1	FENNEMORE CRAIG, P.C. J. Christopher Gooch (State Bar No. 019101)	
2	cgooch@fclaw.com Scott Day Freeman (State Bar No. 019784)	
3	Sfreeman@fclaw.com John P. Kaites (State Bar No. 012767)	
5	2394 E. Camelback Road Suite 600 Phoenix, Arizona 85016	
6	Telephone: (602) 916-5000 Facsimile: (602) 916-5999	
7	(002) > 10 0>>>	
8	THEODORA ORINGHER PC Todd C. Theodora, Esq. (<i>Pro Hac Vice</i> to be	Filed)
9	ttheodora@tocounsel.com Jeffrey H. Reeves, Esq. (<i>Pro Hac Vice</i> to be 1	Filed)
10	jreeves@tocounsel.com Cheryl Priest Ainsworth, Esq. (<i>Pro Hac Vice</i>	to be Filed)
11	cainsworth@tocounsel.com Jessica Hernandez Diotalevi (<i>Pro Hac Vice</i> to	o be Filed)
12	jdiotalevi@tocounsel.com Kevin R. Royer (<i>Pro Hac Vice</i> to be Filed)	
13	kroyer@tocounsel.com 535 Anton Boulevard, Ninth Floor	
14	Costa Mesa, California 92626-7109 Telephone: (714) 549-6200	
15	Facsimile: (714) 549-6201	
16	Attorneys for Plaintiff the CITY OF PRESCOTT	
17	SUPERIOR COURT OF T	THE STATE OF ARIZONA
18	COUNTY O	F YAVAPAI
19	CITY OF PREGOTT	C N
20	CITY OF PRESCOTT,	Case No.
21	Plaintiff,	COMPLAINT FOR:
22	VS.	(1) PUBLIC NUISANCE, SEEKING CIVIL PENALTIES,
23	ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; WATSON	ABATEMENT, AND INJUNCTIVE RELIEF
24	PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON	(2) NEGLIGENCE(3) NEGLIGENCE PER SE
25	LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a	(4) UNJUST ENRICHMENT(5) NELIGENT FAILURE TO
26	WATSON PHARMA, INC.; MALLINCKRODT, LLC; TEVA	WARN (6) FRAUDULENT TRANSFER
27	PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS	(7) CIVIL CONSPIRACY(8) VIOLATION OF CONSUMER
28	USA, INC.; CEPHALON. INC.: ENDO HEALTH	FRAUD ACT

1	SOLUTIONS INC.; ENDO
2	PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS,
3	INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a
4	JANSSEN PHARMACEUTICALS,
	INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN
5	PHARMACEUTICALS, INC.; PURDUE PHARMA L.P.; PURDUE
6	PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.;
7	RICHARD SACKLER; THERESA
8	SACKLER; KATHE SACKLER; JONATHAN SACKLER; MORTIMER
9	D.A. SACKLER; BEVERLY SACKLER; DAVID SACKLER; ILENE
10	SACKLER LEFCOURT; INSYS THERAPEUTICS, INC.; MCKESSON
11	CORPORATION; CARDINAL
	HEALTH, INC.; AMERISOURCEBERGEN; DR.
12	DOUGLAS J. CAMPBELL, an individual; DR. RANDY JOE SPICER,
13	an individual; and DOES 1 through 1000,
14	,
14	Defendants
15	Defendants.
	Defendants.
15	Defendants.
15 16 17	Defendants.
15 16 17 18	Defendants.
15 16 17 18	Defendants.
15 16 17 18 19 20	Defendants.
15 16 17 18 19 20 21	Defendants.
15 16 17 18 19 20	Defendants.
15 16 17 18 19 20 21	Defendants.
15 16 17 18 19 20 21 22 23	Defendants.
15 16 17 18 19 20 21	Defendants.
15 16 17 18 19 20 21 22 23 24	Defendants.
15 16 17 18 19 20 21 22 23 24 25	Defendants.

DEMAND FOR JURY TRIAL

1159968.7/81650.01001

2

14809093

I. INTRODUCTION

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

- Opiates¹ are killing people every day in this country and Arizonans have not been spared. Each of the Defendants in this action engaged in an industry-wide effort to downplay the dangerous and deadly potential effects of the misuse of prescription opioids. The opioid epidemic has hit every community in Arizona hard, including the City of Prescott ("Prescott"). Prescott brings this complaint seeking redress for the societal and financial ills it has suffered at the hands of those directly responsible for the crisis—the manufacturers, distributors, and in some cases, the prescribers, of prescription opioids.
- 2. This case is about corporate greed. Simply put, each of the Defendants put its desire for profits above the health and well-being of Prescott's residents. Prescott and its citizens have paid dearly as a result.

The Manufacturer Defendants' Two-Part Scheme to Increase Opioid Sales A.

3. First, as part of a broader scheme to target all municipalities in the United States where the elements that are most conducive to opioid addiction were prevalent, Defendants ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT, LLC; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; **ENDO HEALTH SOLUTIONS** INC.; **ENDO** PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-**MCNEIL-JANSSEN** PHARMACEUTICALS, INC. n/k/a **JANSSEN** PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE

26

27

28

1159968.7/81650.01001

14809093

23 24

²⁵

¹ The term "opiate" technically refers only to chemicals that occur naturally in the opium plant, including morphine, codeine, thebaine and papaverine. "Opioid," by contrast, refers instead to compounds that have the same effect as opiates but do not occur naturally in the opium plant, such as heroin, oxycodone, hydrocodone, hydromorphone and oxymorphone ("semi-synthetic" opioids) as well as methadone, fentanyl, meperidine and tramadol ("synthetic" opioids).

PURDUE FREDERICK COMPANY, INC.; INSYS THERAPEUTICS, INC.; and the individual defendants JOHN KAPOOR; and MICHAEL BABICH ("the Manufacturer Defendants"), targeted the State of Arizona, including the residents of Yavapai County and Prescott. More specifically, the Manufacturer Defendants developed and engaged in a sophisticated, manipulative scheme designed to increase the number of opioid prescriptions written across the state, including in Prescott. Defendants' scheme was particularly well-suited to Prescott, because Prescott is home to a multitude of economically and medically vulnerable populations that Defendants knew were uniquely predisposed to opioid addiction, including the elderly and veterans. Indeed, the only Arizona Health Care System hospital in Yavapai County (which is one of just three such hospitals in the entire State of Arizona) is located in Prescott and provides services to over 27,000 veterans across Northern Arizona. Prescott is also home to the Dr. Cameron McKinley Department of Veterans Affairs Veterans Center, which serves both veterans and their family members upon request.²

4. <u>Second</u>, the Defendant Manufacturers succeeded in dramatically increasing the number of opioid prescriptions being written in Prescott and across the country by (1) affirmatively concealing the truth about the risk of addiction and death associated with long-term use of their products, and (2) pressuring their respective sales forces to deceive (even bribe) local physician, physician assistant and nurse practitioner prescribers to flood Arizona—and Prescott—with enough opioid prescriptions for every single person in the city to have one.

 $21 \parallel /$

22 || /

23 || / /

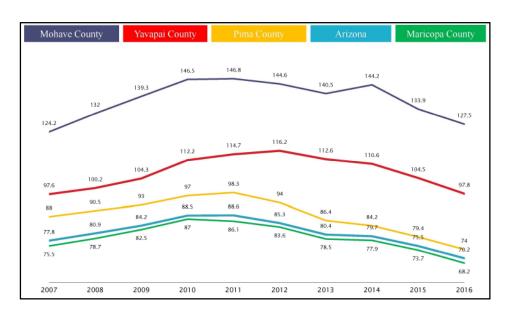
24 |

25 ||

///

² Northern Arizona VA Health Care System, https://www.prescott.va.gov/about/; see also https://www.va.gov/directory/guide/facility.asp?ID=381.

431 MILLION opioid pills were prescribed in 2016 enough for every Arizonan to have a 2.5 week supply



Opioid Prescriptions* Dispensed in Arizona 2007 to 2016 (*Per 100 persons)

- B. The Distributor Defendants Turned a Blind Eye to the Manufacturers' Scheme.
- 5. Defendants McKesson, AmerisourceBergen and Cardinal Health (the "Distributor Defendants") shipped the Manufacturer Defendants' products throughout the country, including to addresses in Prescott. Rather than meet their obligations under Arizona law to report suspicious orders of opioids, the Distributor Defendants willfully ignored impossibly large orders being shipped into geographic locations where it was simply

inconceivable that any legitimate medical need could have come close to creating legitimate demand for opioids in the quantities shipped. They entirely failed to report any of these suspicious shipments despite being under clear statutory and common law obligations to do so, and in contravention the Distributor Defendants' own internal policies and procedures. The Distributor Defendants' breaches of their respective reporting obligations was willful, motivated entirely by the desire to maximize profits by any means necessary, no matter the cost to Plaintiff or its citizenry.

- C. The Individual Defendants Directed Defendant Purdue's Scheme from Behind The Scenes, Downplaying Their Involvement to Enrich Themselves At Plaintiff's Expense.
- 6. Defendants Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler (the "Sackler Defendants") controlled Purdue's misconduct from their respective seats on the company's Board of Directors. Though the Sackler Defendants held a controlling majority of the Board and wielding absolute power over Purdue Pharma Inc. and Purdue Pharma L.P.'s sales and marketing practices, the Sackler Defendants constantly downplayed the significance of their involvement in order to retain the anonymity and continue paying themselves and their family billions of dollars.
- 7. Defendant Dr. Richard Sackler, for example, who founded Defendant Purdue and both engineered and oversaw the company's scheme to increase sales of OxyContin, no matter the cost, claimed at a deposition that he was unaware that Defendant Purdue's sales representatives were "falsely represent[ing] that OxyContin . . . resulted in less abuse potential." During the same deposition, Dr. Sackler also pleaded ignorance to the fact that Defendant Purdue had "[t]rained Purdue sales representatives and told some healthcare providers that it was more difficult to extract the Oxycodone form an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed that drug abuser could

³ R. Sackler Depo., p. 253:24-25, 254:1-8 (Aug. 28, 2015).

extract approximately 68 percent of the Oxycodone from a single 10 milligram OxyContin tablet by crushing the tablet, stirring it in water and drawing the solution through cotton into a syringe."⁴

- 8. Despite Dr. Sackler insistence that his testimony was accurate and truthful, internal e-mails between the Individual Defendants expressly contradict this proposition. Indeed, on or about February 27, 1997 Robert Kaiko, the inventor of OxyContin, expressly admonished Dr. Sackler, emphasizing that "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability," as "oxycodone containing products are still among the most abused opioids in the U.S." In response to Robert Kaiko's warning, Dr. Sackler had only this to say: "How substantially would it improve your sales?"
- 9. Two years later, Dr. Sackler became the CEO of Defendant Purdue, and worked hand-in-hand with Individual Defendants Jonathan Sackler, Kathe Sackler, Mortimer Sackler—Purdue's Vice Presidents at the time—to mail thousands of doctors promotional videos asserting the same false and misleading representations that Robert Kaiko had already debunked and warned them not to disseminate:

There's no question that *our best, strongest pain medicines are the opioids*. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, *the rate of addiction* amongst pain patients who are treated by doctors *is much less than one percent*. They don't wear out, they go on working, *they do not have serious medical side effects*.⁷

^{23 4} *Id.*, at p. 237:18-25, 238:1-13.

⁵ 1997-02-27 e-mail from Robert Kaiko (explaining to Dr. Sackler that "[i]f OxyContin is uncontrolled, . . . it is highly likely that it will eventually be abused"). (*See* Complaint, n. 62-63 (June 12, 2018), *Commonwealth of Massachusetts v. Purdue Pharma L.P.*, et al (C.A. No. 1884-cv-01808 (BLS2) ("MA AG Complaint").)

⁶ 1997-03-02 e-mail from Richard Sackler.

⁷ "I Got My Life Back" video, transcript. [FN 73 to MA AG Complaint] (emphases added).

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

D. The Prescriber Defendants Manipulated Their Patients to Enrich Themselves.

- 10. Defendant Douglas J. Campbell, M.D. and Defendant Randy Joe Spicer, N.M.D. (the "Prescriber Defendants") were an important component of the Defendant Manufacturers' scheme to flood the State of Arizona, including Prescott, with a wildly inappropriate, medically unnecessary quantity of opioids. In return for bribes, kickbacks and all-expenses-paid "speaking engagements," the Prescriber Defendants facilitated the Manufacturer Defendants' scheme by (i) passing out "savings cards" to encourage patients who had never tried opioids before ("opioid naïve" patients) to buy Defendants' drugs; (ii) increasing these patients' respective dosages until they became addicted; and (iii) withholding all treatment from patients who refused to take their prescribed dosages of opioids, even though the Defendant Prescribers knew their patients could not physically tolerate such a large amount of opioids without overdosing and/or dying.
- Each of the Defendants was fully aware that their products placed patients at an 11. unreasonable risk of opioid-related addiction and/or death, particularly patients who continued taking opioids for three or more consecutive months. Despite this knowledge, Defendants continued to manufacture, market, distribute and prescribe opioids to the nation at large, as well as to Plaintiff's local, and often its most vulnerable, citizens. This is the conduct that precipitated the opioid crisis that has ravaged Plaintiff's communities since the early 2000s, and will continue to do so for many years, even decades, to come. The extent to which Defendants' scheme succeeded cannot be overstated. The death toll they have caused in Prescott and elsewhere is unconscionable. Prescott dedicates substantial portions of its tax revenues to provide and pay for a broad array of services for its population, including health care, pharmaceutical care, law enforcement, foster care, public assistance and other necessary services and programs for families and children. However, as a result of the opioid epidemic, Prescott has been severely hampered in its ability to continue to provide the requisite level of service in each of these categories. This creates a perverse dichotomy. The overburdened service areas require a greater share of Prescott's scarce tax dollars, while at the same time,

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

the crisis itself *decreases* the tax dollars Prescott can generate. That is because opioid addiction takes productive members of society out of the economy, usually due to death or the inability to work. Simply put, most who become addicted to opioids are no longer able to work, and therefore are no longer able to care for their families, earn a paycheck or spend money in the same way they did before they fell victim to addiction. That means Prescott's tax revenues have suffered. These harms are the direct and proximate result of Defendants' scheme to increase their profits without regard for the end users of Defendants' drugs, or the municipalities that must bear the brunt of the increased demand for their services brought on by the epidemic.

12. In addition to its tax-related damages, Prescott, a thriving community of trade and tourism, has suffered irreparable damage to its reputation at the hands of Defendants. This is due, in large measure, to the fact that Prescott in recent years became a destination city for sober living homes and addiction rehabilitation treatment centers – facilities that would never have existed anywhere, much less in Prescott, were it not for the opioid epidemic.⁸ This local phenomenon exploded to such a degree that Prescott, with its typical population hovering at

⁸ Properly regulated addiction treatment facilities can be, and often are, a necessary element of any thriving community that is sensitive to the mental health of its population. That said, the sober living phenomenon in Prescott and elsewhere wrought by the opioid crisis has a far different character. All too often in light of the sudden demand for opioid addiction treatment centers, opportunistic operators have erected treatment or rehabilitation centers virtually overnight. (See D. Segal, City of Addict Entrepreneurs, The New York Times (Dec. 27, 2017), https://www.nytimes.com/interactive/2017/12/27/business/newdrug-rehabs.html.) The intent of these operators is to collect high fees from distraught families of loved ones who need help. And patients come in droves. But all too often shortly after paying the hefty enrollment fee, shady and unlicensed operators, including in Prescott, promptly evict these patients once funds from insurance or other sources dry up. Often opioid-addicted patients have come to these facilities in Prescott from all over the country. And once these addicts leave the sober living facilities, voluntarily or involuntarily, they are often left behind in the streets of Prescott. Addicts are more likely to become homeless or commit crimes, either by stealing in order to fuel their addiction, or by participating in the illegal black market for illicit opioids like heroin. Either way, Prescott's social services are taxed in the extreme. These are some of the realities that Prescott has had to confront and combat – at great taxpayer expense – due to Defendants' intentional and callous conduct.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

around 42,000 people, was home in 2016 to at least 170 sober living homes.⁹

13. Plaintiff has been able to ameliorate this problem, to a degree, only by dedicating substantial—and previously unallocated—tax dollars to measures designed to restore its once sterling reputation as one of the most desirable communities in all of Arizona. As one example, on or about October 11, 2016, Plaintiff added a brand-new chapter to its municipal code dedicated exclusively to ensuring that all sober living homes operating in Prescott are properly licensed and operated in accordance with the standards of care that Plaintiff specifically designed to protect its community. ¹⁰ By taking proactive steps to address the sober living home problem, and thereby help to repair and preserve its reputation, Prescott has succeeded in reducing the number of these treatment facilities down to approximately 30 as of December 2018.11

The Daily Courier: "Most drug, alcohol group homes in City of Prescott [are] not state-licensed."



14. Things were not always this way in Prescott. Though Defendants have been manufacturing, marketing, selling and/or prescribing prescription opioids for decades including brand-name drugs like OxyContin¹² and Percocet, as well as generic formulations

1159968.7/81650.01001

14809093

⁹ Segal, supra at n. 8.

¹⁰ See Prescott City Code, Ch. 4-11: Structured Sober Living Homes (effective Jan. 1, 2017),

https://www.codepublishing.com/AZ/Prescott/html/Prescott04/Prescott0411.html#4-11.

¹¹ Segal, supra at n. 8.

¹² OxyContin, the ratio of morphine to oxycodone is two-to-one—something which "[w]e

such as oxycodone and hydrocodone—only since the late 1990s have Defendants' powerful narcotic painkillers been used to treat more than just short-term, acute or cancer-related pain. Indeed, for the vast majority of the twentieth century, Defendants' drugs were considered too addictive and debilitating for patients suffering from long-term (chronic) pain due to non-cancer conditions like arthritis, fibromyalgia and migraines.¹³

sophisticated marketing and distribution scheme premised on deception to persuade patients that opioids can and should be used to treat chronic pain. Defendants spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) Downplayed the serious risk of addiction;¹⁴ (2) promoted the concept of "pseudoaddiction," claiming that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no good evidence to support those benefits.

16. Defendants knew that their longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of Defendants' misrepresentations has been confirmed by the

[Purdue] feared that the 'cancer pain experts' would object to . . . (Deposition of Richard Sackler, M.D. ("R. Sackler Dep.") at p. 79:12-14.)

¹³ In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

Addiction is classified as a spectrum of "substance use disorders" that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, "addiction" refers to the entire range of substance abuse disorders. [American Society of Addiction Medicine Public Policy Statements: https://www.asam.org/docs/default-source/public-policy-statements/1-terminology-spectrum-sud-7-13.pdf?sfvrsn=d93c69c2_2.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), including by the CDC in its Guideline for Prescribing Opioids for Chronic Pain, issued in 2016 and approved by the FDA (2016 CDC Guideline). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, Defendants continue to misrepresent the risks and benefits of long-term opioid use in Arizona, including in Prescott, and continue to fail to correct their past misrepresentations.

