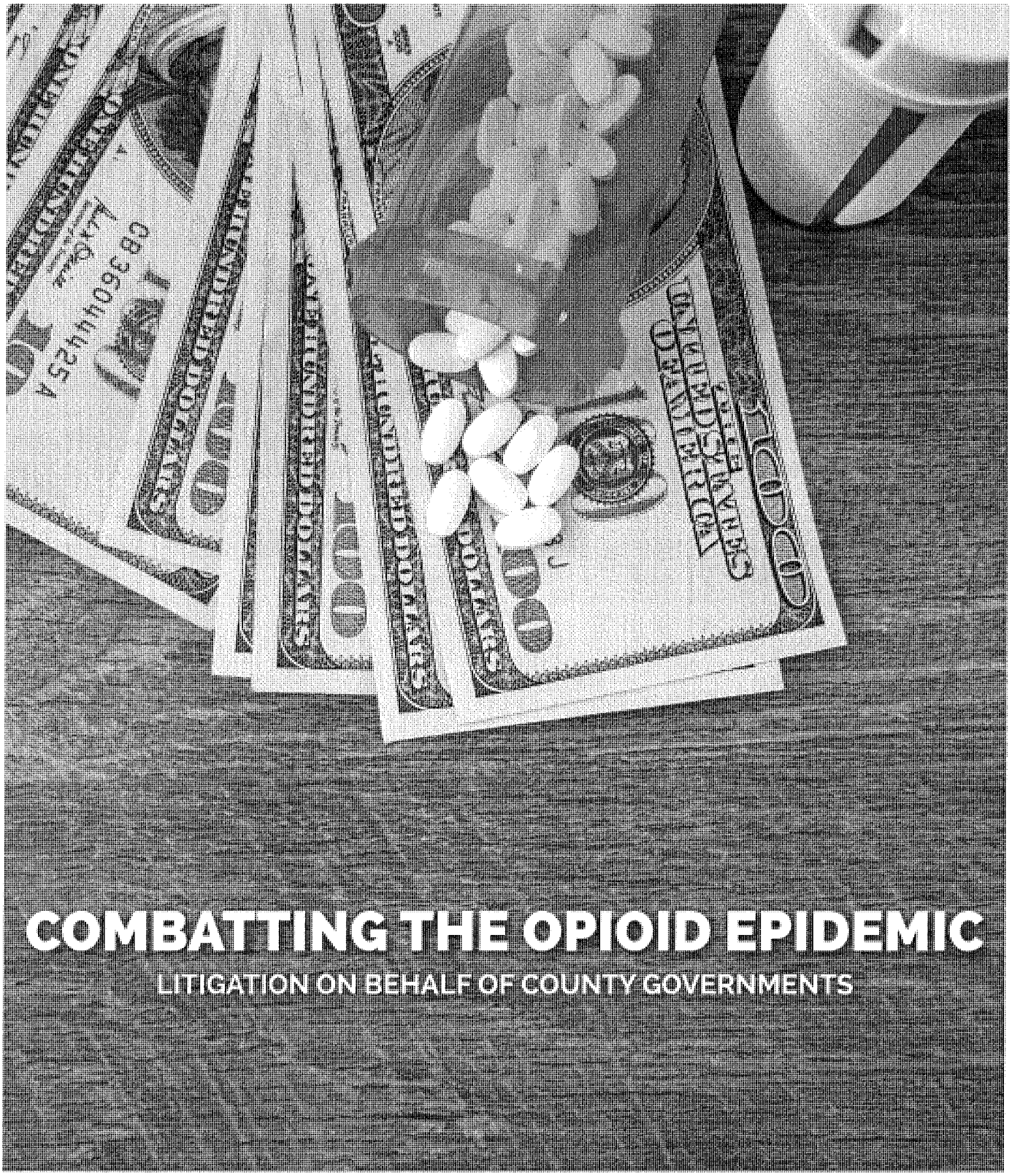
Item # 16 a

Crueger Dickinson

von Briesen

von Briesen & Roper, s.c. | Attorneys at Law



COMBATTING THE OPIOID EPIDEMIC

LITIGATION ON BEHALF OF COUNTY GOVERNMENTS

THE OPIOID EPIDEMIC: A PUBLIC HEALTH CRISIS

Opioid addiction and abuse have reached epidemic levels over the past decade. Indeed, 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."[1]

In the last decade, the epidemic has exploded. From 1999 to 2013 the amount of opioids dispensed in the United States quadrupled.

In 2013, nearly 207 million opioid prescriptions were written. A year later, that number grew to 259 million.

Those sales are big business for the pharmaceutical companies that manufacture and sell opioids including Purdue, Teva, Janssen, Cephalon and Endo (referred to as "Pharma"). In 2015 alone, the sale of opioids generated nearly $10 Billion in revenue for Pharma.

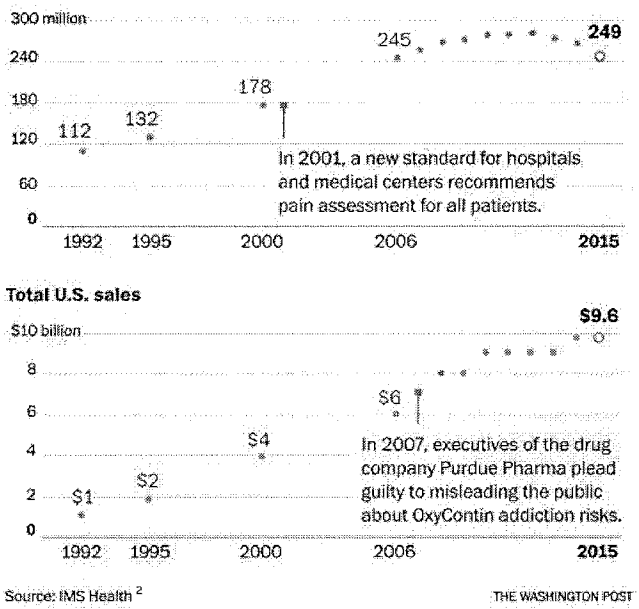
Sales and profits have grown dramatically over the past several decades.

4X

From 1999 to 2013, the amount of prescription opioids dispensed in the U.S. nearly **quadrupled.**

Tracking opioid use and sales

The opioid-drug market has grown dramatically over the past 25 years.



Source: IMS Health [2] THE WASHINGTON POST

1 http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm

2 https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.2d1327bf59ae

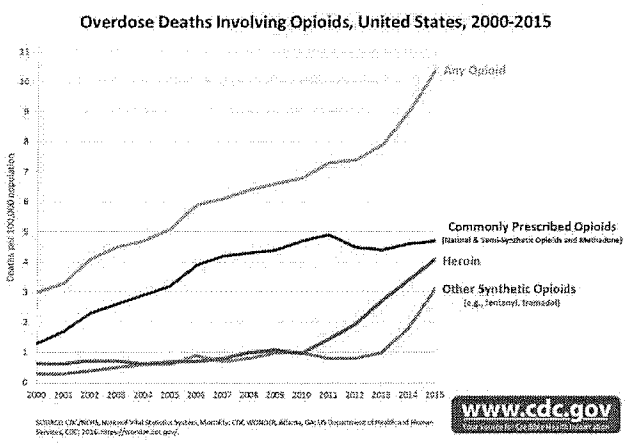
This spike in sales has had devastating and catastrophic effects. 2015 Data from the National Survey on Drug Use and Health showed that in the year 2013 over a third of the people in the United States had used prescription opioids with a significant number suffering from addiction as a result.

37.8% Americans used prescription opioids
(91.8 MILLION PEOPLE)

4.7% misused them
(11.5 MILLION PEOPLE)

.8% had a use disorder
(1.9 MILLION PEOPLE)

Additionally, deaths from opioids dramatically spiked with increased sales:



As described below, these dramatically increased sales and the spike in abuse and resultant deaths directly corresponds to Pharma's decision to market opioids for long-term use despite their known addictive effects.

PHARMA'S ROLE IN CREATING THE OPIOID EPIDEMIC

Opioids were historically used to provide effective treatment for short-term pain management. Controlled studies of the safety and efficacy of opioids were limited to short-term use. Pharma knew the limitations of the controlled studies. However, Pharma knew that profits could sky rocket if they were able to market and sell opioids for long-term use, including to treat chronic pain. In order to expand their market and achieve a dramatic increase in profits, Pharma decided to create a false marketing campaign designed to give the medical community and the public the false impression that opioids were safe and efficacious for long-term use. This false marketing campaign began in the late 90's, but exponentially increased starting in about 2006 and continues to the present.

Pharma was successful.

SINCE 1999
Prescription sales of opioids have **quadrupled**

IN 2010
254 million opioid prescriptions were written

IN 2013
37.4% of the population had been prescribed Opioids

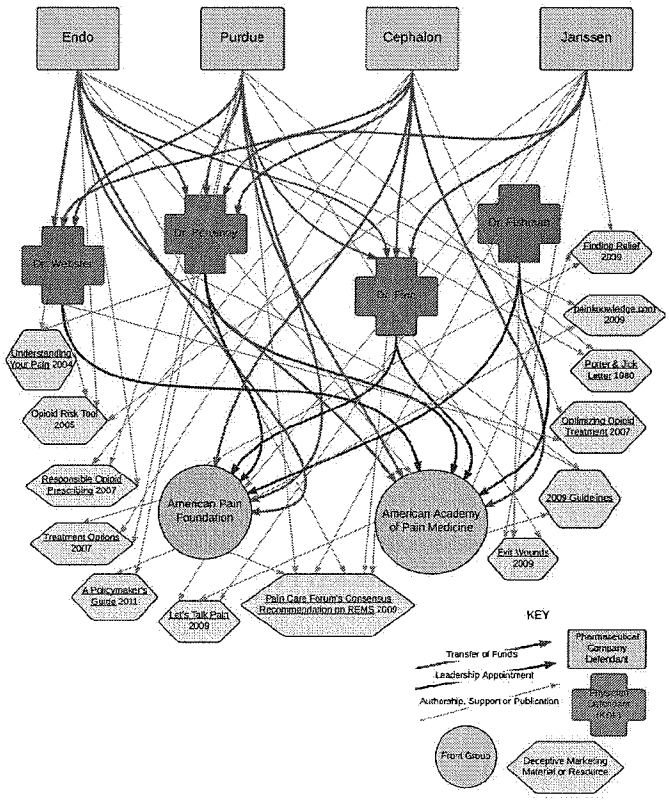
The result was a public health crisis that has had a profound impact on individuals, families and communities across the country.

The National Institute for Health ("NIH") identified Pharma as directly responsible for this crisis. In 2015, the NIH found that "several factors are likely to have contributed to 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 pharmaceutical companies.*"[3]

That "aggressive marketing campaign" included distorting medical and public perception of existing scientific data to create the false impression that opioids were safe and efficacious for long-term use. To accomplish this, Pharma poured money into generating articles, continuing education courses, sales groups and advocacy groups to create a phony "consensus" supporting the long-term use of opioids. Pharma and a select group of doctors and "front groups" banded together to create false legitimacy and the impression that these drugs were safe and efficacious for long-term use.

91 91 Americans die every day from an **opioid overdose** (that includes prescription opioids and heroin).

The following graphic depicts how this worked:



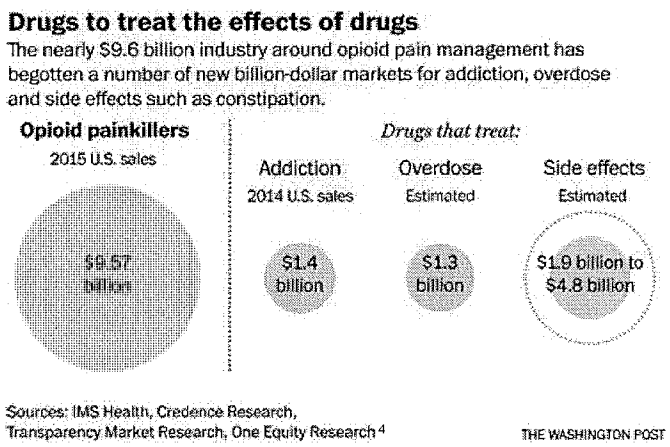
County of Suffolk v. Purdue Pharm L.P. et al., Case No. NYSCEF 613760/2016, Doc. No. 2, Ex. A.

WHY DID PHARMA DO THIS?

The answer is simple. Pharma made blockbuster profits. In 2012 alone, Pharma raked in $8 Billion from the sale of opioids. Purdue alone made $3.1 Billion from the sale of the opioid Oxycontin.

3 https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse

Not only has the Pharma industry profited from selling opioids but companies have also profited from treating the effects. As illustrated in a recent Washington Post article, the profits have been enormous:



COUNTIES BEAR THE COSTS

While Pharma was raking in profits, county governments have been forced to spend a significant amount of money combatting this epidemic. Costs to counties include health care costs, addiction and treatment costs, social costs, programming, training and education costs, criminal justice and victimization costs and lost productivity.

COUNTIES AND STATES FILE LAWSUITS

A number of government entities have brought litigation against the Pharma companies for their role in creating the Opioid Epidemic. This includes the State of Kentucky, the State of Ohio, the City of Chicago and counties in New York, West Virginia and Illinois. More and more cases are filed every week. A chart summarizing the current litigation is attached in the Appendix hereto (Tab 1). Additionally, major news outfits have been covering the opioid epidemic and resulting litigation. (Several recent examples have been included in the attached Appendix, Tab 2).

HOLDING PHARMA ACCOUNTABLE: CLAIMS

Lawsuits seek to hold opioid manufacturers accountable for the costs communities incur as a result of the opioid epidemic.

Lawsuits have alleged that Pharma and a select group of doctors worked together to create a false impression of the safety and efficacy of opioids for long term use. Allegations are that Pharma and the doctors misled the medical community and consumers into believing that opioids were non-addictive and were a viable option for treatment of chronic pain. Legal claims have included:

- Misrepresentation
- Consumer Fraud/Violation of Consumer Protection Statutes
- False Advertising
- Nuisance
- Civil RICO

Different cases have taken different approaches, but the facts and allegations are similar. A sample of one of the Complaints, filed by Suffolk County, New York is included in the attached Appendix (Tab 3).

4 https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.2d1327bf59ae

WHAT ARE THE DOLLAR FIGURES?

While it is still early in the investigation into the exact costs to counties, states and municipalities, costs of the Opioid Epidemic are staggering. Indeed, in 2016 researchers from the CDC estimated the annual economic burden of prescription opioid abuse in the U.S. at $78.4 Billion. The study further broke down this cost as follows:

[5]

While the CDC study did not attempt to estimate damages to county governments, the economic impact is significant and, to date, unreimbursed by Pharma.

5 Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care*, October 2016, 54(10): 901 – 906.

FREQUENTLY ASKED QUESTIONS

WHAT IS THE OPIOID LITIGATION AND WHY DOES IT AFFECT COUNTIES?

State and local governments around the country have begun to file lawsuits against several major manufacturers (Purdue, Janssen, Endo, Cephalon and others)(referred to as "Pharma") for their role in creating the Opioid Epidemic. These manufacturers flooded the market with highly addictive drugs, claiming they were safe and efficacious for long term use, manufactured studies to support these false claims and knowingly misrepresented the addictive nature of these drugs. As a result of these misrepresentations, millions of Americans lives have been impacted or destroyed (commonly referred to as the "Opioid Epidemic"). The Opioid Epidemic has in turn imposed huge costs on both county and state governments around the country including health care costs, substance abuse, treatment and prevention costs, criminal justice costs and productivity costs.

WHAT IS THE ECONOMIC IMPACT OF THE OPIOID EPIDEMIC?

