NOT FOR PUBLIC ACCESS

IN THE CIRCUIT/SUPERIOR COURT FOR MARION COUNTY, INDIANA

STATE OF INDIANA, Plaintiff, v. PURDUE PHARMA L.P., PURDUE PHARMA INC., and THE PURDUE FREDERICK COMPANY, Defendants.	Civil Action **COMPLAINT**

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1. The State of Indiana, through its Attorney General, Curtis T. Hill, Jr., brings this suit to hold Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (collectively, "Purdue") accountable for their key role in the epidemic of opioid overprescribing, misuse, abuse, and addiction that currently grips the State of Indiana, and to demand that Purdue contribute financially to the remediation of the opioid crisis, including through payments to fund addiction treatment, prescriber education, and a range of harm-reduction efforts. By way of Complaint, the State of Indiana states:

PRELIMINARY STATEMENT

2. Since the debut of OxyContin (an extended release ("ER") opioid) in 1996, the volume of opioids prescribed nationwide and in Indiana has exploded—rising by 500%. Opioid prescription rates were so high in 2012 that, on average, there were 112 opioid prescriptions for every 100 residents in the State. Since then, the rate of opioid prescribing has declined but remains dangerously high. From 2012 through 2016, there were 58 Indiana counties with opioid prescribing rates greater than 100+ prescriptions per 100 residents.

3. As recently as 2016, there was a statewide average of 84 opioid prescriptions per 100 residents. These numbers have placed Indiana's among the highest opioid prescription rates in the entire country.

4. Indiana's high opioid prescription rates have been coupled with even higher, illegal diversion rates—to devastating effect. While Indiana reported the ninth-highest rate of opioid prescriptions per capita in the United States in 2012, its rate of diversion was the fifth highest in the country. The proliferation of pills—moving through both legal and illegal channels—has increased opioid misuse, abuse, and addiction in Indiana.

5. The effects on the lives and well-being of Hoosiers and the State itself are profound: increased health care costs; premature death and disability; lost productivity during prime work

years; increases in drug-related crime and incarceration; and the consequential devastation of households and extended families. These predictable outcomes have created a full-blown public health crisis.

6. The opioid epidemic in Indiana has claimed thousands of lives and damaged countless more. More than 3,000 Hoosiers died of opioid overdoses between 2010 and 2016 alone. Based on established health experts' estimates, as many as 89,000 Hoosiers currently are battling opioid dependence and addiction. Those who die leave behind grieving family members and financial dependents; the living face a lifetime of chronic disease management that can impair life-long productivity and earning power, injure their families, and interfere with personal relationships. The pain and cost of opioid dependence and addiction fall heavily on those who use opioids and their immediate families—but where, as here, the scale of misuse and addiction rises to epidemic proportions, the costs affect entire communities and, ultimately, the State.

7. The impact of opioids on Indiana's children is devastating. Between 2013 and 2017, the number of Indiana children removed from homes due to parental drug use increased more than 250%—from 3,223 children in 2013, to 8,118 children in 2017. In 2017, parental drug use was a factor in well over half (63%) of total removals.

8. This includes an increasing number of infants born with Neo-natal Abstinence Syndrome ("NAS"), the painful withdrawal condition experienced by babies born opioid-dependent because of *in utero* exposure to opioids. From 2000 to 2012, NAS dramatically rose by a factor of five nationally. In a pilot program launched to improve peri-natal health and reduce infant mortality, participating Indiana hospitals have been testing for potential substance abuse; at the end of October 2017, testing among voluntary program participants suggested that

approximately 14% of newborns had been exposed to opioids while in the womb according to the Department of Health.

9. Among teenagers, the crisis is reflected differently; nationally, one in four has abused prescription drugs, according to 2012 data. In 2015, 16.8% of Indiana teens had abused prescription drugs, including prescription opioids.