17. Specifically, Defendants worked tirelessly to conceal what their own internal documents and communications show they already knew, and had known for decades: not only were Defendants' opioids both medically unnecessary and, in fact, life-threatening for non-cancer patients with chronic pain, but further, none of Defendants' representations about the manageability or prevention of opioid addiction was true. For decades the Defendant Manufacturers and Distributors—including, but not limited to, Defendants Purdue Pharma L.P., INSYS Therapeutics and Janssen—have made and continue to make a series of inaccurate claims about the risks and benefits associated with their opioids, essentially bribing Key Opinion Leader ("KOL") group to substantiate the veracity of Defendants' false statements. ¹⁵ In creating the illusion that Defendants opioids were the best treatment option for chronic pain, Defendants successfully targeted vulnerable patient populations like the elderly and veterans. And, they tainted the sources that some doctors and patients relied upon for guidance, including treatment guidelines, continuing medical education programs, medical

¹⁵ See, e.g., R. Sackler Depo., p. 255:5-16, (Aug. 28, 2015) (noting that "[s]ome of Purdue's

new sales representatives were permitted . . . to draw their own blood level graphs to falsely represent that OxyContin, unlike immediate-release or short-acting opioids, did not swing up

and down between euphoria and pain and resulted in less abuse potential"; and further

revealing that "[o]n or about May 1997, certain Purdue supervisors and employees stated that [while] they were well aware of the incorrect view held by many physicians that Oxycodone

was weaker than morphine, they did not want to do anything 'to make physicians think that Oxycodone as stronger or equal to morphine' or to 'take any steps in the form of promotional

material, symposia, clinical publications, conventions or communications with the filed force

10

that would affect the unique position that OxyContin had in many physicians' minds' ").

23

24

25 26

27

28

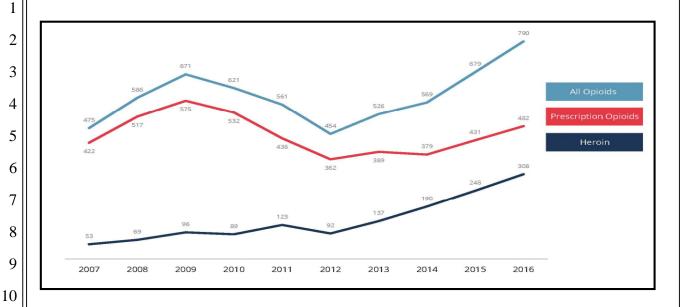
conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way doctors treat chronic pain, opening the floodgates of opioid prescribing and use. Opioids are now the most prescribed class of drugs; they generated \$11 billion in revenue for drug companies in 2014 alone. This explosion in opioid prescriptions and use has padded Defendants' profit margins at the expense of chronic pain patients. As the CDC recently concluded, "for the vast majority of [those] patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits." ¹⁶

18. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in Arizona and, in particular, Prescott. Arizona faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable enjoyment of life and property" (A.R.S. § 13-2917(A)) and because it affects "entire communit[ies]" and "neighborhood[s]" and "any considerable number of persons" (*Id.*) The effects of Defendants' deceptive marketing scheme are catastrophic and are only getting worse. This is especially so in Arizona. More than two Arizonians die each day from an opioid overdose. There has been a 74% increase in deaths among Arizona residents since 2012. As the FDA acknowledged in February 2016, "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence." 17

1159968.7/81650.01001

Thomas R. Frieden et al., *Reducing the Risks of Relief* — *The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

FDA.gov, Califf, FDA top officials call for sweeping review of agency opioids policies, U.S. Food and Drug Administration ("FDA") News Release (Feb. 4, 2016), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.



19. There is little doubt that Defendants' deceptive marketing and distribution scheme has precipitated this public health crisis in Arizona, including in Prescott, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created 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.

- 20. The effects of Defendants' deceptive marketing and distribution scheme have further impacted in a foreseeable way such that Prescott must devote increased resources to the burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For example, tax dollars are required to maintain public safety of places where the addicted homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight the infectious disease brought by the addicted and particularly the addicted homeless. Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant Staphylococcus aureus (MRSA) have been demonstrated to be spread by opioid abuse.
- 21. Defendants' willful and wrongful conduct has further impacted Prescott by creating a public nuisance in Prescott, which Defendants foresaw yet deliberately ignored. As

1

2

3

4

5

6

a result, the City of Prescott, with its reputation as an affordable place to live with pleasant weather and people, has attracted individuals from outside Prescott for attempted rehabilitation. Unscrupulous opioid rehabilitation businesses recruited addicts nationally with false and misleading promises of the medically supervised rehabilitation to help addicts overcome their addiction. The promotion claimed that there was effective rehabilitation available in Prescott. These for-profit rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed that many provided substandard care including use of physicians who have had their license revoked, operating staffs which do not actually supervise patients, and facilities that do not operate programs for addicts. Instead these facilities brought addicts to Prescott, provided substandard care, and threw them out of the facilities to be homeless in Prescott. These addicts brought to Prescott have further contributed to Prescott's burden by discharging addicted homeless into the community who require further care and rehabilitation at Prescott's expense, and who commit crimes in Prescott in order to further feed their addictions. Defendants were aware at all relevant times when they deceptively marketed their products as non-addictive that such addiction would be highly difficult to overcome.

22. The role of Defendants' deceptive marketing and distribution scheme in causing this public health crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health ("NIH"), Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem." ¹⁸ In the years since her comments were initially published, Dr. Volkow's message has become the dominant view of the top experts and influencers in the medical community, who are finally realizing just how dangerous Defendants' opioids are, and how devastating the economic and social costs of Defendants intentional deception has

26

27

28

17

18

19

20

21

22

23

24

25

¹⁸ N. Volkow, M.D., America's Addiction to Opioids: Heroin and Prescription Drug Abuse, **National** Institute on Drug Abuse, (May 14, 20014), available https://www.drugabuse.gov/about-nida/legislative-activities/testimony-

been.¹⁹ Indeed, according to government estimates, some 50,000 Americans died from an opioid overdose

- 23. Absent Defendants' deceptive marketing scheme, improper distribution, and improper prescribing, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 24. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, and by improperly distributing and prescribing prescription opioids as set forth herein, Defendants have not only engaged in false advertising and unfair competition, they have also created or assisted in the creation of a public nuisance. Although this Complaint focuses on Defendants' misconduct during the past six years and only references their earlier misconduct, every act of malfeasance committed by each Defendant since the late 1990's as part of its deceptive marketing and distribution scheme subjects that Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. (*See* A.R.S. § 13-2917(A)).
- 25. Accordingly, Defendants' conduct, both individually and collectively, has violated and continues to violate Arizona's Public Nuisance Law, A.R.S. § 13-2917. Prescott does not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, Prescott seeks order requiring Defendants to cease their unlawful promotion, distribution, and prescribing of opioids, to correct their misrepresentations, and to abate the public nuisance they have created. To redress and punish Defendants' previous and current violations of law that cause and continue to cause harm to Prescott and its citizens, Prescott seeks a judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law.
 - 26. By this action, Prescott further seeks to recoup tax dollars spent already for the

tocongress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

¹⁹ E. O'Brien, *Here's What it Would Cost to Fix the Opioid Crisis, According to 5 Experts*, Time Money (Nov. 27, 2017), http://time.com/money/5032445/cost-fix-opioid-crisis/

consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its impact on Prescott, and to abate the opioid nuisance so Prescott will not be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants' wrongful conduct.

II. PARTIES

A. Plaintiff

- 27. Prescott, Arizona, by and through its attorneys hereto, hereby brings this action on behalf of the People of Prescott to protect the public from false and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public nuisance.
- 28. Prescott is a city in Yavapai County, Arizona. The population of the city is just over 40,000. Prescott is known as Arizona's "big-little town" and as an affordable place to live for families and retirees. Prescott's slogan is "Everybody's Hometown." Given that Prescott is just two hours from Phoenix and enjoys pleasant weather year-round, Prescott's economy relies heavily on tourism, including attracting visitors to its restaurants, golfing, shopping, and outdoor activities.

B. The Individual Defendants

1. The Sacklers

- 29. Defendants Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler controlled Purdue's misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, they always held the controlling majority of the Board, which gave them full power over both Purdue Pharma Inc. and Purdue Pharma L.P. They directed deceptive sales and marketing practices deep within Purdue, sending hundreds of orders to executives and line employees. From the money that Purdue collected selling opioids, they paid themselves and their family billions of dollars.
- 30. As a members of the boards of Purdue entities, the Sacklers oversaw all aspects of marketing and promotion of opioid products. As board members who were personally active in directing Purdue's operations, the Sackler Defendants knew, or should have known,

of the deceptive marketing tactics of opioid products.

- 31. The Sackler Defendants were also aware of specific examples of deceptive marketing through receipt of call note reviews in their capacity as board members. On information and belief, as board members, the Sacklers received reports of opioid overdoses and reports of misuse and abuse. Adverse event reports circulated to the Sacklers included reports of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.
- 32. The Sackler Defendants were personally aware that: (1) OxyContin was being prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine
- 33. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers voted that the Purdue Frederick Company should plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse events and side effects than other pain medications.²⁰ The official court records containing the details of Defendant Purdue's guilty plea prove that Defendant's scheme was grounded not in science, but rather sales.²¹
- 34. The Sackler Defendants, as members of the family that owns Purdue, personally benefitted from the success of OxyContin. At various points, as directors, they approved the distribution of funds from Purdue to shareholders, including themselves and their extended family
 - 35. As evidenced by Purdue's board minutes and other internal documents and

1159968.7/81650.01001

²⁰ B. Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, The New York Times (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html

²¹ R. Sackler Depo., p. 251:6-12 (Aug. 28, 2015) ("Remember that we tried to reposition OxyContin as powerful as morphine and we could not, finally we decided not to mess with this perception since it was helping us in the non-cancer market.").

communications, the Sackler Defendants were aware since at least 1999 of potential liability for Purdue, and those acting in concert with Purdue because of the addictive nature of OxyContin. Knowing full well that OxyContin was dangerously addictive and medically inappropriate for non-cancer patients for chronic pain, each of the Sackler Defendants was active in directing Purdue to continue marketing the drug as the safest and effective treatment for these patients. Indeed, Dr. Richard Sackler, the founder and mastermind of Defendant Purdue's scheme, admitted during a deposition that he was aware of OxyContin's dangerous propensity for addiction, abuse, diversion and death as early as 2000.²²

- 36. With the intention of shielding from creditors the proceeds of their wrongdoing, the Sackler Defendants have stripped Purdue and the Purdue-related entities each and every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other opioid-containing medications, including a generic form of Oxycontin sold by Defendant, Rhodes Pharma. All such transfers were and are fraudulent and all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy the opioid related liabilities of the companies from which they were transferred.
- 37. It is believed that Purdue may lack sufficient assets to satisfy their liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for their role in creating the opioid epidemic because billions of dollars of profits have been distributed to the Sacklers since the 1980's. Accordingly, the Sacklers and their controlled entities, including the Purdue Related Persons and/or Entities have also knowingly participated in the wrongdoing of Purdue as alleged in the original complaint and knowingly profited and received the benefits of that wrongdoing.

2. Directors, Executives and Officers of Purdue Pharma, L.P.

- 38. Defendants Peter Boer, Judith Lewent, Cecil Pickett, Paulo Costa, and Ralph Snyderman took seats on the Board and knowingly advanced the Sacklers' scheme.
 - 39. Defendants John Stewart, Mark Timney, and Craig Landau each directed

²² Dr. R. Sackler Depo., p. 269.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Purdue's deception as CEO of Purdue Pharma Inc. and Purdue Pharma L.P. Defendant Russell Gasdia carried out the misconduct as Vice President of Sales and Marketing.

- 40. Beverly Sackler, Jonathan Sackler, Kathe Sackler, Paulo Costa, Mark Timney, and Craig Landau reside in Connecticut. David Sackler, Ilene Sackler Lefcourt, and Mortimer Sackler reside in New York. Richard Sackler, Peter Boer, and John Stewart reside in Florida. Judith Lewent and Cecil Pickett reside in New Jersey. Ralph Snyderman resides in North Carolina. Theresa Sackler resides in the United Kingdom. Russell Gasdia resides in Massachusetts.
- 41. The Court has jurisdiction over all the Individual Defendants for the reasons set forth on Section III. below.

C. Manufacturer Defendants

1. Allergan

42. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in June 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is registered to do business in the State of Arizona as a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis PLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson

Laboratories, Inc. are referred to in this Complaint as "Actavis.")

43. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and California. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

2. Cephalon

- 44. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation which is registered to do business in California and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.
- 45. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain." Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." In 2008, CEPHALON pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay \$425 million.

3. Endo

46. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "ENDO.")

47. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and California. 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% of ENDO's total revenue in 2012. ENDO also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Arizona, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

4. Janssen

- 48. Janssen Pharmaceuticals, Inc. ("Janssen") (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutical) 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. These entities, which are collectively referred to herein as "Janssen," acted in concert with one another—as agents and/or principals of one another—in connection with the conduct described herein.
- 49. J&J is the only company that owns more than 10% 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 Pharmaceutical, Inc., and J&J are referred to as "Janssen").
- 50. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and California, 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, which also generated substantial sales revenue for the company, accounting for \$172 million in sales in 2014 alone.
- 51. While Janssen has repeatedly disclaimed responsibility for its part in causing the opioid crisis, insisting that "[e]verything that we [Janssen] have done with our products when we've promote opioid products . . . was appropriate and responsible," internal memoranda and

communications between high-level executives at Janssen show the company funded and pushed bogus research to lend false credibility to a series of dangerous fictions, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain," and enabling "Janssen's representatives [to] promote[] Nucynta and Nucynta ER as safer, milder, and less addictive than competitor opioids like OxyContin."²³

5. Purdue

- 52. 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").
- 53. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,²⁴ and Targiniq ER in the U.S. and California. 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 fourfold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

6. Mallinckrodt

54. Defendant Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt PLC was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien PLC, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of

²³ M. Aron, *State sues Johnson & Johnson subsidiary for deceptively marketing opioids*, NJTV News (Nov. 13, 2018), https://www.njtvonline.org/news/video/state-sues-johnson-johnson-subsidiary-for-deceptively-marketing-opioids/

²⁴ Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.

56. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, LLC. Mallinckrodt PLC and Mallinckrodt, LLC are referred to as "Mallinckrodt."

existing under the laws of the State of Delaware and licensed to do business in Arizona.

- 57. Mallinckrodt manufactures, markets, and sells drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S.
- 58. Mallinckrodt currently manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In addition, Mallinckrodt previously developed, promoted, and sold the following branded opioid products: Magnacet, TussiCaps, and Xartemis XR.
- 59. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.
- 60. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.
- 61. In 2017, Mallinckrodt agreed to settle for \$35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged that even though Mallinckrodt knew that its oxycodone was being diverted to

illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("CSA").

62. Defendants Actavis, Cephalon, Janssen, Purdue, Endo, and Mallinckrodt are collectively referred to as the "Manufacturer Defendants."

7. Insys

- 63. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. INSYS manufactures, markets, sells and distributes nationwide several types of opioids, including Subsys—a fentanyl sublingual spray and semi-synthetic opioid antagonist—as well as Syndros, a cannabinoid medicine used in adults to treat common side-effects of opioid use, particularly for patients whose nausea and vomiting have not improved with usual anti-nausea and vomiting medicines. The FDA approved Subsys in 2012, and Syndros in 2016.
- 64. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain." The indication also specifies that "Ssubsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.
- 65. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, INSYS reported revenues of \$331 million. Of that total, \$329.5 million was

The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

derived from sales of Subsys. The majority of Insys' sales of Subsys are through wholesalers, including Defendants AmerisourceBergen, McKesson and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of INSYS' total gross sales of Subsys.

- 66. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation fentanyl products are "the most potent and dangerous opioids on the market."26
- 67. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.
- 68. Despite Subsys' limited indication and the potent danger associated with fentanyl, INSYS falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain and other off-label pain conditions.27 Moreover, as of June 2012, INSYS defined BTP in cancer patients to include mild pain: a "flare of mild-to-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy. 28 INSYS trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.
 - According to a 2014 article in *The New York Times*, only 1% of prescriptions for 69.

pubmed/1697056.

28

27

²⁶ Dina Gusovsky, The Painkiller: A Drug Company Putting Profits Above Patients, NBC News (Nov. 5, 2015), https://www.nbcnews.com/business/business-news/painkiller-drugcompany-putting-profits-above-patients-n457511

²⁷ In the Matter of Insys Therapeutics, Inc., Notice of Unlawful Trade Practices and Proposed Resolution (July 10, 2015).

²⁸ Portenoy's paper, which was featured in the 1990 issue of Pain, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity—i.e., to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, Breakthrough pain: Definition, prevalence and characteristics, National Center for Biotechnology Information (July 1990), https://www.ncbi.nlm.nih.gov/

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others, including dentists and podiatrists, writing prescriptions as well.²⁹

- 70. On September 6, 2017, Senator McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the System Manipulation of Prior Authorization" was published. The report found that INSYS manipulated the prior authorization process by misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.³⁰
- On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out these messages were exaggerations at best and outright lies at worst.³¹

Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.

72. Less than two years later, Insys' former chief executive officer pleaded guilty to participating in a nationwide scheme to bribe doctors in exchange for prescribing Subsys.³² The Arizona Attorney General, Mark Brnovich, has also filed a lawsuit against INSYS on behalf in connection with the aforementioned kickback scheme.³³

25

1159968.7/81650.01001

14809093

²⁹ Katie Thomas, Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller, N.Y. TIMES (May 13, 2014).

³⁰ HSGAC Minority Staff Report, Fueling an Epidemic—Insys Therapeutics and the Systemic Manipulation of Prior Authorization (2017).

³¹ See, LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable, September 12, 2017, at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8 vAo (last accessed Mar. 17, 2019).

³² Nate Raymon, Former Insys CEO pleads guilty to opioid kickback scheme, REUTERS (Jan. 9, 2019), https://www.reuters.com/article/us-insys-opioids/former-insys-ceo-pleadsguilty-to-opioid-kickback-scheme-idUSKCN1P312L.

³³ AG Brnovich Files Lawsuit Against Opioid Manufacturer Insys Teherapeutics and Three Arizona Doctors, AZAG.gov (Aug. 31, 2017), https://www.azag.gov/pressrelease/ag-brnovich-files-lawsuit-against-opioid-manufacturer-insys-therapeutics-and-three

D. Distributor Defendants

1. Teva

73. Teva Ltd.., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of CEPHALON's specialty sales," including inter alia sales of Fentora. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon" for the remainder of this Complaint.

2. McKesson

75. Defendant Distributor McKesson Corporation ("McKesson") is a publicly-traded company headquartered in California, with its principal place of business at One Post Street, San Francisco, California 94104 and incorporated under the laws of Delaware. At all relevant times, McKesson was in the business of distributing substantial amounts of

prescription opioids to providers and retailers. McKesson has engaged in consensual commercial dealings with the People of Prescott and its residents, and has purposefully availed itself of the advantages of conducting business with and within Prescott. McKesson is in the chain of distribution of prescription opioids.

3. AmerisourceBergen

76. Defendant Distributor AmerisourceBergen ("AmerisourceBergen") is a publicly traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. At all relevant times, AmerisourceBergen was in the business of distributing substantial amounts of prescription opioids to providers and retailers. AmerisourceBergen has engaged in consensual commercial dealings with the People of Prescott and its residents, and has purposefully availed itself of the advantages of conducting business with and within Prescott. AmerisourceBergen is in the chain of distribution of prescription opioids.

4. Cardinal Health

- 77. Defendant Distributor Cardinal Health, Inc. (hereinafter "Cardinal Health") is a publicly traded company headquartered in the State of Ohio and incorporated under the laws of Ohio. At all relevant times, Distributor Cardinal Health was in the business of distributing substantial amounts of prescription opioids to providers and retailers. Cardinal Health has engaged in consensual commercial dealings with the People of Prescott and its residents, and has purposefully availed itself of the advantages of conducting business with and within Prescott. Cardinal Health is in the chain of distribution of prescription opioids.
- 78. Defendants Teva, Insys, McKesson, AmerisourceBergen, and Cardinal Health are collectively referred to as the "Distributor Defendants." Manufacturers of opioids have transferred prescription opioids to the Distributor Defendants for years. The Distributor Defendants dominate 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at \$378.4 billion in 2015. The Distributor Defendants supplied opioids to hospitals, pharmacies, doctors and other healthcare providers, which then dispensed the drugs to patients in Arizona, including in Prescott. The Distributor Defendants have had substantial contacts and business relationships with the People of the Prescott. The Distributor

Defendants have purposefully availed themselves of business opportunities within Prescott.