While it is still early in the investigation, studies have analyzed the economic impact of the Opioid Epidemic. In the most recent major study, published in 2016 by CDC researchers, the annual estimated economic burden of prescription opioid abuse in the United States was determined to be $78.4 Billion. Of that number the economic impact broke down as follows:

LOST PRODUCTIVITY
$42 Billion (53.3%)

HEALTH INSURANCE
$26.1 Billion (33.3%)

CRIMINAL JUSTICE
$7.6 Billion (9.7%)

SUBSTANCE ABUSE TREATMENT
$2.8 Billion (3.6%)

[6]

Predictably, as the epidemic has worsened, so has the economic burden. Indeed, a similar study in 2007 found the annual economic impact was $55.7 Billion. And a recent 2017 study funded by the U.S. Department of Health and Human Services found that more than one third of U.S. civilian, noninstitutionalized adults reported prescription opioid use, with substantial numbers reporting misuse and use disorders. As the problem has worsened since 2013, it is expected that the impact has correspondingly worsened.

6 Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care*, October 2016, 54(10): 901 – 906.

WHAT IS THE GOAL OF THE OPIOID LITIGATION?

To hold Pharma responsible for their role in creating the Opioid Epidemic and to return to the counties the money spent battling the epidemic and the expense of other critical programming. While it is unrealistic to think that the lawsuit will solve the problem, Pharma should be responsible for funding solutions to a problem they created.

WHAT KINDS OF COSTS WOULD A LAWSUIT SEEK TO RECOVER?

The counties would seek repayment for the costs they have expended related to the Opioid Epidemic. Those costs include but are not limited to:

- County funded healthcare costs for employees and dependents related to opioid addiction, substance abuse treatment, hospitalizations, etc.
- County funded programs for residents for prevention, treatment, health visits, substance abuse programs etc.
- Criminal Justice and law enforcement costs associated with opioids
- Loss of county employee productivity related to opioid abuse and addiction
- General societal mayhem and opioid related death costs

WHAT IS THE REASON THE COUNTIES SHOULD GET IN INVOLVED IN THE OPIOID LITIGATION?

The only way to recover any of the significant costs the counties have faced as a result of Pharma's role in the Opioid Epidemic is to bring suit. Any county who does not get involved, risks receiving no recovery. While recovery in this type of litigation is not certain, one certain way to get nothing is to stay out of the litigation.

WHAT IF THE COUNTIES DO NOT GET INVOLVED?

Counties who do not get involved will not get a recovery in the event that there is one.

WHO WILL PAY FOR THE LITIGATION?

The counties will not be asked to bear the costs of the Opioid Litigation. The law firms proposing to represent the counties will work on a contingent fee basis (only getting paid out of a portion of the recovery if there is one) and bearing all costs of the litigation.

WHAT WILL BE EXPECTED OF A COUNTY BRINGING SUIT?

Counties bringing suit will be expected to participate in some significant ways. The most major of which is document collecting and information gathering to support the county's claim for costs associated with the Opioid Epidemic. The team of private attorneys will work on site with county employees to help identify, gather and assemble this information, however, county employee time will also be necessary. Affected departments will likely be Health and Human Services, Human Resources, Medical Examiner/Coroner, District Attorney's Office, Office of the Sheriff, Circuit Courts, Department of Administration.

WHAT IS THE REASON TO COORDINATE EFFORTS ACROSS COUNTIES IN THE LITIGATION?

It will be very important to coordinate efforts both among counties in each state and between counties nationally. Government entities will face a well-financed, well-funded and coordinated defense from Pharma. Unless a critical mass of counties not only file suit and coordinate efforts, it is a safe bet that Pharma will simply continue to fight each individual case without contemplating a resolution.

WILL THE STATE BE INVOLVED AND HOW WILL THAT IMPACT THE COUNTIES AND THEIR ABILITY TO RECOVER?

The State of Ohio has brought suit and other states are contemplating suit. It is safe to assume that state governments will bring similar suits. The states and counties will have separate damages, however, and the counties should be able to recover even if the states bring suit. As the tobacco litigation demonstrated, there is no reason to expect that the counties can simply let the states file suit and wait for their portion of the states' recovery. The best way for the counties to protect their interests is to pursue their own litigation.

CATEGORIES OF INFORMATION SUPPORTING COUNTY COSTS

COUNTY DEPARTMENT OF HEALTH AND HUMAN SERVICES/SOCIAL SERVICES/COMMUNITY PROGRAMS	Information regarding community education; outreach and prevention; opioid abuse treatment; education of medical professionals; and costs associated with such programs. Information regarding county funded (for residents/indigents) opioid-related office visits, toxicology screenings, inpatient therapy, medical claims, medical diagnosis, pharmacy claims, emergency department visits, emergency department claims, opioid treatment programs; days missed from work for opiate treatment or offenses, prescription drug plans, mental health screenings, mental health hospital visits, mental health diagnosis and Medicaid claims. Information regarding opiate treatment programs, funding for opiate treatment programs, inpatient and outpatient treatment data, cost of drugs for opiate treatment programs, insurance information for treatment and relapse information. Information from delinquency and court services regarding opioid-related interventions and programs designed to curb or prevent opioid use.
DEPARTMENT OF HUMAN RESOURCES	Information regarding county funded employee opioid-related office visits, toxicology screenings, inpatient therapy, medical claims, medical diagnosis, pharmacy claims, emergency department visits, emergency department claims, opioid treatment programs; days missed from work for opiate treatment or offenses, prescription drug plans, mental health screenings, mental health hospital visits, mental health diagnosis Information regarding county employees' opioid-related disability claims, funding used for substance abuse, workers compensation claims, and mental health treatment.
MEDICAL EXAMINER/ CORONER	Information regarding the number of opioid overdose deaths, costs associated with those deaths.
DISTRICT ATTORNEY	Information regarding the prosecution of opioid-related crimes committed within the county.

OFFICE OF THE SHERIFF/ COUNTY JAIL	Information regarding opioid-related arrests and charges, illegal trafficking data, prescription-related DWI's, incarceration records, probation records, drug court data, sheriff/deputy overtime data regarding opioid-related offenses, data from Narcan program, sheriff/data resources data dedicated to heroin epidemic including prevention, emergency dispatch data, repeat offender data, involuntary treatment programs, emergency dispatch data. Information regarding costs associated with housing inmates with addiction arrests, requiring addiction treatment programs.
DEPARTMENT OF ADMINISTRATION	Information regarding costs associated with expenditures incurred, or resources allocated, to combat opioid addiction or abuse.
COUNTY-OWNED HOSPITALS/NURSING HOMES	Information regarding costs of opioid treatment at county-owned hospitals and nursing homes.

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Item # 16b

TAB 1

Court	Case No.	Plaintiff(s)	Defendant(s)	Date Filed	Firms Representing
Cleveland County, OK	CJ-2017-816	State of Oklahoma; AG Mike Hunter	Purdue Pharma LP; Purdue Pharma Inc; The Purdue Frederick Company Inc,; Teva Pharmaceuticals USA Inc.; Cephalon Inc; Johnson & Johnson; Janssen Pharmaceuticals Inc; Ortho-McNeil-Janssen Pharmaceuticals Inc; Jansen pharmaceceutica, Inc.; Allergan PLC; Watson Laboratories Inc; Actavis LLC; Actavis Pharma, Inc.	6/30/2017	Whitten Burrage; Nix Patterson & Roach LLP; Glenn Coffee & Associates, PLLC
CNDC	17-CV-203	Cherokee Nation	McKesson Corp., Cardinal Health, Inc., Amerisourcebergen, CVS Health, Walgreens Boots Alliance, Inc., Wal-Mart Stored, Inc.	4/20/2017	Filed in Tribal Ct.
EDCA	17-CV-1485	County of San Joaquin; City of Stockton; Montezuma Fire Protection District	Purdue Pharma, L.P.; Purdue Pharma, Inc.; Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Phamaceutica, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; McKesson Corporation	7/17/2017	Law Offices Of Francis O. Scarpulla; Parish Guy Castillo, PLC;
EDTN	17-CV-122	Barry Staubus, Tony Clark, Dan Armstrong and Baby Doe	Purdue Pharma LP, Purdue Pharma, Inc., The Purdue Frederick Company, Mallinckrodt PLC, Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Center Pointe Medical Clinic, LLC, Elizabeth Ann Bowers Campbell, Pamela Moore and Abdelrahman Hassabu Mohamed	7/27/2017	
Montgomery County, Ohio	17-CV-2647	The City of Dayton	Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Co., Inc.; Teva Pharm. USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharm., Inc.; Ortho-McNeil-Janssen Pharm., Inc.; Janssen Pharmaceutica, Inc.; Endo Pharm., Inc.; Allergan PLC; Actavis, Inc.; Watson Lab., Inc.; Actavis LLC; Actavis Pharma, Inc.; Endo Health Solutions Inc.; McKesson Corp.; Cardinal Health, Inc.; AmerisourceBergen Corp.; Russell Portenoy; Perry Fine; Scott Fishman; and Lynn Webster.	6/5/2017	Napoli Shkolnik, PLLC; Climaco, Wildcox, Peca, & Garofoli, C.O., L.P.A.
NDIL	1:14-cv-04361	City of Chicago	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.; Depomed, 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; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.	2015	Motley Rice/Wexler Wallace
NY State Court	EFCA2017-252	Broome County NY	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.; Russell Portenoy; Perry Fine; Scott Fishman; Lynn Webster	2/1/2017	Simmons Hanly

NY State Court	Dutchess County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	6/6/2017	Simmons Hanly
NY State Court	Erie County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	2/1/2017	Simmons Hanly
NY State Court	Orange County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	5/11/2017	Simmons Hanly
NY State Court	Nassau County NY	Purdue Pharma LP; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; et al.	6/12/2017	Napoli Shkolnik
NY State Court	Schenectady County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	6/15/2017	Simmons Hanly
NY State Court	Seneca County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	6/7/2017	Simmons Hanly

NY State Court		Suffolk County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	8/31/2016	Simmons Hanly
NY State Court	2017-961	Sullivan County NY	Purdue Pharma LP; 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.; and Endo Pharmaceuticals, Inc.; as well as physicians Russell Portenoy, Perry Fine, Scott Fishman and Lynn Webster	6/7/2017	Simmons Hanly
Ross County, Ohio		State of Ohio & Mike DeWine	Purdue Pharma LP; Purdue Pharma Inc; The Purdue Frederick Company Inc, Teva Pharmaceutical Industries LTD; Teva Pharmaceuticals USA Inc.; Cephalon Inc; Johnson & Johnson; Janssen Pharmaceuticals Inc; Ortho-McNeil-Janssen Pharmaceuticals Inc; Jansen pharmaceuticals Inc; Endo Health Solutions; Endo Pharmaceuticals Inc; Allergan PLC; Watson Pharmaceuticals Inc; Watson Laboratories Inc; Actavis LLC	5/31/2017	Hagen Berman Sobol Shapiro
SDIL	17-CV-616	People of the State of Illinois; St. Clair County, Illinois	Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Abbott Laboratories; Abbott Laboratories, Inc.	6/9/2017	Cates Mahoney, LLC; Law Office of Christopher Cueto , LTD; Holland, Groves, et al.; Goldenberg Heller & Antognoli PC
SDOH	17-CV-663	Belmont County Board of County Commissioners	AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation	7/28/2017	Hill, Peterson, Carper, Bee & Deitzler, PLLC
SDOH	17-CV-664	Brown County Board of County Commissioners	AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation	7/28/2017	Hill, Peterson, Carper, Bee & Deitzler, PLLC
SDOH	17-CV-662	Clermont County Board Of County Commissioners	AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation	7/28/2017	Hill, Peterson, Carper, Bee & Deitzler, PLLC
St. Louis, MO County Court		The State of Missouri; Joshua D. Hawley	Purdue Pharma, L.P.; Purdue Pharma, Inc.; Purdue Prederick Company; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Janssen Pharmaceuticals, Inc.; Johnson & Johnson	6/21/2017	
The Superior Court of Orange County, CA	30-2014-00725287	The People of the State of California	Actavis LLC; Actavis Pharma, Inc.; Actavis, Inc.; Actavis, PLC; Cephalon, Inc.; Endo Health Solutions, Inc.; Endo Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Janssen Pharmaceuticals, Inc.; Johnson & Johnson; Ortho-McNeil-Janssen Pharmaceuticals; Purdue Pharma, LP; Purdue Pharma Inc.; Purdue, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.' The Purdue Frederick Company, Inc.; Watson Laboratories, Inc.; Watson Pharmaceuticals, Inc.	5/21/2014	

WDWA	17-CV-209	Snohomish County	Purdue Pharma L.P.; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; John and Jane Does 1 through 10	2/10/2017	Kelley, Goldfarb; Huck; Roth; & Riojas, PLLC
WDWA	17-CV-209	The City of Everett	Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Co., Inc.; John and Jane Does 1 through 10, individuals who are executives, officers, and/or directors of Purdue.		Kelley, Goldfarb, Huck, Roth & Riojas, PLLC
WVSD	17-CV-2028	Boone County Commission	AmerisourceBergen Drug Corporation, Rite Aid of Maryland, Inc., Kroger Limited Partnership II, Cardinal Health, Inc., McKesson Corporation, Kroger Limited Partnership I, H.D. Smith Wholesale Drug Co., Anda, Inc., Generics Bidco I, LLC, Anda Pharmaceuticals, Inc., Bellco Drug Corp. and Qualitest Pharmaceuticals, Inc.	3/27/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-1665	Cabell County Commission	AmerisourceBergen Drug Corporation, CVS Indiana, L.L.C., Cardinal Health, Inc., Rite Aid of Maryland, Inc., Wal-Mart Stores East, LP, Kroger Limited Partnership II, McKesson Corporation, Walgreen Eastern Co., Inc., Kroger Limited Partnership I and H.D. Smith Wholesale Drug Co.	3/9/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-1957	Fayette County Commission	Cardinal Health, Inc., CVS Indiana, L.L.C., AmerisourceBergen Drug Corporation, Rite Aid of Maryland, Inc., Wal-Mart Stores East, LP, Kroger Limited Partnership I, Kroger Limited Partnership II, McKesson Corporation and Top Rx, LLC	3/21/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-1666	Kanawha County Commission	AmerisourceBergen Drug Corporation, Rite Aid of Maryland, Inc., Cardinal Health, Inc., Kroger Limited Partnership II, CVS Indiana, L.L.C., Omnicare Distribution Center LLC, McKesson Corporation, Wal-Mart Stores East, LP, Miami-Luken, Inc., Kroger Limited Partnership I, The Harvard Drug Group, L.L.C., Walgreen Eastern Co., Inc., Anda, Inc., Anda Pharmaceuticals, Inc., Masters Pharmaceutical, Inc. and Keysource Medical, Inc.	3/9/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-2296	Logan County Commission	Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Drug Corporation, Rite Aid of Maryland, Inc., Wal-Mart Stores East, LP, Kroger Limited Partnership II, H. D. Smith Wholesale Drug Co., The Harvard Drug Group, L.L.C., Kroger Limited Partnership I, Miami-Luken, Inc., Anda Pharmaceuticals, Inc., Cedardale Distributors LLC, Anda, Inc., Bellco Drug Corp., SAJ Distributors and Masters Pharmaceutical, Inc.	4/11/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-1362	The City of Huntington	AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation and Gregory Donald Chaney	2/23/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-946	The County Commission of McDowell County	AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, Harold Anthony Cofer, Jr., & Cardinal Health 110, LLC	1/25/2017	The Bell Law Firm, Morgan & Morgan Complex Litigation Group, and Troy Law Firm
WVSD	17-CV-1962	Wayne County Commission	Rite Aid of Maryland, Inc., CVS Indiana, L.L.C., McKesson Corporation, Cardinal Health, Inc., SAJ Distributors, Wal-Mart Stores East, LP, AmerisourceBergen Drug Corporation and Top Rx, LLC	3/21/2017	Hendrickson & Long/Powell & Majestro (WV firms)
WVSD	17-CV-2311	Wyoming County Commission	AmerisourceBergen Drug Corporation, Rite Aid of Maryland, Inc., McKesson Corporation, H. D. Smith Wholesale Drug Co., Miami-Luken, Inc., J M Smith Corporation, Anda, Inc. and The Harvard Drug Group, L.L.C.	4/12/2017	Hendrickson & Long/Powell & Majestro (WV firms)

Mississippi

Item #16c

TAB 2

DOW JONES, A NEWS CORP COMPANY ▼

DJIA ▲ 22070.58 0.20% S&P 500 ▲ 2475.26 0.13% Nasdaq ▲ 6348.68 0.13% U.S. 10 Yr ▼ -12/32 Yield 2.268% Crude Oil ▲ 49.54 1.04%

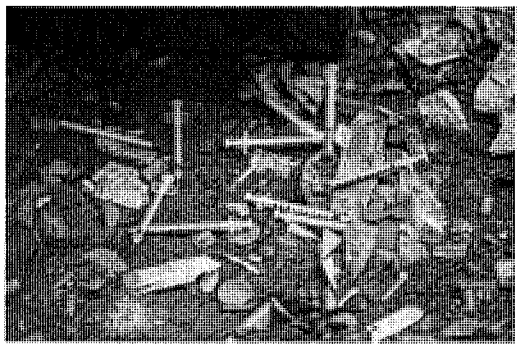
THE WALL STREET JOURNAL.

https://www.wsj.com/articles/opioid-addiction-diagnoses-up-nearly-500-in-past-seven-years-study-shows-1498737603

U.S.

