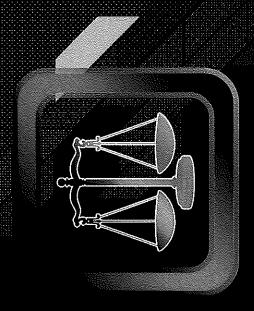
- » In Re: Gadolinium-based Contrast Agents Products Liability Litigation
- » Federal Trade Commission v. Steris Corp.
- » Unique Product Solutions Ltd. v. Hy-Grade Valve Inc.

Education

- » Harvard Law School, J.D. (1976)
- » Harvard College, A.B. (1972)

LOCAL GOVERNMENTS MUST HAVE SKANEINBRIED GANDERO RECOVER DAMAGES

If you are waiting on the West Virginia Attorney General to rescue you....



WHO ARE THE DEFENDANTS?



MANUFACTURERS

- Purdue Pharma

Endo Health

- Solutions
- Insys Therapeutics

Janssen Pharma

- Teva Pharma
- Cephalon
- Actavis

DISTRIBUTORS

- McKesson Corp.
- Cardinal Health
- AmerisourceBergen

These three distributors account revenues from drug distribution for 85 to 90 percent of all in the country



PRESCRIBERS

- Rx data is revealing
- Recent push for criminal prosecution
- Board of Medicine now acting

PHARMACIES/PHARMACISTS

- Obligations to report
- Pill mill laws changed
- Pharmacy

WV Board of



Causes of Action

Negligence Unfair & Deceptive Practices Unjust Enrichment

Public Nuisance

Public Nuisance

PUBLIC NUISANCE:

An unreasonable interference with a common right to the general public. SOL does not begin to run untuil nuisance is abated.

UNREASONABLE INTERFERENCE::

- Acts that significantly interfere with public health, safety, peace, comfort, or convenience;
- Conduct that is contrary to a statute ordinance, or regulation;
- Conduct that is of a continuing nature or one which has produced permanent or long-lasting effect upon the public right, an effect in which the actor is aware of should be aware

Types of Damages (Exches)

Government Clients will seek to recover:

- > Cost impact to programs (Historical)
- > Cost impact to EHBP and Risk Mgt (Historical and Prospective)
- > Lost tax revenue (Historical and Prospective)
- Costs to fix or abate (Prospective)

Reimbursement of Expenses

Healthcare

Fire Rescue and EMT call outs

À

- Narcan/Naloxone
- Hospital or direct healthcare costs

À

Employee Benefits

٨

Employee Services

A

- > Workers Compensation
- > Prison/ Jail healthcare

Law Enforcement

- Police (training, policing, prosecution)
- Jails/Prisons (inmates overpopulation, treatment programs)

A

- > Drug Court
- Probation & drug testing



Additional Misc. Expenses

- > Code Enforcement
- ➤ Blight abatement/Clean up public spaces
- > Medical Examiner
- Consequential Damages- Employee health benefit impact for post overdose and secondary health problems, for ex. Hep C, liver transplant A
- Decrease in property and sales tax revenue, bed tax, B+O tax, etc.

Remedies

Public Nuisance remedy is remediation or abatement.

Abatement is a quasi-injunctive remedy which carries broad relief designed to stop, fix and clean up the offending conduct or contamination.

How does a government define what it takes to abate this problem?

HOW DO WE CLEAN UP THIS MESS?

Begin with stopping the offending conduct:

Cut off the flow of necessary medications? No!

Establish evidencebased thresholds and stick to them

Emergency efforts to prevent overdose death

Identify suspicious orders, prevent diversion, report offending parties

Naloxone/Narcan
Education, increased
oversight, and police
education

Needle exchange programs to reduce hepatitis

How to clean up this mess:

What is already being done, and what is working or not working.

- > Education,
- ➤ Law enforcement,
- > Treatment, alternative therapies, medical care,
- > Homeless,
- > Job placement,
- > Foster care,
- Prison,
- ➤ LTC

Building Damages Models

Cost impact to most programs and projected cost for creating new programs are known or knowable. Our models are plug and play:

(Population) x (Rx abuse incidence rate) x (Program Expense)

Examples:

Methadone Treatment: \$5k per patient per year

Drug Court: 4FTE per 7,500 addicts

Primary School Education: \$30 per student, per year

Fees & Costs

- > Fees wholly contingent on recovery
- > Costs & expenses advanced by team
- > Approximately 25% of client recovery
- > Will pursue defendant-paid fee

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION WAS IN RECEIPT OF A CHECK FROM THE STATE OF WV IN THE AMOUNT OF \$1,420.80 WHICH REPRESENTS REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY PROGRAM GRANT NUMBER F18-HS-03-405D.