E. Prescriber Defendants

1. Dr. Douglas J. Campbell

79. Dr. Douglas J. Campbell, M.D. is a family medicine physician who formerly practiced and prescribed opioids in Prescott with a medical practice address at 1672 Oaklawn Drive, Prescott, Arizona 86305. On information and belief, Dr. Campbell currently practices at Cobre Valley Regional Medical Center, 5994 S. Hospital Drive, Globe, Arizona 85501.

2. Dr. Randy Joe Spicer

80. Dr. Randy Joe Spicer, NMD, is a naturopathic doctor from Prescott. Prior to being arrested on suspicion of prescription drug fraud and sentenced to over 13 years in prison in June of 2013, Dr. Spicer operated his own medical practice at 343 S Montezum St, Prescott, AZ 868303.

F. DOE Defendants

81. Prescott is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 1000 inclusive, and they are therefore sued herein under Arizona Justice Court Rules of Civil Procedure §110. Prescott will amend this Complaint to show their true names and capacities if and when they are ascertained. Prescott 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.

III. JURISDICTION AND VENUE

- 82. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising and unlawful, unfair, and deceptive business practices, and creating or assisting in the creation of a public nuisance in Prescott, and the People of Prescott through their attorneys have the right and authority to prosecute this case on behalf of the People of Prescott.
 - 83. Venue is proper in this Court because Defendants transact business in Arizona,

and in particular Prescott, which is located in Yavapai County. Some of the acts complained of also occurred in this venue. Further, Distributor Defendant INSYS' principal place of business is in Arizona, INSYS conducted business and continues to do business throughout Arizona, and INSYS regularly and continuously distributes prescription opioids throughout Arizona, including in Prescott. (*See* A.R.S. § 12-401, subdivs. (7), (10) and (18).)

IV. FACTUAL ALLEGATIONS

A. Background on Pain Medicine

- 84. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as risk of non-treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risk of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.
- 85. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction, and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, and have now been made illegal in China.
- 86. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States. Many doctors prescribed opioids solely to avoid patients' withdrawal. Both the number of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.
- 87. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of

potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

- 88. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed poor outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.
- 89. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use. On the contrary, evidence shows that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health condition (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.
- 90. Opioids are highly addictive. Patients using opioids for more than a few days can experience severe withdrawal symptoms if they stop taking the drugs, including: anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Withdrawal can last so long and be so painful that it is difficult to stop taking opioids.
- 91. Putting patients on opioids puts them at risk. Patients who take opioids at higher doses and for longer periods face higher and higher risk of addiction and death. Relative to the general population, the risk of opioid-death is 35-times higher for patients receiving three consecutive months of opioid therapy
 - B. The Manufacturer Defendants' Impact on the Perception and Prescribing of Opioids
 - 92. Before the Manufacturer Defendants began the marketing campaign complained

of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for acute pain, or for patients nearing the end of life. The Manufacturer Defendants changed this perception and took advantage of addiction to make money. The tradition of limiting opioids to short-term treatment ended after Defendants introduced and began aggressively marketing opioids with deceptive claims.

93. The Manufacturer Defendants' efforts were wildly successful. And they knew it, as evidenced by a Mid-Year Board Update for Defendant Purdue from 2016, which demonstrates just how much Defendants' scheme had shifted public opinion about the risks and benefits of opioids.

The Manufacturer Defendants' efforts were wildly successful. And they knew it, as evidenced by a Mid-Year Board Update for Defendant Purdue from 2016, which demonstrates just how much the Manufacturer Defendants' scheme had shifted public opinion about the risks and benefits of opioids.

- 94. The Manufacturer Defendants' marketing campaign resulted in skyrocketing opioid prescriptions. The shocking increase in prescriptions has been a gold mine for the Manufacturer Defendants. It has been a massacre and tragedy for patients and the People of Prescott. Prescott has lost citizens young and old to the opioid epidemic too many children in Prescott have lost their parents and too many parents have buried their children. Too many grandparents are raising their grandchildren.
- 95. Patients who survive addiction need lengthy, difficult, and expensive treatment. People who are addicted to opioids are often unable to work. The addiction of parents can force their children into foster care. Babies are born addicted to opioids, because they are exposed to the drugs in the womb. The Manufacturer Defendants' misconduct has imposed heavy costs on the people of Prescott.

Critical Shifts in The National Discussion about Pain And Opioids	
From	То
Undertreatment of Pain	Opioid Epidemic
Abuse	Addiction
Abuse	Addiction

C. The Manufacturer Defendants Engaged in a Deceptive and Unbranded Marketing Campaign

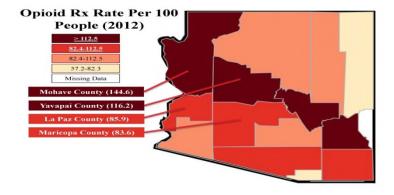
96. To profit from their dangerous drugs, the Manufacturer Defendants engaged in a deadly and illegal to deceive doctors and patients. First, the Manufacturer Defendants deceived Prescott doctors and patients to get more people on their dangerous drugs. The Manufacturer Defendants targeted vulnerable people who could be introduced to opioids, including elderly patients, veterans, and people who had never taken opioids before. The Manufacturer 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 observed that existing evidence showed 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. The Guideline therefore concluded that there are "special risks of long-term opioid use for elderly patients" and recommended 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 posttraumatic stress disorder, which interact dangerously with opioids.

- 97. <u>Second</u>, the Manufacturer Defendants misled them to take higher and more dangerous doses.
- 98. <u>Third</u>, the Manufacturer Defendants deceived them to stay on their drugs for longer and more harmful periods of time.

100. Each part of the scheme earned the Manufacturer Defendants more money from Prescott opioid sales and caused more addiction and death in Prescott. And each Manufacturer Defendant participated in and profited from the scheme in Prescott, as set forth below.

D. The Manufacturer Defendants Targeted Prescott With Their Unfair and Deceptive Sales Campaigns

101. Prescott patients died after taking the Manufacturer Defendants' drugs because the Manufacturer Defendants targeted Prescott with a massive deceptive sales campaign. To spread their false and misleading statements, the Manufacturer Defendants deceptively marketed their branded opioids directly to doctors and patients in Prescott. The Manufacturer Defendants also deployed seemingly unbiased and independent third parties to spread their false and misleading statements about the risks and benefits of opioids for the treatment of chronic pain throughout Arizona and, specifically, in Prescott.



102. The Manufacturer Defendants' most powerful tools of deception were sending sales representatives to promote opioids to Prescott doctors, nurses, and pharmacists face to face. During sales visits, the Manufacturer Defendants' representatives made false and

misleading claims directly to the professionals who care for Prescott patients. The Manufacturer Defendants assigned representatives to Prescott and gave them lists of Prescott doctors to visit.

103. Each of these visits cost the Manufacturer Defendants money. But the Manufacturer Defendants made this money back many times over, because they convinced doctors to prescribe their addictive drugs. The Manufacturer Defendants rewarded high prescribing doctors with meals, money, and gifts. The Manufacturer Defendants' sales representatives who generated the most prescriptions won bonuses and prizes. These detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including Prescott doctors.

104. The Manufacturer Defendants' representatives have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

105. The Manufacturer Defendants also conducted and continue to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, the Manufacturer 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.

106. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011, 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" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arizona.

107. The Manufacturer Defendants³⁴ also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer 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 give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

108. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, the Manufacturer Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as the Manufacturer Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo, and \$2 million by Actavis.

109. The Manufacturer Defendants also deceptively marketed opioids in Arizona 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

³⁴ Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

111. The Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (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."

112. The Manufacturer Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." The Manufacturer

³⁵ The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs ("CMEs"), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the Manufacturer Defendants.

113. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General ("NY AG") found in its 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. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. The Manufacturer Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

114. The Manufacturer 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 Manufacturer Defendants were able to direct and exert control over each of these activities

through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

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"—which include, but are not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine—generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. Indeed, they stand in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

- 116. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. Defendants also exercised 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 APF gave it direct, contractual control over APF's work. In doing so, the Manufacturer Defendants made sure that the Groups would generate only the messages the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.
- 117. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, the Manufacturer Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. 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 the Manufacturer 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 the Manufacturer Defendants determined would reduce 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 that were available and accessible after May 21, 2011.

E. The Manufacturer Defendants Deceived Doctors and Patients to Get More People on Dangerous Drugs, at Higher Doses, for Longer Periods

118. To convince doctors and patients in Arizona that opioids can and should be used to treat chronic pain, the Manufacturer Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, the Manufacturer Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and misleading, Plaintiff is informed and believes the Manufacturer Defendants have not corrected them and continue to spread them today, including as set forth specifically below.

1. Deception About Addiction

- 119. The Manufacturer Defendants always knew that their opioids carry grave risks of addition and death. Instead of being honest about these risks, the Manufacturer Defendants obscured them, including by falsely stating and implying that "appropriate patients" won't get addicted. To convince doctors and patients that opioids are safe, the Manufacturer 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.
- 120. First, the Manufacturer 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 misleading claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Purdue and Cephalon 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.
- c. 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." This website was still available online after May 21, 2011.
- d. Endo and Cephalon 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 which was accessible online after May 21, 2011.
- e. 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." This guide is still available online.
- f. Janssen runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to

	COUNSELORS AT LAW	
1111) (() () () ()		

"misconceptions about opioid addiction[]." This publication is still available online.

- h. Since at least May 21, 2011, detailers for Purdue, Endo, Teva and Janssen in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Arizona, including Prescott, about 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.
- 121. Moreover, Purdue, in a pamphlet for doctors, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices*, wrote that addiction "is not caused by drugs." Instead, Purdue assured doctors that addiction happens when the wrong patients get drugs and abuse them: "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse."³⁶
- 122. Purdue also promoted its opioids to Prescott patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign. Purdue created a website, *In the Face of Pain*, that promoted pain treatment by urging patients to "overcome" their "concerns about addiction." Testimonials on the website that were presented as personal stories were in fact by Purdue consultants, whom Purdue had paid tens of thousands of dollars to promote its drugs.³⁷
- 123. Another Purdue publication, the *Resource Guide for People with Pain*, falsely assured patients and doctors that opioid medications are not addictive:

"Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a 'high'." ³⁸

1159968.7/81650.01001

³⁶ Purdue Pharma LP, *Providing Relief, Preventing Abuse* (2008), pg. 12; *see also* K. Nelson, *Purdue Pharma lawsuit: Terms you need to know to understand OxyContin blitz*, Knox News (July 13, 2018),

 $[\]frac{https://www.knoxnews.com/story/news/health/2018/07/13/purdue-pharma-lawsuit-terms-know-understand-oxycontin-blitz/779173002/$

³⁷ Purdue Pharma LP, *In the Face of Pain* (Oct. 24, 2011).

³⁸ Purdue Pharma LP, *Resource Guide for People with Pain*, p. 8 (2009).

- 125. Purdue funded and distributed many more publications that were similarly misleading. *Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and their Families* misleadingly claimed: "Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." ³⁹
- 126. Responsible Opioid Prescribing told doctors that only a "small minority of people seeking treatment may not be reliable or trustworthy" and not suitable for addictive opioid drugs.⁴⁰
- 127. Over and over, Defendants said opioids could be given to "trusted" patients without risk of addiction, even though that was false. To promote their drugs, the Manufacturer Defendants pushed the myth that addiction is a character flaw, and "trustworthy" people do not get addicted to drugs.
- These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline approved by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." 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." (Emphasis added.)
- 129. The FDA further exposed the falsity of the Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk

³⁹ Purdue Pharma LP, Exit Wounds, p. 107 (2009).

of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

- 130. Thus, the warnings on the Manufacturer Defendants' own FDA-approved drug labels 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.
- 131. The New York Attorney General, 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 until at least April 2012 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 the NY AG found that Endo had no evidence for that statement. Consistent with this, 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 Arizona.

2. Deception to Get Vulnerable Patients on Opioids

132. Second, to expand the market for opioids, the Manufacturer Defendants also trained sales reps to target vulnerable populations and encourage doctors to put them on opioids, without disclosing the risks. The Manufacturer Defendants deceptively promoted opioids for elderly patients, veterans, patients who had never taken opioids, and patients with

⁴⁰ Purdue Pharma LP, Responsible Opioid Prescribing, p. 11 (2007).

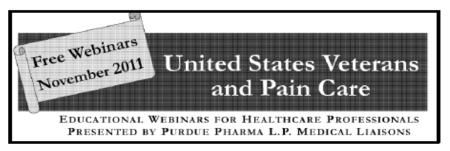
osteoarthritis—putting thousands more patients at risk.

Elderly Patients

133. The Manufacturer Defendants knew that prescribing opioids to elderly patients increase their risk of death. Elderly patients are at greater risk of dangerous interactions between drugs. They are also at a greater risk of respiratory depression—in which patients suffocate and die. But the Manufacturer Defendants saw the opportunity to earn millions of dollars by getting elderly patients on opioids because the public would pay through Medicare. For instance, Purdue's internal documents show it targeted "Patients over the age of 65 as more Medicare Part D coverage is achieved."⁴¹

Veterans

- 134. The Manufacturer Defendants also targeted veterans with its deceptive claims that they should take opioids. Like the elderly, many veterans' prescriptions are paid for by the public, providing another source of revenue when the Manufacturer Defendants got veterans on drugs.
- 135. To target veterans, Purdue sponsored free webinars for, and disseminated misleading advertisements to, healthcare professionals in an attempt to persuade them to prescribe more opioids.



Purdue flyer from 2011

136. In addition, Purdue funded a book, *Exit Wounds*, which as packaged as the story of a wounded veteran but was really part of Purdue's deceptive marketing campaign. The book repeated Purdue's lie that patients would not become addicted to opioids:

The pain-relieving properties of opioids are unsurpassed; they are

⁴¹ Purdue Pharma LP, *Pain Products Presentation*, p. 12 (Jan. 28, 2015).

today considered the 'gold standard' of pain medications, and so are often the main medications used in the treatment of chronic pain. Yet, despite their great benefits, opioids are underused. For a number of reasons, healthcare providers may be afraid to prescribe them, and patients may be afraid to take them. At the core of this wariness is the fear of addiction, so I want to tackle this issue head-on Long experience with opioids show that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."⁴²

Opioid-Naive Patients

137. The Manufacturer Defendants also targeted patients who were not already taking opioids, described in the field as "opioid-naive." The Manufacturer Defendants unfairly and deceptively marketed their drugs as appropriate treatments for opioid-naïve patients, without disclosing that they face even higher risks of overdose and death.

CLOSE #1

Opioid-naïve (5 mcg/hour):

 "Doctor, either today or tomorrow, do you anticipate seeing this commercially insured, opioid-naïve patient with moderate to severe chronic pain, who you believe would benefit from Butrans?

Purdue sales script from 2011

- 138. For instance, Purdue trained its sales reps to promote their drugs specifically for opioid-naïve patients. In training calls, Purdue managers instructed:
 - "Your opportunity here is with the naïve community, let's use the naïve trial to make the case."
 - "You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more pat to write this for his patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short-acting [opioids]."
 - "This was an example of what a good call looks like ... [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients ..."
- 139. Purdue also promoted its drugs for opioid-naïve patients using the deceptive term "first line opioid." "First line" is a medical term for the preferred first step in treating a

⁴² Purdue Pharma LP, *Exit Wounds*, p. 106-07 (2009).

patient. Opioids are not an appropriate first line therapy. Nevertheless, Purdue's internal documents and testimony from sales reps show that Purdue repeatedly promoted OxyContin as "first line"—"the first thing they would take to treat the pain."

140. The Manufacturer Defendants also found vulnerable opioid-naïve patients by targeting prescribers with the least training in the risks of opioids. The Manufacturer Defendants determined that nurse practitioners, physician assistants, and primary care doctors were especially responsive to sales reps, so it targeted them to sell more drugs.



Purdue opioid promotion from 201512

141. Opioids are not approved to treat osteoarthritis. For instance, Purdue conducted a single study on osteoarthritis for Butrans, and it failed. Purdue admitted in internal documents that its opioids "are not indicated for a specific disease" and "it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis."

- 142. Nevertheless, to meet their business goals, the Manufacturer Defendants trained their sales representatives to mislead doctors by promoting opioids for osteoarthritis. For instance, a Purdue marketing presentation concluded that its sales reps were "identifying appropriate patients" because osteoarthritis was specifically mentioned during at least 35% of sales visits.
- 143. The Manufacturer Defendants also directed their sales reps to use marketing materials that highlight patients with osteoarthritis, even though their drugs were never indicated for that disease.

3. The Manufacturer Defendants Deceived Doctors and Patients to Use **Higher and Higher Doses**

144. <u>Third</u>, the impetus behind the Manufacturer Defendants' scheme is as simple as it is nefarious—enticed by the exponentially greater profits that would result from increases in opioid dose mix, the Manufacturer Defendants deceived (or bribed) Prescott's local prescribers in order to increase the supply of prescription opioids in Plaintiff's territory and drown Plaintiff's community in a sea of highly addictive, medically unnecessary drugs.

			9	6 shift from 20mg a	nd 15mg down to 10	mg
Dose	Forecast (Rx)	Forecast (\$)	1%	Shift	2% Shift	3% Shift
10 mg	1,226,840	\$ 135,005,554	1,242,664	\$ 136,746,931	\$ 138,488,308	\$ 140,229,68
15mg	180,831	\$ 33,261,232	179,023	\$ 32,928,620	\$ 32,596,008	\$ 32,263,395
20mg	1,401,616	\$ 361,951,330	1,387,599	\$ 358,331,817	\$ 354,712,303	\$ 351,092,790
30mg	519,945	\$ 193,796,793	519,945	\$ 193,796,793	\$ 193,796,793	\$ 193,796,79
40mg	1,085,624	\$ 577,483,835	1,085,624	\$ 577,483,835	\$ 577,483,835	\$ 577,483,835
60mg	436,272	\$ 326,705,155	436,272	\$ 326,705,155	\$ 326,705,155	\$ 326,705,155
90mg	768,198	\$ 931,583,802	768,198	\$ 931,583,802	\$ 931,583,802	\$ 931,583,802
Total	5,619,324	\$ 2,559,787,701	5,619,324	\$ 2,557,576,952	\$ 2,555,366,204	\$ 2,553,155,456
MINISTER STREET	nall shift of ro or 15mg dow	ughly 15K pr			\$6,6	32,244 PURDUE

Purdue internal strategy presentation from 2012

\$57 million ph/ph/et/sales/is attributed to lower demand

- \$21 million due to lower number of tabs per script than assumed
- \$11 million due to lower overall script volume than budgeted

27

28

14809093

1159968.7

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

145. The Manufacturer Defendants also falsely instructed doctors and patients that the 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 Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Teva, and Purdue—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011, are described below:

- a. Purdue, Cephalon and Endo 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. Endo also distributed this document before and after May 21, 2011.
- 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." This website was accessible online until May 2012.
- 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. This CME program was still available after May 21, 2011.
- 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." This pamphlet was still distributed after May 21, 2011.

- e. Purdue sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone 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. This CME program was still available after May 21, 2011.
- f. Before and after May 21, 2011, detailers for Purdue have directed doctors and their medical staffs in Arizona, including Prescott, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.
- g. Purdue and Cephalon 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." (emphasis added.) This publication is still available online.
- 146. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline 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."
- of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to

do so in Arizona.