Opioid-Addiction Diagnoses Up Nearly 500% in Past Seven Years, Study Shows

Analysis of insurance claims illustrates the growing epidemic in the U.S.



Opioid-use disorder is the clinical term for addiction to opioids, which include prescription painkillers and illicit narcotics such as heroin. PHOTO: MICHAEL BRYANT/THE PHILADELPHIA INQUIRER/ASSOCIATED PRESS

By Anne Steele
June 29, 2017 8:00 a.m. ET

An analysis of millions of Americans' medical claims showed diagnoses of opioid-use disorder surged nearly 500% over the past seven years, according to a review by the Blue Cross Blue Shield Association.

The analysis, which examined the claims of over 30 million people with commercial insurance provided by Blue Cross Blue Shield insurers between 2010 and 2016, underscores the rising tide of addiction in the U.S. Opioid-use disorder is the clinical term for addiction to opioids, which include prescription painkillers and illicit narcotics such as heroin.

Twenty-one percent of the people reviewed in the analysis filled at least one opioid prescription in 2015, according to BCBSA, with higher doses and longer-duration prescriptions associated with higher addiction rates.

RELATED

- The Victims of the Opioid Crisis
- When the Mailman Unwittingly Becomes a Drug Dealer
- Fatal Student Opioid Overdoses Prompt Colleges to Action
- States Launch Bipartisan Probe of Opioid Marketing and Addiction
- Opioid Use Soars Among Middle Aged and Elderly

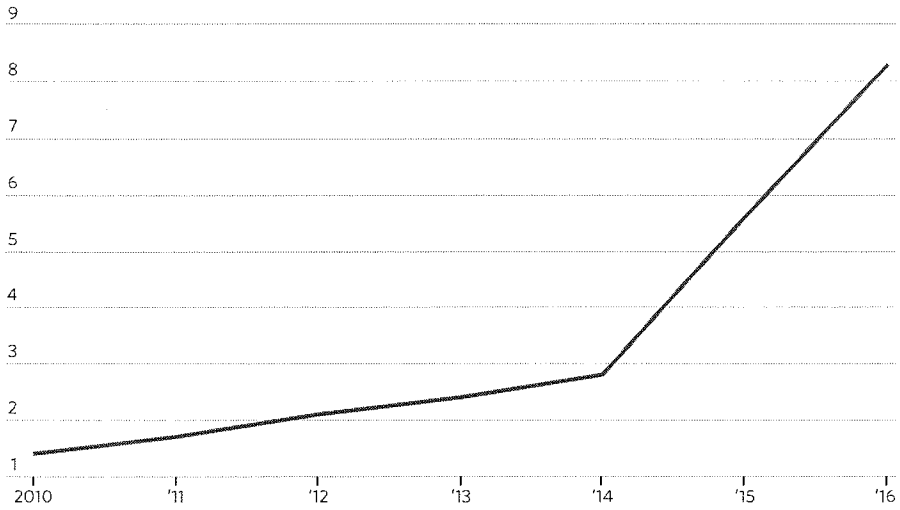
Opioid-use disorder was 40 times more likely in patients prescribed high doses for a short duration, compared with low doses for a short duration. And the disorder was seven times more likely when patients were prescribed a high dose for a long duration than a low dose for a long duration.

"You have to be concerned not just how long the script goes but how high a dose you're prescribing," says David Pizza, BCBSA's managing director of strategy and data analytics. "The way in which they're provided is key to addressing the dependency issue."

John Kelly, an associate professor of psychiatry in addiction medicine at Harvard Medical School, who wasn't involved in the study, said the results show "we are now at

Soaring

Rate of opioid-use disorder per 1,000 commercially insured Blue Cross Blue Shield members



Source: Blue Cross Blue Shield, The Health of America Report

THE WALL STREET JOURNAL

the public health equivalent of 'DEFCON 5' with this opioid crisis."

"High-dose, long-duration prescribing practices, which can drive up rates of opioid-use disorder, are still too common. This needs much closer attention and monitoring to curb the onset of new cases of opioid-use disorder," he said.

The analysis also showed that use of medications to treat opioid addiction, such as buprenorphine or methadone, grew by 65% over the period of the study—a rate dwarfed by the 493% increase in opioid-use disorder diagnoses.

Kim Holland, vice president for state affairs at BCBSA, said the necessary infrastructure to support people getting the treatment they need to address substance abuse effectively is lacking.

The analysis found more people with opioid-use disorder are treated with medication in New England than in the South and parts of the Midwest.

"It tells us there's work to do," says Ms. Holland. "Not everyone is getting the treatment they need."

She said opioids are an important part of a physician's ammunition to help alleviate pain.

"But to recognize potential dangers it's important to understand the extent to which they are prescribed," she said.

Ninety-one Americans die each day from an opioid overdose, according to the Centers for Disease Control and Prevention.

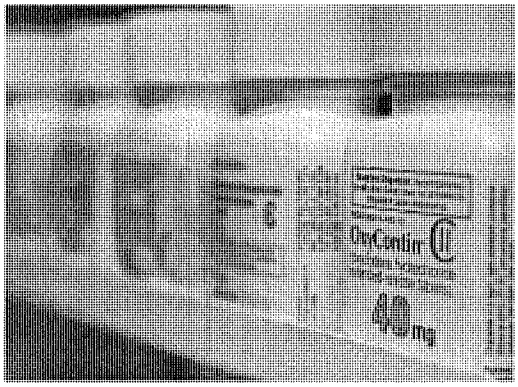
The amount of prescription opioids sold in the U.S. has nearly quadrupled since 1999 even though there has been no change in the amount of pain reported by Americans, the CDC says. Meanwhile, deaths from prescription opioids have more than quadrupled over the same period.

Write to Anne Steele at Anne.Steele@wsj.com

U.S.

Oklahoma Sues Opioid Painkiller Makers

State alleges Purdue Pharma, Teva, Johnson & Johnson and Allergan misrepresented addictive risks of drugs



Oklahoma is suing Purdue, which sells the painkiller OxyContin, among other pharmaceutical companies . PHOTO: GEORGE FREY/REUTERS

By Jeanne Whalen

Updated June 30, 2017 4:35 p.m. ET

Oklahoma became the latest state to file a lawsuit against opioid painkiller makers, alleging they caused widespread addiction by misrepresenting the benefits and addictive risks of their drugs.

The lawsuit filed in state court by Oklahoma's Republican Attorney General, Mike Hunter, targets the parent companies and subsidiaries of Purdue Pharma L.P., Johnson & Johnson , Teva Pharmaceutical Industries Ltd. and Allergan PLC.

"Over a period of several years, defendants executed massive and unprecedented marketing campaigns through which they misrepresented the risks of addiction from their opioids and touted unsubstantiated benefits," the lawsuit alleges. "The damage defendants' false and deceptive marketing campaigns caused to the state of Oklahoma is catastrophic." The state is seeking damages and penalties to compensate it for costs related to addiction.

RELATED

- Ohio Sues Five Drugmakers, Saying They Fueled Opioid Crisis (May 31)
- Overdose Fatalities From Opioids Hit New Peaks (Jan. 6, 2017)
- Opioid-Addiction Diagnoses Up Nearly 500% in Past Seven Years, Study Shows (June 29)
- The Children of the Opioid Crisis (Dec. 15, 2016)

Purdue, which sells the painkiller OxyContin, said: "While we vigorously deny the allegations in the complaint, we share the attorney general's concerns about the opioid crisis and we are committed to working collaboratively to find solutions."

Johnson & Johnson, whose subsidiary Janssen sells the opioid drug Duragesic, said: "We recognize opioid abuse is a serious public health issue that must be addressed. At the

same time, we firmly believe Janssen has acted responsibly and in the best interests of patients and physicians."

Allergan, which sells the painkillers Kadian and Norco, said "it has a history of supporting—and continues to support—the safe, responsible use of prescription medications," including opioids and said the drugs "play an appropriate role in pain relief for millions of Americans" when used correctly.

Teva, which sells the opioid drugs Actiq and Fentora, said it is "committed to the appropriate promotion and use of opioids."

Oklahoma's lawsuit follows similar suits filed by Mississippi, Ohio and Missouri.

The state lawsuits come amid mounting public concern over opioid addiction, which has helped drive U.S. overdose rates to all-time highs.

Many people became addicted by taking powerful opioid painkillers and often progressed to heroin if they couldn't get access to pills. Public-health officials have long blamed aggressive company marketing and lax prescribing for sparking the crisis.

Write to Jeanne Whalen at jeanne.whalen@wsj.com

The New York Times | https://nyti.ms/2rqd6fm

U.S.

Ohio Sues Drug Makers, Saying They Aided Opioid Epidemic

By RICHARD PÉREZ-PEÑA MAY 31, 2017

The State of Ohio filed a lawsuit on Wednesday against the pharmaceutical industry over the opioid epidemic, accusing several drug companies of conducting marketing campaigns that misled doctors and patients about the danger of addiction and overdose.

Ohio's attorney general, Mike DeWine, sued the drug makers in a case similar to one that was filed by Mississippi in 2015 and is still pending. In another case, West Virginia went after major drug distributors and has reached settlements that will pay the state tens of millions of dollars. The City of Chicago, and counties in New York, California and West Virginia, have all started litigation.

Complaints like these are being closely watched by state and local governments around the country that are trying to decide how to proceed — decisions that are complicated by differences in state laws.

"We are in ongoing discussions with attorneys general about what can only be described as a national epidemic," said Michael P. Canty, a lawyer in New York whose firm, Labaton Sucharow, is advising states on possible opioid litigation.

In 2015, more than 25,000 people in the United States died in 2015 from overdosing on opioids like fentanyl, oxycodone and hydrocodone, more than twice as

those narcotics, now kill more Americans than homicide, and are approaching traffic accidents as a cause of death.

Middle-aged white men suffer disproportionately from opioid abuse, and the states with the highest overdose tolls are Ohio, Kentucky, New Hampshire and West Virginia.

The drugs were once used primarily for acute, or short-term pain, but over the last two decades, doctors have increasingly prescribed them to treat chronic pain, giving them to patients for months or years at a stretch. Drug makers promoted that change, Mr. DeWine charged in his suit, spending "millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain."

In addition, he said, the companies provided funding to prominent doctors, medical societies and patient advocacy groups to win their support for the drugs' use. By 2012, the suit says, opioid prescriptions in Ohio equaled 68 pills a year for every resident of the state, including children.

Defendants in the case include Purdue Pharma, Teva Pharmaceutical Industries, Johnson & Johnson, Endo Pharmaceuticals, Allergan and others.

Purdue, the maker of OxyContin, a time-release opioid, released a statement saying, "We share the attorney general's concerns about the opioid crisis and we are committed to working collaboratively to find solutions," and calling the company "an industry leader in the development of abuse-deterrent technology."

Pharmaceutical Research and Manufacturers of America, the leading industry group, said it would not comment on litigation involving specific companies.

Ohio's lawsuit seeks to recover money the state has spent on the drugs themselves, through programs like Medicaid, and on addiction treatment. States took a similar approach in suing the tobacco industry in the 1990s, which eventually led to settlements worth more than $200 billion.

A version of this article appears in print on June 1, 2017, on Page A17 of the New York edition with the headline: Ohio Sues Drug Makers Over Opioid Crisis.

Item # 16d

TAB 3

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE COUNTY OF SUFFOLK, *Plaintiff,* v. 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.; RUSSELL PORTENOY; PERRY FINE; SCOTT FISHMAN; and LYNN WEBSTER, *Defendants.*	Index No. **COMPLAINT**

Plaintiff, the County of Suffolk, New York ("Plaintiff"), by and through the undersigned attorneys, 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 Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Russell Portenoy, Perry Fine, Scott Fishman, and Lynn Webster (collectively, "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 also provides a wide range of other services on behalf of its residents, including services for families and children, public assistance, and law enforcement.

3. Plaintiff is one of the largest employers on Long Island, employing approximately 10,000 people in 22 departments. Plaintiff funds its own health insurance plan for the benefit of its employees, through which it pays part or all of its employees' health care costs, including the cost of prescription drugs, including opioids.

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

5. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured,

promoted, and marketed opioids for the management of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

6. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.[1] 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.

7. 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 ("chronic pain").

8. Defendants knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.[2]

9. 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.

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[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

[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).

10. To date, there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.

11. Despite the foregoing knowledge, in order 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.

12. 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.

13. 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.

14. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

15. 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. 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]

16. Defendants' campaign has been extremely profitable for them. In 2012 alone, opioids generated $8 billion in revenue for drug companies.[7] Of that amount, $3.1 billion went to Purdue for its OxyContin sales.[8]

17. Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also

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[3] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: http://www.cdc.gov/drugoverdose/epidemic/index.html (accessed March 31, 2016) (internal footnotes omitted).

[4] 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 March 31, 2016).

[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).

quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose.[9]

18. 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]

19. Opioid addiction and overdose 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]

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[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 March 31, 2016).

20. 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.[13]

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 pharmaceutical companies*."[14] 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[15] and the commission of criminal acts to obtain opioids

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[13] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

[14] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed March 31, 2016) (emphasis added).

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

throughout the United States, including New York State and Suffolk County. Consequently, public health and safety throughout the United States, including Suffolk 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. Between 1996 and 2006, the New York State consumption of hydrocodone increased from approximately 2,000 milligrams (mgs) per person to 12,000 mgs per person. Oxycodone consumption increased from approximately 1,000 mgs per person to 16,000 mgs per person. At the same time, health care admissions for opioid analgesic abuse have risen both nationally and in New York State at rates of greater than 300%.

24. In Suffolk County in 2012, there were 8,271 emergency room visits due to opiate use. Substance abuse programs in Suffolk County served 18,724 people for opioid abuse. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. In 2012 there were 214 overdose deaths related to opioids.

25. The commission of criminal acts to obtain opioids is an inevitable consequence of opioid addiction. For example, on June 19, 2011, David Laffer and his wife, prescription opioid abusers desperately seeking opioids, robbed the Haven Pharmacy in Medford, New York. During the robbery, Laffer brutally executed four unarmed, unsuspecting customers and employees.[16]

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[16] *Id.*

26. 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.

JURISDICTION AND VENUE

27. This Court has jurisdiction over this action pursuant to New York Constitution, article VI, § 7(a) and CPLR 301 and 302.