ORDER

On this date, the County Commission of Wood County was in receipt of a check from the State of West Virginia in the amount of one thousand four hundred twenty dollars and eighty cents (\$1,420.80) which represents reimbursement to Wood County for expenses incurred during the month of December, 2017, in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-405D. Receipt of the aforementioned check is pursuant to an ORDER appearing in Order Book 74, at Page 462 and bearing the date of January 18, 2018, at which time David Blair Couch, in his official capacity as President and on behalf of the County Commission, was AUTHORIZED to EXECUTE the Request for Reimbursement.

Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Coych, Pres

Robert K. Tebay, Commissioner,

James E. Colombo, Commissioner

Instrument No 8 Date Recorded 10 Document Type 10 Prages Recorded

3

No 8779504 Ted 100 Ted

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION WAS IN RECEIPT OF A CHECK FROM THE STATE OF WV IN THE AMOUNT OF \$1,017.06 WHICH REPRESENTS REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY PROGRAM **GRANT** NUMBER F18-HS-03-DOHDD.

ORDER

On this date, the County Commission of Wood County was in receipt of a check from the State of West Virginia in the amount of one thousand seventeen dollars and six cents (\$1,017.06) which represents reimbursement to Wood County for expenses incurred during the month of December, 2017, in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-DOHDD. Receipt of the aforementioned check is pursuant to an Order appearing in Order Book 74, at Page 456 and bearing the date of January 18, 2018, at which time David Blair Couch, in his official capacity as President and on behalf of the County Commission, was AUTHORIZED to EXECUTE the Request for Reimbursement.

Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair 🕰

Robert K. Tebay, Commissioner

ames E. Colombo, Commissioner

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION WAS IN RECEIPT OF A CHECK FROM THE STATE OF WV IN THE AMOUNT OF \$727.37 WHICH REPRESENTS REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY PROGRAM GRANT NUMBER F18-HS-03-405B.

<u>ORDER</u>

On this date, the County Commission of Wood County was in receipt of a check from the State of West Virginia in the amount of seven hundred twenty-seven dollars and thirty-seven cents (\$727.37) which represents reimbursement to Wood County for expenses incurred during the month of December, 2017, in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-405B. Receipt of the aforementioned check is pursuant to an ORDER appearing in Order Book 74, at Page 460 and bearing the date of January 18, 2018, at which time David Blair Couch, in his official capacity as President and on behalf of the County Commission, was AUTHORIZED to EXECUTE the Request for Reimbursement.

Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Bla

Robert K. Tebay, Commissioner

Colombo, Commissioner

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION WAS IN RECEIPT OF A CHECK FROM THE STATE OF WV IN THE AMOUNT OF \$3,250.96 WHICH REPRESENTS REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY **PROGRAM GRANT** NUMBER F18-HS-03-402.

ORDER

On this date, the County Commission of Wood County was in receipt of a check from the State of West Virginia in the amount of three thousand two hundred fifty dollars and ninety-six cents (\$3,250.96) which represents reimbursement to Wood County for expenses incurred during the month of December, 2017, in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-402. Receipt of the aforementioned check is pursuant to an Order appearing in Order Book 74, at Page 458 and bearing the date of January 18, 2018, at which time David Blair Couch, in his official capacity as President and on behalf of the County Commission, was AUTHORIZED to EXECUTE the Request for Reimbursement.

Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch

Robert K. Tebay, Commissioner

Colombo, Commissioner

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION DID HEREBY AUTHORIZE DAVID BLAIR COUCH, AS PRESIDENT, TO SIGN THE REQUEST FOR REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY PROGRAM GRANT NUMBER F18-HS-03-408. SAID REQUEST IS IN THE AMOUNT OF \$0.00

ORDER

On this date, the County Commission of Wood County, upon a motion made by Robert K. Tebay, seconded by James E. Colombo and made unanimous by David Blair Couch, did hereby AUTHORIZE David Blair Couch, in his official capacity as President and on behalf of the County Commission, to sign the Request for Reimbursement in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-408. The Request for Reimbursement is in the amount of zero dollars and zero cents (\$0.00) for the month of February, 2018. The Request for Reimbursement form and the Reimbursement Worksheet have been submitted.

A copy of the Request for Reimbursement is attached to this Order and should be made a part thereof.

Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch, President

Robert K. Tebay, Commissioner

Colombo, Commissione

GOVERNOR'S HIGHWAY SAFETY PROGRAM

5707 MacCorkle Avenue SE P. O. Box 17600

Charleston, West Virginia 25317-0010

T	elephone: (304) 926-250	9	Fax: (304) 926	3880
	REQUES	T FOR REIMBUR	SEMENT	
	(For GHSP Use Only)	Sub- Grantee:	ood County Co	mmission
		Address: C	ne Court Square,	
			Parkersburg, W\	
		P. O. Number		03408
		Grant Number: FEIN Number:		-03-408 00 417
		Funds are hereby rec		
		For the period of:		2/28/18
PROJECT	CASH EXPENDITURES	Account	Number	Amount
				\$0.00
			TOTAL	\$0.00
			IVIAL	φυ,υυ
BY:	nspection at the request of the C David Blair Couch,		- //	2018
	(Typed Name An	d Title)	(Signature)	(Date)
	(Authorized Official or Grant Fi	nancial Officer Only)		
	GOVERNOR'S HIGH	REMARKO AND SECURITOR SECU	ROGRAM USE (
	ADM	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		DNLY
This request		INISTRATIVE APPRO	OVAL	DNLY
	is approved for the amount of:	INISTRATIVE APPR	OVAL	ONLY
Purs	is approved for the amount of:	INISTRATIVE APPR	OVAL · (Approved)	ONLY (Date)
	is approved for the amount of:		(Approved)	(Date)
			(Approved)	(Date)
	uant to the authority vested in n	ne, I certify that this reque	(Approved) est is correct and prope (Director)	(Date)
	uant to the authority vested in n		(Approved) est is correct and prope (Director)	(Date)
	uant to the authority vested in n	ne, I certify that this reque	(Approved) est is correct and prope (Director)	(Date) r for payment.
	uant to the authority vested in n	ne, I certify that this reque	(Approved) est is correct and prope (Director)	(Date) r for payment.
	uant to the authority vested in n	ne, I certify that this reque	(Approved) est is correct and prope (Director)	(Date)
	uant to the authority vested in n	ne, I certify that this reque	(Approved) est is correct and prope (Director)	(Date) r for payment.
	uant to the authority vested in n	ne, I certify that this reque	(Approved) est is correct and prope (Director)	(Date) r for payment.

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION DID HEREBY AUTHORIZE DAVID BLAIR COUCH, AS PRESIDENT, TO SIGN THE REQUEST FOR REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY PROGRAM GRANT NUMBER F18-HS-03-DOHWZ. SAID REQUEST IS IN THE AMOUNT OF \$0.00

<u>ORDER</u>

On this date, the County Commission of Wood County, upon a motion made by Robert K. Tebay, seconded by James E. Colombo, and made unanimous by David Blair Couch, did hereby AUTHORIZE David Blair Couch, in his official capacity as President and on behalf of the County Commission, to sign the Request for Reimbursement in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-DOHWZ. The Request for Reimbursement is in the amount of zero dollars and zero cents (\$0.00) for the month of February, 2018. The Request for Reimbursement form, and the Monthly Progress Report have been submitted.

A copy of the Request for Reimbursement is attached to this Order and should be made a part thereof.

Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch, President

Robert K. Tebay, Commissioner

Lanes E. Colembo, Commissioner

GOVERNOR'S HIGHWAY SAFETY PROGRAM

5707 MacCorkle Avenue SE P. O. Box 17600

Charleston, West Virginia 25317-0010

Telephone: (304) 926-250	9	Fax: (304) 926	-3880
REQUES	T FOR REIMBURS	EMENT	
(For GHSP Use Only)	Sub- Grantee: Wo	od County Co	mmission
	I .	ie Court Square, Parkersburg, W\	
	P. O. Number	MV1803	
	Grant Number:	F18-HS-0	3-DOHWZ
	FEIN Number:	556 00	0 417
	Funds are hereby requ		
	For the period of:	2/1/18 -	2/28/18
NAC IPAT A AGII PVMPAINITIINEA	A		A4
PROJECT CASH EXPENDITURES	Account N	umber	Amount
			\$0.00
		TOTAL	\$0.00
•		I VIAL)	Ψ0.00
available for inspection at the request of the BY: David Blair Couch	Dunnislant (Program. en m 3/172	2018
(Typed Name Ar (Authorized Official or Grant F	,	(Signature)	(Date)
GOVERNOR'S HIGH	ndoru Gilgy a Best Stiller Stiller synd at Hesit Brees a Strovenska Skipe Systematon av		NLY
ADM	INISTRATIVE APPRO	VAL	
This request is approved for the amount of:			
		(Approved)	(Date)
Pursuant to the authority vested in a	ne, I certify that this request	is correct and proper	for payment.
(Date)		(Director)	
	ng/Accounts Payable	Control of the Contro	
			300k-Pag
			· 구. 살

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION DID HEREBY AUTHORIZE DAVID BLAIR COUCH, AS PRESIDENT, TO SIGN THE REQUEST FOR REIMBURSEMENT IN REGARD TO THE GOVERNOR'S HIGHWAY SAFETY PROGRAM GRANT NUMBER F18-HS-03-406. SAID REQUEST IS IN THE AMOUNT OF \$0.00

ORDER

On this date, the County Commission of Wood County, upon a motion made by Robert K. Tebay, seconded by James E. Colombo, seconded by Jimmy Colombo and made unanimous by David Blair Couch, did hereby AUTHORIZE David Blair Couch, in his official capacity as President and on behalf of the County Commission, to sign the Request for Reimbursement in regard to the Governor's Highway Safety Program Grant Number F18-HS-03-406. The Request for Reimbursement is in the amount of zero dollars and zero cents (\$0.00) for the month of February, 2018. The Request for Reimbursement Form, the Project Financial Report, and the Monthly Progress Report have been submitted.