10. The State has taken decisive action to combat the opioid crisis: with legislation, treatment, educational programs, and other funding to curb over-prescribing, stop misuse and abuse, prevent diversion, and reduce harms. Indiana has:

- Passed legislation that establishes strict limits—seven days—for first-time prescriptions of opioids;
- Passed legislation that allows any person to purchase naloxone, an opioid overdose reversal drug, without a prescription and creates immunity for first responders and laypersons who administer it;
- Published new and more detailed opioid prescribing guidelines for doctors and other health care professionals;
- Developed best practices for opioid prescribing and educated health care providers through training programs, online webinars, and print materials;
- Launched the "Bitter Pill" public awareness campaign, which provides Indiana citizens with key information and resources about the risks of opioid use, abuse, and addiction;
- Integrated the State's prescription drug monitoring program with pharmacy and electronic health records state-wide and mandated broader and more immediate use of the system by pharmacists, prescribers, and other health care professionals;
- Increased Medicaid coverage for evidence-based, medication-assisted treatment (MAT), and in-patient detoxification;
- Expanded the State's treatment infrastructure by funding new facility construction and sending mobile treatment units into underserved parts of the State with the goal of putting every resident of the State within a one-hour drive of an opioid treatment program;
- Funded a program to protect infant and maternal health by providing training for OB/GYNs about MAT and developing screening and reporting protocols used to

assess the number of Indiana infants born opioid-dependent to encourage faster detection and treatment;

- Implemented a new program in State prisons, "Recovery While Incarcerated," that provides incarcerated persons with inpatient and outpatient treatment, relapse prevention services, and expanded access to both oral and injectable forms of naltrexone, a medication to manage opioid dependence;

- Made grants to localities to fund the Jail Chemical Addiction Program (JCAP);

- Launched a new public awareness campaign, "Know the 'O' Facts," to help build awareness and understanding of opioid use disorder and the stigma around opioid use disorder, providing information and resources for locating treatment and best practices for treatment; and

- Continued prescription drug takeback events across the State. In 2018, the Office of the Indiana Attorney General held Drug Takeback Events in 20 locations across the State of Indiana, reaching nearly 900 constituents and collecting over 3,000 pounds of drugs.

11. Indiana's efforts have been extensive and effective—but the opioid crisis has become so large that its effects will continue to impact the State, its communities, and citizens for decades. Even as the rate of opioid prescribing has declined between 2012 and 2016, the current rate is still very high, and—over the same period—the number of opioid-related fatalities more than doubled: from 369 deaths in 2012 to 794 deaths in 2016.

12. Purdue bears significant responsibility for the opioid crisis in Indiana because it promoted widespread overprescribing through a deceptive and misleading marketing campaign. Long-term use of prescription opioids is dangerous and medically unnecessary for many chronic pain conditions. But it nevertheless became mainstream medical practice because Purdue mounted a long-running and hugely successful campaign that downplayed the addictive potential of opioids and overstated their benefits in treating chronic pain.

13. **Section I** of the general allegations sets forth the foundation of Purdue's campaign of deception: to change the long-standing medical consensus and public perception that opioids were dangerous, addictive drugs.

14. Prescription opioids like OxyContin, Butrans, and Hysingla—manufactured and marketed by Purdue—are narcotics, closely related to heroin and its root ingredient, opium. In addition to dampening the perception of pain, opioids can create a euphoric high. Opioids also carry significant risks. They are addictive and withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—can occur if opioids are delayed or discontinued. Depending on the length of use, substantial withdrawal symptoms may persist for months, or even years, after complete cessation of use.

15. At higher doses or with any sudden increase in dosage, opioids cause respiratory depression that can be fatal. Patients who use opioids continuously grow tolerant to the drugs' analgesic effects, requiring progressively higher doses to obtain the same levels of pain relief, thus increasing the risks of withdrawal, addiction, and fatal overdose.

16. Historically, the seriousness of these risks had been reflected in a careful and cautious approach to prescribing and taking opioids. Before the 1990s, opioids typically were used only to treat short-term, acute pain (*e.g.*, trauma and post-surgical pain), cancer pain, or palliative care (including end-of-life care) because they were considered too dangerous, too addictive, and too debilitating for long-term use.

