IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS

	_ DIVISION	
STATE OF ARKANSAS, ex rel. LESLIE RUTLEDGE, ATTORNEY GENERAL		PLAINTIFF
LESLIE RUILEDGE, ATTORNET GENERAL		FLAINTIFF
v.	CASE NUMBER: _	
PURDUE PHARMA L.P.;		
PURDUE PHARMA, INC.;		
THE PURDUE FREDERICK COMPANY, INC.;		
JOHNSON & JOHNSON;		
JANSSEN PHARMACEUTICALS, INC.;		
ORTHO-MCNEIL-JANSSEN PHARMACEUTIO	CALS, INC.	
n/k/a JANSSEN PHARMACEUTICALS, INC.;		
JANSSEN PHARMACEUTICA INC.		
n/k/a JANSSEN PHARMACEUTICALS, INC.;		
ENDO HEALTH SOLUTIONS INC.;		
ENDO PHARMACEUTICALS, INC.;		
AND DOES 1 THROUGH 100, INCLUSIVE		DEFENDANTS

COMPLAINT

TABLE OF CONTENTS

					<u>Page</u>		
I.	INTR	RODUC	TION .		1		
II.	JURI	RISDICTION AND VENUE5					
				5			
	A.	Plain	tiff		5		
	В.				5		
IV.					VS8		
A. Defendants Used Multiple Avenues to Di		Used M	Sultiple Avenues to Disseminate Their False and Deceptive Using Opioids for Chronic Pain				
		1.			spread and continue to spread their false and deceptive hrough direct marketing of their branded opioids9		
		2.	sprea	d false	used a diverse group of seemingly independent third parties to and deceptive statements about the risks and benefits of		
			a.	Key	Opinion Leaders ("KOLs")12		
			b.	Fron	t Groups13		
				(1)	American Pain Foundation ("APF")14		
				(2)	American Academy of Pain Medicine15		
	B.				ting Scheme Misrepresented the Risks and Benefits of		
		1.	Defe term	ndants :	falsely trivialized or failed to disclose the known risks of long- use		
		2.	Defe	ndants	grossly overstated the benefits of chronic opioid therapy27		
	C.	Defe	ndants [Targete	d Susceptible Prescribers and Vulnerable Patient Populations.30		
	D.		ough Defendants Knew That Their Marketing of Opioids Was False and eptive, They Fraudulently Concealed Their Misconduct				
E. Defendants' Conduct Is Not Excused by the Actions of Any				ct Is Not Excused by the Actions of Any Third Parties33			
	F.	Defendants' Marketing Conduct Foreseeably Led to Opioid Abuse that has Wrought Havoc on Arkansas Communities.					
	G.	Defe	ndants'	Condu	ct Has Caused Arkansas Substantial Economic Injury38		

			TIVE TRADE PRACTICE ET SEQ	
			D FALSE CLAIMS ACT	
THIRD	CAUSE OF ACTION:	PUBLIC NUISANCE		42
FOURT	H CAUSE OF ACTION	N: UNJUST ENRICH	MENT	43
FIFTH (CAUSE OF ACTION:	CIVIL CONSPIRACY		44
PRAYE	R FOR RELIEF			45
JURY D	EMAND			46

Plaintiff, the State of Arkansas, by and through its Attorney General Leslie Rutledge (hereafter "Arkansas" or "the State"), brings this law enforcement action in a *parens patriae* capacity, alleging as follows:

I. INTRODUCTION

- 1. Defendants produce, market, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like OxyContin and Percocet, and generic drugs like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain, migraines, and arthritis), opioids were used only to treat short-term acute pain or for cancer or palliative (end-of-life) care.
- 2. However, by the late 1990s, and continuing today, each Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used to treat chronic pain, opening the door to a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids.
- 3. In connection with this scheme, each Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them to treat chronic pain. As to the risks, Defendants falsely and misleadingly, and sometimes contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to

¹ In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

prevent abuse and addiction. Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though, as the Centers for Disease Control and Prevention ("CDC") has concluded, there is "no good evidence" supporting these claims.

- 4. Defendants disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians that Defendants recruited and compensated. Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known that opioids are addictive drugs, unsafe in most circumstances for long-term use was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.
- 5. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the CDC, including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). The FDA and CDC have found that continuing use of opioids for over three months creates a risk of "opioid disorder" and that opioid use creates a substantial risk of misuse, abuse,

withdrawal, addiction, overdose, and death. Opioid manufacturers, including Defendants Endo Pharmaceuticals and Purdue Pharma, have also entered into settlements with public entities, including (in the case of Purdue) with Arkansas, that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use while failing to correct past misrepresentations.

- 6. Defendants' efforts have been wildly successful. Opioids are now the <u>most</u> prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone. The result has been a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.
- 7. Arkansas has been acutely affected by Defendants' practices and is confronting a public health crisis of historic proportions. In 2016, Arkansas had the second highest opioid prescribing rate in the country and there were more opioid prescriptions issued in the state than there were Arkansans. This elevated rate of prescribing has resulted in a staggering quantity of dispensed pills 235,934,613 in 2016 to be exact enough to supply every man, woman and child in Arkansas with 78 opioid doses each.
- 8. As opioid prescribing has skyrocketed in Arkansas, so too have overdose deaths. Today, prescription opioids are the leading cause of drug-related death in Arkansas, and by a wide margin. Arkansas also has seen a dramatic surge in hospital and in-patient admissions linked to opioid abuse. Alarmingly, and in keeping with a pattern seen across the nation, many Arkansans addicted to prescription opioids are now turning to heroin because it supplies a similar high at a fraction of the street cost of prescription opioids.