A copy of the Request for Reimbursement is attached to this Order and should be made a part thereof. Documentation pertaining to the Governor's Highway Safety Program Grant is on file in the Office of the County Administrator.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch, President

Robert K. Tebay, Commissioner

James E. Colombo, Commissioner

GOVERNOR'S HIGHWAY SAFETY PROGRAM

5707 MacCorkle Avenue SE P. O. Box 17600

Charleston, West Virginia 25317-0010

91	lephone: (304) 926-250	the contract of the contract o	Fax: (304) 926	ーうひひひ
	REQUES	T FOR REIMI	BURSEMENT	
(F	For GHSP Use Only)	Sub- Grantee:	Wood County Co	mmission
		Address:	One Court Square,	Suite 203
			Parkersburg, W\	
		P. O. Numb		03406
		Grant Numb		-03-406
		FEIN Number	er: 550 Vi by requested to cover ex	00 417
		For the period of		2/28/18
dagaareen Tragologia erangangan dikeminin diberin	iktaria mista — 1870—1876 ili 1870 ili 1880 ili			
PROJECT	CASH EXPENDITURES	Acco	ount Number	Amount
	•			\$0,00
			TOTAL	\$0.00
BY:	David Blair Couch (Typed Name An (Authorized Official or Grant Fi	nd Title) inancial Officer Only)	(Signature)	(Date)
	GOVERNOR'S HIGH	zelity kilneg zajde Ziljskejić. Iš šelok distore ili spjejšio spesiovate sa ka		JNLY
	AUM	INISTRATIVE A	PPROVAL	
This request is	s approved for the amount of:			
		<u> </u>	(Approved)	(Date)
Pursu	ant to the authority vested in r	ne, I certify that this	request is correct and prope	r for payment.
	(Date)	<u></u>	(Director)	
		ng/Accounts Pa	yable Use Only	
	Annual in the state of the stat			Market Control of the
				<u> </u>
				Page 1
				<u> </u>

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION DENIED AN ERRONEOUS ASSESSMENT APPLICATION IN THE NAME OF DP ASSOCIATES

$\underline{\mathbf{O}} \underline{\mathbf{R}} \underline{\mathbf{D}} \underline{\mathbf{E}} \underline{\mathbf{R}}$

On this date, the County Commission of Wood County, upon a motion duly made, seconded and passed, DENIED Erroneous Assessment Application No. 701777 pertaining to personal property in Vienna Taxing District and bearing the date of January 19, 2018. Said Erroneous Assessment Application is in the name of DP Associates and was not signed by Prosecuting Attorney Pat LeFebure.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch, President

Robert K. Tebay Commissioner

James Fredombo, Commissioner

A/1913

Son Share

The reason Nohe signed for taxpayer is because this Exon was originally done back in September. They thought I lost it, but eventually they found it on Andy's desk. Taxpayer signature is on original exon, which I have attached.

I asked Sarah if there was proof (backup) that DP Associates was out of business. She emailed me that she didn't have any proof, she did this on behalf of Andy.

I took the exon back up to the Assessor's Office.

It was sent back down with a Deed for his personal home that he sold to David Nohe. The deed is not for the business.

I don't have any proof that DP Associates is out of business.

Wood County Commission

Erroneous Assessment Application

Tax Ticket: 701777 Tax Year: 2017 Upon the application of D P ASSOCIATES whose address is 1008 CHARLET RDG DR FLOYDS KNOBS, IN 47119- aggrieved by an erroneous assessment in VIENNA District (10), in the County of Wood, for the 2017 tax year. The County Commission therefore, orders that the said applicant be and hereby exonerated from the said erroneous assessment and from the payment of the taxes so assessed in and for the 2017 tax year. If the taxes have been paid the Sheriff shall refund the same to them; or if more than a year from the time the property books were delivered to the Sheriff for the the affected tax year, the Sheriff shall allow a credit on future taxes payable. DUE TO CLERICAL ERROR THE ABOVE MENTIONED TAX TICKET IS INCORRECT. MR. BELL WAS NOT IN BUSINESS IN WOOD COUNTY AS OF JULY 1, 2016. All of which is ordered to be certified to the Auditor of the State of West virginia and the Sheriff of WOOD County Transaction Type Amount Tax Rate 07/01/2017 BILLING 66,36 3.112120 2,132 -2,132 09/25/2017 PENDING EXONERATION -66.36 3.112120 0.00 Adjusted N Adjusted Net Ta Taxpayer Prosecutor Commissioner Commissioner County Commission President At a regular session of the County Commission of Wood County, West Virginia, held at the Courthouse of said County, The County Commission did approve this exoneration on JAN 192018 RECEIVED County Administrator JAN 292018iioi County Administrati