28. Venue is proper in Suffolk County pursuant to CPLR 503(a).

29. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

PARTIES

30. Suffolk County comprises ten towns in eastern Long Island, New York. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care. As mentioned above, Plaintiff also funds its own health insurance plan for its approximately 10,000 employees.

31. Plaintiff brings this action on its own behalf and also as subrogee of its employees and residents and, as such, Plaintiff stands in the shoes of its subrogors, and is entitled to all the rights of its subrogors. In making the payments it has made on behalf

of its employees and residents, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

32. Defendant Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

33. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

34. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

35. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Suffolk County, including the following:

Table 1. Purdue Opioids

Drug Name	**Chemical Name**	**Schedule**[17]
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Byprenorpine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II

[17] 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.

Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

36. 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 analgesic drugs (*i.e.*, painkillers).

37. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

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

39. 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 Suffolk County, including the following:

Table 2. Cephalon Opioids

Drug Name	**Chemical Name**	**Schedule**
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

40. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Suffolk County.

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

42. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

43. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

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

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

46. 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.

47. 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 Suffolk County, including the following:

Table 3. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta[18]	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

48. 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.

49. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

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

51. EHS and EPU (collectively, "Endo") manufacture, promote, distribute and sell opioids nationally and in Suffolk County, including the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

52. Opioids made 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

[18] Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

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.

53. Russell Portenoy, M.D., is an individual residing in New York. Dr. Portenoy was instrumental in promoting opioids for sale and distribution nationally and in Suffolk County.

54. Perry Fine, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in Suffolk County.

55. Scott Fishman, M.D., is an individual residing in California. Dr. Fishman was instrumental in promoting opioids for sale and distribution nationally and in Suffolk County.

56. Lynn Webster, M.D., is an individual residing in Utah. Dr. Webster was instrumental in promoting opioids for sale and distribution nationally and in Suffolk County.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. The Pain-Relieving and Addictive Properties of Opioids

57. The pain-relieving properties of opium have been recognized for millennia. So has the magnitude of its potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

58. 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 ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States,[19] 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.

59. 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.

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

[19] 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).

effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

61. In 1986, Dr. Portenoy, 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."[20]

62. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding 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.*[21]

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

[21] 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).

According to Dr. 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."[22]

63. For all the reasons outlined by Dr. 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."[23]

64. 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, 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.

65. 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

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[22] *Id.*

[23] 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)).

he has become accustomed – up to and including doses that are "frighteningly high."[24] 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.

66. 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.

67. 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.

68. 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, 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

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

alternative treatments are inadequate."[25] The FDA required that - going forward - opioid makers of long-acting formulations clearly communicate these risks in their labels.

69. 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.[26]

70. 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

71. 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 failed to disclose the substantial scientific evidence that chronic opioid therapy actually makes patients sicker.

72. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a

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[25] 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).

[26] 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 March 31, 2016).

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.

73. 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.[27]

74. 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.

75. While opioids may work acceptably well for a while, when they are used on a long term basis, function generally declines, as does 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.[28]

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[27] 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).

[28] *See* A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

76. The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable 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 cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

77. 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 medications.

C. Defendants' Scheme to Change Prescriber Habits and Public Perception

78. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

79. 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 opioids not just for short term pain relief but also for long-term chronic pain relief, they

could achieve blockbuster levels of sales and their profits. Further, they recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

80. Defendants knew that in order 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. Defendants needed, in other words, to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

81. 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.

82. 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 medical and public perception of existing scientific data.

83. As explained more fully herein and illustrated in Exhibit A, 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 phony "consensus" supporting the long-term use of opioids.

D. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws

84. Drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can evade the extensive regulatory framework governing branded communications.

85. 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. 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 assess accurately the risks and benefits of drugs for their patients.

86. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") places further 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. 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. Thus, Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

87. 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 materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The 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.

88. Defendants generally avoided using branded advertisements to spread their deceptive messages and claims regarding opioids. Defendants did so in order to evade regulatory review.

89. Instead, Defendants disseminated much of their false, misleading, imbalanced, and unsupported statements through unregulated 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.

90. 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.

91. 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; (iii) treatment guidelines; (iv) CMEs; and (v) unbranded patient education materials disseminated through groups purporting to be patient-advocacy and professional organizations ("Front Groups"), which exercised their influence both directly and indirectly through Defendant-controlled KOLs who served in leadership roles in these organizations.

92. 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.

93. Even where such unbranded messages were disseminated through third-party vehicles, Defendants adopted these messages as their own when they cited to,

edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. As described herein, Defendants' sales representatives distributed third-party marketing material to Defendants' target audience that was deceptive.

94. Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by third parties, 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 fraudulently to promote the use of opioids for the treatment of chronic pain.

95. 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.

i. Defendants' KOLs

96. Defendants cultivated a select circle of doctors who were chosen and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. As set forth herein and as depicted in Exhibit A, pro-opioid doctors 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 doctors 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 their KOLs.

97. In return for their pro-opioid advocacy, Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish.

98. Defendants cited and promoted their KOLs and studies or articles by their KOLs to broaden the chronic opioid therapy market. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy.

99. Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of their agenda. Defendants also kept close tabs on the content of the materials published by these KOLs.

100. In their promotion of the use of opioids to treat chronic pain, Defendants' 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 themselves and Defendants.

ii. Defendants' Corruption of Scientific Literature

101. Rather than actually test the safety and efficacy of opioids for long- term use, Defendants led physicians, patients, and health care payors to believe that such tests had already been done. As set forth herein and as depicted in Exhibit A, 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.

102. 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.

103. 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.

104. In these materials, Defendants (or their 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.

105. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, 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 is also cited in two CME programs sponsored by Endo. Defendants and those acting on their behalf failed to reveal that this "article" is 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 patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154 Boston University Medical Center

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

106. 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. 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, for how long. None of these serious limitations was disclosed when Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

107. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has.

108. Defendants worked to not only create and promote favorable studies in the literature, but to discredit or suppress negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants – often with the help of third-party consultants – 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.

109. Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – was flatly inconsistent with their legal

obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

iii. Defendants' Misuse of Treatment Guidelines

110. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are 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.

a. FSMB

111. 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.

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

113. 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 Suffolk County.

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

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

b. AAPM/APS Guidelines

116. 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.[29] 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 Defendant Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

117. 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 Defendant Dr. Portenoy and Defendant Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

118. 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 Suffolk County during the relevant time period, and were and are available online.

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

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

c. Guidelines that Did Not Receive Defendants' Support

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

121. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects."[30]

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[30] 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).

122. 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."[31]

123. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, 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.[32]

iv. Defendants' Misuse of CMEs

124. A CME (an acronym for "Continuing Medical Education") is a professional 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. Because CMEs

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

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

typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

125. 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 aimed to reach general practitioners, whose broad area of 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.

126. 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, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

127. 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."[33]

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[33] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011).

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

129. By sponsoring CME programs put on by Front Groups like APF, AAPM and others, Defendants could expect 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.

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

130. 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."[34] 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 approved.[35] Recognizing this

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

[35] 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.

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

131. Defendants entered into arrangements with numerous Front Groups (*i.e.*, groups purporting to be patient-advocacy and professional organizations) to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, 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 use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

d. American Pain Foundation

132. The most prominent of Defendants' Front Groups was the American Pain Foundation ("APF"), which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

McKinlay *et al.*, *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

133. APF issued purported "education guides" for patients, the news media, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly 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 Suffolk County.

134. 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.

135. APF held itself out as an independent patient advocacy organization, yet engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing. In reality, APF functioned largely as an advocate for the interests of Defendants, not patients.

136. 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.

137. The close 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 supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

138. In May 2012, the U.S. Senate Finance Committee began looking into APF to 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."[36]

e. The American Academy of Pain Medicine

139. 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.

140. 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.

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[36] American Pain Foundation Website. Available at http://www.painfoundation.org (accessed March 31, 2016).

141. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids - 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs and Defendants, Dr. Fine, Dr. Portenoy, and Dr. Webster. Dr. Webster was elected president of AAPM while under a DEA investigation. Another past AAPM president, Defendant 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."[37]

142. 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 in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

143. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain.

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[37] *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 March 31, 2016).

144. 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. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including to Suffolk County prescribers and patients.

145. One Vehicle for Defendants' marketing collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

146. 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.

147. 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.[38] This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

F. Defendants' Misrepresentations

148. 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 Suffolk County. These promotional messages were intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

149. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew

[38] 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.

doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Defendants did not disclose to prescribers, patients or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, Suffolk County doctors began prescribing opioids long-term to treat chronic pain – something that most never would have considered prior to Defendants' campaign.

150. Drug company marketing materially impacts doctors' prescribing behavior.[39] 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.

151. Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent

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[39] 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).

survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[40] These results are directly due to Defendants' fraudulent marketing campaign.

152. As described in detail below, Defendants:

- misrepresented the truth about how opioids lead to addiction;
- misrepresented that opioids improve function;
- misrepresented that addiction risk 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;
- falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

153. Defendants' misrepresentations were aimed at doctors, patients, and payors.

154. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants'

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

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.[41]

i. Defendants, acting individually and collectively, misrepresented the truth about how opioids lead to addiction.

155. Defendants' fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. Through their well-funded, comprehensive, aggressive marketing efforts, Defendants succeeded in changing the perceptions of many physicians, patients, and health care payors and in getting them to accept that addiction rates are low and that addiction is unlikely to develop when opioids are prescribed for pain. That, in turn, directly led to the expected, intended, and foreseeable result that doctors prescribed more opioids to more patients - thereby enriching Defendants.

156. Each of the Defendants claimed that the potential for addiction from its drugs was relatively small or non-existent, even though there was no scientific evidence to support those claims.

157. For example, Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

158. For another example, Endo sponsored a website, painknowledge.com, through APF, which claimed that: "[p]eople who take opioids as prescribed usually do

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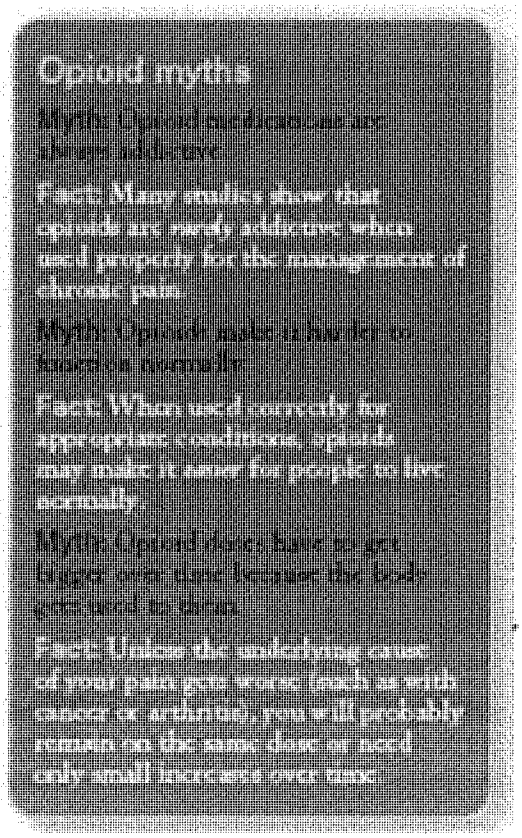
[41] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

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 as long as a prescription is given, opioid use will not become problematic.

159. For another example, Endo distributed a patient education pamphlet edited by KOL Defendant 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, which is unsupported and untrue.

160. For another example, 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 as a "myth" the fact that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."



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 as long as a prescription is given, opioid use is unlikely to lead to addition, which is untrue.

161. The guide states as a "fact" that "Many studies" show that opioids are *rarely* addictive when used for chronic pain. In fact, no such studies exist.

162. For another example, Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught, "[l]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.

163. 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.[42] This publication also falsely asserted that pain is undertreated due to "misconceptions about opioid addiction."

164. For another example, in the 1990s, Purdue amplified the pro-opioid message with promotional videos and 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."[43]

165. 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 relieved their pain using long-term opioid therapy were following the compassionate (and professionally less risky) approach. Defendants claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. The Treatment Options guide funded by Purdue and Cephalon states "[d]espite the great benefits of opioids, they

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[42] In support of this contention, it misleadingly cites a 1996 article by Dr. Kathleen Foley concerning cancer pain.

[43] Excerpts from one such video, including the statement quoted here, may be viewed at http://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

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."[44]

166. *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, a serious problem in the United States."

ii. Defendants, acting individually and collectively, misrepresented that opioids improve function

167. 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.

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[44] This claim also appeared in a 2009 publication by APF, *A Reporter's Guide*.

168. Although opioids may initially improve patients' function by providing pain relief in the short term, there exist no controlled studies of the use of opioids beyond 12 weeks and no evidence that opioids improve patients' function in the long-term. Indeed, 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.[45] 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.

169. Claims that opioids improve patients' function are misleading because such claims have "not been demonstrated by substantial evidence or substantial clinical experience."[46]

170. The Federation of State Medical Boards' Responsible Opioid Prescribing (2007), sponsored by drug companies including Cephalon, Endo and Purdue, taught that relief of pain itself improved patients' function: "While significant pain worsens function, relieving pain should reverse that effect and improve function."

171. 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

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

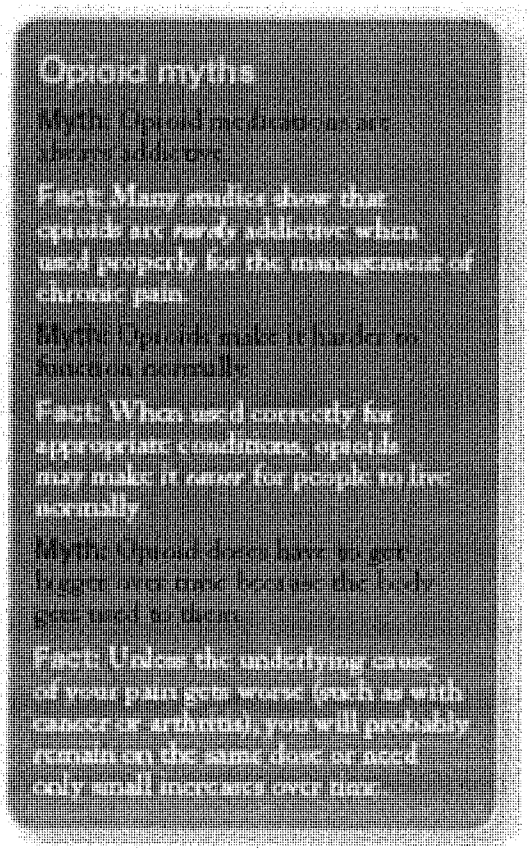
[46] Letter from Thomas W. Abrams, RPh., MBA, Dir., Div. of Marketing, Advertising and Communications to Brian A. Markison, Chairman, *King Pharmaceuticals*, Re: NDA 21-260 (March 24, 2008).

"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 available online.

172. Endo sponsored a website, painknowledge.com, through the APF, 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.

173. 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.

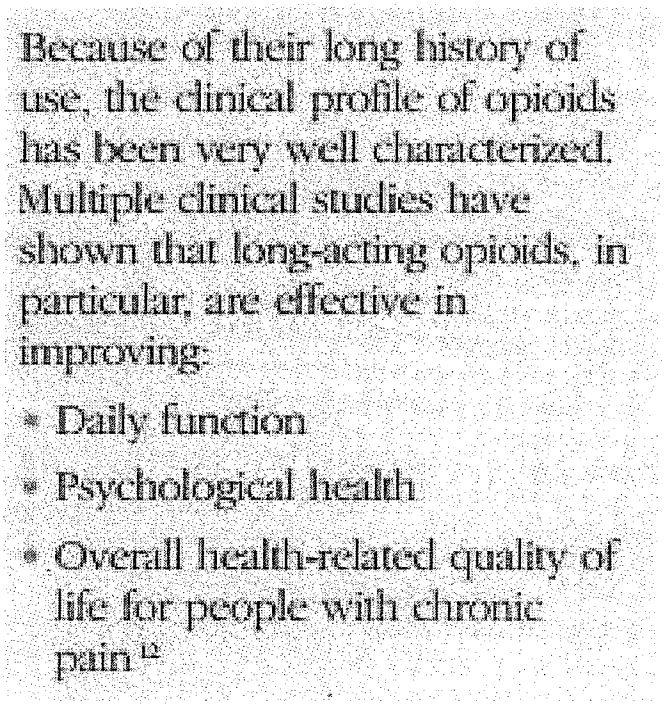
174. As set forth in the excerpt below, the guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative support for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population.