- 9. Arkansans who suffer from chronic pain deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign has deprived Arkansas patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Patients have suffered enormously as a result.
- 10. Defendants' conduct also has imposed a direct and foreseeable financial burden on Arkansas. The State has spent millions on opioid prescriptions, and its agencies have devoted an increasingly large segment of the State's precious resources on public health, law enforcement, and outreach initiatives designed to combat the crisis created by Defendants' marketing scheme. And these efforts are only the beginning. Abating the epidemic for the next generation of Arkansans will require an enormous further outlay of state resources, and millions of dollars, to re-educate providers, treat the addicted, and heal Arkansas communities ravaged by opioid abuse. Having caused the crisis Arkansas confronts, Defendants bear legal responsibility for the costs the State will incur in cleaning it up.
- 11. With this action, Arkansas, by and through its Attorney General Leslie Rutledge, seeks to hold Defendants accountable, individually and collectively, for engaging in deceptive and unconscionable trade practices contravening the Deceptive Trade Practices Act (Ark. Code Ann. §§ 4-88-101 et seq.), violating the Medicaid Fraud False Claims Act (Ark. Code Ann. §§ 20-77-901 et seq.), creating a public nuisance, unjustly enriching themselves at the State's expense, and participating in a civil conspiracy. Arkansas seeks all remedies available, including but not limited to injunctive relief, civil penalties, damages, restitution, and abatement.

II. JURISDICTION AND VENUE

- 12. This Court has subject matter jurisdiction by grant of authority under Amendment 80 § 6(A) of the Constitution of the State of Arkansas.
- 13. This Court has personal jurisdiction over Defendants under the long-arm statute of the State of Arkansas (Ark. Code Ann. § 16-4-101), and the Constitution of the United States, because Defendants conduct business in Arkansas, purposefully direct or directed their actions toward Arkansas, and/or have the requisite minimum contacts with Arkansas necessary to permit the Court to exercise jurisdiction.
- 14. Venue in this Court is proper pursuant to Ark. Code Ann. §§ 16-60-103, 4-88-104, and 20-77-908.

III. PARTIES

A. Plaintiff

15. This action is brought on behalf of the sovereign State of Arkansas, by and through Leslie Rutledge, the duly-elected Attorney General and chief law officer for the State.

B. Defendants

- 16. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").
- 17. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States and Arkansas. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

sales of \$800 million. OxyContin constitutes roughly 30 percent of the entire market for analgesic drugs (painkillers).

- In May 2007, Purdue entered into a Consent Judgment with the State of Arkansas, based principally on Purdue's direct promotion of OxyContin up to May 8, 2007, the effective date of the Consent Judgment. In this Complaint, the State does not seek to enforce any provision of that Consent Judgment, and is not seeking any relief against Purdue under consumer protection laws specified in section (I)(1)(M) of the Consent Judgment based on any conduct by Purdue on or before May 8, 2007 relating to Purdue's promotional and marketing practices regarding OxyContin. The State does, however, assert claims arising under Arkansas law independent of the Consent Judgment, and seeks restitution, in addition to declaratory and injunctive relief, as afforded by law.
- 19. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10 percent of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.")

- 20. Janssen manufactures, promotes, sells, and distributes drugs in the United States and Arkansas, including the opioid Duragesic. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.
- 21. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a whollyowned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")
- 22. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and Arkansas. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10 percent of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States and Arkansas, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.
- 23. The State lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Ark. Code Ann. § 16-56-125. The State will amend this Complaint to show their true names and capacities if and when they are ascertained. The State is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in

some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

IV. FACTUAL ALLEGATIONS

- 24. Before the 1990s, generally-accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Doctors generally did not prescribe opioids for chronic pain due to the lack of evidence that opioids improved patients' ability to overcome pain and to function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects.
- 25. To take advantage of the lucrative market for chronic pain patients, Defendants had to change this narrative. Each Defendant thus developed a well-funded marketing scheme using both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence.

A. Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Using Opioids for Chronic Pain.

26. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Arkansas. Defendants also bankrolled and controlled professional societies and other ostensibly neutral third parties in order to lend these deceptive statements a veneer of independence and scientific legitimacy.

- 1. Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.
- 27. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.
- 28. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo has distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands," which implied that OxyContin would help the writer work more effectively.
- 29. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" sales representatives who visited individual doctors and medical staff in their offices and small-group speaker programs. Defendants have not corrected this misinformation. In 2014 alone, Defendants spent \$152 million on detailing branded opioids to doctors, including \$108 million spent by Purdue, \$34 million by Janssen, and \$10 million by Endo.
- 30. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be

selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations.

- 31. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. In 2014-2015, more than half of all doctors who wrote an opioid prescription for a Medicare patient received a payment from an opioid manufacturer, and researchers have shown a strong correlation in payments received and the amount of opioids prescribed. In 2014-2015, for example, doctors whose opioid prescription volume (among Medicare patients) ranked in the top 5% received twice as much money from opioid manufacturers as doctors who prescribed opioids at the median rate.
- 32. Defendants employed the same marketing schemes and deployed the same messages in Arkansas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. Consistent messaging is promoted through national and regional training and shared use of the same speaker slides and presentation materials. Defendants' sales representatives and physician speakers are required to stick to prescribed talking points and sales messages, report on the effectiveness of the prescribed talking points in persuading physicians, and supervisors ride along with them periodically to confirm core-message compliance.
- 33. In February 2018, with legal challenges mounting, Purdue announced that it would cease detailing physicians in respect to Purdue's branded opioids. Purdue did not,

however, make any commitment to correct the misrepresentations its multi-decade detailing campaign has engendered in the medical community. Nor did Purdue commit to cease other deceptive marketing tactics, including the practice addressed below of laundering promotional messages through front groups and other ostensibly unbiased third parties.