Tax Type: Personal Property

Wood County Commission

Erroneous Assessment Application

Tax Type: Personal Property Tax Ticket: 701777 Tax Year: 2017 Upon the application of D P ASSOCIATES whose address is 1008 CHARLET RDG DR FLOYDS KNOBS, IN 47119- aggrieved by an erroneous assessment in VIENNA District (10), in the County of Wood, for the 2017 tax year. The County Commission therefore, orders that the said applicant be and hereby exonerated from the said erroneous assessment and from the payment of the taxes so assessed in and for the 2017 tax year. If the taxes have been paid the Sheriff shall refund the same to them; or if more than a year from the time the property books were delivered to the Sheriff for the the affected tax year, the Sheriff shall allow a credit on future taxes payable. DUE TO CLERICAL ERROR THE ABOVE MENTIONED TAX TICKET IS INCORRECT. MR. BELL WAS NOT IN BUSINESS IN WOOD COUNTY AS OF JULY 1, 2016. All of which is ordered to be certified to the Auditor of the State of West virginia and the Sheriff of WOOD County Date Transaction Type Class Amount Tax Rate Net Value 07/01/2017 BILLING 3.112120 4 66.36 2,132 3.112120 09/25/2017 PENDING EXONERATION -66.36 -2,1320.00 Adjusted Net Taxes Adjusted Net Value 304-482-31 Prosecutor Assessor Commissioner County Commission President Commissioner At a regular session of the County Commission of Wood County, West Virginia, held at the Courthouse of said County, The County Commission did approve this exoneration on

	Statement	123	/pe	
District 1	O-VIENNA	Personal	Property	
	Transaction His	itory		₽
Date	Transaction Type	1st Half	2nd Half	0
2017/07/01	BILLING .	45.68	45.68	Ĭ
2017/08/10	REGULAR PAYMENT	-44.85	-44.85	
2017/09/25	PENDING EXONERATION	-33,18	-33.18	

Aggount	Year	Ticket
1020096	2017	701777
roperty Descrip	tion	

NON- FILE

Value: 2,132

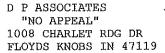


Distribution of Original Base	e Taxes	Rate	Class	Gross Val,	Exemption	Net Val
STATE	.00	3.112120	4	2,132	0	2,132.
COUNTY	.00		Total	2,132	0	2,132
SCHOOL CURRENT	.00			• •		
SCHOOL EXCESS	.00					
SCHOOL BONDS	.00					
· VIENNA CURRENT	.00					
. VIENNA EXCESS	.00			•		
COUNTY EXCESS	.00			•		

	Payment Schedule	ings of the second section in the second	
If Paid By	First Half Due	Second Half Due	Full Year Due
Saturday, September 30, 2017			0,00
Tuesday, October 31, 2017			0.00
Thursday, November 30, 2017			0.00
Sunday, December 31, 2017			0.00
Wednesday, January 31, 2018			0.00
Wednesday, February 28, 2018			0.00
Thursday, March 1, 2018		•	0.00
Saturday, March 31, 2018			0.00
Monday, April 30, 2018			0.00

If paid in the month of September 2017 your amount due will be \$.00

Make Checks Payable and Remit To: STEVE STEPHENS, SHERIFF P O BOX 1985 PARKERSBURG WV 26102-1985 First Half Dates To Remember: Payable beginning July 15, 2017 2 1/2% discount ends September 1, 2017 Interest charges begin October 1, 2017 Delinquent list published May 1, 2018 Second Half Dates To Remember: Payable thru February 2018 2 1/2% discount ends March 1 2018 Interest charges begin April 1 2018 Delinquent list published May 1, 2018





Wood Tax Statement 10-VIENNA

BILLING

Date

2017/07/01

2017/08/10

2017/09/25

Personal Property

2nd Half

45.68

-44.85

-33.18

1st Half

45.68

-44.85

-33.18

Account 1020096

Year

701777

Property Description

NON- FILE .

Value: 2,132

DUE TO CLERICAL ERROR THE ABOVE MENTIONED TAX TICKET IS INCORRECT. MR. BELL WAS NOT IN BUSINESS IN WOOD COUNTY AS OF JULY 1, 2016.