148. The Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer 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 that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after March 21, 2011 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. Purdue sponsored a November 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."
- c. 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.
- d. Since at least May 21, 2011, detailers for Purdue have touted and continue to tout to doctors in Arizona, including Prescott, the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.
- 149. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.

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."

4. The Manufacturer Defendants Peddled Falsehoods to Keep Patients Away from Safer Alternatives

A. Deception about Lower-Dose Opioids

150. The Manufacturer Defendants deceptively claimed that its opioids provided more effective pain relief than traditional immediate-release opioids (sometimes called IROs). For instance, Purdue records show that the sales reps repeatedly claimed that OxyContin's "steady state is better than peak and trough w/ [IROs]." Purdue claimed that OxyContin provides a "full tank of gas," but immediate-release opioids require "stopping at each exit to refuel." Purdue bolstered these misrepresentations with marketing materials that misrepresented data to indicate that Purdue drugs provided more consistent pain relief than more frequently dosed, lower-dose opioids.

B. Deception about Quality of Life

151. The Manufacturer Defendants also steered patients away from safer alternatives with the false claim that its opioids improve patients' "quality of life." For instance, Purdue's internal documents admit that "Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life." Nevertheless, Purdue sales reps repeatedly claimed that its opioids improve quality of life. Purdue also devised and funded third-party publications to say that opioids give patients the "quality of life we deserve."

C. Deception about Risk of Abuse

152. In addition to visiting prescribers and pharmacists hundreds of thousands of

times, the Manufacturer Defendants distributed thousands of copies of its deceptive publications, including *Providing Relief*, *Preventing Abuse*; *Resource Guide for People with Pain*; *Exit Wounds*; *Opioid Prescribing: Clinical Tools and Risk Management Strategies*; *Responsible Opioid Prescribing*; and *Clinical Issues in Opioid Prescribing*. *Purdue's In The Face of Pain*.

5. The Manufacturer Defendants Downplayed Opioids Withdrawal

153. Fourth, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer 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. For example, a 2011 non-credit educational program 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% for 10 days. 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. This publication was available on APF's website until the organization dissolved in May 2012. And detailers for Janssen, since at least May 21, 2011, have told and continue to tell doctors in Arizona, including Prescott, that their patients would not experience withdrawal if they stopped using opioids.

154. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal—which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction—and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet 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." (Emphasis added.) The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" 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."

- 155. Numerous Arizona patients struggling with opioid addiction, including in Prescott, have described how difficult it is to stop taking prescription opioids due to the extreme withdrawal symptoms. For example, one patient who was prescribed opioids for chronic pain was told that tapering off the drugs would be easy. However, when the patient became addicted and tried to stop taking opioids, she became so sick from opioid withdrawal that she began buying opioids illicitly, and at one point even considered using heroin to get through her withdrawal symptoms. While the patient ultimately opted to seek treatment for her addiction rather than resort to heroin, she was unable to work during the time she was receiving treatment.
- 156. Prescribers and patients in Prescott relied on the truth of the Defendant Manufacturers' representations about both the benefits of opioid analgesics and the risks of opioid addiction. Because each of the Manufacturer Defendants willfully concealed the truth about their opioids despite knowing their representations were false at the time they were made, Plaintiff's citizens have suffered and continue to suffer as a direct result of Defendants' greed.

6. The Manufacturer Defendants Hid the Greater Risks to Patients at Higher Dosages of Opioids

157. The Manufacturer Defendants were in the best position to know, and in fact did know, that—relative to the general population—the risk of opioid-related death increases

exponentially after a patient takes opioids for several consecutive months.

158. Specifically, the Manufacturer 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 the Manufacturer 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 of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:

- a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Purdue and Cephalon 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.⁴³ This guide is still available for sale online.
- c. 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." The website was still accessible online after May 21, 2011.

The Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See, e.g., Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).)

- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 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."
- e. Janssen sponsored a patient education guide entitled *Finding Relief:* Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.
- f. Through March 2015, 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.
- g. 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.
- h. Purdue sponsored a CME entitled Overview of Management Options that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.
- j. Since at least May 21, 2011, Purdue's detailers have told doctors in California, including in Orange County, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.
- 159. Through a series of internal strategy presentations and other communications with its sales force and prescriber-accomplices, Purdue aimed to "drive" patients toward higher doses of opioids for longer periods by dramatically increasing the supply. Apparently unsatisfied with a supply-centric strategy, however, Purdue also sought to increase consumer demand for opioids, namely by offering discounts to patients on their first prescriptions. These discounts ultimately proved to be one of Purdue's most powerful tactics to keep patients

1159968.7/81650.01001

on opioids longer, as Purdue's return on investment from these discounts was a staggering 4.28—*i.e.*, every \$1,000,000 Purdue gave away in first-time patient discounts came back to Purdue as \$4,280,000 in revenue.

160. Through a series of internal strategy presentations and other communications with its sales force and prescriber-accomplices, Purdue aimed to "drive" patients toward higher doses of opioids for longer periods by dramatically increasing the supply. Apparently unsatisfied with a supply-centric strategy, however, Purdue also sought to increase consumer demand for opioids, namely by offering discounts to patients on their first prescriptions. These discounts ultimately proved to be one of Purdue's most powerful tactics to keep patients on opioids longer, as Purdue's return on investment from these discounts was a staggering 4.28—*i.e.*, every \$1,000,000 Purdue gave away in first-time patient discounts came back to Purdue as \$4,280,000 in revenue.

Drive appropriate titration and length of therapy with continuing patients, to maintain total Kg within 2% of forecast

Purdue internal strategy presentation from 2012

- 161. 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.
- 162. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

- Finally, the Manufacturer Defendants' deceptive marketing of the so-called 163. abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and 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.
- 164. These abuse deterrent formulations ("AD opioids") are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are "not impossible" to abuse. 44 They can be defeated—often quickly and easily—by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.
- Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that any communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the Claims for AD opioid products that are false, misleading, and/or particular drug. insufficiently proven do not serve the public health.⁴⁵
 - Despite this admonition, the Manufacturer Defendants have made and continue 166.

1159968.7/81650.01001

57

14809093

25 26

27

28

See U.S. Food and Drug Administration ("FDA"). Abuse-Deterrent Opioids— Evaluation and Labeling: Guidance for Industry, p. 23 (Apr. 2015),

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidance s/ucm334743.pdf

⁴⁵ *Ibid*.

167. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 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. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And since 2012, detailers for Endo have informed Arizona doctors, including doctors in Prescott, that Opana ER is harder to abuse, and nurse practitioners have reported receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana ER's purposed abuse deterrent properties.

- 168. In a 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG 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.
- 169. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.⁴⁶
 - 170. Likewise, Purdue has engaged and continues to engage in deceptive marketing

⁴⁶ FDA News Release, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017),

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm

of its AD opioids—*i.e.*, reformulated Oxycontin and Hysingla—since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, numerous Arizona prescribers report that, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

- 171. These statements and omissions by Purdue are false and misleading and conflict with or are inconsistent with the FDA-approved label for Purdue's AD opioids—which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.
- 172. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin" and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other opioid products.
- 173. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third

of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting 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.⁴⁷ 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.

174. Similarly, 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."

175. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, the Manufacturer Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Indeed, several California prescribers have reported that Purdue has conveyed that its sale of AD opioids is "atonement" for its earlier sins even though its true motive was to preserve the profits it would have lost when its patent for OxyContin expired. Indeed, Purdue introduced its first AD opioid days before that patent would have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe and; thereby, prevent generic competition. Second, these claims are falsely assuaging doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids -- which are far more expensive than other opioid products even though they provide little or no additional benefit.

⁴⁷ Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin*, 72.5 JAMA Psychiatry, 424-30 (2015).

⁴⁸ Perrone, Drugmakers push profitable, but unproven, opioid solution (Dec. 15, 2016).

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

176. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

7. The Manufacturer Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy

177. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." (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 ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, they continue to make them today.

178. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:

- a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like

- c. 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 stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal." This guide was still available after May 21, 2011.
- d. 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.
- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo, Cephalon and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- f. Purdue and Cephalon 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 May 2012.
- g. 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. This website was still accessible online after May 21, 2011.
- h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs 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.
- i. 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 or
YouTube.	

- j. 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.
- k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of 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.
- 1. Since at least May 21, 2011, Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in California, including in Orange County, the message that opioids will improve patient function.
- 179. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." The CDC reinforced this conclusion throughout its 2016 Guideline:
 - "No 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..."
 - "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
 - "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."
- 180. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical

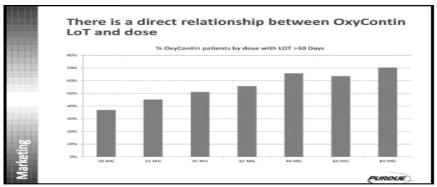
evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described above, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it publicly made clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

- 182. The Manufacturer 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, the Manufacturer Defendants, before and after May 21, 2011, 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. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.
- 183. In addition, since at least May 21, 2011, Purdue has misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose.

184. 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 is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and misleading, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

185. Indeed, Purdue's internal strategy presentation from 2012 confirms the company was well aware of the fact that no direct relationship exists between OxyContin LoT and dose.



Purdue internal strategy presentation from 2012

advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours since at least May 21, 2011. And at Purdue's instruction, Purdue's sales representatives continue to tell Arizona doctors that OxyContin lasts a full 12 hours. If a doctor suggests that OxyContin does not last 12 hours, these sales representatives—also at Purdue's instruction—recommend increasing the dose, rather than the frequency of use. Purdue gave its sales representatives these instructions

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

to prevent doctors from switching to a different drug and to address the unwillingness of insurers to pay for more frequent use of OxyContin.

8. The Manufacturer Defendants Also Engaged in Other Unlawful and Unfair Misconduct

- 187. Since at least May 21, 2010, Purdue's sales representatives have pressed doctors to prescribe its opioids in order to be rewarded with talks paid by Purdue.
- 188. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed Purdue about its legal "obligation to design and operate a system to disclose . . . suspicious orders of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs after May 21, 2010, despite knowing about it for years.
- 189. For over a decade, Purdue has been able to track the distribution and prescribing of its opioids down to the retail and prescriber levels. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors in Arizona and could identify Arizona doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite Purdue's knowledge of illegal prescribing, Purdue did not report until after law enforcement shut down Arizona clinics that overprescribed

OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

- 190. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue's sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a "no-call" list.
- 191. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, "Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people's lives has a responsibility to report it." The NY AG's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers in Arizona, including in Prescott.
- 192. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.
 - F. Although the Manufacturer Defendants Knew That Their Marketing of Opioids Was False and Misleading, They Fraudulently Concealed Their Misconduct
 - 193. The Manufacturer Defendants, both individually and collectively, made,

21

22

23

24

25

26

27

28

1

2

3

4

5

6

7

8

9

promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned the Manufacturer Defendants of this, and Purdue entered into settlements in the hundreds of millions of dollars to address similar misconduct that occurred before 2008. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

194. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

195. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties The Manufacturer 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 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer 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 the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiff.

197. As detailed in allegations below, the Sacklers were intimately aware of the potential liabilities against the Purdue entities because the Sacklers controlled the companies. The Sacklers personally participated in the misconduct or at least acquiesced to the misconduct by way of their knowledge of the wrongful acts combined with their failure to act. The Sacklers also performed multiple fraudulent transfers of billions of dollars to enrich themselves while leaving the Purdue entities hopelessly undercapitalized if ever forced to pay for the injuries they had caused.

///

21 || / /

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

- G. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Manufacturer Defendant Has Created or Assisted in the Creation of a Public Nuisance in Prescott
 - 1. The Manufacturer Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid **Prescriptions and Use in Prescott**
- 198. The Manufacturer Defendants' misrepresentations deceived and continue to deceive doctors and patients in Prescott about the risks and benefits of long-term opioid use. Studies also reveal that some doctors and many patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. Indeed, Arizona residents in treatment for opioid addiction, including residents of Prescott, confirm that they were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.
- 199. The Manufacturer Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.
- 200. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors in Prescott to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.
 - 201. The Manufacturer Defendants' deceptive marketing scheme and their unlawful

and unfair business practices also caused and continue to cause patients in Arizona, including patients in Prescott, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. The Manufacturer Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in Plaintiff's city.

202. In Prescott, the Manufacturer Defendants' deceptive marketing of the abuse-

202. In Prescott, the Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids during the past few years has been particularly effective. For example, one survey reports that pain specialists were more likely to recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using more of it than those who did not know it was an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in opioid sales revenue in 2015).

203. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' spending on their deceptive marketing scheme. The Manufacturer Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

2. By Causing an Explosion in Opioid Prescriptions and Use, the Manufacturer Defendants Have Created or Assisted in the Creation of a Public Nuisance in Prescott

- 204. The escalating number of opioid prescriptions written by doctors who were deceived by the Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Arizona, including in Prescott.
 - 205. Representing the NIH's National Institute of Drug Abuse in hearings before the

1159968.7/81650.01001

Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

206. In August 2016, 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."

207. Scientific evidence 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. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

208. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors in Arizona note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

209. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. The overprescribing of opioids for chronic pain caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arizona who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

- 210. The Manufacturer Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed Prescott. The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.
- 211. The rise in opioid addiction caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.
- 212. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will successfully complete it; many of those patients will relapse, returning to opioids or some other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.
- 213. Absent each Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in Prescott, would have been averted or much less severe.
- 214. These harms in Prescott, caused by the Manufacturer Defendants' deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they are "injurious to health" and interfere "with the comfortable enjoyment of life" and "property," and because they "affect[] at the same time" "entire communit[ies]" and "neighborhoods" and "any considerable number of persons." (A.R.S. 13-2917(A).)

28 || / /

3. The Manufacturer Defendants Knew and Should Have Known That Their Deceptive Marketing Schemes Would Create or Assist in the Creation of This Public Nuisance in Prescott

215. The Manufacturer Defendants knew and should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in Prescott. The Manufacturer 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. The Manufacturer Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors in Prescott to prescribe, and patients in Prescott to use, their opioids for chronic pain.

4. The Manufacturer Defendants' Conduct and Role in Creating or Assisting in the Creation of the Public Nuisance Is Not Excused by the Actions of any Third Parties

- 216. The Manufacturer Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give the Manufacturer Defendants license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.
- 217. Nor is the Manufacturer 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. The Manufacturer 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.

1159968.7/81650.01001

H. The Manufacturer Defendants' Fraudulent Marketing Has Led To Record Profits

218. While the use of opioids has taken an enormous toll on Prescott and its residents, the Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like the Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

I. The Individual Defendants Led Purdue's Misconduct

219. This section of the Complaint identifies the individuals who are personally responsible for Purdue's illegal scheme (the "Individual Defendants"). Arizona laws against both the creation of a public nuisance as well as unfair and deceptive conduct in commerce applies to individuals regardless of whether they are officers, directors, or employees. Holding individuals personally liable for their misconduct does not require piercing a corporate veil. Individuals are personally liable if: (a) they participated in the misconduct; or (b) they knew about the misconduct and failed to stop it; or (c) they should have known about the misconduct and they failed to stop it.⁴⁹ In this case, the Individual Defendants made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected many millions of dollars from the deception.

1. Summary Of The Individuals' Misconduct

- 220. The individual defendants were the chief architects and beneficiaries of Purdue's deception. In summary:
- 221. The individual defendants controlled the misconduct described in paragraphs 1-208, above.
- 222. Each individual defendant knowingly and intentionally sent sales representatives to promote opioids to prescribers in Arizona thousands of times.

⁴⁹ See A.R.S. § 10-830.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

- 223. Each individual defendant knew and intended that the sales reps in Arizona would unfairly and deceptively promote opioid sales that are risky for patients, including by:
 - falsely blaming the dangers of opioids on patients instead of the addictive drugs;
 - pushing opioids for elderly patients, without disclosing the higher risks;
 - pushing opioids for patients who had never taken them before, without disclosing
 - higher risks;
 - pushing opioids as substitutes for safer medications, with improper comparative
 - claims;
 - falsely assuring doctors and patients that reformulated OxyContin was safe;
 - pushing doctors and patients to use higher doses of opioids, without disclosing the
 - higher risks;
 - pushing doctors and patients to use opioids for longer periods of time, without
 - disclosing the higher risks; and
 - pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.
- 224. Each individual defendant knew and intended that the sales reps would not tell doctors and patients in Arizona and Prescott about the truth about Purdue's opioids. Indeed, they knew and intended these unfair and deceptive tactics achieved their purpose by concealing the truth.
- 225. Each individual defendant knew and intended that prescribers, pharmacists, and patients in Arizona would rely on Purdue's deceptive sales campaign to prescribe, dispense, and take Purdue opioids. Securing that reliance was the purpose of the sales campaign.
- 226. Each individual defendant knew and intended that staff reporting to them would pay top prescribers tens of thousands of dollars to encourage other doctors to write dangerous prescriptions across the State of Arizona as well as in Prescott.
- Each individual defendant knew and intended that staff reporting to them would 227. reinforce these misleading acts through thousands of additional acts in Prescott including by

sending deceptive publications to Plaintiff's local doctors and deceptively promoting Purdue opioids at Plaintiff's local healthcare facilities and other institutions.

- 228. Each individual defendant knew and intended that staff reporting to them would reinforce these misleading acts through thousands of additional acts in Arizona, including by sending deceptive publications to Arizona doctors and deceptively promoting Purdue's opioids in Prescott.
- 229. Each individual defendant knowingly and intentionally took money from Purdue's deceptive business in Arizona.
- 230. Each individual defendant knowingly and intentionally sought to conceal his or her misconduct.
 - 2. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler
- the Sacklers—who made decisions for their own pecuniary benefit that caused much of the opioid epidemic. The Sackler family owns Purdue, and have always held a majority of the seats on its Board. They controlled their own privately held drug company, and as a result, the Sacklers had the power to decide how their addictive narcotics were sold. They hired hundreds of workers to carry out their plan, and they fired those who failed to sell enough drugs. They got more patients on opioids, at higher doses, and for longer, than ever before. And to reward themselves, they paid themselves billions of dollars. They are responsible for addiction, overdose, and death that damaged millions of lives. They should be held accountable now.

3. The Sacklers' Misconduct Leading To The 2007 Judgment

232. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was neither new, nor accidental. Indeed, it was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they presided over a decade of illegal and immoral conduct, which led to

criminal convictions, a judgment of this Court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their subsequent and sustained misconduct was knowing and intentional.

- 233. Purdue Frederick Company, the Scakler's first drug company, was purchased by them in 1952. In 1990, they created Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board.⁵⁰ For events before July 2012, this Complaint uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.
- 234. The Sacklers insisted that the family control Purdue at all times. From 1990 until today, the family has consistently held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers should receive "all Quarterly Reports and any other reports directed to the Board."
- 235. Purdue launched OxyContin in 1996. It quickly earned the superlative "honor" of becoming one of the deadliest drugs of all time. The FDA scientist, Curtis Wright, who evaluated OxyContin wrote in his original review: "Care should be taken to limit competitive promotion." The Sacklers disagreed. From its inception, the Sacklers viewed limits on opioids as an obstacle to profits. To make more money, the Sacklers considered whether they could sell OxyContin in some countries as an uncontrolled drug. Staff reported to Richard Sackler that selling OxyContin as "non-narcotic," without the safeguards that protect patients from addictive drugs, would provide "a vast increase of the market potential." The inventor of OxyContin, Robert Kaiko, wrote to Richard to oppose this dangerous idea. Kaiko wrote that he was "very concerned" about the danger of selling OxyContin without strict controls. Kaiko warned: "I don't believe we have a sufficiently strong case to argue that OxyContin has

⁵⁰ Purdue Pharma Inc.'s 1991 filings with the Secretary of State of Connecticut state that it was incorporated in New York on October 2, 1990. Richard, Ilene, Jonathan, and Kathe Sackler are all listed as directors on the earliest (1991) report. Beverly, Mortimer, and Theresa all appear on the 1995 report. (*See* The Office of Secretary of State Denise W. Merill, https://www.concord-sots.ct.gov/CONCORD/online?sn=PublicInquiry&eid=9740.)