- 2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.
- 34. Defendants also deceptively marketed opioids in Arkansas through unbranded advertising *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.
- 35. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA, which gave the false appearance that the deceptive messages came from an independent and objective source.
- 36. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted the fine print in its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy	Opana ER Advertisement	
(Unbranded)	(Branded)	
"People who take opioids as prescribed usually do not become addicted."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."	

a. Key Opinion Leaders ("KOLs")

- 37. Among the third-parties Defendants have utilized to spread their messages are doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." As they rose to prominence touting the benefits of chronic opioid treatment, these KOLs' professional reputations became dependent on furthering Defendants' pro-opioid message, even in activities Defendants did not directly fund.
- 38. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage 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. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."
- 39. Defendants' KOLs have been effective in changing prescribing behavior because, as Defendants recognized, doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

For example, the State of New York found in a 2015 settlement with Purdue that through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

40. Defendants have utilized numerous KOLs, and many have been engaged by multiple Defendants. Two of the most prominent are (1) Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York; and (2) Dr. Lynn Webster, the former head of Lifetree Pain Clinic and Lifetree Clinical Research in Salt Lake City.

b. Front Groups

- 41. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing, and by conducting outreach to vulnerable patient populations targeted by Defendants.
- 42. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants exercised overt control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. For example, Purdue's consulting agreement with the American Pain Foundation (discussed further below) gave it direct, contractual control over APF's work. These efforts assured that Front Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups concealed the extent to which they were bankrolled by

Defendants, holding themselves out as independent professional societies faithfully serving the needs of their constituencies – whether patients suffering from pain or doctors treating those patients.

43. To reach a wide audience, and give the impression of professional consensus, opioid manufacturers have supported a diverse array of Front Groups. All told, Purdue, Janssen, and Endo contributed to more than a dozen Front Groups, including many of the same ones. Two of the most prominent are described below, but there are many others.

(1) American Pain Foundation ("APF")

- 44. The most prominent of Defendants' Front Groups was APF, which received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.
- 45. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes including death among returning soldiers. APF also engaged in a significant multimedia campaign to educate patients about their "right" to pain treatment, namely opioids.
- 46. APF's Board was composed of KOLs who received funding from Defendants and other opioid manufacturers. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Endo and others to avoid using its line of credit.

- 47. APF held itself out as an independent patient advocacy organization, but in practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications. APF also assisted in other marketing projects for drug companies. One project funded by another drug company APF Reporter's Guide: Covering Pain and Its Management (2009) recycled text that was originally created as part of the company's training document.
- 48. APF's clear lack of independence in its finances, management, and mission and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine

49. The American Academy of Pain Medicine ("AAPM") received millions of dollars from opioid manufacturers since 2009, including nearly \$1.2 million from Defendants Purdue and Janssen in the 2012-2017 period alone. AAPM also maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate, of which Defendants Endo and Purdue were members.

- 50. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, 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."
- 51. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.
- 52. Recognizing the importance of opioid treatment guidelines in securing the acceptance of chronic opioid therapy, AAPM and the American Pain Society ("APS") issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from, among others, Janssen, Endo and Purdue.
- 53. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper,

Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members.

- 54. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The Guidelines have been cited 732 times in academic literature, were disseminated and referenced by Defendants in Arkansas during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.
- Defendants also worked *together* through Front Groups. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as a side project of APF. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which would have reduced prescribing. PCF also worked to address a perceived "lack of coordination" among its members and developed "key" messages that were disseminated in programs and industry-run websites.

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

56. To convince doctors and patients in Arkansas that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by or

were contrary to the scientific evidence. Defendants have not corrected these misrepresentations and continue to spread them today.

1. Defendants falsely trivialized or failed to disclose the known risks of longterm opioid use.

- 57. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations which are described below reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.
- 58. *First*, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:
 - a. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
 - b. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you

- know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
- c. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.
- d. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- e. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- f. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management which claims that less than 1 percent of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.
- g. Detailers for Purdue, Endo, and Janssen minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.
- 59. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder)." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."
- 60. Defendants' claims are inconsistent with the warnings on their FDA-approved drug labels that caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

- 61. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but New York found that Endo had no evidence for that statement. Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Arkansas.
- 62. **Second**, Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction" a term coined by the now infamous Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, and Purdue. Defendants claimed that the pseudoaddiction concept is supported by scientific evidence when, in fact, it is not. Some illustrative examples of these deceptive claims are described below:
 - a. Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online.
 - b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
 - c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by

- teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many opioid pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." This publication is still available online.
- 63. No scientific evidence supports the concept of pseudoaddiction. The 2016 CDC Guideline does not endorse the concept of pseudoaddiction and, to the contrary, explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."
- 64. In its 2016 settlement with Endo, the State of New York found that "[t]he pseudoaddiction concept has never been empirically validated." An Endo vice president testified to New York "that he was not aware of any research validating the 'pseudoaddiction' concept." Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York, but remains free to do so in Arkansas.
- 65. *Third*, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably

identify patients predisposed to addiction and safely prescribe opioids to a "screened" population. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Endo, Janssen and Purdue all linked websites they ran or administered to Dr. Lynn Webster's Opioid Risk Tool, a brief questionnaire that gave doctors false confidence in prescribing opioids for chronic pain.
- c. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use:* Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- d. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients and not opioids are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.
- 66. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at

low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

- 67. **Fourth**, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.
- 68. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10-20 percent for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.
- 69. Defendants deceptively minimized the significant symptoms of opioid withdrawal and grossly understated the difficulty of tapering, particularly after long-term opioid use. Contrary to Defendants' pronouncements, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