Transaction History

Transaction Type

REGULAR PAYMENT

PENDING EXONERATION

Distribution of Original Base	Taxes		Rate	Class	Gross Val,	Exemption	Net Val
STATE		.00	3.112120	4	2,132	.0	2,132
COUNTY		.00		Total	2,132	0	2,132
SCHOOL CURRENT		.00			-,	, ,	_,
, SCHOOL EXCESS	•	.00				,	
SCHOOL BONDS		.00	•		•		
. VIENNA CURRENT		.00	,				
VIENNA EXCESS		.00		•	•		
COUNTY EXCESS		.00					

		Payment Sc	hedule .		
If Paid By	· .	First	: Half Due	Second Half Due	Full Year Due
Wednesday, January 31, 2018					0.00
Wednesday, February 28, 2018	•				. 0.00
Thursday, March 1, 2018		•	•		0.00
Saturday, March 31, 2018		•			0.00
Monday, April 30, 2018					0.00

If paid in the month of January 2018 your amount due will be \$.00

Make Checks Payable and Remit To: STEVE STEPHENS, SHERIFF P O BOX 1985 PARKERSBURG WV 26102-1985

First Half Dates To Remember: Payable beginning July 15, 2017 2 1/2% discount ends September 1, 2017 Interest charges begin October 1, 2017 Delinquent list published May 1, 2018

Second Half Dates To Remember: Payable thru February 2018 2 1/2% discount ends March 1 2018 Interest charges begin April 1 2018 Delinquent list published May 1, 2018



Angi Graham

From:

Sarah Edelen

Sent:

Monday, January 22, 2018 11:44 AM

To:

Angi Graham

Subject:

RE: DP Associates

Angi,

Good Morning. I don't have any proof. I did this exon on behalf of Andy. You will have to contact Andy to ask for this information.

Thanks, Sarah

From: Angi Graham

Sent: Monday, January 22, 2018 11:38 AM

To: Sarah Edelen < sedelen@woodcountywv.com>

Subject: FW: DP Associates

Good Monday Morning!!

Connie brought me the DP Associates exon on Friday. There is only a tax ticket with it. Can you send me the back-up (proof)?

Thanks.

Angi

From: Angi Graham

Sent: Thursday, January 18, 2018 11:44 AM

To: Sarah Edelen < sedelen@woodcountywv.com>

Subject: RE:

Don't see anything for them. I went back to August.

From: Sarah Edelen

Sent: Thursday, January 18, 2018 11:22 AM **To:** Angi Graham <angi@woodcountywv.com>

Subject: RE:

It is for tax year 2017 & it's for business personal property.

From: Angi Graham

Sent: Thursday, January 18, 2018 11:20 AM

To: Sarah Edelen < sedelen@woodcountywv.com >

Subject: RE:

I'm not holding anything for DP Associates. What year is it for and is it personal or real? Maybe I can look it up that way. I did a search where things are recorded after we process them and nothing came up for DP Associates.

From: Sarah Edelen

Sent: Thursday, January 18, 2018 10:38 AM
To: Angi Graham <angi@woodcountywv.com>

Subject:

Angi,

I have a pending exoneration from September 25, 2017 for DP Associates. The account number is 1020096 & ticket number 701777. Can you tell me when I can expect this to be completed? The tax office contact me about it today.

Thank you, Sarah Edelen

DEED

THIS DEED, made this \frac{1}{2} day of \frac{1}{2} \text{Line} \frac{1}{2}, 2015, by and between \frac{1}{2} \text{DAVID P. BELL and ROBERTA S. BELL, hereinafter referred to as parties of the first part, and

DAVID C. NOHE and PAMELA S. NOHE, hereinafter referred to as parties of the second part.

WITNESSETH, that for and in consideration of the amount of Five (\$5.00) Dollars, cash in hand paid, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties of the first part, the said parties of the first part do hereby grant and convey unto the parties of the second part, jointly with the right of survivorship and to the survivor thereof, their heirs and assigns, with covenants of **general warranty**, all of that certain lot, tract or parcel of land, situate, lying and being in the City of Vienna, Wood County, West Virginia, more particularly bounded and described as follows:

BEING all of Lot No. 4 of William Heinselman Heirs Property, as shown on a plat of said Property prepared by Paul K. Marshall, LLS #580, dated December 5, 1989, which plat is of record in the Office of the Clerk of the County Commission of Wood County, West Virginia, in Deed Book 884, at page 859.

Being the same real estate conveyed unto David P. Bell and Roberta S. Bell by deed dated November 23, 1998 and of record in the Office of the Clerk of the County Commission of Wood County, West Virginia, in Deed Book 991, at page 137.

This conveyance is specifically made subject to those certain restrictive covenants of record in the aforesaid Clerk's Office in Deed Book 884, at page 857.

This conveyance is made subject to any and all exceptions, agreements, restrictions, covenants, easements and rights-of-way set forth in prior deeds of record.

DECLARATION OF CONSIDERATION

The undersigned hereby declares that the total consideration paid for the property conveyed by this document is \$ 260 500.500.

Witness the following signature and seal:

DAVID P. BELL

Roberte SBULL

STATE OF WEST VIRGINIA, COUNTY OF WOOD, to wit:

I, Shaller, Notary Public of and for the County and State aforesaid, do hereby certify that David P. Bell and Roberta S. Bell, whose names are signed to the foregoing record, have this day acknowledged the same before me in my said County and State.