⁵¹ Curtis Wright, ultimately approved OxyContin for wide use. Shortly after approval, he

minimal or no abuse liability." To the contrary, Kaiko wrote, "oxycodone containing products are still among the most abused opioids in the U.S." Kaiko predicted: "If OxyContin is uncontrolled, ... it is highly likely that it will eventually be abused." In response, Richard Sackler asked, "How substantially would it improve your sales?"

236. As widely told, at the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said: "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white...." Over the next twenty years, the Sacklers made Richard's boast come true. They created a manmade disaster. Their blizzard of dangerous prescriptions buried children and parents and grandparents across Massachusetts, and the burials continue.

237. The Sacklers were—and have always been—behind Purdue's decision to deceive doctors and patients about the risks and benefits of Purdue's opioids. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined—and recorded in internal correspondence—that doctors had the beneficial but crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. The truth was that OxyContin is more potent than morphine. Richard directed Purdue staff not to tell doctors the truth, because the truth would reduce OxyContin sales.

238. Above all else, the Sacklers cared about money. Why aim for millions when there were billions to be had on the, literally, aching backs of patients? There is little doubt that this family cared more about money than about patients, their employees, or the truth. In 1999, when employee Michael Friedman reported to Richard Sackler that Purdue was making more than \$20,000,000 per week, Richard replied with disappointment, noting that sales were "not so great." "After all, if we are to do 900M this year, we should be running at 75M/month.

left the FDA, joining Purdue within two years of his departure.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?"

In 1999, Richard Sackler became the President of Purdue. Jonathan, Kathe, and 239. Mortimer were Vice Presidents. The company hired hundreds of sales representatives and taught them all the false claims they would need to sell drugs. Purdue managers tested the sales representatives on the most important false statements during training at company headquarters. On the crucial issue of addiction, which would destory so many lives, Purdue trained its sales representatives to deceive doctors by insisting that the risk of addiction was "less than one percent." Purdue mailed thousands of doctors promotional videos with that same false claim:

> "There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects.'

A sales representative told a reporter: "We were directed to lie. Why mince words about it? Greed took hold and overruled everything. They saw that potential for billions of dollars and just went after it."53

- 240. In 2000, the Sacklers were warned that a reporter was "sniffing about the OxyContin abuse story." The Sackler family put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that "deflects attention away from the company owners."
- In January 2001, a Purdue sales representative contacted Richard Sackler with a dire message to report. The sales representative described a community meeting at a local high school, organized by mothers whose children overdosed on OxyContin and died. "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."
 - The next month, a federal prosecutor reported 59 deaths from OxyContin in a 242.

⁵² Barry Meier, *Pain Killer* (1 ed. 2003) at 99.

C. Glazek, The Secretive Family Making Billions From The Opioid Crisis, Esquire

single state. As awful as that statistic was, the Sacklers knew that the reality was worse and that the reports underestimated the death and destruction. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse." The next week, on February 14, a mother wrote a letter to Purdue:

"My son was only 28 years old when he died from Oxycontin on

"My son was only 28 years old when he died from Oxycontin on New Year's Day. We all miss him very much, his wife especially on Valentines' Day. Why would a company make a product that strong (80 and 160 mg) when they know they will kill young people? My son had a bad back and could have taken Motrin but his Dr. started him on Vicodin, then Oxycontin then Oxycontin SR. Now he is dead!"

A prescient (or just perceptive) Purdue staff member noted: "I see a liability issue here. Any suggestions?"

- 243. Also in February of 2001, Richard Sackler came up with Purdue's grand plan for the onslaught of negative publicity for his massive money-maker: blame and stigmatize people who become addicted to opioids. Sackler wrote, "We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." Richard followed that strategy for the rest of his career: collect millions from selling addictive drugs, and blame the terrible consequences on the people who became addicted. By their misconduct, the Sacklers have hammered Arizona families in every way possible. And the stigma they used to attack the victims, added insult to injury, and escalated the crisis.
- 244. Not long after the devastated mother's Valentine's Day letter to Purdue, the Sacklers delighted in their success by landing on the front page of the *New York Times* which reported that "OxyContin's sales have hit \$1 billion, more than even Viagra's." The only dark spot? The article reported that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."
- 245. When *Time* magazine published an article about OxyContin deaths, Purdue employees told Richard Sackler they were worried. Richard responded with his thematic message to the staff: *Time*'s coverage of people who lost their lives to OxyContin was not

Magazine (Oct. 16, 2017).

"balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain—who far outnumber the drug addicts abusing our product."

- 246. In the spring of 2001, Purdue executives met with the U.S. Drug Enforcement Agency ("DEA"). A senior DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table and told Richard: "People are dying. Do you understand that?"⁵⁴
- 247. Meanwhile, Purdue kept pushing opioids and people kept dying. Soon, the company was engulfed in a wave of investigations by state attorneys general, the DEA, and the U.S. Department of Justice. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents. But those resignations were superficial. The Sacklers remained in control of the company. They still owned Purdue. They still controlled the Board. They still paid themselves the profits. And they continued to direct Purdue's deceptive marketing campaign.
- 248. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids.⁵⁵ In May 2007, The Purdue Frederick Company confessed to a felony and effectively went out of business.⁵⁶ However, the Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.
- 249. The Sacklers voted to admit in an Agreed Statement Of Facts that, for more than six years, supervisors and employees *intentionally* used to deceive doctors about OxyContin:

⁵⁶ Purdue Pharma LP Board minutes (May 3, 2007).

⁵⁴ Pain Killer: A "Wonder" Drug's Trail of Addiction and Death by Barry Meier, pg. 158 (2003) (describing 2001 meeting).

⁵⁵ Purdue Pharma LP Board minutes (Oct. 25, 2006); U.S. Department of Justice, Statement of U.S. Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executes for Illegally Misbranding OxyContin (Oct. 25, 2006), https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

"Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." ⁵⁷

- 250. Straight to the point, the Sacklers entered into a plea agreement that stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty." Those intentional violations of the law happened while Richard Sackler was President; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board. Their fingerprints were everywhere. They were officially a billionaire crime family.
- 251. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. As part of the agreement, the family promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.⁵⁹
- 252. Finally, the Sacklers voted to enter into a Consent Judgment in this Court ("2007 Judgment"). The 2007 Judgment ordered that Purdue "shall not make any written or oral claim

⁵⁷ To remove any doubt, the Sacklers voted to enter into a plea agreement that stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty." Those intentional violations of the law happened while Richard Sackler was CEO; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board. 2007 Agreed Statement of Facts, on file with the Department of Justice at https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf
⁵⁸ 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

³⁸ 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

⁵⁹ 2007-05-09 Plea Agreement. https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf

that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide balance regarding risks and benefits in all promotion of OxyContin. That judgment required balance in presentation of the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.⁶⁰

253. The 2007 Judgment also required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

"Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." ⁶¹

254. The 2007 Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to break the law again and again, expanding their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

4. The Sacklers Continue Their Misconduct From The 2007 Judgment Until Today

255. From the 2007 Judgment to 2018, the Sackler family controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives to visit doctors thousands more times than they otherwise could. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied and adopted unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the

⁶⁰ 2007-05-15 Consent Judgment, *Commonwealth v. Purdue Pharma L.P. et al.*, No. 07-1967(B), Mass. Super. Ct.

⁶¹ *Id*.

authorities. None of this was accidental. The family was well informed: They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and supervise representatives face-to-face.

256. The Sacklers' micromanagement was so intrusive that staff sought relief. The VP of Sales and Marketing wrote to Purdue's CEO:

"Anything you can do to reduce the direct contact of Richard into the organization is appreciated."

- 257. The Sacklers' iron rule impacted everyone in the company from the top down. When they berated sales managers, the managers turned around and passed angry messages to the sales representatives in the field. When Richard complained to sales managers, sales manager threatened their sales representatives with termination.
- 258. In July 2007, staff informed the Sacklers that more than 5,000 cases of "adverse events" had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 "Reports of Concern" about abuse and diversion of Purdue opioids during Q2 2007. Shockingly, staff reported to the Sacklers that they completed only 21 field inquiries in response to these reports. Staff also told the Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.
- 259. Purdue's intentional failure to report abuse and diversion continued unabated, even though the 2007 Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales representatives to stop visiting them, the Sacklers, like any ambitious drug dealer, chose to keep pushing opioids to whoever prescribed the most.
- 260. The Sacklers were further aware that Purdue staff members continued to mail out thousands of deceptive marketing materials, including 12,528 publications in the first half

1159968.7/81650.01001

of 2007. The single most-distributed material was volume #1 of Purdue's "Focused and Customized Education Topic Selections in Pain Management" (FACETS). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life." In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Staff told the Sacklers that another of the publications they had sent most often to doctors was "Complexities in Caring for People in Pain." In it, Purdue repeated again its false claim that warning signs of addiction are really "pseudoaddiction" that should be treated with more opioids.

- 261. At the same time, staff also reported to the Sacklers that Purdue was making more money than expected. A few months earlier, they had projected a profit of \$407,000,000; now they expected more than \$600,000,000. The Sacklers were assured that "sales effort" was a key reason that profits were high. Staff told the Sacklers that Purdue employed 301 sales representatives to promote opioids and that sales representatives were the largest group of Purdue employees by far. In comparison, Purdue employed only 34 people in drug discovery.
- 262. As a result of Purdue's overwhelming number of sales representatives—which varied from a low of 300 reps in mid-2007 to a peak of over 700 reps in 2015—the impact of Purdue on Arizona and Prescott was significant and direct—from the 2007 felony conviction to 2018, Purdue sales representatives visited Plaintiff's local prescribers at least once a month.
- 263. In August of 2007, Howard Udell was still serving as Purdue's top lawyer, even after his 2007 criminal conviction for assisting Purdue in misleading doctors and patients by claiming that OxyContin was less prone to abuse than similar drugs. He wrote to Richard, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler: "Over the last week there have been numerous news stories across the nation reporting on the Associated Press's analysis of DEA data showing very large increases in the use of opioids analgesics (particularly OxyContin)

⁶² Purdue Pharma LP Board Report, p. 46 (July 15, 2007).

- 264. In October, staff told the Sacklers that Purdue received 284 Reports of Concern about abuse and diversion of Purdue's opioids in Q3 2007, and they conducted only 46 field inquiries in response. Staff reported to the Sacklers that they received 39 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.
- 265. The Sacklers had also been informed by Purdue staff that Purdue had hired more sales representatives and was succeeding at promoting its highest doses of opioids: "OxyContin 80mg is at Rx levels not seen in over 2 years."
- 266. In preparation for an upcoming Board meeting in late 2007, Richard Sackler instructed staff to give him the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin—its most powerful, most profitable, and most dangerous pill.
- 267. In January 2008, the Sacklers again heard that Purdue still employed 304 sales representatives and they were succeeding at the goal of promoting higher doses of opioids: "OxyContin 80mg continues to grow." Staff told the Sacklers that, in 2007, Purdue's net sales were just over \$1 billion, almost double what the company had projected. OxyContin accounted for more than 90% of those sales.
- 268. The Sacklers were informed by Purdue staff that Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, and they conducted only 21 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities. The Sacklers did nothing to comply with their obligations.
- 269. Instead of being alarmed at these staff reports and complying with their legal obligations, the Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter "Sales VP"),

seeking information about Purdue's opioid savings cards. He asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings card scheme. Richard sent Gasdia a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.

- 270. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they couldn't get up to 4 bottles or more. Such micromanagement was the *modus operandi* of Purdue, as the Sacklers made it a point to become personally involved in various decision-making process of the company, ranging from selling opioids door-to-door and arranging inperson visits to doctor's offices and hospitals, to pressuring Purdue's sales forces to increase orders—whatever the cost.
- 271. The Sacklers also ensured that their top-performing sales representatives were rewarded. For example, top sales representatives were rewarded with bonuses and lavish, all-expense-paid vacations to tropical islands, hoping all the while that Purdue's relatively less productive sales representatives would hone in on the perks of increasing their sales, and ignore the clear risks of pushing higher doses of Purdue's opioids on vulnerable patients.
- 272. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue's patent monopoly. The Sacklers learned that another company was planning clinical research to test whether crush-proof opioids are safer for patients. Mortimer Sackler suggested that Purdue conduct similar studies to find out whether reformulated OxyContin was really safer *before* selling it to millions of patients. He wrote to Richard Sackler: "Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up ...? Shouldn't we have studies like this ...?" The Sacklers decided not to do the research because they wanted the profits from a new product, regardless of whether the deaths continued. Richard didn't want a paper trail, so he instructed Mortimer to call him, and CEO John Stewart met with his staff to plan how to

phrase a carefully worded reply. Later that month, Stewart wrote to Richard that reformulating OxyContin "will not stop patients from the simple act of taking too many pills."

273. The Sackler family, including Jonathan, Kathe, Mortimer and Richard Sackler received projections indicating that OxyContin sales could plateau. Mortimer demanded explanations for why sales would not grow. Richard, too, wanted answers immediately. Staff emailed among themselves about how the Sacklers' demands were unrealistic and harmful and then decided it was safer to discuss the problem by phone.

OxyContin. He directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. Staff delivered the data early one Sunday morning; Richard responded with detailed instructions for new data that he wanted that same day. An employee sent Richard the additional data only a few hours later and pleaded with Richard: "I have done as much as I can." The employee explained that he needed to attend to family visiting from out of town. Richard responded by calling him at home, insisting that the sales forecast was too low, and threatening that he would have the Board reject it. On

18 19

20

21

22

23

24

25

26

27

28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

⁶³ Five years later, Purdue published two studies about the crush-proof formulation. Neither concluded the crush-proof tablets lowered the risks of addiction, overdose and death associated with OxyContin use. One was a single-session research study conducted by three full-time Purdue employees and a paid Purdue consultant to assess "the attractiveness" of the crush-proof tablets to recreational drug users. Thirty recreational opioid users were interviewed by two researchers. "This study did not include safety, pharmacokinetic, or efficacy evaluations, and no drugs were administered." Participants' answers to "open-ended questions" indicated that the crush-proof tablets "might be less attractive to recreational opioid abusers" than original OxyContin. The study concluded that "among the available opioid products that we included in this study, recreational opioid users judged [crush-proof OxyContin tablets] to be the least attractive, the least valuable and the least desirable, with the least likelihood for tampering and the lowest street value." In the second study, by the same Purdue authors, volunteers snorted OxyContin (original and crush-proof), oxycodone, and a placebo over a seven-day treatment phase and rated the drugs. The study concluded that "reformulated OxyContin has a reduced abuse potential compared to the original formulation upon intranasal

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Monday, staff emailed among themselves to prepare for meeting with Richard, highlighting that Richard was looking for results that could only be achieved by hiring more sales reps. Meanwhile, Richard met with John Stewart to discuss his analysis of the weekend's data and new graphs Richard had made.

In response to clear indications that Purdue's VP of Sales, Russell Gasdia, had doubts about the company's increasingly aggressive sales tactics, Richard Sackler immediately ramped up the pressure, both pushing staff to sell more of the highest doses of opioids and get more pills in each prescription, as well as sending Gasdia another set of instructions, directing him to identify tactics for "exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)."64 Gasdia quickly bent to Richard Sackler's will and, the very next day, started writing up plans for how adding sales reps, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

276. True to form, and at the same time, Jonathan, Kathe, and Mortimer Sackler were pushing staff about sales. Staff told these Sacklers that they would use opioid savings cards to meet the challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, "in spite of all the pressures." Kathe demanded that staff identify the "pressures" and provide "quantification of their negative impact on projected sales."

277. In April of 2008, staff told the Sacklers that Purdue employed 304 sales representatives and that the representatives had obtained data showing which pharmacies stocked higher strengths of OxyContin, which helped them convince area doctors to prescribe the highest doses. At that time, the Sacklers learned that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and they had conducted only 17 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the

administration." Purdue amended its OxyContin label to reference these studies in 2013. ⁶⁴ 2008-03-08 email from Richard Sackler,

authorities.

278. On April 18, 2008, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a memorandum about how to keep money flowing to their family. Richard wrote that Purdue's business posed a "dangerous concentration of risk." Ever concerned about their own bottom line above all else, and in light of the criminal investigations that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard recommended John Stewart for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.

- 279. When the Sacklers directed Purdue to pay their family, they knew and intended that they were paying themselves from opioid sales in Arizona. Purdue and the Sacklers tracked revenue and staff reported to the Sacklers that prescriptions of Purdue's highest doses provided seven-figure revenues per year and represented a significant percentage of Purdue's overall revenues from high-dose opioids.
- 280. Richard Sackler also sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times. Richard Sackler specifically wanted to know how many Purdue patients had insurance that would let them take unlimited quantities of Purdue opioids; how many patients were limited to 60 tablets per month; and how many patients had any limit on the number of tablets or dose or number of tablets per day.
- 281. In May of 2008, the Sacklers received more ideas from Purdue staff about ways to promote Purdue's opioids. One strategy that particularly pleased the Sacklers was to deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted. "KEY MESSAGES THAT WORK" included this dangerous lie: "It's not addiction, it's abuse. It's about personal responsibility."
 - 282. Meanwhile, Richard Sackler asked sales staff for more information about

1159968.7/81650.01001 91

Purdue's opioid savings cards. Staff reported to Richard, Jonathan, Kathe, and Mortimer Sackler that 67,951 patients had used Purdue's opioid savings cards, and that the cards provided a discount on a patient's first five prescriptions.

- 283. Predictably, after five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. Staff told Richard, Jonathan, Kathe, and Mortimer Sackler that 27% of patients (more than 18,000 people) had used the cards for all five prescriptions.
- 284. In July, Purdue's Fleet Department reported to the Sacklers that Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. Staff also told the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.
- 285. Staff also told the Sacklers that they promoted Purdue opioids in various presentations, which echoed the company's messaging from presentations such as "The Assessment and Management of Chronic Pain with an Emphasis on the Appropriate Use of Opioid Analgesics" and "The Role of Urine Drug and other Biofluid Assays in Pain Management." Through these presentations, the Sacklers intentionally ensured that a dangerous (and false) message would be disseminated to Arizona doctors and elsewhere—i.e., Purdue opioids were the best way to manage chronic pain and that urine tests protected patients from addiction were both part of Purdue's unfair and deceptive scheme.
- 286. In October of 2008, staff told the Sacklers that surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." Staff told the Sacklers that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin." On the same day, staff told the Sacklers that Purdue had begun a new "Toppers Club sales contest" for sales reps to win bonuses, based on how much a rep increased OxyContin use in her territory and how much the rep increased the broader prescribing of opioids—the same

"availability of product" and "prescribing practices" factors that worsen the risk of diversion and abuse. In the same report, staff told the Sacklers that they received 163 tips to Purdue's compliance hotline during Q3 2008, but did not report any of them to the authorities.

287. To the contrary, the Sacklers' decided to expand Purdue's sales forces, which effectively increased both the number of in-person visits to Arizona prescribers, as well as the disastrous consequences that would follow.

288. In 2009, Kathe Sackler instructed staff to report on Purdue's grants and donations, including in Arizona. The Sacklers were also tracking the ever-increasing size of Purdue's sales forces, as well as the dramatic success they were having in promoting Purdue's high-dose opioids. Staff reported to the Sacklers that "for the first time since January 2008, OxyContin 80mg strength tablets exceeded the 40mg strength." In connection with those reports, the Sacklers had a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales representatives the company should employ, and how many prescribers each representative would visit each year. The Sacklers told sales executives to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website *Partners Against Pain*.