- 70. *Fifth*, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:
 - a. Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.
 - b. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."
 - c. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint 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."
 - d. Janssen sponsored and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
 - e. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
 - f. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.
 - g. Purdue sponsored a CME entitled *Overview of Management Options*, which was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
 - h. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

- 71. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.
- 72. *Finally*, Defendants' deceptive marketing of the so-called abuse-deterrent properties of certain opioids, described below, has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.
- 73. In reality, abuse-deterrent opioids ("AD opioids") are easily defeated, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the pills have been dissolved. AD opioids also do not stop oral intake, the most common avenue for opioid misuse and abuse. In this regard, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."
- 74. Defendants promoted AD opioids even though they knew their abuse-deterrent properties were ineffective. For example, until July 2017 when Endo withdrew Opana ER from the market in response to FDA pressure, Endo marketed Opana ER as tamper-resistant and less

prone to misuse and abuse even though: (1) the FDA rejected Endo's petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

- 75. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. The State of New York also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.
- 76. Likewise Purdue has touted the so-called abuse deterrent properties of its opioid products as a primary selling point, claiming that its AD formulations prevent tampering and reduce abuse. These representations are inconsistent with the FDA-approved label for Purdue's AD opioids which indicates that the abuse-deterrent properties of these formulations can be defeated by crushing, snorting, or dissolving the pills. In a 2015 study, *one-third* of the participating patients were able to defeat the deterrent mechanism in Purdue's AD opioids to inhale or inject the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin. Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.
- 77. Defendants' false and misleading claims about the abuse-deterrent properties of their opioids are especially dangerous because they falsely assuage doctors' warranted concerns as to the risks of chronic opioid treatment. These claims also are the centerpiece of a deceptive

effort by Defendants to rehabilitate their image, which continues to this day. For example, in response to the flood of litigation filed against the company, Defendant Purdue has been taking out full-page advertisements in the *Wall Street Journal* and *New York Times* touting its efforts to stem the opioid epidemic. Chief among Purdue's claims is its development of opioids with "abuse-deterrent properties." In reality, abuse-deterrent formulations have been a catalyst for the overprescription of opioids.

2. Defendants grossly overstated the benefits of chronic opioid therapy.

- 78. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there were significant benefits to long-term opioid use. But as the 2016 CDC Guideline now makes clear, "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (emphasis added). In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)." In 2013, the FDA similarly stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."
- 79. Despite this, Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:
 - a. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
 - b. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stair and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.""

- c. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- d. Responsible Opioid Prescribing (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.
- f. Endo's NIPC website *painknowledge.com* 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. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.
- i. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which 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." The Policymaker's Guide was originally published in 2011 and is still available online today.
- j. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, promoted opioids, including Purdue's opioids, to chronic pain patients' quality of life, and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

- 80. These claims find no support in the scientific literature. The CDC has found that, far from improving functionality and quality of life, addiction and the risk of death inherent in chronic opioid treatment can "cause distress and inability to fulfill major role obligations."
- 81. Defendants also have promoted opioids as providing far more effective pain relief than non-opioid alternatives even through there is no scientific evidence supporting that conclusion. Researchers recently analyzed the comparative effectiveness of opioids in the treatment of 240 chronic pain patients. Half of the patients received a regimen of opioids, the other half was prescribed non-opioid alternatives, such as NSAIDs (*e.g.*, ibuprofen) and acetaminophen (*e.g.*, Tylenol). The study found that "[t]here was no significant difference in pain-related function between the 2 groups over 12 months" and that "[p]ain intensity was significantly better in the nonopioid group" over the same period. In other words, ibuprofen and Tylenol can be more effective than opioids in treating chronic pain.
- 82. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids.
- 83. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This "end of dose" failure renders Purdue's promise of 12 hours of relief false and deceptive; it also makes OxyContin more dangerous

because the declining pain relief patients experience drives them to take more OxyContin before the next dosing period begins, spurring overuse and dependence.

84. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Undeterred, Purdue's sales representatives continued to tell doctors that OxyContin lasts a full 12 hours and recommended increasing the dose, rather than the frequency of use, for patients who experience "end of dose" failure. Purdue gave its sales representatives these instructions to keep patients on OxyContin and because insurers were unwilling to pay for more frequent use of the drug.

C. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

- 85. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the United States, including in Arkansas. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients, but, because pain management is but one of many aspects of their practices, were less likely to be educated about treating pain and thus more susceptible to Defendants' misrepresentations.
- 86. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. For example, Defendants Endo and Janssen launched branded advertising, supported unbranded patient education, and published reprints of journal articles all promoting the use of opioids to treat osteoarthritis. Janssen did so despite the fact the FDA found, in reviewing the New Drug Application for Nucynta ER, that Nucynta ER was no more effective than placebo in reducing osteoarthritis pain. Similarly, Purdue sponsored *Exit Wounds*, a 2009 publication distributed by APF with grants from Janssen. Written as a personal narrative of one veteran, *Exit Wounds* describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It

notes that opioid medications "increase a person's level of functioning" and that "[1]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." Importantly, the publication fails to disclose the risk that opioids may cause fatal interactions with benzodiazepines taken by a significant number of veterans.