Given under my hand this '\ day of \ \ \lambda_\text{neurs}

AFFIX OFFICIAL SEAL

Notary Public

My commission expires:

OFFICIAL SEAL NOTARY PUBLIC STATE OF WEST VIRGINIA Stephen P. Shaffer

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: COMMISSION APPOINTED COLOMBO TO THE WOOD COUNTY 9-1-1 ADVISORY BOARD.

ORDER

On this date, the County Commission of Wood County, upon a motion made by Robert K. Tebay, seconded by David Blair Couch and passed, appointed James E. Colombo, County Commissioner, to the Wood County 9-1-1 Advisory Board. Commissioner David Blair Couch was appointed by Order dated January 5, 2017 and Commissioner Colombo will be replacing him.

APPROVED:

THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch, President

Robert K. Tebay, Commission

James E.

A/1912

IN THE COUNTY COMMISSION OF WOOD COUNTY, WEST VIRGINIA

IN RE: THE COUNTY COMMISSION ORDERED THAT THE NEW ROAD NAME REQUEST FORM FROM HINO MOTORS MANUFACTURING USA BE APPROVED. THE NEW ROAD NAME WILL BE HINO DIVE.

ORDER

The County Commission of Wood County was in receipt of a New Road Name Request Form from Hino Motors Manufacturing USA, to name the road to their business, HINO DRIVE. The said Request does not interfere with the scheduled readdressing and mapping for the E-9-1-1 Master Street Addressing Guide. The road to be known as HINO DRIVE is the old Coldwater Creek Drive in City District, Tax Map 154, Parcel 3.1. The request by Hino Motors Manufacturing USA is in accordance with Chapter 7, Article 1, Section 3 of the Code of West Virginia, 1931, as amended, which deals, in part, with the County Commission naming or renaming thereof of roads, ways, streets, avenues, drives and the like to assure uniform, nonduplicative conversion of all rural routes to city-type addressing on a permanent basis.

The County Commission does hereby find that the said request, made in writing, by Hino Motors Manufacturing USA, and the approval from the Wood County E-9-1-1, is in proper form and is hereby ORDERED to be filed.

NOW, THEREFORE, the County Commission of Wood County, upon a motion made by James E. Colombo, seconded by David Blair Couch and made unanimous by Robert K. Tebay, does hereby ORDER that the aforementioned road be named HINO DRIVE. The County Commission does further ORDER that a copy of this ORDER, along with the New Road Name

Request Form, be certified by the Clerk of the County Commission for entry in the Office of the Clerk of the County Commission.

APPROVED:

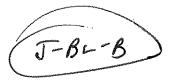
THE COUNTY COMMISSION OF WOOD COUNTY

David Blair Couch, President

Robert K. Tebay, Commissioner

James E. Colombo, Commissioner

A/1911



County Administrator

Please complete the upper portion of this request form. Return it to: Central Telecommunications Center, 911 Core Road, Parkersburg, WV 26104.

		WOOD COUNTY 9-1-1	L	
	1	EW ROAD NAME REQUEST FOR	RM	
	Applicant Name: //10 Mofa	s Manfactoren U.CA lu	Steve Stope Sa. V. P. i Plan	Mge.
	Applicant Phone #: 304-	375-6700		
1	Property Owner Name: Hino	Motors Manufacturin	U.S.A.	
M	Current Road Name or Highway	. N.T	ter Creek Drive	
7,	Tax District: 05		Parcel #: 3.1	
HNGE Regues	ocres. Applicant al 5-154-1.1 (34.86 o	cres). Changing Cold	.05 ocres) and	
17	List Three Road Name Suggesti	ons: 1st Hino Drive *		
	751	3 rd		
X.	Please prioritize. Signature of Applicant:	11.11.1		
Cr	OFFICIAL USE ONLY	Luc Almer		
8	Coordinated with the Map Proce	essor:		
Jan	Processor Signature:	ence enl Process Date: c	2/26/18	
ad Name	Granted Street Name:			
(x		d telephone number all of the homeoust be 100% of the residents if less th		
	Signature	Existing Address	Phone #	0 .66
W.	Dane 2. Book	122 Coldwater Creek D. Mineral Wells, WV	304-485-3391 26150	Ynessage
0	Spac Juth ringer sh	Mine-al Wells, wu	304-834-276	9
		Lesidence - Alice R.	Bosley Estate	
			110000000000000000000000000000000000000]

Please complete the upper portion of this request form. Return it to: Central Telecommunications Center, 911 Core Road, Parkersburg, WV 26104.