289. Further, staff informed the Sacklers that they received 122 tips to Purdue's compliance hotline during the first quarter of 2009, one of which was from an outside monitor. Staff explained to the Sacklers that the compliance problems included improper use of OxyContin marketing materials and opioid savings cards.⁶⁸

290. In addition to disregarding non-compliance, the Saclkers further instructed Purdue management to disregard supervision requirements under federal law mandating that—in order to mitigate the high risk of misconduct by sales representatives—Purdue

⁶⁵ Purdue Pharma LP Board Report, p. 5, 28 (Apr. 16, 2009).

 $^{25 \}parallel ^{66} 2009-04-21$ email from Russell Gasdia.

^{67 2009-04-30} email from Russell Gasdia.

⁶⁸ 2009-04-16 Board report, p. 24-25.

managers needed to supervise sales representatives in-person at least five days each year.⁶⁹

291. In June, Richard Sackler asked sales staff how a competing drug company had increased sales: "What is happening???" Staff replied that it was all about sales representatives:

"They have 500 reps actively promoting to top decile MDs ... Their messaging is 'we are not OxyContin,' alluding to not having the 'baggage' that comes with OxyContin.

Interestingly, their share is highest with MDs we have not called on due to our downsizing and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%."⁷¹

292. A few days later, seemingly in response to this threat to market share, staff reported to the Sacklers that Purdue had expanded its sales force at the Board's direction: "As approved in the 2009 Budget, 50 New Sales Territories have been created." Staff told the Sacklers the expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales reps.⁷²

293. In July, staff told the Sacklers that Purdue employed 429 sales reps.⁷³ Richard Sackler was not satisfied with that number, and demanded that the Board modify its agenda to discuss a plan to "boost" them.⁷⁴

294. In August, Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." Richard Sackler emphasized that \$200,000,000 in profit was at stake.⁷⁵ At the meeting, staff told the Sacklers that the 80mg OxyContin pill was far-and-

1159968.7/81650.01001 94

⁶⁹ Purdue Corporate Integrity Agreement section III.K.

 $^{1^{70}}$ 2009-06-12 email from Richard Sackler.

⁷¹ 2009-06-13 email from Russell Gasdia.

^{| 72 2009-06-16} email from Pamela Taylor; 2009-05-20 Executive Committee notes.

⁷³ 2009-07-30 Board report, pg. 19.

⁷⁴ 2009-07-20 email from Richard Sackler, PPLPC012000232016.

⁷⁵ 2009-08-12 email from Richard Sackler, PPLPC012000234970-971; *see also* 2009-08-10 email from John Stewart, PPLPC012000234801 ("Richard has asked me about this at

295. Staff also reported to the Sacklers about their newest OxyContin sales campaign, with the slogan: *Options*.⁷⁷ The *Options* campaign exemplifies the strategy that Purdue would follow for years to come—pushing doctors and patients up the ladder to higher doses. To make it easy for sales reps to promote higher doses, the campaign materials emphasized the "range of tablet strengths," provided a picture of each dose, and said: "You can adjust your patient's dose every 1 to 2 days." Staff told the Sacklers that they would advertise the *Options* campaign in medical journals reaching 245,000 doctors.⁷⁸

296. Staff also reported to the Sacklers that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before.⁷⁹ Staff also told the Sacklers that they would advertise OxyContin using a special television network and that thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.⁸⁰

297. As set forth throughout this complaint, the Sackler Defendants paved the way for the opioid epidemic in Prescott by organizing and ensuring the execution of an intentional, underhanded strategy to combine strong-arm sales tactics with misrepresentation about the benefits and risks of Purdue's opioids, and to debase and defame Purdue's victims. The Sacklers accomplished their goal through not only their individual and combined actions, but also through the actions of their executive-agents, including Peter Boer, Judith Lewent, Cecil Pickett, Paulo Costa, Ralph Snyderman, John Stewart, Russel Gasdia, Mark Timney and Craig

 $\frac{1}{3}$ least 5 times over the past few weeks").

1159968.7/81650.01001

⁷⁶ 2009-08-19 Board slides, slide 7.

^{77 2009-08-12} email from Russell Gasdia.

⁷⁸ 2009-08-19 Board slides, slides 12, 16; see also Options marketing materials.

⁷⁹ 2009-08-19 Board slides, slide 12.

⁸⁰ 2009-08-19 Board slides, slide 19; *see also* 2009-04-27 email from Lindsay Wolf (showing that Purdue spent approximately \$100 for each doctor who watched the advertisement, but it made the money back when the doctors prescribed Purdue's opioids).

Landau. And they did so while making themselves extraordinarily wealthy. Ultimately, a single family, the Sacklers, drove much of the opioid epidemic, at the expense of Prescott, Arizona, as well as the entire nation.

J. Distributor Defendants' Violation of Duty

298. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

299. Specifically, under A.R.S. § 36-2523(A), all "[p]ersons registered to manufacture, distribute or dispense controlled substances"—*i.e.*, "Registrants"—are obligated to design and operate a system to disclose to the registrant suspicious orders of controlled substances, especially opioids. Each of the Distributor Defendants is a registrant for purposes of this section and, therefore, must satisfy certain reporting requirements of any and all "suspicious orders." Orders of controlled substances that are either unusual in size or frequency, or otherwise substantially deviate from a normal pattern, qualify as "suspicious orders."

K. Distributor Defendants Knew or should have Known they were Facilitating Widespread Opioid Diversion

300. Opioid diversion in the supply chain has always been a widespread problem and has been highly publicized. Numerous publications, studies, federal agencies, Arizona agencies, and professional health organizations have highlighted the epidemic rate of opioid abuse and overdose rates in Prescott, as well as throughout the United States.

301. Prescription drug abuse is the fastest-growing drug problem in the United States, particularly in Arizona. In 2010-2011, 4/76%-6.37% of Arizonians engaged in non-medical use of pain relievers.

27 // 28 //

Average Past Year Prevalence of Non-Medical Use

of Pain Relievers, 2010-2011

303. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA)). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA pointed out "red flags" distributors should look for in order to identify potential diversion. This initiative was created to help distributors understand their duties with respect to diversion control.

304. Since 2007, the DEA has hosted at least five conferences to provide registrants

with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including McKesson, AmerisourceBergen, and Cardinal Health attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies and procedures.

305. Since 2008, the DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances. (HDMA, "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," (2008).

306. On September 27, 2006 and again on December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded registrants that they were required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. These letters explained that as part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling.

307. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The December 2007 letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious

order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

- 308. The Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing controlled substances.
- 309. Opioid distributors themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.
- 310. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."
- 311. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."
- 312. These assurances, in addition to obligations imposed by law, show that Distributor Defendants understand and have undertaken a duty to protect the public against diversion from their supply chains, and to curb the opioid epidemic.
- 313. However, despite these statements and duties, Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered by state and federal agencies, including actions by the DEA.
- 314. In 2008, Cardinal Health paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion

between 2009 and 2012 in multiple states. Even very recently, in December 2016, a Department of Justice press release announced that, in connection with CSA violations, the United States reached a \$34 million settlement for civil penalties under the CSA. During the investigation of Cardinal, the DEA discovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal took no action and failed to notify the DEA or cut off the supply of drugs to the pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased to almost 2 million doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

- 315. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. After 2008, McKesson still failed adhere to its duties and it was discovered that in Colorado, from 2008 to 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from only a single consumer. Early this year in 2017, it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.
- 316. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against the diversion of particular controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."
 - 317. Although these Distributor Defendants have been penalized by law enforcement

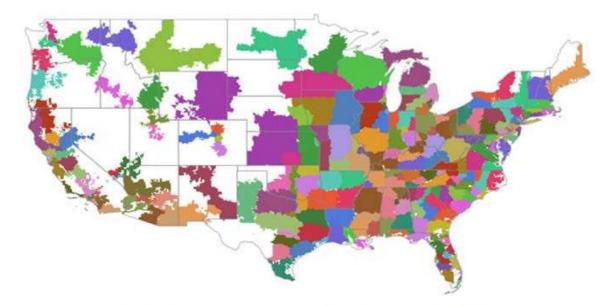
1159968.7/81650.01001 100

authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry which generates billions of dollars in revenue.

L. Local Prescriber Defendants Facilitated Widespread Opioid Diversion

Defendants' Sales Representatives Were Required to Visit Local Prescribers

318. The Manufacturer Defendants worked hand-in-hand with local prescribers in Prescott to establish the supply and demand of opioids that Defendants needed to meet their respective sales projections. As Defendant Purdue's internal board documents reveal, the Defendant Manufacturers impacted every state in the nation, particularly rural areas like Yavapai County and Prescott.



Purdue internal map of planned sales rep territories for 2018

319. Despite the fact that Defendant Purdue and three of its former executives pleaded guilty in 2007 to criminal charges that they misled regulators, doctors and patients about OxyContin's risk of addiction and potential for abuse⁸¹, Defendant Purdue continued to leverage and instruct its army of sales representatives to visit, persuade and deceive Plaintiff's local prescribers, just as Defendant had done in the past.

1159968.7/81650.01001 101

⁸¹ B. Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, The New York Times (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

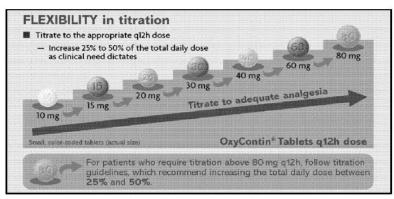
AGO graphic based on Purdue's internal Board documents

320. For example, over the arc of the opioid crisis, Defendant Purdue's sales representatives visited several prescribers either located or treating patients in Prescott and peddled various falsehoods about the risks and benefits of Defendants' opioids. Seeking to distance their products from traditional stigmas against morphine and other dangerously addictive opiates, the Defendant Manufacturers, including Defendant Purdue, as well as the Individual Defendants maintained those risks and benefits could be managed through various strategies, such as individualizing opioid doses and titration.

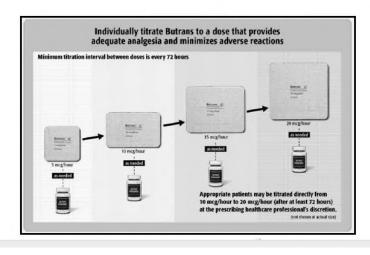
\$57 million ph/lower/sqles/is attributed to lower demand

- \$21 million due to lower number of tabs per script than assumed in budget;
- \$11 million due to lower overall script volume than budgeted
- \$25 million due to higher strengths scripts declining more rapidly than lower strength scripts.

Stewart's notes on a slide identifying the problem of lower sales in higher doses



Purdue opioid promotion from 2008



- 321. Despite knowing that the risks and benefits of opioid addiction could not be adequately managed through individualized doses, titration and other strategies, the Individual Defendants nevertheless ordered their sales representatives to visit prescribers located in Prescott—at least once per month—and convince these prescribers that such strategies would, in fact, be successful in managing the risk of opioid addiction.
- 322. Purdue's internal Board documents also show these representatives were required to make similar visits thousands of times.

23 |

24 || / /

25 //

26 || / / .

27 || / /

28 || /

1159968.7/81650.01001

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

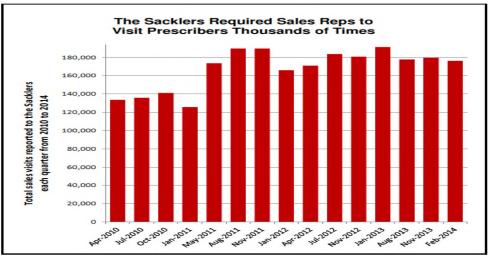
24

25

26

27

28



AGO graphic based on Purdue's internal Board documents

323. Moreover, Internal e-mails between Purdue's executives further demonstrate both the aggressiveness with which Purdue's owners (including Dr. Richard Sackler) directed the company's sales force to manipulate local prescribers through frequent visits, as well as the company's dedication to protecting its owners from criminal and civil liability.

To: Gasdia, Russell[Russell.Gasdia@pharma.com] From: Weinstein, Bert Thur 6/16/2011 7:47:14 PM Sent: Re: Feedback from District Manager Advisory Council - FYI LOL - I told him you raised concerns with me. We agreed Richard needs to be mum and be anonymous From: Gasdia, Russell To: Weinstein, Bert Sent: Thu Jun 16 17:08:15 2011 Subject: Fw: Feedback from District Manager Advisory Council - FYI spoke to John and he said Stuart cleared Dr Richard observing calls with reps. I told him I spoke with you and you have concerns...he said he'd speak with you From: Sackler, Dr Richard To: Gasdia, Russell Cc: JHS (US) Sent: Thu Jun 16 16:45:56 2011 Subject: Re: Feedback from District Manager Advisory Council - FYI One more thing. Who have you chosen for me to go to the field with the week after the budget meetings? Where are they? Can we conveniently do two reps each day especially if I travel to get to the right place as I probably should do.

Purdue internal emails

324. The Individual Defendants' scheme to flood Prescott with opioids was made all the more successful by corrupt, local prescribers who were willing to prescribe opioids to Plaintiff's residents in return for kickbacks and other forms of monetary gain. Dr. Douglas J.

1159968.7/81650.01001 104

Campbell, M.D., for example, facilitated Defendants' scheme by diverting massive amounts of opioids into Prescott during the peak years of the opioid crisis (2009-2012). Indeed, Dr. Campbell prescribed to just one of his Prescott patients 3,200 oxycodone doses/tablets and 1,080 doses/tablets of hydromorphone—per month. Dr. Campbell prescribed these opioids to this patient with full knowledge that the human body cannot process this much medication and, eventually, would begin failing internally as a result of chronic overdose. On or about October 29, 2012, that patient was found dead in his home at the age of 52. The Manufacturer Defendants continued to target Dr. Campbell and enable his dangerous prescribing practices, despite Dr. Campbell's manifest disregard for the concept of medical necessity and the safety of his patients. Indeed, it was Dr. Campbell's common practice to execute opioid contracts with patients that, among other things, allowed Dr. Campbell to stop seeing patients who refused his instructions to take the full, massive dosages of the opioids that Dr. Campbell prescribed, even for patients who Dr. Campbell knew were addicted to opioids.

massive amounts of opioids into Prescott during the peak years of the opioid crisis (2009-2012). For example, Dr. Campbell prescribed to just one of his Prescott patients 3,200 oxycodone doses/tablets and 1,080 doses/tablets of hydromorphone—per month. Dr. Campbell prescribed these opioids to this patient with full knowledge that the human body cannot process this much medication and, eventually, would begin failing internally as a result of chronic overdose. On or about October 29, 2012, that patient was found dead in his home at the age of 52. The Manufacturer Defendants continued to target Dr. Campbell and enable his dangerous prescribing practices, despite Dr. Campbell's manifest disregard for the concept of medical necessity and the safety of his patients. Indeed, it was Dr. Campbell's common practice to execute opioid contracts with patients that, among other things, allowed Dr. Campbell to stop seeing patients who refused his instructions to take the full, massive dosages of the opioids that Dr. Campbell prescribed, even for patients who Dr. Campbell knew were addicted to opioids.

326. Another prescriber who operated in Prescott and helped facilitate the

suspicion of prescription drug fraud and sentenced to over 13 years in prison in June of 2013. Prior to his arrest, Dr. Spicer operated his own medical practice. Dr. Spicer's fraudulent prescribing practices occurred concurrently with the rise, peak and fall of the opioid crisis in Prescott, and included the illegal prescription and sale of Defendants' opioids. In 2012, detectives with the Partners Against Narcotics Trafficking ("PANT") received information regarding Dr. Spicer's prescribing practices that eventually led to his arrest. After Dr. Spicer was granted bail in connection with that arrest, an undercover detective with the Prescription Pill Task Force arranged to visit Dr. Spicer, claiming to be interested in (illegally) purchasing narcotics from him. Despite the clear risk of having his bail revoked, Dr. Spicer agreed to prescribe and sell to the undercover detective a large amount of narcotics. Dr. Spicer's bail was then revoked, after which he both pled guilty to Conspiracy to Commit Transportation of a Dangerous Drug and was sentenced by the Yavapai County Superior Court to 13.5 years in the Arizona Department of Corrections, where he remains today.

Manufacturer Defendants scheme was Dr. Randy Joe Spicer, NMD, who was arrested on

M. Each of the Defendant's Misconduct Has Injured and Continues to Injure the City of Prescott and Its Citizens

327. Defendants' predatory and willful misrepresentations in manufacturing, marketing and/or distributing opioids have imposed enormous tax-based economic damages on Plaintiff. By falsely reassuring the medical community that patients would not become addicted to Defendants' prescription opioid pain relievers, Defendants intentionally ushered in an era of opioid overprescribing and misuse. As a direct and proximate result of the public nuisance that Defendants created, Plaintiff has suffered damages in the form of increased tax expenditures as well as tax revenue forgone.

328. As the number of addicted persons in Plaintiff's city has grown over the course of the opioid epidemic, so too has the demand for both specialty treatment, hospital and emergency services, as well as additional public safety services from the Prescott Police Department and Prescott Fire Department. To meet this demand, Plaintiff has allocated and continues to allocate increasingly large portions of its tax revenues to protect the health and

1159968.7/81650.01001 106

safety of its citizens against the public nuisance that Defendants created. These revenues would not have been expended but for the opioid crisis that Defendants' willfully and foreseeably caused in Arizona generally and Prescott specifically

329. Moreover, as Defendants' opioids continue to wreak havoc on Plaintiff's community and incapacitate and/or kill Plaintiff's citizens, Plaintiff has also been deprived of the benefits these citizens would have conferred to Plaintiff's community but for Defendants' wrongful conduct. Plaintiff has lost both the productivity of Plaintiff's citizens who have been hospitalized, incarcerated, killed or otherwise incapacitated by Defendants' opioids, including the property and/or sales taxes these citizens would have paid had Defendants' simply told the truth about the risks and benefits of their opioids.

1. Tax Revenue Expended—Healthcare-Related Costs

330. Drugs kill more Arizonans each year than motor vehicle accidents. ⁸² According to the CDC, the number of drug-related deaths in Arizona is among the highest in the nation and continues to increase each year. ⁸³ In 2010, for instance, 1,141 persons died in Arizona as a direct consequence of drug use. ⁸⁴ That figure exceeds the number of deaths in Arizona from motor vehicle accidents (792) and firearms (931) in the same year. Moreover, in Arizona, the rate of drug-induced death (17.9 per 100,000 population) likewise exceeds the national rate (12.9 per 100,000 population). ⁸⁵

331. Even within Arizona, the risk of drug-related death is particularly high in Yavapai County, which the Office of National Drug Control Policy ("ONDCP") considers a

1159968.7/81650.01001 107

⁸² Executive Office of the President of the United States, *Arizona Drug Control Update - 2010*, p. 1 (2010), https://obamawhitehouse.archives.gov/sites/default/files/docs/state_profile-arizona.pdf.

⁸³ CDC, National Center for Injury Prevention and Control – Division of Unintentional Injury Prevention, *Drug Overdose Deaths: Number and Age-Adjusted Rates of Drug Overdose Deaths by State* (2017),

https://www.cdc.gov/drugoverdose/data/statedeaths.html.

⁸⁴ Executive of the Office of the President of the United States – *Arizona Drug Control Update*, pg. 1.

⁸⁵ Executive of the Office of the President of the United States – *Arizona Drug Control Update*, pg. 1.