- 87. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly, many of whom started on opioids for chronic back pain or arthritis, have grown at twice the rate of prescriptions for adults between the ages of 40 and 59. Veterans have been similarly affected: one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.
- 88. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. Given these special risks, the CDC Guideline recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. Although Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct.

89. Defendants knew and should have known about the harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in

opioid use, addiction, injury, and death. In short, Defendants knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain, and they knew the lethal consequences of that endeavor.

- 90. Defendants also knew that patients were not the only ones harmed by their conduct. They knew that opioid dependency would place enormous burdens on government resources, including those of Arkansas.
- 91. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing conduct. For example, Defendants disguised their own role by funding and working through third parties like Front Groups and KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and organizations without disclosing their role in shaping, editing, and approving the content of information and materials the third parties disseminated. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which was run by the NIPC, did not disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.
- 92. Moreover, many Front Groups selectively disclose their donors or provide no information whatsoever concerning industry backers. After studying payments to opioid-advocacy Front Groups in the 2012 to 2017 period, the U.S. Senate Homeland Security & Government Affairs Committee concluded that neither pharmaceutical companies nor Front Groups "fully or routinely disclose the extent of their financial relationships" and both the companies and the groups "fail to adequately disclose manufacturer contributions" resulting in a "lack of transparency."

- 93. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, complete, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Arkansas.
- 94. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that Arkansas now asserts. Arkansas did not know of the existence or scope of Defendants' industry-wide deception and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

E. Defendants' Conduct Is Not Excused by the Actions of Any Third Parties.

- 95. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels. This action in no way challenges any determination made by the FDA, including as to the approved uses of opioids or information opioid drug labels must contain.
- 96. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

F. Defendants' Marketing Conduct Foreseeably Led to Opioid Abuse that has Wrought Havoc on Arkansas Communities.

- 97. Most opioid use begins with prescribed opioids, and that is why Defendants' deceptive marketing campaign was a primary cause of the opioid epidemic that has unfolded in Arkansas and across the country. The efficacy of Defendants' marketing efforts can be seen by comparing opioid use in the United States against other countries, where restrictions on pharmaceutical advertising typically are more stringent. Although the United States contains only 4.6 percent of the world's population, Americans consume 80 percent of the global supply of prescription opioids.
- 98. The role of Defendants' marketing scheme in contributing to the opioid epidemic has now been acknowledged by members of the medical community. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate, Dr. Nora Volkow explained in 2014 that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."
- 99. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught incorrectly that opioids are not addictive when prescribed for legitimate pain."
- 100. Scientific evidence also demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses.

The CDC thus concluded that efforts to curtail opioid prescribing for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

- 101. The individual and combined effects of Defendants' conduct have caused an explosion in opioid prescribing, abuse, and overdose. The data are staggering. In 2016, the opioid prescribing rate in Arkansas was 114 percent, meaning that there were more opioid prescriptions issued in Arkansas than there were people. Only Alabama had a higher prescribing rate in 2016. Arkansas's prescribing rate has in fact exceeded 100 percent for the entirety of the last decade, reaching a high of 123 percent in 2014.
- 102. Overprescribing is a statewide problem. In 2016, 64 of Arkansas's 75 counties had prescribing rates above the national average, which itself is disturbingly high. Prescribing rates in at least 17 Arkansas counties more than doubled the national average, including in Baxter, Boone, Clay, Craighead, Crawford, Desha, Garland, Greene, Howard, Independence, Jackson, Little River, Ouachita, Phillips, Sebastian, Sharp, and Stone counties.
- 103. Prescription rates in this stratosphere translate into an alarming quantity of dispensed pills. Data maintained by the Arkansas Prescription Drug Monitoring Program reflect that there were 235,934,613 opioid pills sold in Arkansas in 2016. That is enough to supply every man, woman, and child living in the state with 78 opioid pills each more than enough for every Arkansan to overdose and die. No other prescribed, controlled substance is as widely dispensed in Arkansas. By way of comparison, there were more opioids sold in Arkansas in 2016 than the next two most popular categories of controlled substances depressants and stimulants combined.
- 104. As opioid prescribing has proliferated, so too have opioid-related overdoses. Overall, drug overdose deaths nearly tripled in Arkansas between 2000 and 2015. The bulk of this increase is attributable to prescription opioids, with data maintained by the Arkansas

Department of Health indicating that prescription opioid overdose deaths increased more than 600 percent between 2000 and 2015. The number of deaths caused by prescription opioids in the State now significantly outstrips deaths resulting from all other known drugs combined. And this says nothing of the many opioid-related deaths that go unreported.

105. Moreover, the CDC has estimated that for every one overdose death there are on average 10 abuse treatment admissions, 26 emergency department visits for misuse, 108 people dependent on opioids, and 733 non-medical users. Arkansas bears out these grim calculations. Between 2007 and 2013, for example, the rate of inpatient admissions in Arkansas involving a diagnosis of opioid use nearly doubled. The number of Arkansans seeking treatment for an opioid disorder increased 300 percent between 2001 and 2011. The Substance Abuse and Mental Health Services Administration estimates that, all told, nearly 5 percent of all Arkansas adults – or approximately 150,000 people – misused pain relievers in the 2015 to 2016 period. And young Arkansans have been severely affected. In the 2013 to 2014 period, approximately 6.2 percent of Arkansas adolescents aged 12 to 17 years misused prescription pain relievers – the highest rate in the nation.