175. 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.

176. 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 pain [12]

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

177. Purdue sponsored and Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "increase your level of functioning" (emphasis in the original).

iii. Defendants, acting individually and collectively, misrepresented that addiction risk can be effectively managed

178. Defendants each continue to maintain to this day that most patients safely can take opioids long-term for chronic pain without becoming addicted. Presumably to explain why doctors encounter so many patients addicted to opioids, Defendants have

come to admit 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 say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

179. 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 doctors can depend on the screening tools currently available to materially limit the risk of addiction. Even if the tools are effective, they may not always be applied correctly, and are subject to manipulation by patients. Second, there is no reliable scientific evidence that high-risk or addicted patients identified through screening can take opioids long-term without triggering or worsening addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

180. 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."[47] 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 are not proven to work in the real world, even when well meaning, but doctors were misled to employ them.[48]

181. 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, of the more than half million prescribers of opioids during that time period, only 385 were identified as pain specialists.[49]

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

[48] 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).

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

182. In materials they produced, sponsored, or controlled, 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 and patients deemed high risk were also to receive opioids on a long-term basis but with more frequent visits, tests and monitoring – 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.

183. 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."

184. 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 Defendant 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.

185. Purdue sponsored a 2011 webinar taught by Defendant 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."

iv. Defendants, acting individually and collectively, misled physicians, patients, and payors through the use of misleading pseudowords like "pseudoaddiction."

186. 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 Dr. J. David Haddox, who later went to work for Purdue, and was popularized in opioid therapy for chronic pain by Defendant 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.

187. In the materials they produced, sponsored, or controlled, Defendants misrepresented that the concept of "pseudoaddiction" is substantiated by scientific evidence.

188. 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."

189. 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."[50]

190. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its unbranded website, PartnersAgainstPain.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. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated."

v. Defendants, acting individually and collectively, claimed withdrawal is simply managed.

191. In an effort to underplay the risk and impact of addiction, Defendants claimed that, while patients become physically "dependent" on opioids, physical

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

dependence is not the same as addiction and can be addressed, if an when pain relief is no longer desired, by gradually tapering patients' dosage to avoid the adverse effects of withdrawal. Defendants fail 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 the drugs.

192. 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.

193. 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 successful at all.[51]

194. 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 the significant hardships that often accompany cessation of use.

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

vi. Defendants, acting individually and collectively, misrepresented that increased doses pose no significant additional risks.

195. 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.

196. 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.

197. 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.[52]

198. Cephalon sponsored a CME written by KOL Defendant Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from

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[52] 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).

September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics 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.

199. 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.

200. Endo distributed a patient education pamphlet edited by KOL Defendant 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."

201. 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.

202. 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 Defendant Dr. Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

vii. Defendants, acting individually and collectively, deceptively omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

203. 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.

204. 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;"[53] hormonal dysfunction;[54] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[55] neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth), and potentially fatal interactions with alcohol or benzodiazepines, which are

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[53] 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).

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

[55] See 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).

used to treat post-traumatic stress disorder and anxiety. Post-traumatic stress disorder and anxiety also often accompany chronic pain symptoms.[56]

205. 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.[57] *Treatment Options* also warned that risks of NSAIDS increase if "taken for more than a period of months," with no corresponding warning about opioids.

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

207. Janssen and Purdue sponsored and Endo provided grants to APF to distribute *Exit Wounds* (2009), which omits warnings of the risk of potentially fatal

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[56] 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).

[57] 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).

interactions between opioids and certain anti-anxiety medicines called benzodiazepines, commonly prescribed to veterans with post-traumatic stress disorder.

208. 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.[58]

G. Defendants' Promotion of Their Branded Drugs Was Also Deceptive

209. 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 Suffolk County. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate

[58] 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).

their opioids and to allay individual prescribers' concerns about prescribing opioids for chronic pain.

210. 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 doctors in Suffolk County.

H. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was False, Unfounded, and Dangerous and Would Harm Plaintiff and its Residents

211. 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.

212. 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.

213. When they began their deceptive marketing practices, Defendants recklessly 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 Fraudulently Concealed their Misrepresentations

214. Defendants took steps to avoid detection of, and to fraudulently conceal, their deceptive marketing and conspiratorial behavior.

215. 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.

216. 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.

217. 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 no support. The true lack of support for Defendants' deceptive messages was not apparent to 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.

218. 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.

219. 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.

220. 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. Defendants Entered into and Engaged in a Civil Conspiracy

221. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein, and intended to benefit both independently and jointly from their conspiratorial enterprise.

222. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

223. This network is interconnected and interrelated, as demonstrated by Exhibit A, which is incorporated herein, and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

224. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

FIRST CAUSE OF ACTION
DECEPTIVE ACTS AND PRACTICES - NEW YORK GENERAL BUSINESS LAW § 349
(AGAINST ALL DEFENDANTS)

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

226. Defendants violated New York General Business Law § 349, because they engaged in deceptive acts or practices in the conduct of business, trade or commerce in this state.

227. Plaintiff and its residents have been injured by reason of Defendants' violation of § 349.

SECOND CAUSE OF ACTION
FALSE ADVERTISING - NEW YORK GENERAL BUSINESS LAW § 350
(AGAINST ALL DEFENDANTS)

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

229. Defendants violated New York General Business Law § 350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

230. Plaintiff and its residents have been injured by reason of Defendants' violation of § 350.

THIRD CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

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

232. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Suffolk County by their production, promotion, and marketing of opioids for use by residents of Suffolk County.

233. Defendants' conduct is unreasonable.

234. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

235. Defendants' conduct constitutes a public nuisance.

236. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

237. Plaintiff and its residents suffered special injuries distinguishable from those suffered by the general public.

FOURTH CAUSE OF ACTION
VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-B
(AGAINST ALL DEFENDANTS)

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

239. Defendants violated Social Services Law § 145-b, because they knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies

furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law. Plaintiff is a "political subdivision" of the State of New York as that term is used in § 145-b (1) (b) and a "local social services district" as that term is used in § 145-b (2).

240. By reason of Defendants' violation of § 145-b, Plaintiff has been damaged.

FIFTH CAUSE OF ACTION
FRAUD
(AGAINST ALL DEFENDANTS)

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

242. 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.

243. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

244. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

245. Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions.

246. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff and its residents suffered actual pecuniary damage.

247. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

SIXTHCAUSE OF ACTION
UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

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

249. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.

250. 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.

251. Defendants have been unjustly enriched at the expense of Plaintiff.

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. treble damages, penalties, and costs pursuant to Social Services Law § 145-b;

iii. Treble damages and attorney's fees pursuant to General Business Law §§ 349(h) and 350-3(3);

iv. punitive damages;

v. interest, costs, and disbursements; and

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

Dated: August 31, 2016

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Attorneys for Plaintiff

Human Services Board Agenda - Jefferson County

Jefferson County Workforce Development Center, 874 Collins Road, Room 103
Jefferson, WI 53549

Date: Tuesday, September 12, 2017 Time: 8:30 a.m.

Committee Members:	**Mode, Jim (Chair)**	**McKenzie, John (Secretary)**
	Jones, Dick (Vice Chair)	**Crouse, Cynthia**
	Kutz, Russell	**Schultz, Jim**
	Tietz, Augie	

1. Call to Order
2. Roll Call (Establish a Quorum)
3. Certification of Compliance with the Open Meetings Law
4. Approval of the September 12, 2017 Agenda
5. Public Comment (Members of the public who wish to address the Board on specific agenda items must register their request at this time.)
6. Approval of August 8, 2017 Board Minutes
7. Communications
8. Review of the July, 2017 Financial Statement
9. Discuss and Approve August, 2017 Vouchers
10. Division Updates: Child and Family Division, Behavioral Health, Administration, Economic Support, and Aging & Disability Resource Center
11. Discussion and Possible Action on New Professional Service Contracts (Therapy Services, Home Modification, Adult Alternate Care, Child Alternate Care)
12. Discussion and Possible Action of Appointment of Attorneys to prosecute Termination of Parental Rights cases under 48.09(6) Wis. Stats.
13. Discussion and possible action on approving Carol Battenberg for the Nutrition Project Council
14. Discussion and possible recommendation on changing Aging & Disability Resource Center Advisory Committee (ADRC) By-laws from 11 to 7 members.
15. Discussion and Possible Action on a Memo of Understanding with the Wisconsin Association of Free & Charitable Clinic, Inc. for a VISTA worker
16. Discussion and Possible Action to Support WCA Resolution to Sue Opioid Manufacturers
17. Director's Report
18. Adjourn

Next Scheduled Meetings:

Tuesday, October 10, 2017 at 8:30 a.m.
Tuesday, November 14, 2017 at 8:30 a.m.

A Quorum of any Jefferson County Committee, Board, Commission or other body, including the Jefferson County board of Supervisors, may be present at this meeting.

Special Needs Request - Individuals requiring special accommodations for attendance at the meeting should contact the County Administrator 24 hours prior to the meeting at 920-674-7101 so appropriate arrangements can be made.

JEFFERSON COUNTY HUMAN SERVICES
Board Minutes
August 8, 2017

Board Members Present: Jim Mode, Richard Jones, Russell Kutz, Cynthia Crouse, John McKenzie and Augie Tietz

Absent: Jim Schultz

Others Present: Director Kathi Cauley; Deputy Director Brent Ruehlow; Administrative Services Division Manager Brian Bellford; Economic Support Manager Jill Johnson; Aging & Disability Resource Division Manager Sharon Olson; Office Manager Donna Hollinger, Maintenance Supervisor Ryan Mundt, and County Administrator Ben Wehmeier.

1. **CALL TO ORDER**
   Mr. Mode called the meeting to order at 8:30 a.m.

2. **ROLL CALL/ESTABLISHMENT OF QUORUM**
   All present/Quorum established.

3. **CERTIFICATION OF COMPLIANCE WITH THE OPEN MEETINGS LAW**
   Ms. Cauley certified that we are in compliance.

4. **REVIEW OF THE AUGUST 8, 2017 AGENDA**
   Item #15 will be moved up to follow item #10.

5. **PUBLIC COMMENTS**
   No Comments

6. **APPROVAL OF THE JULY 11, 2017 BOARD MINUTES**
   Mr. Kutz made a motion to approve the July 11, 2017 board minutes.
   Mr. Tietz seconded.
   Motion passed unanimously.

7. **COMMUNICATIONS**
   No communications

8. **REVIEW OF JUNE 2017 FINANCIAL STATEMENT**
   Mr. Bellford reviewed the June 2017 financial statement (attached) and reported that there is a projected positive year-end fund balance of $63,812. This includes our carryover from 2016 but excludes any prepaid adjustments. Projections this early in the year are subject to change. He also presented the summary and financial statements (attached) that detail revenue, expenses, tax levy and variance by program within each Division and discussed the areas that are having the most impact on the budget. He also presented reports showing Detox and Alternate Care statistics (attached).

9. REVIEW AND APPROVE JULY, 2017 VOUCHERS

Mr. Bellford reviewed the July 2017 summary sheet of vouchers totaling $488,939.55 (attached).

Mr. Jones made a motion to approve the July 2017 vouchers totaling $488,939.55.

Mr. McKenzie seconded.

Motion passed unanimously.

10. DIVISION UPDATES: CHILD & FAMILY RESOURCES, BEHAVIORAL HEALTH, ADMINISTRATION, ECONOMIC SUPPORT, AND AGING & DISABILITY RESOURCE CENTER

Child & Family Resources:

Mr. Ruehlow reported on the following items:

- All Key Outcome Indicators are all being met except for Juvenile Justice, which set a difficult goal of 90% of the youth on delinquency orders will remain in the community. We are at 89%.
- Alternate Care is down and we returned 11 children to their homes, and took 13 new children into care the last two months. Two children are in the hospital awaiting difficult to find placements.
- We have 120 children being served in the CLTS and are working to get more children off of the waiting list.
- We received a nice letter from the DCF congratulating our Foster Care Program on doing the rate setting within the 30-day placement timeline. The state is using our numbers to drive the rest of the state up. This is a direct result of Katie Schickowski, our Foster Care Coordinator.
- Katie also held a Foster Care picnic last month, which was very successful. All food and gifts were donated.
- I was named one of the tri-chairs of the WCHSA Children and Families Pact.

Behavioral Health:

Ms. Cauley reported on the following items:

- Key Outcome Indicators are all being met
    - We had 16 emergency detentions in July, and 286 assessments for the year, compared to 234 for all of last year.
- We received the opioid grant so we were able to fund a new psychotherapist and still have about $20,000 for medication assisted therapy.
- In the last month, one of our staff started presenting information to staff and external stakeholders on the impact of trauma. It has been very well received.
- We are hosting a 3-day "DBT in schools" training for 70 people in 5 school districts that will provide a social and emotional curriculum in the school system. The trainers wrote the book on DBT.
- Our Project Yes grant may be ending one and a half years early, but we will discuss it more next year during the budget process.
- The Legislative Audit Bureau is the agency that does research for legislators when writing a bill. The Bureau has been here discussing our emergency mental health and emergency detention processes with us. They are determining whether it is cost effective and if it would work across the state.

Administration:

Mr. Bellford reported on the following items:

- We have been working on the 2018 budget.
- We are finalizing the WIMCR report and are trying to recover MA costs from 2016.
- The concrete project will be the last capital project for the year.

Economic Support:

Ms. Johnson reported on the following items:

- Our **Key Outcome Indicators** were as follows:
    - *We have 30 days to get 100% of all applications processed.* We processed 95.87% of them timely.
    - *The Consortium Call Center must answer calls timely within 95% of the time.* The Call Center was at 98.87%. A report comparing 10 consortiums was presented.
- We received a Child Care Performance Award from DCF for meeting all the mandated performance standards in 2016. We were one of 34 counties to receive this award. The staff does a great job.
- We have a new worker, so we are fully staffed again.
- On August 22, I will meet with entities to divide up donation money from the Emergency Food & Shelter program. We usually get about $1,000 for our food pantry.
- Ready Kids for School will be held on August 12, which distributes school supplies.
- The Consortium trainer took a new position so we will be doing interviews on Monday.

ADRC:

Ms. Olson reported on the following items:

- The key outcome indicator for the Adult Protective Services and Elder Abuse program was met. In August, APS staff will be attending the National Adult Protective Services Conference in Milwaukee.
- The ADRC's KOI has improved for July 2017 as screens are at 100% compliance to improve response time of functional screen assessment. During the month of July, 17 of the 17 screens were completed and calculated for eligibility within 14 days.
- We are still waiting to hear about a grant proposal of $3,150 to fund renovations for the ADRC to become ADA compliant. A suggestion was to review/consider replacing the door at the front office with a glass door. If someone came to the ADRC in a wheelchair, even with the doorbell it would allow the staff to see into the lobby area for patrons. Estimates are from $1,200 for a plain wood/glass door to $8,300 for a wood prefinished glass with bullet resistance of level 1.
- The Home Delivered Meal Program's KOI was met in July. There were four new home delivered meal requests and no one was denied. One person was referred to Dane County. In July, we served 2,055 meals, and our average was 102 meals a day.
- The Transportation Program's KOI is to meet qualifying ride requests 100% of the time. In July, there were 407 scheduled 1-way trips, 38 were canceled and eight trips were nc/ns leaving 461 trips for the Driver Escort Program. The Veteran's Van provided 72 one-way trips provided.