High Intensity Drug Tracking Area ("HIDTA").86

332. While Defendants' reaped billions of dollars in profits from their deceptive conduct, Plaintiff has suffered—and continues to suffer—irreparable damage in the form of increased healthcare-related costs, which Arizona law requires that Plaintiff pay to protect the health and safety of its citizenry. Plaintiff would not have incurred these costs had Defendants' not concealed the dangers (and misrepresented the benefits) of their opioids.

333. Specifically, each of the Defendants has directly and proximately caused Plaintiff to divert precious tax dollars and local resources to address its citizens' everincreasing need for (a) specialty services—*e.g.*, detoxification, residential, inpatient and outpatient methadone programs; (b) hospital and emergency medical services; and (c) foster care services.

(a) Treatment Admissions—Sober Living Homes

334. Following the passage of the 2008 Mental Health Parity and Addiction Equity Act as well as the Affordable Care Act in 2010, substance abuse treatment became an "essential" health benefit, allowing millions of insured lives to access and finance through their respective health insurance plans a wide range of substance abuse treatments, including both traditional (and well-regulated) operations like half-way houses, standard living accommodations and substance abuse treatment facilities, as well as untraditional—and essentially unregulated—facilities like sober living homes. Similar changes were made at the state level in 2010, which entitled persons covered under the Arizona Health Care Cost Containment System ("AHCCCS")—including approximately 50,000 AHCCCS beneficiaries living in Yavapai County to access "medically necessary" substance abuse treatment from

1159968.7/81650.01001 108

⁸⁶ Exec. Office of the Pres. of the U.S., *Arizona Drug Control Update* – 2010, p. 4 (2010), https://obamawhitehouse.archives.gov/sites/default/files/docs/state_profile-arizona.pdf.

⁸⁷ Letter to G. Dodaro fr. E Warren (June 2, 2016), https://www.warren.senate.gov/files/documents/2016-6-

² Letter to GAO on sober living homes.pdf

⁸⁸ See AZAHCCS, AHCCS Population by County (Apr. 2019), https://www.azahcccs.gov/Resources/Downloads/PopulationStatistics/2019/Apr/PopulationbyCountyReport.pdf

sober living homes and opioid treatment from Behavioral Health Out Patient Clinics.⁸⁹

335. These laws, however well intentioned, did not account for the relative dearth in Arizona of licensing and standard of care regulations for sober living homes. At the time, the sober living homes in Prescott fell into a "regulatory gap"—they were neither required to register with the city, nor establish and implement training requirements for house managers and operational plans for discharging patients from rehab.⁹⁰ This regulatory gap made it extraordinarily difficult for Plaintiff to ascertain, *inter alia*, the number of sober living homes in Prescott, the types of recovery services they provided and the standards under which they operated.

336. Before the Arizona legislature authorized Plaintiff to start filling certain aspects of that regulatory gap in 2016, Plaintiff had already been listed by recovery-related news websites as one of "The 10 Best Sober Living Cities" in the nation. Further, with an estimated 2,000 recovering addicts living in approximately 200 sober living homes as of January 2017, Prescott had already expended substantial portions of its tax revenues to address its citizens' concerns that these unlicensed facilities were leading to substantial increases in drug diversion, property crimes, noise and traffic, among other public nuisances. 92

337. While Plaintiff's enforcement activities regarding sober living licensing and standards of care have successfully reduced the number of these facilities to approximately 30

⁸⁹ Medicaid State Plan Amendment, Attachment 3.1-A, p. 9(b)-(9)(j) (effective July 1, 2010),

 $[\]frac{https://archive.azahcccs.gov/archive/Resources/Governmental\%20Oversight/State\%20Plan\%20Amendments/2010/SPA10-009Approval.pdf}{}$

⁹⁰ T. Boyle, *Hundreds of sober living homes in Prescott face new rules*, Arizona Capitol Times (Jan. 3, 2017), https://azcapitoltimes.com/news/2017/01/03/hundreds-of-sober-living-homes-in-prescott-face-new-rules/

⁹¹ M. Wilkerson, *The 10 Best Sober Living Cities*, TheFix.com (May 10, 2012), https://www.thefix.com/content/10-best-sober-living-cities.

⁹² T. Boyle, *Hundreds of sober living homes in Prescott face new rules*, Arizona Capitol Times (Jan. 3, 2017), https://azcapitoltimes.com/news/2017/01/03/hundreds-of-sober-living-homes-in-prescott-face-new-rules/

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

as of early 2017⁹³, Plaintiff has not recovered the substantial expenditures it was required to allocate to protect its citizens from the drug diversion, property crimes, noise, traffic and other aspects of the public nuisance that Defendants willfully introduced and continue to sustain in the City of Prescott.

(b) Medical **Emergency** Treatment—Opioid-Related **Emergencies**

338. The number of opioid-related encounters in Arizona hospitals increased from 20,365 in 2009 to 51,473 in 2016—an increase of roughly 153%. 94 Opioids have a significant impact upon Arizona's medical care system due to the volume of encounters involving opioids, and the costs of these encounters. While the full economic burden of opioids upon the healthcare system is difficult to precisely calculate, a reasonable measure may be derived using hospital reported charges adjusted using national cost to charges ratios provided by the Department of Health and Human Services. Using this approach, the cost of all 'opioidrelated' encounters in Arizona from 2009-2015 increased by 125% and—in 2016—equaled \$341,457.011.95 The average cost per opioid-related unique encounter is \$8,241.96

On information and belief, the incidence of opioid-related hospitalizations in 339. Prescott—which can be tracked by various medical billing and documentation codes, such as the Healthcare Common Procedure Coding System ("HCPCS") and the American Medical Association's Current Procedural Terminology (CPT), including National Drug Codes (NDCs) and International Classification of Diseases ("ICD") codes—similarly increased during the relevant period. On information and belief, the substantial increases to the cost of treating opioid-related conditions have caused at least two general acute hospitals located in

110

1159968.7/81650.01001

14809093

23 24

⁹³ *Id*.

⁹⁴ Arizona Department of Health Services, 2016 Arizona Opioid Report, p. 5-6 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-25 recommendations/prescribing-guidelines/arizona-opioid-report.pdf 26

⁹⁵ Arizona Department of Health Services, 2016 Arizona Opioid Report, p. 5 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelinesrecommendations/prescribing-guidelines/arizona-opioid-report.pdf

- 340. As the number of opioid-related hospital encounters in Prescott has ballooned, the costs of treatment and supplies have also increased by at least 125%. ⁹⁸ This increase has strained—and continues to strain—Plaintiff's General Fund, which provides the Prescott Fire Department with the financial resources it needs to respond appropriately to an increasingly large demand for opioid-related emergency medical services in Prescott. In the past two years alone, for example, Plaintiff has allocated over \$30,000,000 from the General Fund to finance the operation of the Prescott Fire Department, which has experienced increased call volume over the arc of the opioid epidemic in Prescott—7,500 service calls in 2009, 8,500 in 2011 and 8,619 in 2018.⁹⁹
- 341. While the demand for the Prescott Fire Department has increased with the city's general population, the number of fire department full-time equivalent ("FTE") employees has decreased from 131 in 2009 to 83 in 2018. Further, the number of available fire stations and fire engines available to the Prescott Fire Department has remained unchanged for the past five years. Thus, each FTE is now responsible for providing life-saving services to a greater proportion of Plaintiff's citizens. ¹⁰¹
- 342. At the same time, the costs of providing emergency medical services in opioid emergencies have likewise increased, as these patients tend to suffer from serious airway issues that require complex—and expensive—Advanced Life Support ("ALS") services,

1159968.7/81650.01001 111

⁹⁶ *Id.*, *supra*, n. 216 at p. 6.

⁹⁷ City of Prescott, *Comprehensive Annual Financial Report*, p. 9 (June 30, 2018), http://www.prescott-az.gov/wp-content/uploads/2018/11/CAFR-2018-Web.pdf

⁹⁸ Arizona Department of Health Services, *2016 Arizona Opioid Report*, p. 5-6 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf

⁹⁹ City of Prescott, *Comprehensive Annual Financial Report*, p. 134 (June 30, 2018), http://www.prescott-az.gov/wp-content/uploads/2018/11/CAFR-2018-Web.pdf

 $^{|| 100 \,} Id.$

¹⁰¹ *Id*.

including multiple doses of naloxone titrated specifically to the treatment needs of each patient. Generally, the Prescott Fire Department's paramedics (which respond to opioid emergencies in three-person crews), begin furnishing ALS services from the moment they arrive on scene and continue providing them until the patient's care can be transferred to a clinician at the receiving health facility. This process can take hours, particularly where the receiving facility is, itself, overwhelmed, requiring Prescott Fire Department employees to work overtime in order to protect the people of Prescott.

(c) Foster Care Placement

343. Defendants' actions that fueled the opioid crisis have also devastated many American families, and the child welfare system has felt the effects. Between 2010 and 2012, after more than a decade of sustained declines in the national foster care caseload, the number of children entering foster care started to rise—just as opioid deaths began to spike. Today, more than 258,000 children are in the foster care system nationwide, nearly 18,000 of which are right here in Arizona. Arizona.

344. Arizona's foster-care system is designed to protect children from abuse and neglect, removing children from their homes if they face an "unreasonable risk of harm." ¹⁰⁵ The Arizona Department of Child Safety ("ADCS") defines "unreasonable risk of harm" to

1159968.7/81650.01001 112

¹⁰² Arizona Department of Health Services, *Opioid Statistics*, p. 5 (2016), https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/opioid-stats.pdf

¹⁰³ Laura Radel, Substance Use, the Opioid Epidemic, and the Child Welfare System: Key Findings from a Mixed Methods Study, U.S. Dept. of Health and Human Services, p. 2 (Mar. 7, 2018),

 $[\]underline{https://aspe.hhs.gov/system/files/pdf/258836/SubstanceUseChildWelfareOverview.pdf}$

¹⁰⁴ Mary Jo Pitzl, 'Biggest challenge, biggest opportunity': DCS aims to keep more kids at home, THE ARIZONA REPUBLIC (Feb. 4, 2018),

https://www.azcentral.com/story/news/local/arizona-investigations/2018/02/04/child-welfare-agency-policy-aims-clearly-define-when-safe-leave-kids-home/881208001/

Bob Ortega, *A Horrifying Journey through Arizona foster care, and why we don't know how many more children may be abused*, THE ARIZONA REPUBLIC (June 4, 2017), https://www.azcentral.com/story/news/local/arizona-investigations/2017/06/04/arizona-foster-care-child-abuse/362836001/

mean that "the totality of the circumstances specific to the incident, the behavior and/or action or inaction of the parent, guardian or custodian placed the child at a level of risk of harm to which a reasonable (ordinarily cautious) parent, guardian or custodian would not have subjected the child." ADCS has characterized the increase in opioid-related cases in emergency departments as "alarming," and the Arizona Substance Abuse Partnership ("ASAP") has likewise recognized the importance of removing a child living in home in which opioid abuse is occurring.

345. The number of Arizona children that are removed from their homes by the state foster care system—*i.e.*, the "Removal Rate"—is about three-times higher than the national average. Moreover, from 2013 to 2016, the Removal Rate increased by roughly 30 percent outside the normal range, even for states hit hardest by the opioid epidemic, and after factoring in Arizona's high childhood poverty rate. As a result, Arizona child welfare agencies and their community partners are struggling to meet families'

¹⁰⁶ Department of Economic Security—Division of Children Youth and Families, *Child and Family Services: Annual Progress Report 2012, State of Arizona*, p. 225 (June, 2012), https://dcs.az.gov/file/5405/download?token=1ZRcWAmV

¹⁰⁷ B. Ortega, Arizona's DCS: Why are kids taken away? Too often the answer is unknown, The Arizona Republic (Mar. 14, 2017),

https://www.azcentral.com/story/news/local/arizona-investigations/2017/01/22/arizona-department-child-safety-why-kids-taken-away-too-often-answer-unknown/96539080/; *see also* L. Radel, *supra*, Note 16 at p. 8 ("Child welfare caseloads nationally increased by 10 percent between fiscal years 2012 and 2016.")

Nicole Carrol, *Arizona child welfare: There are some issues we just won't let go*, THE ARIZONA REPUBLIC (Aug. 28, 2016), https://www.azcentral.com/story/news/local/arizona-investigations/2016/08/28/arizona-child-welfare-there-some-issues-we-just-wont-let-go/89313770/.

¹⁰⁹ E. Birnbaum, *Opioid crisis sending thousands of children into foster care*, THE HILL (June 20, 2018), https://thehill.com/policy/healthcare/393129-opioid-crisis-sending-thousands-of-children-into-foster-care

Emily Bregel, *Despite state progress in Arizona*, 'a lot of desperation, isolation', ARIZONA DAILY STAR (Mar. 9, 2018), https://tucson.com/news/local/despite-state-progress-in-arizona-a-lot-of-desperation-isolation/article_fb7af064-224b-11e8-a96b-fbbdaba17d9c.html

needs, including in Prescott¹¹¹, with many counties experiencing at least a 50% increase in their respective caseloads and local agencies reporting family members across multiple generations are more frequently becoming addicted to, or dying from, opioids.¹¹²

346. Consistent with the above, in March of 2018 the U.S. Department of Health and Human Services ("DHHS") confirmed that "the high levels of opioid sales and drug overdose deaths spreading across the nation in recent years raise the concern that additional counties may experience increased child welfare caseloads in the coming years." DHHS reported that, while drug-related hospitalization rates vary widely between substances such as opioids, stimulants and hallucinogens, the opposite is true with respect to foster care, such that "a 10 percent increase in hospitalizations due to any of these substance types corresponded with approximately a 2 percent increase in foster care entry rates." 114

347. To address the demand for foster care services in Prescott resulting from the opioid epidemic, Plaintiff funds the Prescott Police Department Victim Services Unit ("VSU"), which provides a variety of services including responding to reports of neglect, removing children from unreasonable dangerous homes and providing resource and referral information, community legal services, custodial advice and/or counseling to individuals whose opioid addiction and lack of family support have rendered them unfit to care for their children. ¹¹⁵

2. Tax Revenue Expended—Crime-Related Costs

348. In addition to imposing on Plaintiff significantly higher healthcare-related costs, Defendants' scheme has spread thin Plaintiff's resources by causing a sharp uptick in criminal justice costs, including those associated with opioid-related arrests, investigations and other local police programs. The funds necessary to maintain the day-to-day operating expenses

1159968.7/81650.01001 114

¹¹¹ See L. Radel, supra, Note 16 at p. 1.

 $^{^{112}\,}$ See L. Radel, supra, Note 16 at p. 4.

¹¹³ *See* L. Radel, *supra*, Note 16 at p. 8-9.

¹¹⁴ See L. Radel, supra, Note 16 at p. 4-5.

Prescott-AZ.gov, *Child Abuse – City of Prescott Police Department Victim Services*, (Apr. 2018), http://www.prescott-az.gov/wp-content/uploads/2018/04/Child-Abuse.pdf

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

and equipment for these programs come from Plaintiff's general revenues, including Plaintiff's revenues from Plaintiff's privilege (sales) taxes and property taxes. 116

349. Because Plaintiff finances the operation of the Prescott Police Department through the city's General Fund, the increased burden on the Prescott Police Department resulting from Defendants' misconduct has likewise damaged Plaintiff. Over the past two years alone, the Prescott Police Department's operating expenditures—which equaled \$41 million—were consistently and significantly higher than any other city department's expenditures during this period.¹¹⁷ Moreover, Plaintiff's police and court expenditures for 2018 exceeded those in 2017 by \$7.1 million, including increased expenditures to fund opioidrelated arrests, investigations, pension contributions and other community services. 118

Arrests and Investigations to Protect Public Health and (a) **Safety**

350. The effects of Defendants' deceptive marketing and distribution scheme has further impacted Plaintiff by creating various public nuisances—including public health and safety hazards—which Plaintiff is obligated to abate. Plaintiff has dedicated substantial tax dollars to maintain the public safety of places, such as city parks, schools and public lands, where patients-turned-addicts attempt to congregate. Plaintiff has also dedicated significant funds to enable the Prescott Police Department to mitigate the increase in drug and property crimes committed by opioid addicts who are both actively looking to feed their addictions, as well as suffering from serious medical conditions associated with the spread opioid abuse, such as Hepatitis B and C, HIV, sexually transmitted diseases and methicillin-resistant staphylococcus aureus ("MRSA"), among other conditions.

351. From 2000 to 2018, there were at least 350 recorded opioid overdose cases in

115

1159968.7/81650.01001

14809093

21

22

23

24

25

26

27

¹¹⁶ City of Prescott, Comprehensive Annual Financial Report, p. 17, 27 (June 30, 2018), http://www.prescott-az.gov/wp-content/uploads/2018/11/CAFR-2018-Web.pdf

¹¹⁷ City of Prescott, Comprehensive Annual Financial Report, p. 9 (June 30, 2018), http://www.prescott-az.gov/wp-content/uploads/2018/05/FY19-Budget-Book Council-Workshop.pdf

¹¹⁸ *Id.*, at p. 18.

Prescott, each of which required the dedicated time of several police officers to perform various tasks, including—but not limited to—investigations, arrests, bookings, report writing, evidence impounding, scene security and follow up time. During the same time period, the Prescott Police Department made over 8,000 arrests for drug-related charges, including for possession and/or sale of opioids and opioid-related paraphernalia.

352. In abating the opioid nuisance to protect the health and safety of citizens of Prescott, Plaintiff has suffered pecuniary damages, proximately caused by Defendants' misrepresentations and omissions of material fact.

(b) Community Services—Police Department Victim Services Unit

353. Plaintiff also dedicates significant portions of its general revenues to enable the Prescott Police Department to protect the health and safety of its citizens, including through the VSU. The VSU can provide services to victims of crime inclusive of intimate partner and domestic violence, sexual assault and child abuse. Prescott also provides victims' advocates, who work closely with the Investigations Section to ensure communication is ongoing, which helps ensure victims are able to navigate the criminal justice system with greater understanding and clarity.¹¹⁹

354. In addition, Plaintiff's victim advocates work with victims of crime helping connect them with community resources for shelter, food, clothing, etc., assisting in navigating the criminal justice system, and ensuring their rights as a victim are being honored. These advocates can act as a liaison between the victim and various agencies involved, not only keeping the victim informed, but giving them a voice. Specific examples of the services provided by the VSU include:

- Information and Community Resource Referrals;
- Assistance with orders of protection and injunctions against harassment;

¹¹⁹ Prescott-AZ.gov, *Victim Assistance*, http://www.prescott-az.gov/services-safety/police/victim-resources.

- Safety planning;
- Emotional support;
- Case updates;
- Court accompaniment for criminal matters; and
- Victim rights information.
- 355. As the utilization of the VSU by Prescott's citizens has increased over the years of the opioid crisis, so too have Plaintiff's allocations to maintain these important public programs and maintain the health and safety of Plaintiff's citizens.

3. Tax Revenue Foregone

- 356. Tax revenue forgone is a consequence of incapacitation. The principal events associated with incapacitation include specialty treatment, hospitalization and death. As a result of such incapacitation, the citizens of Prescott who became addicted to Defendants' opioids are unable to work or contribute to Prescott's financial health through sales, property and other taxes.
- 357. Leading up to and following the peak years of the opioid crisis (2008-2015), Plaintiff's total tax revenue per capita fell each and every year. Over the same period, Plaintiff's general property taxes decreased from roughly \$3.15 million in 2009 to about \$1.6 million in 2015. As set forth below, Defendants' willful, dishonest scheme made it much more difficult—and significantly more expensive—for Plaintiff to ameliorate its tax-related damages associated with the incapacitation of both its citizens and others who either died in Prescott, or were incapacitated in Prescott due to specialty treatment and/or hospital services.