106. Tragically, opioid abuse also has affected newborns in Arkansas, with the number of diagnoses of neonatal abstinence syndrome (NAS) – a constellation of symptoms resulting from drug use during pregnancy – skyrocketing in the last decade. NAS is associated with increased incidence of seizures, respiratory problems, feeding difficulties and low birth weight, along with common symptoms of drug withdrawal, including diarrhea, excessive crying, fever, hyperactive reflexes, and sleeping difficulties. In Arkansas, NAS newborns spend an average of 11 days in the hospital at costs exceeding \$31,000, compared to two hospital days and costs of \$3,533 for babies without NAS. The Arkansas Department of Health has explicitly linked the alarming increase in NAS to the use of prescription opioids by women of reproductive age.

- 107. In a pattern playing out across the country, many Arkansans addicted to prescription opioids are turning to heroin, a chemically-related substitute that can be obtained at a fraction of what prescription opioids cost on the street. National studies reflect that at least 75 percent of all people who began to abuse opioids in the 2000s, started with prescription drugs. The heroin being sold in Arkansas also is increasingly laced with fentanyl, a powerful synthetic opioid. The Arkansas State Crime Lab has reported a 1223 percent increase in cases involving heroin between 2010 and 2016 and a 560 percent increase in fentanyl cases over the same period.
- Attorney General has taken aggressive steps to combat opioid misuse and abuse, including by sponsoring prescription drug "take back" events, hosting an annual Prescription Drug Abuse Prevention Summit, and launching an innovative educational program for high-school students. The Arkansas State legislature also has taken steps to combat the opioid crisis, most notably by instituting a Prescription Monitoring Program and passing initiatives designed to expand access to Naloxone, a drug that can reverse an opioid overdose.
- 109. Despite the scope of these statewide efforts, the effects of Defendants' marketing scheme have yet to be reversed and continue to ravage the State and Arkansas families. Prescription opioid abuse has an enormous impact on the health and safety of individuals as well as communities they inhabit. Some of the repercussions facing individuals include job loss, loss of custody of children, physical and mental health problems, homelessness, and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services. Arkansas, like many states across the country, is reeling from these effects and the enormous burden they impose.

G. Defendants' Conduct Has Caused Arkansas Substantial Economic Injury.

- 110. While Defendants experienced a material increase in sales, revenue, and profits from their deceptive marketing of opioids, this unlawful scheme has imposed an enormous financial burden on Arkansas.
- 111. By way of example, between 2006 and 2017, Arkansas's Department of Human Services, which administers the Arkansas Medicaid Program, spent millions on Defendants' opioids. Many of these prescriptions were for chronic pain, prescriptions which the State generally would not have paid for had Defendants told the truth and made a complete disclosure about the risks and benefits of their drugs.
- 112. These expenditures on Defendants' opioids also say nothing of the enormous costs the State has incurred combating the opioid crisis. These costs, borne across an array of state agencies including, but not limited to, the Department of Health, Department of Human Services, Department of Corrections, the State Police, and the entire state court system are massive, direct, quantifiable, and would not have been incurred but for Defendants' conduct. They also do not express the full extent of the State's injuries. Abating the opioid crisis in Arkansas will require an expanded outlay of State resources, including to treat opioid addicts, reeducate providers, support community health programs, sponsor preventative education, fund Naloxone distribution, monitor opioid prescribing, safely dispose of unused pills, police opioid-related crime, and to process and rehabilitate opioid offenders through the criminal justice system.

FIRST CAUSE OF ACTION:

ARKANSAS DECEPTIVE TRADE PRACTICES ACT ("ADTPA") ARK. CODE ANN. §§ 4-88-101, ET SEQ.

113. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

- 114. The ADTPA renders unlawful "[d]eceptive and unconscionable trade practices," which are defined to include, *inter alia*, "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services or as to whether goods are original or new or of a particular standard, quality, grade, style, or model." Ark. Code Ann. § 4-88-107(a)(1). It is also a deceptive and unconscionable trade practice to "[d]isparag[e] the goods, services, or business of another by false or misleading representation of fact." Ark. Code Ann. § 4-88-107(a)(2). Additionally, it is a deceptive trade practice to engage in "any other unconscionable, false, or deceptive act or practice in business, commerce, or trade." Ark. Code Ann. § 4-88-107(a)(10). These unlawful deceptive and unconscionable trade practices are in addition to other unfair trade practices actionable at common law or under other statutes of Arkansas. Ark. Code Ann. § 4-88-107(b).
- 115. The ADTPA also provides that "in connection with the sale or advertisement of any goods, services, or charitable solicitation, the following shall be unlawful: (1) [t]he act, use, or employment by any person of any deception, fraud, or false pretense; or (2) [t]he concealment, suppression, or omission of any material fact with the intent that others rely upon the concealment, suppression, or omission." Ark. Code Ann. § 4-88-108.
- 116. As alleged herein, each Defendant, at all times relevant to this Complaint, violated the ADTPA by making deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. These omissions rendered even Defendants' seemingly truthful statements about opioids deceptive. Each Defendant also violated the ADTPA by making false and misleading statements of fact concerning alternatives to opioids, including nonsteroidal anti-inflammatory drugs (NSAIDs).

- 117. These representations and concealments were deceptive and, as described more specifically above, they constitute a repeated course of conduct, contrary to public policy and the public's interest, which continues to this day.
- 118. But for these deceptive representations and concealments of material fact, Arkansas would not have expended millions of dollars of its resources, and as a direct and proximate cause of Defendants' deceptive conduct, Arkansas has been injured.
- 119. Each of Defendants' deceptive statements that entered Arkansas constitutes a distinct violation of the ADTPA.
- 120. Pursuant to Ark. Code Ann. § 4-88-113(a)-(e), the State seeks a declaratory judgment that Defendants violated the ADTPA, an injunction enjoining Defendants' misrepresentations described in this Complaint, civil penalties of \$10,000 per violation, costs, attorney's fees, and all other relief available under Ark. Code Ann. § 4-88-113(a)-(e) in an action brought by the State in a *parens patriae* capacity. The State also seeks enhanced civil penalties of \$10,000 per violation pursuant to Ark. Code Ann. § 4-88-202 because Defendants' deceptive practices were directed toward elder and disabled persons.