- Our Dementia Care Specialist team has been providing memory screens. They are also ramping up the Language Enriched Exercise Plus Socialization (LEEPS) program as well as Memory Connections and Music and Memories.

11. DISCUSSION AND POSSIBLE ACTION ON NEW PROFESSIONAL SERVICE CONTRACTS (ADULT ALTERNATE CARE, HOME MODIFICATION)

Ms. Cauley reported that we have two new service providers. (attached)
Mr. McKenzie made a motion to approve the contracts as listed.
Mr. Kutz seconded.
Motion passed unanimously.

12. DISCUSS PEOPLE AGAINST DOMESTIC AND SEXUAL ABUSE (PADA) FINANCIAL INFORMATION

Ms. Cauley reported that PADA submitted some financial information (attached) and answered some of the questions that we had.
Mr. McKenzie made a motion to change the donation to $50,000 and not to disburse funds until we receive their complete financial information and evidence that they are in compliance with established goals listed in the contract.
Mr. Jones seconded.
Motion passed unanimously.

13. DISCUSSION AND POSSIBLE ACTION ON THE 2018 BUDGET PRESENTATION

Ms. Cauley reviewed the budget and commended Mr. Bellford on all of his work.
Mr. Tietz made a motion to approve the budget as presented and to send it to Finance.
Ms. Crouse seconded.
Motion passed unanimously.

14. DISCUSSION AND POSSIBLE ACTION ON COMPREHENSIVE COMMUNITY SERVICES (CCS) BILLING RATES

Mr. Bellford presented a report on the 2017 CCS Billing/Charge Rates (attached). He said that there is a need to increase rates to get in line with expenses. He said that these changes would begin with the May 1 billing.
Mr. Jones made a motion to approve the 2017 CCS billing/charge rates as presented.
Mr. McKenzie seconded.
Motion passed unanimously.

15. DISCUSSION AND POSSIBLE ACTION ON REVIEWING SIDEWALK/CONCRETE BIDS

Mr. Mundt reported that we received three concrete bids (attached) and although it is not the lowest bid, he recommends the bid from Kramer Enterprises. He said that it includes a few things that weren't requested and will make a nicer project. Ms. Cauley reported that the resolution will go to the county board tonight. Mr. Wehmeier said that Corporation Counsel added language to identify the reasons for choosing a higher bid.
Mr. Jones made a motion to approve the bid from Kramer Enterprises in the amount of $33,603.00.
Mr. Tietz seconded.
Motion passed unanimously.

16. REVIEW AND DISCUSS MOVING WRAPAROUND POSITION TO THE COMMUNITY SUPPORT PROGRAM

Ms. Cauley reported that there has been a resignation on the Wraparound team, and with every vacancy, we review the needs throughout the agency. We are seeing more children and feel that we could use another staff in the Community Support Program. This new position would provide psychotherapy, thereby savings $30,000 in tax levy.
Mr. Jones made a motion to eliminate the wraparound coordinator position and create a new community support position.
Mr. Kutz seconded.
Motion passed unanimously.

17. DISCUSSION AND POSSIBLE ACTION FOR PROCLAMATION IN SUPPORT OF SEPTEMBER RECOVERY MONTH

Ms. Cauley reported that September is National Recovery Month and we have fundraising activities planned. The donations will go to clients.
Mr. McKenzie made a motion to approve the proclamation in support of September Recovery Month.
Mr. Tietz seconded.
Motion passed unanimously.

18. DIRECTOR'S REPORT

Ms. Cauley reported on the following items:

- Staff on the Children's teams attended the NIATx Change Leader Academy, which was originally designed for Behavioral Health. The team's goal was to reduce hospitalizations. The Vice President came here to meet the staff who went to the training. He was very impressed with how we incorporated the NIATx process throughout the Department.
- The Watertown Community Foundation is leading "All Children Thrive" within the Watertown and Dodgeland school districts. There are three action teams who will focus on children's health, preparation for kindergarten, and 3rd grade reading levels. We have staff serving on each action team. There will also be a transformation committee and Ms. Cauley has been asked to chair this committee.

19. DISCUSS POTENTIAL AGENDA ITEMS FOR THE SEPTEMBER BOARD MEETING

There is nothing at this time.

20. ADJOURN

Mr. Tietz made a motion to adjourn the meeting.
Mr. Jones seconded.
Motion passed unanimously.
Meeting adjourned at 10:15 a.m.

Respectfully submitted by Donna Hollinger

NEXT BOARD MEETING
Tuesday, September 12, 2017 at 8:30 a.m.
Workforce Development Center, Room 103,
874 Collins Road, Jefferson, WI 53549

Item #8

Financial Statement Summary
July, 2017

We are projecting a positive year-end fund balance of $57,445. This includes our carryover from 2016 but excludes any prepaid adjustments. This compares to a projected year-end balance of $63,812 at the end of June. Since last month, CCS and ADRC revenue projections have increased. These increases have been offset by increased alternate care, placement, and hospitalization expense projections.

Summary of Variances:

Revenue: Overall, revenues are projected to be unfavorable by $1,870,920. Last month, this projection was $1,902,181. We ended 2016 with an unfavorable balance of $925,005.

- We are projecting CLTS revenue to be under budget by $1,296,716. Conversely, we are projecting CLTS expenses to be under budget by $1,313,139.

- CCS revenues are projected to be under budget by $390,956. Conversely, CCS expenses are projected to be under budgeted by $315,605. A comparison of cash basis CCS revenue and expenses for the past few years is below.

	2015	2016	2017 Projections (July)	2017 Projections (June)	2017 Budget
Revenue	1,084,926	1,275,015	1,446,113	1,373,040	1,837,069
Expenses	957,412	1,250,422	1,442,882	1,466,521	1,758,487

Expenditures: Overall, expenses are projected to be favorable by $1,928,365. Last month, this projection was $1,965,993. We ended 2016 with a favorable balance of $1,313,161. The favorable projection in 2017 is primarily due to underspending of the following programs by the following projected amounts: CLTS waiver of $1,313,139; salary & fringes of $447,295 CCS of $315,605; and hospitals of $310,491.

Major Classifications Impacting the Balance

- **Salary expenses are projected to be under budget by $349,917:** Salaries were under budget by $159,485 in 2016. Unpaid time taken in early 2017 is contributing to this variance. Additionally, some other expenses – such as step increases, the COLA, positions budgeted for mid-year, and payouts due to retirements – show up later in the year.

- **Fringes and benefit expenses are projected to be under budget by $97,378:** Fringes were under budget by $223,167 in 2016. Fringes would correlate with salaries. Health insurance expenses are projected to be under budget by $71,711.

- **Children Alternate Care expenses are projected to be over budget by $173,027*:** This projection includes some additional, anticipated high-cost placement for the last few months

of the year. Children's Alternate Care was under budget by $28,613 in 2016. A comparison of costs incurred is below:

	2017	2016
July	$195,414	$173,510
Monthly Average	$204,259	$166,447
YTD Total (through June)	$1,429,815	$1,165,128

* = This budgeted analysis does not include our carryover of $267,180 from 2016.

- **Children's Waiver expenses are projected to be under budget by $1,313,139:** We have been reallocating funds to other clients in the program or to add clients to the program. Our 2017 budget includes $337,775 of State match expenses, but we are projecting to spend our match with Children's COP funds.

- **Hospital/Detox is projected to be under budget by $416,661 (Net basis):**

	Budget	Actual	Projection
Revenue	$321,591	$321,890	$436,761
Expenditures	$1,314,353	$545,369	$1,003,862
Net	$(992,762)	$(223,479)	$(576,101)

We ended 2016 with a net balance of $(898,905). The improved 2017 projection is due to reduced hospitalizations and a large collection in March 2017 for numerous prior months. However, we are projecting almost as many hospitalization expenses in the last 5 months of the year as we incurred in the first 7 months of the year. This is due to increased utilization of the State's Mental Health Institutions. That is partially offset by decreased utilization of the Trempealeau Co IMD.

- **Operating Costs are projected to be under budget by $259,652:** Operating costs were under budget by $418,979 in 2016. Capital outlay and supplies and services are projected to be under budget by $29,539 and $50,783, respectively.

- **Other Contracted costs are projected to be over budget by $12,639**: These costs were under budget by $319,816 in 2016. The change in position this year is due to increased costs in the 1915i Program, which are projected to be over budget by $92,315 in 2017. We have had a few high-cost placements, and anticipate more in the last few months of the year. Offsetting this are Miscellaneous Services, which include purchased care and services for certain consumers, and are projected to be under budget by $104,063. This purchased care is under budget, because of the work we have been able to do internally.

- **Community Care costs are projected to be over budget by $223,224:** These costs, which include the AODA residential costs, were over budget $115,217 in 2016.

BEHAVIOR HEALTH DIVISION: Projected favorable balance of $20,958.

In June of 2017, we received a charge for Winnebago/Mendota of $63,278. In July of 2017, we received a charge for Winnebago/Mendota of $99,235.

CHILDREN & FAMILY DIVISION: Projected unfavorable balance of $118,777, which is due to the high cost of alternate care placements.

ECONOMIC SUPPORT DIVISION: Projected favorable balance of $36,649.

AGING & ADRC DIVISION: Projected favorable balance of $62,140, which is up from last month's unfavorable balance of $24,172. This change is due to increased ADRC revenue projections and a reclassification of the vehicle escrow account.

ADMINISTRATIVE DIVISION: Projected favorable balance of $56,474, which is down from last month's favorable balance of $136,469. This change is due to an increase in unfunded services expenses and a reclassification of the vehicle escrow account.

Statements are unaudited.

JEFFERSON COUNTY HUMAN SERVICES DEPARTMENT
STATEMENT OF REVENUES & EXPENDITURES
Projection based on July 2017 - Financial Statements

	Y-T-D @ Ledgers	Adjust -ments	Y-T-D Projection	Prior Y-T-D Projection	Prorated Budget	Year End Projection	2017 Budget	Year End Variance
SUMMARY								
Federal/State Operating Revenues	4,716,161	3,235,234	7,951,394	6,571,692	9,007,411	13,570,355	15,441,276	(1,870,921)
County Funding for Operations (tax levy & transfer in)	5,311,141	0	5,311,141	4,460,675	5,168,390	8,860,097	8,860,097	0
less: Prepaid Expense Transfer	0	0	0	0	0	0	0	0
Total Resources Available	10,027,302	3,235,234	13,262,536	11,032,367	14,175,801	22,430,453	24,301,373	(1,870,920)
Total Adjusted Expenditures	12,270,771	963,809	13,234,580	10,949,570	14,409,558	22,773,838	24,702,203	1,928,365
OPERATING SURPLUS (DEFICIT)	(2,243,469)	2,271,425	27,955	82,797	(233,757)	(343,385)	(400,830)	57,445
Balance Forward from 2016-Balance Sheet Operating Reserve	400,830		400,830	744,772		400,830	400,830	0
NET SURPLUS (DEFICIT)	**(1,842,639)**	**2,271,425**	**428,785**	**827,569**	**(233,757)**	**57,445**	**(0)**	57,445
REVENUES								
STATE & FEDERAL FUNDING								
MH & AODA Basic County Allocation	422,339	716,895	1,139,234	977,924	1,140,911	1,952,972	1,955,848	(2,876)
Children's Basic County Allocation	230,496	294,995	525,491	447,600	509,238	900,841	872,979	27,862
Family Care County Contribution	0	0	0	0	0	0	0	0
Children's L/T Support Waivers	317,775	125,810	443,585	(741)	939,244	760,431	1,610,132	(849,701)
Behavioral Health Programs	156,354	(14,364)	141,990	119,287	178,521	302,572	306,036	(3,464)
Community Options Program	71,542	64,308	135,850	72,706	127,236	232,886	218,118	14,768
Aging & Disability Res Center	286,406	233,650	520,056	608,208	509,870	939,540	874,063	65,477
Aging/Transportation Programs	345,979	54,199	400,178	338,527	384,239	682,450	658,696	23,754
Project YES!	89,639	96,090	185,729	151,776	191,517	318,392	328,314	(9,922)
Youth Aids	357,916	34,335	392,251	354,079	405,591	672,429	695,298	(22,869)
IV-E TPR	19,828	4,235	24,062	14,615	35,095	41,250	60,163	(18,913)
Family Support Program	0	0	0	0	0	0	0	0
Children & Families	65,520	(5,184)	60,335	57,068	35,050	103,432	60,086	43,346
ARRA Birth to Three	0	0	0	0	0	0	0	0
I.M. & W-2 Programs	495,829	394,102	889,931	711,864	929,343	1,525,596	1,593,160	(67,564)
Client Assistance Payments	136,368	25,742	162,110	146,400	177,123	277,903	303,639	(25,736)
Early Intervention	166,804	(68,985)	97,819	82,782	96,579	167,690	165,564	2,126
Total State & Federal Funding	**3,162,794**	**1,955,825**	**5,118,619**	**4,082,095**	**5,659,556**	**8,878,384**	**9,702,096**	**(825,838)**
COLLECTIONS & OTHER REVENUE								
Provided Services	772,607	1,015,281	1,787,888	1,803,192	2,258,694	3,117,256	3,872,046	(754,790)
Child Alternate Care	60,953	0	60,953	43,856	81,558	104,492	139,814	(35,322)
Adult Alternate Care	124,645	0	124,645	115,949	140,512	213,676	240,878	(27,202)
Children's L/T Support	83,526	81,034	164,560	212,240	425,319	282,103	729,119	(447,016)
1915i Program	40,309	53,470	93,779	78,961	90,351	160,616	154,887	5,729

	Y-T-D @ Ledgers	Adjust-ments	Y-T-D Projection	Prior Y-T-D Projection	Prorated Budget	Year End Projection	2017 Budget	Year End Variance
Donations	40,231	0	40,231	39,342	46,115	62,928	79,054	(16,126)
Cost Reimbursements	58,262	5,312	63,575	54,834	96,373	107,272	165,211	(57,939)
Other Revenues	372,833	124,312	497,145	141,223	208,933	643,629	358,171	285,458
Total Collections & Other	**1,553,367**	**1,279,408**	**2,832,775**	**2,489,597**	**3,347,855**	**4,691,972**	**5,739,180**	**(1,047,208)**
TOTAL REVENUES	**4,716,161**	**3,235,234**	**7,951,394**	**6,571,692**	**9,007,411**	**13,570,355**	**15,441,276**	**(1,873,046)**
EXPENDITURES								
WAGES								
Behavioral Health	874,401	0	874,401	689,839	808,397	1,538,282	1,385,823	152,459
Children's & Families	1,093,279	10,000	1,103,279	928,397	1,099,404	1,892,331	1,884,796	7,535
Community Support	481,331	6,000	487,331	384,735	491,665	834,978	842,855	(7,877)
Comp Comm Services	408,989	10,000	418,989	279,525	511,870	718,267	877,491	(159,224)
Economic Support	618,136	5,000	623,136	545,345	655,031	1,068,232	1,122,911	(54,679)
Aging & Disability Res Center	271,718	0	271,718	258,734	249,756	465,802	428,153	37,649
Aging/Transportation Programs	239,667	0	239,667	246,103	245,911	410,858	421,562	(10,704)
Childrens L/T Support	98,491	0	98,491	78,049	108,211	168,842	185,504	(16,662)
Early Intervention	178,728	1,000	179,728	151,827	182,981	308,106	313,682	(5,576)
Management/Overhead	556,306	26,500	582,806	507,629	743,581	999,097	1,274,710	(275,613)
Lueder Haus	162,942	1,500	164,442	132,027	163,704	281,901	280,635	1,266
Safe & Stable Families	124,778	0	124,778	114,336	135,564	213,905	232,396	(18,491)
Supported Emplymt	0	0	0	0	0	0	0	0
Total Wages	**5,108,767**	**60,000**	**5,168,767**	**4,316,546**	**5,396,075**	8,900,601	**9,250,518**	**(349,917)**
FRINGE BENEFITS								
Social Security	378,731	0	378,731	362,268	406,467	651,961	696,801	(44,840)
Retirement	339,322	0	339,322	312,242	361,079	584,155	618,992	(34,837)
Health Insurance	1,505,030	0	1,505,030	1,436,629	1,549,719	2,584,950	2,656,661	(71,711)
Other Fringe Benefits	79,041	0	79,041	24,155	33,318	111,127	57,117	54,010
Total Fringe Benefits	**2,302,124**	**0**	**2,302,124**	**2,135,293**	**2,350,583**	**3,932,193**	**4,029,571**	**(97,378)**
OPERATING COSTS								
Staff Training	33,258	0	33,258	31,022	32,671	56,909	56,008	901
Space Costs	97,918	0	97,918	99,770	113,754	167,859	195,006	(27,147)
Supplies & Services	566,282	33,300	599,582	442,239	626,164	1,022,641	1,073,424	(50,783)
Program Expenses	79,505	0	79,505	84,281	106,028	136,294	181,762	(45,468)
Employee Travel	81,067	0	81,067	67,213	96,903	138,913	166,119	(27,206)
Staff Psychiatrists & Nurse	250,962	0	250,962	240,467	253,458	430,220	434,500	(4,280)
Birth to 3 Program Costs	119,449	0	119,449	138,168	147,625	204,770	253,071	(48,301)
Busy Bees Preschool	1,422	0	1,422	1,603	1,694	2,438	2,904	(466)
ARRA Birth to Three	0	0	0	0	0	0	0	0
Opp. Inc. Payroll Services	0	0	0	0	0	0	0	0
Other Operating Costs	1,563	0	1,563	67,939	25,552	2,679	43,803	(41,124)
Year End Allocations	(24,866)	33,803	8,937	(14,888)	(256)	13,321	(439)	13,760
Capital Outlay	122,908	162,860	285,768	214,380	211,784	333,519	363,058	(29,539)
Total Operating Costs	**1,329,469**	**229,963**	**1,559,432**	**1,372,194**	**1,615,376**	**2,509,564**	**2,769,216**	**(259,652)**