	WOOD COUNTY 9-1-1		
1	NEW ROAD NAME REQUEST FORM		
Applicant Name:			
Applicant Phone #: 304-	375-6700		
Property Owner Name: Hiro	Motors Manufacturing U.S.A		
Current Road Name or Highwa	y Number, if any: 601 Coldwater Cree	k Drive	
Tax District: 05	Tax Map #: 154 Parcel #: 3.1		
Describe Physical Location: 9 acres. Applicant a 5-154-1.1 (34.86 a	162,000 5F industrial facility 150 awas 5-154-3 (21.05 acres acres).	on 56.98) and	
List Three Road Name Suggest	2 nd		
Please prioritize.	3 rd		
Signature of Applicant:			
OFFICIAL USE ONLY			
Coordinated with the Map Proc	essor:		
Processor Signature:	Process Date:		
Granted Street Name:			
	nd telephone number all of the homeowners agreeing must be 100% of the residents if less than 10 and 75%		
Signature	Existing Address	Phone #	
Jane 2. Bal	The Caks Trailer Park	3e4-485-3394	
San Juth ruger	Wy- Mineral Wells, WV 26150	304-834-276 304-834-276 304-489-135 304 580 1179 845-332-658	9
Duray Landon	#Y	304-489-135	74 異音音
Vet 1	Mailing Address:	504 580 11 19	
andrew Herlin 1	122 Coldwater Creek Dr. Mure-al Wells, WU 26150	845-332-638	
y	Mure-al Wells, WU 26150		3 E 4 4
		·•	21-12 - 12-12 - 120 - 12

United States of America

State of West Birginia



County of Wood, ss:

I, <u>CHAD BEAVER</u> do solemnly swear I will support the Constitution of the United States and the Constitution of the State of West Virginia and I will faithfully discharge the duties of my office as <u>HOLDING CENTER OFFICER</u> of the <u>WOOD COUNTY SHERIFF</u> for the term commencing on <u>Friday</u>, <u>February</u> 16, 2018, to the best of my skill and judgment. So help me God.

CHAD BEAVER

Subscribed and sworn before the undersigned, on Thursday, March 1, 2018.

Markahoser

Mark Rhodes
Wood County Clerk

* Mark Rhodes
#800 County 01:54:09 FM
- Instrument No 8777757
Date Recorded 03/01/2018
- Document Type-9ATH
- Paues Recorded 1
- Book-Page 74-703

STATE OF WEST VIRGINIA COUNTY OF WOOD TO -WIT:

I, <u>Jeffrey Reed</u>, do solemnly swear that I will support the Constitution of the United States, the Constitution of the State of West Virginia, and that I will faithfully and impartially discharge the duties of the office of the <u>Wood County Community Corrections Board</u> in and for Wood County, West Virginia, to the best of my skill and judgment, during my continuance in the same; SO HELP ME GOD.

Subscribed and sworn to, before the County Commission of Wood County, West Virginia, this

EN EL CONFIGNO DE CARRENTE LA DESPENDA CONTRACTO DE CONTRACTO DE LA CONTRACTOR DE CONTRACTOR DE CONTRACTOR DE

27 day of FE

__, 2018.

County Commission of Wood County

STATE OF WEST VIRGINIA COUNTY OF WOOD TO -WIT:

I, <u>Michelle Rusen</u>, do solemnly swear that I will support the Constitution of the United States, the Constitution of the State of West Virginia, and that I will faithfully and impartially discharge the duties of the office of the <u>Wood County Community Corrections Committee</u> in and for Wood County, West Virginia, to the best of my skill and judgment, during my continuance in the same; SO HELP ME GOD.

Subscribed and sworn to, before the County Commission of Wood County, West Virginia, this

27th day of FEBRUARY, 2018.

County Commission of Wood County

STATE OF WEST VIRGINIA

COUNTY OF WOOD

}

TO -WIT:

I, <u>Robert Andrew Waters</u>, do solemnly swear that I will support the Constitution of the United States, the Constitution of the State of West Virginia, and that I will faithfully and impartially discharge the duties of the office of the <u>Wood County Deputy Sheriff</u> in and for Wood County, West Virginia, to the best of my skill and judgment, during my continuance in the same; SO HELP ME GOD.

Robert andrew Waters

Subscribed and sworn to, before County Commission of Wood County, West Virginia, this 15 day

of March, 2018.

County Commission of Wood County



A CONTRACTOR OF THE CONTRACTOR

WOOD COUNTY SHERIFF'S OFFICE

Steve Stephens, Sheriff W. Bruce Riffle, Chief Deputy 304-424-1834 304-424-1832 Fax

DATE: March 1, 2018

TO: Wood County Commission

FROM: Sheriff Steve Stephens

REF: New Hire – Bargeloh

Regina "Gina" Bargeloh will begin work on Monday, March 5, 2018 at the Wood County Tax Office as a tax deputy. Ms. Bargeloh's salary will be \$23,750.00 annually and is to be paid from line item 404-10-103. Ms. Bargeloh will be a full time employee with benefits

RECEIVED

MAR - 2 2018

COUNTY ADMINISTRATO