(a) Specialty Treatment

358. Unlike traditional tourists who have historically visited Prescott and contributed to its economy, the opioid addicts from across the country who are flocking to Prescott in search of sober living and other behavioral health services, draw on Plaintiff's public services

¹²⁰ See City of Prescott, Comprehensive Annual Financial Report, p. 131 (June 30, 2018), http://www.prescott-az.gov/wp-content/uploads/2018/11/CAFR-2018-Web.pdf

¹²¹ *Id.*, p. 121.

without contributing to Plaintiff's community. These individuals have become incapacitated by their addictions and, instead of working, struggle to function and resist relapse. But because the managers of sober living facilities in Prescott are often addicts themselves (many of whom actually attended the same rehab program and lived in the same sober-living home they now manage), patients suffering from opioid addiction who flock to Prescott do not find the recovery they seek.

359. The lost tax revenue attributable to these patients is especially significant for Plaintiff, as the vast majority of such patients would—but for their addiction—be productive members of Plaintiff's community. Indeed, according to a 2016 report published by the Arizona Health Care Cost Containment System's Division of Health Care Management, 91.2% of treatment members were adults, with 77.5% of treatment members in their prime working years (25-64).¹²²

360. Despite the fact that Plaintiff has successfully initiated and continues to enforce various licensing and standard of care requirements for sober living homes in Prescott, the opioid epidemic and public nuisance that resulted from Defendants' deceptive strategy continues to frustrate Plaintiff's ability to recover from the crisis. For instance, the percent of patients receiving referrals by hospitals to behavioral health or substance abuse treatment services after an overdose has increased from 45% in June 2017 to a high of 82% in November 2018. 123

(b) Hospitalization

361. Patients who are hospitalized in connection with opioid-related emergencies are likewise unable to contribute to Prescott's financial health with their labor or through the payment of taxes. Indeed, in 2018 the Arizona Department of Public Health reported that 97%

AHCCCS—Division of Health Care Management, Annual Report on Substance Abuse Treatment Programs: State Fiscal Year 2016, p. 1, 3 (Dec. 31, 2016),

https://www.azahcccs.gov/shared/Downloads/Reporting/AHCCCSDrugAbuseTreatmentProgramsReport_36-2023.pdf

¹²³ AZDHS, *Opioid Response Summary: January 1, 2018-December 31, 2018*, p. 7 (2018), https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-

of patients suffering from an opioid-related emergency survived the immediate pre-hospital event. Moreover, according to a 2018 report published by DHHS, opioid-related hospital stays were consistently longer than those attributable to both hallucinogens and stimulants, including cocaine and methamphetamine. Longer hospital stays are usually more expensive and lead to larger losses of productivity for the hospitalized patient.

362. Even if patients survive the immediate pre-hospital event and are successfully stabilized at, and discharged from, the treating hospital, these patients are frequently referred to specialty treatment facilities in Prescott and continue to be incapacitated by their addictions.

(c) Death

363. According to government estimates, some 50,000 Americans died from an opioid overdose in 2016—*i.e.*, 137 people per day, and roughly one person every 12 minutes. The emotional devastation caused by Defendants' despicable actions is impossible to quantify; however, as described above, the purely economic consequences of the opioid epidemic can and have been successfully tracked in terms of lives, lost productivity, healthcare, criminal justice and other costs. Accordingly, in 2017 President Donald Trump's Council of Economic Advisers estimated that the economic consequences to the nation of the opioid drug epidemic cost the United States \$504 billion in 2015 alone, prompting the President to declare the opioid crisis a nationwide public health emergency.

364. Plaintiff has been hit even harder by the opioid crisis. In the past decade, 5,932 Arizonans died from opioid-induced causes, with Yavapai County "ha[ving] the highest number of possible overdoses reported out of all rural counties" from 2017-2018. ¹²⁷ In 2017,

prevention/opioid-prevention/opioid-response-report-2018.pdf

¹²⁴ *Id*.

¹²⁵ See L. Radel, supra, Note 16 at p. 4.

¹²⁶ Money.com, *Here's What I Would Cost to Fix the Opioid Crisis, According to 5 Experts* (Nov. 27, 2017), http://money.com/money/5032445/cost-fix-opioid-crisis/.

¹²⁷ Arizona Department of Health Services, *Arizona Opioid Emergency Response*, p. 2, 22 (2018), https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/2017-opioid-emergency-response-report.pdf

1159968.7/81650.01001

50% of the accidental overdose cases that were completely reviewed by the Yavapai County Overdose Fatality Review Board occurred in Prescott.¹²⁸

365. The opioid crisis has been particularly devastating to Prescott's ability to generate tax revenue, as from 2006 to 2016 more opioid-related deaths occurred in Arizona for people in their economic primes—*i.e.*, ages 45-54—than for any other age group. Plaintiff has suffered—and continues to suffer—from this deleterious trend, as the number of overdose deaths in Prescott has increased from just one death in 2001, to a staggering 51 deaths in 2018.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

PUBLIC NUISANCE

Violations of Arizona Revised Statutes § 13-2917

(Against All Defendants)

- 366. A.R.S. § 13-2917(A)(1) provides that "[i]t is a public nuisance" for anything "[t]o be injurious to health, indecent, offensive to the senses or an obstruction to the free use of property that interferes with the comfortable enjoyment of life or property by an entire community or neighborhood or by a considerable number of persons."
- 367. A.R.S. § 13-2917(A) notes that a public nuisance is "no less a nuisance because the extent of the annoyance or damage inflicted is unequal."
- 368. Prescott brings this action under A.R.S. § 13-2917(C) to abate, enjoin, and prevent the public nuisance created by the Defendants.
 - 369. Each Defendant, acting individually and in concert, has created or assisted in the

Yavapai County Overdose Fatality Review Board, *Accidental Overdose Death Cases Reviewed for 2017* (July 2018), http://matforce.org/Portals/0/OFRB%20Report-%20July%202018.pdf

¹²⁹ Arizona Department of Health Services, 2016 Arizona Opioid Report, p. 2 (2016), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf ("By age, opioid death rates rise beginning in the late teens until they peak at age 45-54."); see also Yavapai County Overdose Fatality Review Board, Accidental Overdose Death Cases Reviewed for 2017 (July 2018), http://matforce.org/Portals/0/OFRB% 20Report-% 20July% 202018.pdf

harm outweighs any offsetting benefit.

371. Defendants knew and should have known that their promotion, distribution, and prescribing of opioids was false and misleading and that their deceptive marketing scheme and

other unlawful, unfair, and fraudulent actions would create or assist in the creation of the

- 372. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used. Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.
- 373. The public nuisance i.e., the opioid epidemic created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated.
- 374. Pursuant to A.R.S. § 13-2917(C), Prescott requests an order providing for abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations A.R.S. § 13-2917.

SECOND CAUSE OF ACTION

NEGLIGENCE

(Against All Defendants)

375. Prescott re-alleges and incorporates by reference each of the allegations

(average age of decedent was 33 years old).

public nuisance – i.e., the opioid epidemic.

1159968.7/81650.01001

contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

- 376. Under Arizona law, a cause of action arises for negligence when a defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury.
- 377. Each Defendant owed a duty of care to Prescott, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.
- 378. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids by mispresenting the risks and benefits associated with opioids and by distributing and prescribing dangerous quantities of opioids.
- 379. As set forth, the Manufacturer Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses without added risk, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to Prescott.
- 380. The Distributor Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.
- 381. The Distributor Defendants negligently distributed enormous quantities of potent opioids and failed to report such distributions. Distributor Defendants violated their duty of care by moving these dangerous products into Prescott in such quantities, facilitating misuse and abuse of opioids.
- 382. The Prescriber Defendants negligently over-prescribed potent opioids to patients. Prescriber Defendants violated their duty of care by overprescribing opioids to vulnerable patients, facilitating misuse and abuse of opioids.
 - 383. Plaintiff is not asserting a cause of action under the federal Controlled

Substances Act or other federal controlled substances laws cited above. '

384. Defendants are guilty of negligence per se in that the Defendants violated applicable Arizona laws, statutes, and regulations, in the manner in which they advertised, marketed, sold, and distributed opioid products. Plaintiff is a member of the class meant to be protected by the laws, statutes, and regulations which Defendants violated, and Plaintiff's injuries were caused by the violations.

385. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Prescott has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

THIRD CAUSE OF ACTION

NEGLIGENCE PER SE

(Against All Defendants)

- 386. Prescott re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 387. Defendants' actions violate Arizona statutes designed to protect the public from harm. In particular, Defendants' actions violate the Uniform Controlled Substances Act, A.R.S. § 36-2501 *et seq.* (the "CSA") and Arizona requirements regarding the dispensing of medication.
- 388. A.R.S. § 36-2523 requires all registrants which includes manufacturers and distributors under the CSA to maintain records in accordance with Arizona's regulations on the dispensing of medication.
- 389. A.R.S. § 36-2524 states that certain controlled substances shall be distributed by a registrant to another registrant only pursuant to an authorized order form.
- 390. A.R.S. § 36-2531(A)(3) prohibits and makes it unlawful for any person to intentionally or knowingly refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under the CSA.
 - 391. A.R.S. § 36-2531(A)(6) prohibits and makes it unlawful for any person to

1159968.7/81650.01001

1

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

intentionally or knowingly sell, buy, exchange or give away any preparation subject to the CSA, unless the preparation is used for a legitimate medical purpose and in compliance with the CSA.

- 392. A.R.S. § 36-2531(C)(1) prohibits and makes it unlawful for any person intentionally or knowingly to distribute as a registrant certain controlled substances, except pursuant to an order form in accordance with the CSA.
- A.R.S. § 36-2531(2) prohibits and makes it unlawful for any person intentionally or knowingly to furnish false or fraudulent material information in, or omit any material information from, any application, report or other document required to be kept or filed under the CSA or any record required to be kept by the CSA.
- 394. A.R.S. § 36-2531(E) states that a person shall not provide a false prescription for a controlled substance or knowingly or intentionally acquire or obtain possession of a controlled substance by means of forgery, fraud, deception or subterfuge, including the forgery or falsification of a prescription or the nondisclosure of a material fact.
- A.R.S. Title 32, Chapter 18 governs the Arizona Board of Pharmacy and statutory requirements for dispensing medication.
- A.R.S. § 32-1964(A) states that "[e] very proprietor, manager or pharmacist in charge of a pharmacy shall keep in the pharmacy a book or file in which that person places the original of every prescription order of drugs, devices or replacement soft contact lenses that compounded or dispensed at the pharmacy. This information shall be serially numbered, dated and filed in the order in which the drugs, devices or replacement soft contact lenses were compounded or dispensed. A prescription order shall be kept for at least seven years. The proprietor, manager or pharmacist shall produce this book or file in court or before any grand jury on lawful order. The book or file of original prescription orders is open for inspection at all times by the prescribing medical practitioner, the board and its agents and officers of the law in performance of their duties."
- A.R.S. § 32-1983(B) provides that, "[a] full service wholesale permittee may furnish prescription-only drugs to a pharmacy or medical practitioner. The full service

wholesale permittee must first verify that person holds a valid license or permit."

398. A.R.S. § 32-1983(C) provides that, "[t]he full service wholesale permittee must deliver prescription-only drugs to an authorized person or agent of that premises if: (1) The full service wholesale permittee properly establishes the person's identity and authority; and (2) Delivery to an authorized person or agent is used only to meet the immediate needs of a particular patient of the authorized person."

- 399. A.R.S. § 32-1983(D) provides that, "[a] full service wholesale permittee may furnish prescription-only drugs to a pharmacy receiving area if a pharmacist or authorized receiving personnel sign, at the time of delivery, a receipt showing the type and quantity of the prescription-only drug received. Any discrepancy between receipt and the type and quantity of the prescription-only drug actually received must be reported to the full service wholesale permittee by the next business day after the delivery to the pharmacy receiving area."
- 400. A.R.S. § 32-1983(E) provides that, "[a] full service wholesale permittee shall not accept payment for or allow the use of a person or entity's credit to establish an account for the purchase of prescription-only drugs from any other person other than the owner of record, the chief executive officer or the chief financial officer listed on the license or permit of a person or entity legally authorized to receive prescription-only drugs. Any account established for the purchase of prescription-only drugs must bear the name of the licensee or permittee."
- 401. Defendants' acts regarding the manufacture, distribution, and prescribing of opioids described in detail above violated each and every one of these laws. Prescott's citizens are within the class which these laws were designed to protect, and the harm to Prescott's citizens is of the nature the laws were designed to prevent. Consequently, Defendants' violations constitute negligent acts *per se*.

FOURTH CAUSE OF ACTION

UNJUST ENRICHMENT

(Against All Defendants)

402. Prescott re-alleges and incorporates by reference each of the allegations

1159968.7/81650.01001

contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

403. Each Defendant was required to take reasonable steps to prevent the misuse,

- 403. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.
- 404. Rather than prevent or mitigate or wide proliferation of opioids into Prescott, each Defendant instead chose to place its monetary interests first and each Defendant profited from prescription opioids sold in Prescott.
- 405. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it or he manufactured, distributed, or prescribed, again choosing instead to place its or his monetary interests first.
- 406. Each Defendant therefore received a benefit from the sale, distribution, or prescription of prescription opioids to and in Prescott, and these Defendants have been unjustly enriched at the expense of Prescott.

As a result, Prescott is entitled to damages on its unjust enrichment claim in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

NEGLIGENT FAILURE TO WARN

(Against the Manufacturer Defendants)

- 407. Prescott re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 408. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable and ordinary care and skill and in accordance with applicable standards of conduct in adequately warning the medical profession about the risk of addiction from the use of opioid products, and not to over-promote and over-market opioid products so as to nullify, cancel out and render meaningless any written warnings about addiction, however inadequate, about the risk of addiction from the use of opioid products.
 - 409. The Manufacturer Defendants breached their duty to exercise reasonable and

ordinary care by failing to adequately warn the medical profession about the risk of addiction from the use of opioid products. Moreover, the Manufacturer Defendants so over-promoted the products to nullify, cancel out and render meaningless any warnings in the labels about any addiction risk due to the Manufacturer Defendants' marketing, sales and promotional efforts that were designed to stimulate the use of opioid products in situations and for patients who should not have been using those drugs or should have used them only as a last resort before other means were used or other less addictive and dangerous drugs were prescribed.

410. As a direct and proximate cause of the Manufacturer Defendants' unreasonable and negligent conduct, Prescott has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

SIXTH CAUSE OF ACTION

FRAUDULENT TRANSFER

Violation of A.R.S. § 44-1004

(Against The Sackler Defendants)

- 411. Prescott re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 412. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Prescott to punitive damages
- 413. As set forth above, Prescott possesses a variety of causes of action against Purdue and the other Defendants, and as soon as final judgment is entered in this action, Prescott will possess a right to payment from Purdue.
- 414. Prescott has been harmed because Prescott is informed and believes that Purdue has been transferring assets to the Sacklers and other shareholders for years in order to avoid paying the judgment that will be owed Prescott, as well as the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.
 - 415. Prescott is informed and believes that Purdue transferred assets to the Sacklers

and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors, including Prescott.

416. Prescott was harmed as a result of these transfers, and Prescott is entitled to void them pursuant to Arizona Revised Statute § 44-1004.

SEVENTH CAUSE OF ACTION CIVIL CONSPIRACY

(Against Defendant Purdue and The Sackler Defendants)

- 417. Prescott re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 418. As alleged above, Purdue and the Sacklers engaged in a knowing and willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Individual Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection of its judgment against Purdue entered in this action.
- 419. After the Sacklers became aware in or about 1999 that Purdue faced potential liability because of the addictive nature of OxyContin, Purdue and the Sacklers conspired to shield the proceeds of their wrongdoing from creditors like Prescott by stripping Purdue every year of hundreds of millions of dollars of profits from the sale of OxyContin and other opioid-containing medications via distributions from Purdue to shareholders, including the Sacklers and their extended family.
- 420. Purdue and the Sacklers, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.
- 421. Purdue and the Sacklers acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and proximately caused the injuries alleged herein.
- 422. Purdue and the Sacklers acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

- 423. As a proximate result of Purdue and the Sacklers' conspiracy and the distributions of billions of dollars in profits to the Sacklers, Prescott is informed and believes that Purdue lacks sufficient assets to satisfy its liabilities to Prescott pursuant to the judgment entered in this action.
- 424. As a result of Purdue and the Sacklers' conspiracy, Prescott is entitled to compensatory damages in an amount to be proved at trial.
- 425. As alleged herein, Purdue and the Sacklers' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Prescott to punitive damages.

EIGHTH CAUSE OF ACTION

Violations of the Arizona Consumer Fraud Act

A.R.S. §44-1521 et seq.

(Against all Defendants)

- 426. Prescott re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.
- 427. The Arizona Consumer Fraud Act is codified at A.R.S. §44-1521 *et seq.* (CFA). The CFA establishes a comprehensive framework for redressing the violations of applicable law. The conduct at issue in this case falls within the scope of the CFA.
- 428. The CFA prohibits the "use or employment ... of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression, or omission of any material fact with intent that others rely on such concealment, suppression, or omission, in connection with the sale or advertisement of any merchandise ..." Ariz Rev. Stat. Ann. §44-1522. Defendants have engaged in and continue to engage in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct pursuant to a common practice of misleading the public regarding the purported benefits and risks of opioids.
- 429. Prescott has paid money for health care costs associated with prescription opioids for chronic pain. Prescott has also paid significant sums of money treating those

- 430. But these unfair method of competition and unfair and/or deceptive acts or practices in the conduct of trade or commerce, Prescott would not have incurred the massive costs related to the epidemic caused by Defendants, as fully described above.
- A31. Logic, common sense, justice, policy, and precedent indicate the Manufacturing Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. The Manufacturing Defendants knew or reasonably should have known that their statements regarding the risks and benefits of opioids were false and misleading, and that their statements were causing harm from their continued production and marketing of opioids. The Distributor Defendants knew or reasonably should have known that the proliferation of prescription opioids were causing damage to Prescott. Thus, the harms caused by Defendants' unfair and deceptive conduct to Prescott were reasonably foreseeable, including the financial and economic losses incurred by Prescott.

VI. PRAYER FOR RELIEF

Prescott prays that the Court issue:

- 1. An Order declaring that Defendants have created a public nuisance in violation of A.R.S. § 13-2917;
- 2. An Order enjoining Defendants from performing any further acts in violation of A.R.S. § 13-2917;
- 3. An Order Defendants to abate the public nuisance that they created in violation of A.R.S. § 13-2917;
 - 4. An Order that Defendants are negligent under Arizona law;
- 5. An Order that Defendants have been unjustly enriched at Prescott's expense under Arizona law;
 - 6. An Order that Prescott is entitled to recover all measure of damages permissible

1159968.7/81650.01001

5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

2

3

4

under the statutes identified herein and under common law;

- 7. An Order that judgment be entered against Defendants in favor of Prescott;
- 8. An Order that Prescott is entitled to attorney's fees and costs pursuant to any applicable provision of law;
 - 9. An Order voiding any fraudulent transfer by the Sacklers;
 - 10. Compensatory damages in the sum to be proven at trial;
- 11. Punitive damages against Purdue and the Sacklers in the sum to be proven at trial;
 - 12. An Order that the conduct alleged herein violates the Arizona CFA;
 - 13. An Order that Prescott is entitled to damages pursuant to the Arizona CFA;
- 14. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.
- 15. An award of attorneys' fees and costs pursuant to the Arizona Consumer Fraud Act e.g. ARS s 44-1534.

VII. <u>JURY TRIAL DEMAND</u>

432. Prescott demands a trial by jury on all claims and of all issues so triable.

DATED: April 23, 2019 FENNEMORE CRAIG, P.C.

By: /s/ J. Christopher Gooch

J. Christopher Gooch Scott Day Freeman Attorneys for Plaintiff The City of Prescott