	Y-T-D @ Ledgers	Adjust -ments	Y-T-D Projection	Prior Y-T-D Projection	Prorated Budget	Year End Projection	2017 Budget	Year End Variance
BOARD MEMBERS								
Per Diems	2,695	0	2,695	2,695	4,083	4,620	7,000	(2,380)
Travel	902	0	902	0	0	1,546	0	1,546
Training	0	0	0	0	438	0	750	(750)
Aging Committee	0	0	0	0	0	0	0	0
Total Board Members	**3,597**	**0**	**3,597**	**2,695**	**4,521**	**6,166**	**7,750**	**(1,584)**
CLIENT ASSISTANCE								
W-2 Benefit Payments	0	0	0	0	0	0	0	0
Funeral & Burial	0	0	0	0	0	0	0	0
Medical Asst. Transportation	0	0	0	0	0	0	0	0
Energy Assistance	79,364	0	79,364	81,689	91,373	136,052	156,639	(20,587)
Kinship & Other Client Assistance	46,275	7,500	53,775	51,649	51,181	86,569	87,738	(1,169)
Total Client Assistance	**125,639**	**7,500**	**133,139**	**133,339**	**142,553**	**222,622**	**244,377**	**(21,755)**
MEDICAL ASSISTANCE WAIVERS								
Childrens LTS	365,213	106,116	471,328	66,811	1,227,607	807,991	2,104,469	(1,296,478)
Total Medical Assistance Waivers	**365,213**	**106,116**	**471,328**	**66,811**	**1,227,607**	**807,991**	**2,104,469**	**(1,296,478)**
COMMUNITY CARE								
Supportive Home Care	16,665	0	16,665	15,343	16,266	28,569	27,884	685
Guardianship Services	15,072	0	15,072	13,004	18,667	25,838	32,000	(6,162)
People Ag. Domestic Abuse	35,000	0	35,000	30,000	35,000	60,000	60,000	0
Family Support	0	0	0	0	0	0	0	0
Transportation Services	18,545	0	18,545	14,831	29,570	31,792	50,691	(18,899)
Opp. Inc. Delinquency Programs	8,427	0	8,427	8,008	18,685	14,446	32,031	(17,585)
Opp. Inc. Independent Living	0	0	0	0	0	0	0	0
Other Community Care	267,512	77,656	345,168	146,078	220,465	627,412	377,940	249,471
Elderly Nutrition - Congregate	32,460	0	32,460	28,564	26,458	55,646	45,357	10,289
Elderly Nutrition - Home Delivered	52,687	0	52,687	54,422	41,872	90,321	71,781	18,540
Elderly Nutrition - Other Costs	5,125	0	5,125	7,200	12,775	8,786	21,900	(13,114)
Total Community Care	**451,494**	**77,656**	**529,150**	**317,451**	**419,758**	**942,809**	**719,584**	**223,224**
CHILD ALTERNATE CARE								
Foster Care & Treatment Foster	516,531	0	516,531	418,183	658,026	885,481	1,128,045	(242,564)
Intensive Comm Prog	0	0	0	0	0	0	0	0
Group Home & Placing Agency	375,353	0	375,353	285,869	327,800	643,462	561,942	81,520
L.S.S. Child Welfare	0	0	0	0	0	0	0	0
Child Caring Institutions	463,429	0	463,429	314,487	258,962	816,163	443,934	372,229
Detention Centers	27,185	0	27,185	8,050	24,500	46,603	42,000	4,603
Correctional Facilities	0	0	0	0	0	0	0	0
Shelter & Other Care	31,848	0	31,848	28,857	61,542	62,738	105,500	(42,762)
Total Child Alternate Care	**1,414,346**	**0**	**1,414,346**	**1,055,446**	**1,330,829**	**2,454,448**	**2,281,421**	**173,027**

	Y-T-D @ Ledgers	Adjustments	Y-T-D Projection	Prior Y-T-D Projection	Prorated Budget	Year End Projection	2017 Budget	Year End Variance
HOSPITALS								
Detoxification Services	112,998	4,750	117,748	87,338	87,500	151,560	150,000	1,560
Mental Health Institutes	316,436	111,185	427,621	477,633	679,206	852,301	1,164,353	(312,052)
Other Inpatient Care	0	0	0	0	0	0	0	0
Total Hospitals	**429,434**	**115,935**	**545,369**	**564,971**	**766,706**	**1,003,862**	**1,314,353**	**(310,491)**
OTHER CONTRACTED								
Adult Alternate Care (Non-MAW)	171,412	0	171,412	125,878	156,075	293,849	267,557	26,292
Family Care County Contribution	0	364,640	364,640	312,549	364,640	625,097	625,097	0
AODA Halfway Houses	0	0	0	0	0	0	0	0
1915i Program	263,897	0	263,897	255,635	231,634	489,221	397,086	92,135
IV-E TPR	61,697	0	61,697	63,563	87,500	105,766	150,000	(44,234)
Emergency Mental Health	1,975	2,000	3,975	0	0	3,975	0	3,975
Work/Day Programs	0	0	0	0	0	0	0	0
Ancillary Medical Costs	134,712	0	134,712	116,623	141,856	244,916	243,182	1,734
Miscellaneous Services	97,725	0	97,725	97,897	156,346	163,959	268,022	(104,063)
Prior Year Costs	0	0	0	0	0	0	0	0
Clearview Commission	9,272	0	9,272	12,680	17,500	66,800	30,000	36,800
Total Other Contracted	**740,688**	**366,640**	**1,107,328**	**984,825**	**1,155,551**	**1,993,583**	**1,980,944**	**12,639**
TOTAL EXPENDITURES	**12,270,771**	**963,809**	**13,234,580**	**10,949,570**	**14,409,558**	**22,773,838**	**24,702,203**	**(1,928,365)**

JEFFERSON COUNTY HUMAN SERVICES DEPARTMENT State of Program
Projection based on July 2017 Revenue & Expenditures Financial Statement

Summary Sheet

() Unfavorable

	Program	Annual Projection Revenue	Annual Projection Expenditure	Annual Projection Tax Levy	Budget Revenue	Budget Expenditure	Budget Tax Levy	Variance
Behavior Health								
5000	BASIC ALLOCATION	3,212,426	4,158,382	945,956	3,271,377	4,529,696	1,258,319	312,363
5003	LUEDER HAUS	130,441	537,072	406,631	137,000	514,032	377,032	(29,599)
5007	EMERGENCY MENTAL HEALTH	83,234	829,803	746,570	106,000	822,820	716,820	(29,750)
5011	MENTAL HEALTH BLOCK	26,128	38,874	12,746	26,128	26,230	102	(12,644)
5025	COMMUNITY SUPPORT PROGRAM	709,471	1,550,125	840,654	760,039	1,545,707	785,668	(54,986)
5027	COMP COMM SERVICE	1,446,113	1,442,882	(3,231)	1,837,069	1,758,487	(78,582)	(75,351)
5031	AODA BLOCK GRANT	187,638	270,141	82,503	171,299	217,833	46,534	(35,969)
5043	CERTIFIED MENTAL HEALTH	97,609	0	(97,609)	0	0	0	97,609
5044	EMERGENCY MENTAL HEALTH	3,975	3,975	0	0	0	0	0
5063	1915i PROGRAM	160,616	489,530	328,914	252,496	397,086	144,590	(184,324)
5090	YOUTH EMPOWERMENT SOLUTIONS	318,392	316,328	(2,064)	328,314	359,860	31,546	33,610
Total	**Behavior Health**	**6,376,043**	**9,637,113**	**3,261,071**	**6,889,722**	**10,171,751**	**3,282,029**	**20,958**
Children & Families								
5001	CHILDREN'S BASIC ALLOCATION	1,160,084	2,750,099	1,590,016	1,117,171	2,920,525	1,803,354	213,338
5002	KINSHIP CARE	81,851	77,921	(3,930)	84,877	84,877	0	3,930
5005	YOUTH AIDS	671,451	1,912,413	1,240,963	728,739	1,750,555	1,021,816	(219,146)
5006	YOUTH AIDS STATE CHARGES	0	0	0	0	0	0	0
5008	YOUTH INDEPENDENT LIVING	0	0	0	0	3,570	3,570	3,570
5009	YA EARLY & INTENSIVE INT	62,057	151,951	89,893	43,979	150,781	106,802	16,909
5121	CHILDRENS COP PROG	232,886	232,886	0	218,118	0	(218,118)	(218,118)
5020	DOMESTIC ABUSE		60,000	60,000		60,000	60,000	0
5021	SAFE & STABLE FAMILIES	94,009	380,194	286,185	107,586	426,368	318,782	32,597
5036	SACWIS	0	0	0	3,000	10,000	7,000	7,000
5040	CHILDRENS LTS WAIV-DD	737,981	903,294	165,313	1,570,371	1,694,044	123,673	(41,640)
5041	CHILDRENS LTS WAIV-MH	0	82	82	0	0	0	(82)
5042	CHILDRENS LTS WAIV-PD	0	78	78	0	0	0	(78)
5068	FOSTER PARENT TRAINING	761	1,855	1,095	2,000	8,348	6,348	5,253
5070	IV-E TPR	41,250	105,769	64,519	60,163	150,000	89,837	25,318
5080	YOUTH DELINQUENCY INTAKE	0	870,490	870,490	0	867,246	867,246	(3,244)
5082	AUTISM	304,554	292,204	(12,350)	768,880	769,381	501	12,851
5175	EARLY INTERVENTION	203,404	709,982	506,578	203,564	744,040	540,476	33,898
5105	KINSHIP ASSESSMENTS	2,565	3,455	890	6,916	9,450	2,534	1,644
5120	Coordinated Services Team	60,000	84,559	24,559	62,123	88,190	26,067	1,508
5188	BUSY BEES PRESCHOOL	3,729	54,303	50,574	4,000	55,930	51,930	1,356
5189	INCREDIBLE YEARS	10,467	21,657	11,190	0	15,551	15,551	4,361
Total	**Children & Families**	**3,667,047**	**8,613,193**	**4,946,146**	**4,981,487**	**9,808,856**	**4,827,369**	**(118,777)**

JEFFERSON COUNTY HUMAN SERVICES DEPARTMENT State of Program
Projection based on July 2017 Revenue & Expenditures Financial Statement

Summary Sheet

() Unfavorable

	Program	Annual Projection Revenue	Annual Projection Expenditure	Tax Levy	Budget Revenue	Budget Expenditure	Budget Tax Levy	Variance
Economic Support Division								
5051	INCOME MAINTENANCE	1,438,209	2,032,477	594,268	1,446,038	1,956,887	510,849	(83,419)
5053	CHILD DAY CARE ADMIN	100,868	0	(100,868)	171,886	171,886	0	100,868
5055	W-2 PROGRAM	0	0	0	0	0	0	0
5057	ENERGY PROGRAM	136,052	136,052	0	156,639	156,639	0	0
5071	CHILDREN FIRST	4,000	0	(4,000)	4,800	0	(4,800)	(800)
5073	FSET	14,450	0	(14,450)	0	0	0	14,450
5100	CLIENT ASSISTANCE	5,550	0	(5,550)	0	0	0	5,550
Total	**Economic Support Division**	**1,699,129**	**2,168,529**	**469,400**	**1,779,363**	**2,285,412**	**506,049**	**36,649**
Aging Division & ADRC								
5012	ALZHEIMERS FAM SUPP	33,053	28,252	(4,801)	19,009	19,010	1	4,802
5048	AGING/DISABIL RESOURCE	939,540	842,696	(96,844)	874,063	730,658	(143,405)	(46,561)
5075	GUARDIANSHIP PROGRAM	0	25,838	25,838	0	32,000	32,000	6,162
5076	STATE BENEFIT SERVICES	41,221	100,735	59,514	45,882	143,589	97,707	38,193
5077	ADULT PROTECTIVE SERVICES	56,827	106,679	49,852	56,827	103,360	46,533	(3,319)
5078	NSIP	16,198	26,414	10,216	17,955	17,955	0	(10,216)
5150	AGING - CARE TALKS	4,996	4,996	0	0	0	0	0
5151	TRANSPORTATION	232,794	230,759	(2,035)	223,506	230,959	7,453	9,488
5152	IN-HOME SERVICE III-D	4,271	3,685	(586)	4,271	6,000	1,729	2,315
5154	SITE MEALS	175,083	133,172	(41,912)	175,221	152,333	(22,888)	19,024
5155	DELIVERED MEALS	97,424	151,523	54,098	105,403	141,074	35,671	(18,427)
5157	SCSP	7,986	0	(7,986)	7,986	8,874	888	8,874
5158	ELDER ABUSE	25,077	101,482	76,405	25,025	81,007	55,982	(20,423)
5159	III-B SUPPORTIVE SERVICE	66,606	65,598	(1,008)	66,706	79,909	13,203	14,211
5163	TITLE III-E	29,940	26,393	(3,547)	29,940	39,920	9,980	13,527
5195	Vehicle Escrow Account	386	21,034	20,648	0	65,137	65,137	44,489
Total	**Aging & ADRC Center**	**1,731,403**	**1,869,255**	**137,851**	**1,651,794**	**1,851,785**	**199,991**	**62,140**

JEFFERSON COUNTY HUMAN SERVICES DEPARTMENT State of Program
Projection based on July 2017 Revenue & Expenditures Financial Statement

Summary Sheet

() Unfavorable

	Program	Annual Projection Revenue	Annual Projection Expenditure	Annual Projection Tax Levy	Budget Revenue	Budget Expenditure	Budget Tax Levy	Variance
Administrative Services Division								
5187	UNFUNDED SERVICES	9,992	53,268	43,276	0	52,432	52,432	9,156
5190	Management	0	32,571	32,571	0	778,388	778,388	745,817
5190	Management Cleared	0	0	0	0	(778,389)	(778,389)	(778,389)
5200	Overhead & Tax Levy	8,946,839	87,424	(8,859,415)	8,999,007	168,910	(8,830,097)	29,318
5210	CAPITAL OUTLAY	0	312,485	312,485	0	363,058	363,058	50,573
	Balance Sheet Non Lapsing Funds	400,830	0	(400,830)	400,830	0	(400,830)	0
Total	**Administrative Services Division**	**9,357,660**	**485,748**	**(8,871,912)**	**9,399,837**	**584,399**	**(8,815,438)**	**56,474**
GRAND Total		**22,831,283**	**22,773,838**	**(57,445)**	**24,702,203**	**24,702,203**	**0**	**57,445**

Net Balance

Note: Variance includes Non-Lapsing from Balance Sheet

Detox/AODA CBRF
Jefferson County - HSD

Detox Facility	Clients *	Comments	Billed YTD **	Days **
Tellurian Community	71	July 2017	$52,194	111
Matt Talbot Recovery	0	July 2017	$0	0
Lutheran Social Services	1	July 2017	$1,152	12
Hope Haven - Reb	16	July 2017	$85,425	517
Friends of Women	3	July 2017	$21,855	141
Meta House, Inc	0	July 2017	$0	0
All - July 2017	**91**	**2017 total through July**	**$160,626**	**781**
All - July 2016	**91**	**2016 total through July**	**$107,844**	**569**

* Count is based on Unduplicated Clients.