SECOND CAUSE OF ACTION:

MEDICAID FRAUD FALSE CLAIMS ACT ARK. CODE ANN. §§ 20-77-901, ET SEQ.

- 121. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.
- 122. Under Arkansas Code § 20-77-902, "[a] person shall be liable to the State of Arkansas, through the Attorney General, for a civil penalty of three (3) times the amount of damages if he or she "[k]nowingly makes or causes to be made any false statement or representation of a material fact in any claim, request, or application for any benefit or payment under the Arkansas Medicaid Program." Ark. Code Ann. § 20-77-902(1). The same remedies

are authorized when any person "[k]nowingly makes or causes to be made any omission or false statement or representation of a material fact for use in determining rights to a benefit or payment under the Arkansas Medicaid Program." Ark. Code Ann. § 20-77-902(2).

- 123. Defendants' practices, as described in the Complaint, violated Arkansas Code § 20-77-902. Defendants, through their deceptive marketing of opioids for chronic pain, made or caused to be made false statements, omissions or misrepresentations of material fact in the application for benefits or payments under Arkansas Medicaid Program and for the use in determining rights to the same.
- 124. Defendants knew, at the time of making or causing these statements or omissions that they were untrue, false, or misleading and were made for the purpose of causing doctors to write prescriptions for opioids to treat chronic pain and for the Arkansas Medicaid Program to approve and pay such claims. In addition, Defendants knew that their marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.
- 125. The Arkansas Medicaid Program, unaware of the false statements, omissions, and misrepresentations of material facts, received and approved claims that would not have been paid but for Defendants' illegal practices.
- 126. By reason of Defendants' unlawful acts, the Arkansas Medicaid Program has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Between 2006 and 2017, the Department of Medicaid spent more than \$6 million on Defendants' opioids. The Arkansas Medicaid Program also suffered additional damages for the costs of providing services, such as addiction treatment, related to the long-term use of opioids to treat chronic pain.

- 127. Each Defendant is responsible for the claims submitted and the amount the Arkansas Medicaid Program spent on its opioids. In addition, because Defendants' unbranded marketing caused the doctors to prescribe and the Arkansas Medicaid Program to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims, as well.
- 128. Pursuant to Arkansas Code § 20-77-903(a), each application for benefits under the Arkansas Medicaid Program induced by Defendants' false statements constitutes a violation of the Medicaid Fraud False Claims Act warranting civil penalties of \$11,000 per claim and three times the amount of damages sustained by the State. The Attorney General also is entitled to recover all costs and fees pursuant to Arkansas Code § 20-77-903(c)(1). The Attorney General also seeks, pursuant to Ark. Code § 20-77-903(f), an order enjoining Defendants' conduct violating § 20-77-902 and restoring to the Arkansas Medicaid Program all money and property acquired by means of such violations.

THIRD CAUSE OF ACTION:

PUBLIC NUISANCE

- 129. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.
- 130. Under Arkansas law, a public nuisance is any improper, indecent, or unlawful conduct that injures the public and produces material annoyance, inconvenience, and discomfort. The Attorney General is empowered to institute proceedings to abate public nuisances which affect or endanger public safety.
- 131. Defendants, individually and in concert with each other, have engaged in improper and unlawful conduct that is injurious to public health and safety and has caused

material discomfort and annoyance to the public at large. Defendants knew or should have known that their promotion of opioid use would create a public nuisance.

- 132. The public nuisance created by Defendants' actions is substantial and unreasonable it has caused and continues to cause significant harm to the community and the harm inflicted outweighs any offsetting benefit.
- 133. Defendants acted in concert in creating a public nuisance and their actions combined to inflict a single injury on the State. Immediate judicial intervention is needed to address the nuisance Defendants have created.
- 134. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used. Without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted.
- 135. The health and safety of Arkansans, including those who use, have used or will use opioids, as well as those affected by opioid use, is a matter of great public interest and of legitimate concern to the State.
- 136. The State seeks an order that enjoins Defendants' unlawful marketing scheme and provides for the abatement of the nuisance it has created.

FOURTH CAUSE OF ACTION:

UNJUST ENRICHMENT

- 137. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.
- 138. Under Arkansas law, unjust enrichment can be found when a party has received something of value to which he was not entitled by operative act, intent, or situation to make the enrichment unjust and compensable.

- 139. Through their deceptive and unlawful marketing of opioids for chronic pain, Defendants have been unjustly enriched at the State's expense. Because of Defendants' scheme, the State has overpaid for opioid prescriptions and permitting Defendants to retain overpayments it fraudulently procured would be unjust and inequitable.
- 140. The State seeks restitution of the sum, to be determined at trial, by which Defendants have been unjustly enriched.

FIFTH CAUSE OF ACTION:

CIVIL CONSPIRACY

- 141. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.
- 142. Under Arkansas law, a civil conspiracy occurs when two or more persons have combined to accomplish a purpose that is unlawful or oppressive or to accomplish some purpose, not in itself unlawful, oppressive, or immoral, but by unlawful, oppressive, or immoral means, to injure another.
- 143. As described more fully above, Defendants, together with Front Groups and KOLs, coordinated their efforts, as part of a shared plan and pursuant to a common agreement, to deceptively market opioids for chronic pain in Arkansas and across the nation.
- 144. The purpose of this conspiracy deceiving health care providers, patients and the general public was unlawful, violating, at a minimum, the Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 et seq., the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §§ 4-88-101 et seq., and Arkansas common law.
- 145. To accomplish their unlawful objectives, Defendants, Front Groups, and KOLs, acting collectively, systematically misrepresented to the general public and Arkansas consumers either affirmatively or through half-truths and omissions the risks and benefits of using

opioids for chronic pain. In particular, these conspirators concealed from the State and Arkansas consumers the serious risks and lack of corresponding benefits of using opioids for chronic pain. These misrepresentations ensured that a larger number of opioid prescriptions would be written and filled for chronic pain in Arkansas and elsewhere. This translated into higher sales (and therefore profits) for Defendants.

- 146. The conspiracy was the product of agreement between Defendants, Front Groups and KOLs and operated hierarchically with Defendants controlling the representations made about their respective drugs. The Front Groups and KOLs participated knowing, but without disclosing, that other Front Groups and KOLs were involved in the same scheme. But for their agreement to participate in the conspiracy, Front Groups and KOLs would have been incentivized to disclose Defendants' deceit to their constituents and to protect patients. They each joined the conspiracy with the expectation that the deceit would not be revealed by their coconspirators. And when issues arose during the scheme, each agreed to take actions to hide the scheme and continue its existence.
- 147. The State seeks an order enjoining further operation of the civil conspiracy, damages in an amount to be determined at trial, and all other relief provided by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays:

- A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of Arkansas statutory and common law and that the Court enter a judgment declaring them to be so;
- B. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Arkansas law;

- C. That Plaintiff recover all measures of damages allowable under the State statutes identified herein and the common law, and that judgment be entered against Defendants in favor of Plaintiff;
 - D. That Plaintiff receive an award of all civil penalties provided by law;
- E. That Plaintiff recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorney's fees as provided by law;
- F. That Defendants be ordered to abate the public nuisance that they created in violation of Arkansas law, including by paying the cost of abatement;
- G. That Defendants be ordered to pay punitive and treble damages as provided by law;
- H. That Defendants be ordered to pay restitution to the State, for expenditures made by the State, to the full extent permitted by law;
 - I. That liability be imposed jointly and severally; and
- J. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

JURY DEMAND

The State demands a trial by jury on all claims. DATED this 29^{th} day March, 2018.

Respectfully Submitted,

LESLIE RUTLEDGE ATTORNEY GENERAL

De l' P. Rulledgy

Leslie Rutledge, ABN 2001126 Arkansas Attorney General 323 Center Street, Suite 200 Little Rock, Arkansas 72201 Telephone: (501) 682-2007

Facsimile: (501) 682-8118

 $\underline{Leslie.Rutledge@ArkansasAG.gov}$

Charles J. Harder, ABN 86080 Deputy Attorney General Telephone: (501) 682-4058 Facsimile: (501) 682-2000

Chuck.Harder@ArkansasAG.gov

Shawn Johnson, ABN 2004181 Senior Assistant Attorney General

Telephone: (501) 682-1178 Facsimile: (501) 682-8118

Shawn.Johnson@ArkansasAG.gov

Kate Donoven, ABN 98189 Assistant Attorney General Telephone: (501) 682-8114 Facsimile: (501) 682-8118

Kate.Donoven@ArkansasAG.gov

Dara Hall, ABN 96018 Assistant Attorney General Telephone: (501) 682-7383 Facsimile: (501) 682-8118 Dara.Hall@ArkansasAG.gov

OF COUNSEL:

Gary B. Rogers, ABN 82139 Michael G. Smith, ABN 81146 DOVER DIXON HORNE, PLLC 425 W. Capitol Avenue, Suite 3700

Little Rock, Arkansas 72201 Telephone: (501) 375-9151 Facsimile: (501) 375-6484

grogers@ddh.law msmith@ddh.law

Steve W. Berman HAGENS BERMAN SOBOL SHAPIRO LLP 1918 Eighth Ave., Suite 3300 Seattle, WA 98101

Telephone: (206) 623-7292 Facsimile: (206) 580-6559 steve@hbsslaw.com

Jennifer Fountain Connolly HAGENS BERMAN SOBOL SHAPIRO LLP 1701 Pennsylvania Ave. NW, Suite 200 Washington, D.C. 20006

Telephone: (202) 248-5403 Facsimile: (202) 580-6559 jenniferc@hbsslaw.com

Ben Harrington HAGENS BERMAN SOBOL SHAPIRO LLP

715 Hearst Ave., Suite 202

Berkeley, CA 94710

Telephone: (510) 725-3000 Facsimile: (510) 725-3001

benh@hbsslaw.com

John L. Davidson DAVIDSON BOWIE PLLC 2506 Lakeland Drive, Suite 501 Post Office Box 321405 Flowood, Mississippi 39232 Telephone: (601) 932-0028 Facsimile: (601) 932-0115 jdavidson@dbslawfirm.net

Mike Moore Jonathan Compretta MIKE MOORE LAW FIRM, LLC P.O. Box 321048 Flowood, MS 39232 Telephone: (601) 933-0070 Facsimile: (60) 933-0071 mm@mikemoorelawfirm.com jc@mikemoorelawfirm.com

Jay Ward MCGOWAN, HOOD & FELDER, LLC 321 Wingo Way, Suite 103 Mt. Pleasant, SC 29464 843-388-7202 jward@mcgowanhood.com

All out-of-state counsel to be admitted pro hac vice