** Count is based on bills paid through May with a service date in Comments column.

Costs by Month

Month	Detox	AODA
January	$8,478	$10,930
February	$9,041	$13,090
March	$12,350	$29,680
April	$6,650	$14,900
May	$4,750	$12,150
June	$6,175	$16,070
July	$4,750	$11,612
August - estimated	$7,456	$12,265

Total Estimated Costs Thru August 2017 $180,347

Total Costs Through August 2016 $127,016

Children - Alternate Care Costs

Type of Placement	# of Children	# of Days	Cost	Cost per Day	Cost Per Child
January-17					
Foster Care	56	1,555	$73,498	$47	$1,312
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	6	186	$47,904	$258	$7,984
Kinship Care	26	779	$5,830	$7	$224
Subsidized Guardianship	14	434	$4,119	$9	$294
Supervised Independ Living	1	31	$650	$21	$650
RCC's	6	186	$73,035	$393	$12,172
RCC's - Out of State	1	31	$17,050	$550	$17,050
Total January 2017	**110**	**3202**	**$ 222,086**	**$69**	**$2,019**
		2017 YTD Avg. per Month	**$222,086**		
		2016 YTD Avg. per Month (thru January 2016)	**$209,409**		
February-17					
Foster Care	58	1,418	$75,975	$54	$1,310
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	7	152	$39,998	$263	$5,714
Kinship Care	25	700	$5,800	$8	$232
Subsidized Guardianship	14	392	$4,119	$11	$294
Supervised Independ Living	1	28	$525	$19	$525
RCC's	6	168	$64,896	$386	$10,816
RCC's - Out of State	1	28	$15,400	$550	$15,400
Total February 2017	**112**	**2886**	**$206,713**	**$72**	**$1,846**
		2017 YTD Avg. per Month	**$214,400**		
		2016 YTD Avg. per Month (thru February 2016)	**$199,624**		
March-17					
Foster Care	56	1,518	$81,625	$54	$1,458
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	6	186	$47,921	$258	$7,987
Kinship Care	26	794	$5,942	$7	$229
Subsidized Guardianship	14	434	$4,119	$9	$294
Supervised Independ Living	1	31	$525	$17	$525
RCC's	6	157	$60,862	$388	$10,144
RCC's - Out of State	1	31	$17,050	$550	$17,050
Total March 2017	**110**	**3151**	**$218,044**	**$69**	**$1,982**
		2017 YTD Avg. per Month	**$215,614**		
		2016 YTD Avg. per Month (thru March 2016)	**$183,317**		

Children - Alternate Care Costs

Type of Placement	# of Children	# of Days	Cost	Cost per Day	Cost Per Child
April-17					
Foster Care	52	1,493	$85,268	$57	$1,640
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	6	180	$45,120	$251	$7,520
Kinship Care	29	829	$6,471	$8	$223
Subsidized Guardianship	14	420	$4,119	$10	$294
Supervised Independ Living	1	30	$450	$15	$450
RCC's	5	150	$57,928	$386	$11,586
RCC's - Out of State	1	11	$6,050	$550	$6,050
Total April 2017	**108**	**3113**	**$205,406**	**$66**	**$1,902**
		2017 YTD Avg. per Month	**$213,062**		
		2016 YTD Avg. per Month (thru April 2016)	**$172,106**		
May-17					
Foster Care	58	1,584	$86,485	$55	$1,491
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	7	178	$47,801	$269	$6,829
Kinship Care	28	868	$6,496	$7	$232
Subsidized Guardianship	14	434	$4,119	$9	$294
Supervised Independ Living	0	0	$0	$0	$0
RCC's	5	128	$46,333	$362	$9,267
RCC's - Out of State	0	0	$0	$0	$0
Total May 2017	**112**	**3192**	**$191,234**	**$60**	**$1,707**
		2017 YTD Avg. per Month	**$208,697**		
		2016 YTD Avg. per Month (thru May 2016)	**$166,419**		
June-17					
Foster Care	53	1,373	$77,568	$56	$1,464
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	10	210	$54,564	$260	$5,456
Kinship Care	36	836	$6,465	$8	$180
Subsidized Guardianship	14	420	$4,119	$10	$294
Supervised Independ Living*	1	10	$840	$84	$840
RCC's	5	131	$47,363	$362	$9,473
RCC's - Out of State	0	0	$0	$0	$0
Total June 2017	**119**	**2980**	**$190,919**	**$64**	**$1,604**
		2017 YTD Avg. per Month	**$205,734**		
		2016 YTD Avg. per Month (thru June 2016)	**$165,270**		

* includes June and July rent payments

Children - Alternate Care Costs

Type of Placement	# of Children	# of Days	Cost	Cost per Day	Cost Per Child
July-17					
Foster Care	44	1,342	$74,064	$55	$1,683
Foster Care Special	0	0	$0	$0	$0
Foster Home Level - 1	0	0	$0	$0	$0
Group Home	7	202	$50,665	$251	$7,238
Kinship Care	35	1,041	$7,797	$7	$223
Subsidized Guardianship	14	434	$4,571	$11	$327
Supervised Independ Living	1	31	$854	$28	$854
RCC's	5	155	$57,463	$371	$11,493
RCC's - Out of State	0	0	$0	$0	$0
Total July 2017	**106**	**3205**	**$195,414**	**$61**	**$1,844**
		2017 YTD Avg. per Month	**$204,259**		
		2016 YTD Avg. per Month (thru July 2016)	**$166,447**		
* includes August rent					
		Projected 2017 Cost	**$2,451,112**		
		2017 Budget	$2,281,421		
		Carryover from 2016	$267,180		
		Total 2017	**$2,548,601**		

Item # 11

2017 Provider Contracts (8/31/2017)

Contract Number	Provider	Service	Target	2016			2017			
17-297	Honey Creek Counseling and Recovery Services, LLC	Therapeutic Services	Child		per	unit	37.50	per	unit	7,500
17-298	Community Action Coalition	Home Modification	WDC Rent		per	month	-492.00	per	month	-4,920
17-299	Riverview AFH LLC	Adult Alt Care	Adult		per	daily	361.64	per	daily	46,652
17-300	Lifestriders, Inc	Therapy Services	Child		per	daily	390.00	per	session	3,000
17-301	Family and Children's Center	Child Alt. Care	Child		per	daily	203.39	per	daily	26,441
17-302	Lemke Fence	Home Modification	Child		per	item	11,500.00	per	item	11,500
17-303	Habilitation Centers, LLC d/b/c Millcreek of Arkansas	Child Alt. Care	Child		per	day	530.00	per	day	64,660

VISTA Assignment Description

Title: VISTA Member Substance Abuse Reduction Coordinator

Sponsoring Organization: Wisconsin Association of Free & Charitable Clinics, Inc (WAFCC)
Host Site: Jefferson County Human Services Department
Project Name: WAFCC Outreach & Opiate Abuse Reduction
Project Number:
Project Period: 11/2017-10/2018

Site Name (if applicable): Jefferson, Wisconsin

Focus Area(s) Capacity building to raise awareness and increase funding while developing resources to combat poverty and the substance abuse epidemic in Jefferson County, with an emphasis in opioids.
Primary: Health Futures - Health Care Access

VISTA Assignment Objectives and Member Activities

Goal of the Project:
This project is a collaboration between the Wisconsin Association of Free & Charitable Clinics (WAFCC), and Jefferson County Human Services Department (JCHSD). The location for this project is Jefferson County Human Services Department in Jefferson , WI.

The mission of the Wisconsin Association of Free & Charitable Clinics (WAFCC) is to support, strengthen, and advocate for the uniqueness of the Wisconsin free and charitable clinics, the patients they serve, and the communities with whom they partner.

Jefferson County Human Services Department's mission is to enhance the quality of life for individuals and families in Jefferson County. Currently, individuals and families in Jefferson County are experiencing the impact of the opioid epidemic and the resurgence of methamphetamine.

The VISTA Member's charge is:

1. Raise awareness within the community around the opioid and methamphetamine epidemic as well as other issues related to alcohol and other drug use/abuse.
2. Increase resources to combat the local drug epidemic.
3. Develop collaborative opportunities to address substance use and abuse where community members are.

OBJECTIVE 1: Collaborate with Jefferson County's Alcohol Tobacco and other Drug Addiction Prevention (ATODA) Coalition to raise awareness within the county around the opioid and methamphetamine epidemic as well as other issues related to alcohol and other drug use and abuse.

Member Activities:

1. Attend monthly coalition meetings and participate as a member of the coalition.
2. Complete meeting minutes and agendas as needed.
3. Review last year's Drug-Free Communities grant announcement and share key components with coalition members.
4. Attend town hall meeting scheduled in November.
5. Assist in forming of sub-committees to prepare to write for the DFC grant.
6. Participate in 1-2 sub-committees of the ATODA coalition.
7. Assist in Community Needs Assessment and the gathering of data needed to apply for the DFC grant (including Youth Risk Behavior Survey Data and other data needed to apply for the grant).
8. Identify at least 2 prevention activities that would benefit Jefferson County communities.
9. Review DFC grant announcement in January and share key components with coalition members.
10. Lead in the writing of the DFC grant for the ATODA coalition and submit grant prior to identified

deadline.

OBJECTIVE 2: Work in partnership with key stakeholders in brainstorming and combating barriers to housing in Jefferson County, specifically those barriers faced by residents struggling with opiate addiction. This will include identifying the housing barriers faced and ultimately identifying strategies to address such barriers.

Member Activities:

1. Meet with stakeholders who attended the October 2017 housing summit to gather information shared.
2. Meet with various community members to gather information regarding housing barriers (this should include human services staff and clients, Community Action Coalition of Jefferson County, United Way of Jefferson County, local clergy as well as individuals experiencing homelessness in the county).
3. Gather statistics that will assist with identifying housing barriers (homelessness numbers, information on housing available/not available, waiting lists for admission into low-income housing, etc.).
4. Research what other counties have done to combat barriers to housing issues. This may include anything from internet research to face to face interviews.
5. Meet with key stakeholders to present strategies and ultimately work in partnership to implement 1-2 strategies.

OBJECTIVE 3: Explore the implementation of Peer Recovery Coaches in Jefferson County.

Member Activities:

1. Research reimbursement for recovery coaching to include CCS, CRS and the outpatient clinic as well as specific insurances including Medicaid.
2. Research agencies currently utilizing recovery coaches and identify recruitment ideas, implementation strategies and reimbursement.
3. Explore the use of SBIRT and screening tools that can be utilized by recovery coaches and how other agencies are utilizing this option.

RESOLUTION NO. _____

TO THE HONORABLE BOARD OF SUPERVISORS OF JEFFERSON COUNTY, WISCONSIN

MEMBERS,

WHEREAS, Jefferson County ("County") is concerned with the recent rapid rise in troubles among County citizens, residents, and visitors in relation to problems arising out of the use, abuse and overuse of opioid medications, which according to certain studies, impacts millions of people across the country; and

WHEREAS, issues and concerns surrounding opioid use, abuse and overuse by citizens, residents and visitors are not unique to County and are, in fact, issues and concerns shared by all other counties in Wisconsin and, for that matter, states and counties across the country, as has been well documented through various reports and publications, and is commonly referred to as the Opioid Epidemic ("Opioid Epidemic:); and

WHEREAS, the societal costs associated with the Opioid Epidemic are staggering and, according to the Centers for Disease Control and Prevention, amount to over $75 billion annually; and

WHEREAS, the National Institute for Health has identified the manufacturers of certain of the opioid medications as being directly responsible for the rapid rise of the Opioid Epidemic by virtue of their aggressive and, according to some, unlawful and unethical marketing practices; and

WHEREAS, certain of the opioid manufacturers have faced civil and criminal liability for their actions that relate directly to the rise of the Opioid Epidemic; and

WHEREAS, County has spent millions in unexpected and unbudgeted time and resources in its programs and services related to the Opioid Epidemic; and

WHEREAS, County is responsible for a multitude of programs and services, all of which require County to expend resources generated through state and federal aid, property tax levy, fees and other permissible revenue sources; and

WHEREAS, County's provision of programs and services becomes more and more difficult every year because the costs associated with providing the Opioid Epidemic programs and services which continue to rise, yet County's ability to generate revenue is limited by strict levy limit caps and stagnant or declining state and federal aid to County; and

WHEREAS, all sums that County expends in addressing, combatting and otherwise dealing with the Opioid Epidemic are sums that cannot be used for other critical programs and services that County provides to County citizens, residents and visitors; and

WHEREAS, County has been informed that numerous counties and states across the country have filed or intend to file lawsuits against certain of the opioid manufacturers in an effort to force the persons and entities responsible for the Opioid Epidemic to assume financial responsibility for the costs associated with addressing, combatting and otherwise dealing with the Opioid Epidemic; and

WHEREAS, County has engaged in discussions with certain law firms regarding the possibility of pursuing claims against certain of the opioid manufacturers on a contingent basis; and

WHEREAS, the law firms are currently in the process of drafting an engagement agreement that would contain the specific terms of representation for the County in relation to the potential claims; and

WHEREAS, County is informed that the Wisconsin Counties Association has engaged in extensive discussions with the same law firms and has expressed a desire to assist the law firms, County and other counties in the prosecution of claims against certain of the opioid manufacturers; and

WHEREAS, County believes it to be in the best interest of County, its citizens, residents, visitors and taxpayers to join with other counties in and outside Wisconsin in pursuit of claims against certain of the opioid manufacturers, subject to completing the negotiation of an engagement agreement with the law firms; and

WHEREAS, by pursuing the claims against certain of the opioid manufacturers, County is attempting to hold those persons and entities that had a significant role in the creation of the Opioid Epidemic responsible for the financial costs assumed by County and other public agencies across the country in dealing with the Opioid Epidemic.

NOW, THEREFORE, BE IT RESOLVED:

County authorizes the Board Chair to execute the engagement agreement with the law firms provided that there is no out-of-pocket cost to County and further provided that the Board Chair, Administrator and Corporation Counsel have reviewed and approved the form of the engagement agreement; and

BE IT FURTHER RESOLVED:

County shall endeavor to faithfully perform all actions required of County in relation to the claims contemplated herein and in the engagement agreement and hereby directs all County personnel to cooperate with and assist the law firms in relation thereto.

Respectfully submitted this 12th day of September, 2017.

HUMAN SERVICES BOARD

**[FISCAL NOTE]

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