17. Beginning in the 1990s and continuing to the present day, Purdue aggressively and successfully set out to change the perception of opioids and to increase medical professionals' comfort with and patient demand for them. Purdue proselytized a new narrative—that pain was drastically undertreated and pain treatment should be a higher priority of health care providers. This narrative paved the way for increased prescribing of opioids for chronic pain.[1] Purdue co-

[1] As used in this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

opted aspects of an otherwise appropriate and compassionate patient-centered care model to engage in a campaign of deception and concealment that promoted opioids as safer, more effective, and more appropriate than alternatives (like Tylenol and Advil) for long-term use to treat routine and moderate pain associated with common conditions like back pain, migraines, and arthritis.

18. Purdue has spent hundreds of millions of dollars on an array of promotional efforts that falsely denied or deceptively minimized the risk of addiction and overstated the benefits of opioids. These efforts included:

- directly marketing Purdue opioids to prescribers through advertising and in-person sales visits;
- indirectly marketing opioids to prescribers and consumers through seemingly-independent surrogates—key opinion leaders, professional associations, and advocacy groups—that were actually paid or funded by Purdue; and
- generating a biased body of reference materials—scientific research, treatment guidelines, and continuing medical education seminars—that would encourage, rather than objectively evaluate, the use of opioids for chronic pain.

19. Purdue's massive marketing scheme, joined by other opioid manufacturers, materially changed the medical and patient communities' willingness to prescribe and take opioids.

20. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptive conduct in the sale and marketing of opioids, and Purdue paid $635 million to resolve federal and state government enforcement actions ("the 2007 Settlements"). Purdue took the plea and paid the fine but did not change its ways. Instead, Purdue continued to capitalize on the foundation it had created for making long-term opioid therapy for routine pain conditions a commonplace, and often first-line, treatment.

21. **Section II** sets forth Purdue's actionable misrepresentations and unfair and abusive practices in Indiana. To this day, Purdue has failed to correct—and in fact built upon and continued to profit from—its prior deceptions and the foundation of misunderstanding the company created.

Purdue also devised new deceptive messages to convince prescribers and patients that the benefits of long-term opioid therapy to treat moderate, routine pain easily outweigh any attendant risks.

22. Purdue's deceptive marketing to Indiana health care providers, patients, and the general public falsely and misleadingly mispresented the risks of opioids by:

(1) minimizing or outright denying the serious risk of addiction, including by claiming that signs of addiction merely reflected undertreated pain that should be treated with more or higher doses of opioids;

(2) overstating the effectiveness of screening tools in preventing addiction, which gave prescribers unwarranted confidence they could safely prescribe long-term opioids;

(3) denying or failing to disclose the increased dangers of opioids at higher doses (including the heightened risk of addiction, overdose, and death); and

(4) exaggerating the effectiveness of its "abuse-deterrent" opioid formulations by claiming and implying that these formulations prevent abuse and addiction.

23. Purdue also has misrepresented the benefits of opioids by:

(1) claiming that long-term opioid therapy would improve patients' function and quality of life—despite a lack of scientific evidence;

(2) misrepresenting that OxyContin would provide a full 12 hours of pain relief, when Purdue knew that was untrue, and also that the failure to provide a full 12 hours of pain relief leads to a cycle of higher-dose prescribing and addiction;

(3) promoting the use of "low doses" of OxyContin (10 and 15 milligrams) to reluctant prescribers, even though Purdue had no scientific evidence showing that these low doses provided pain relief; and

(4) grossly overstating the risks of over-the-counter pain relief medications like acetaminophen and ibuprofen without fully disclosing the far greater risks associated with opioids.

24. Purdue has known that its longstanding and ongoing misrepresentations of the risks and benefits of opioids are unsupported by (and, in some cases, directly contrary to) the scientific evidence.

25. Purdue's decision to rely on flawed studies and an absence of long-term controlled studies was exposed in 2016, when the Centers for Disease Control and Prevention ("CDC") published its systematic review of all existing research on chronic opioid therapy and resulting clinical *Guideline for Prescribing Opioids for Chronic Pain* ("2016 CDC Guideline").[2] The CDC reviewed and evaluated the quality of scientific research dating back to the 1990s and concluded:

- "[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";
- "[a]lthough 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"; and
- "evidence 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."

26. Purdue also has engaged in unfair and abusive practices in Indiana. Purdue targeted untapped patient populations—the elderly and the opioid-naïve—to create and capture a new market of long-term customers. Purdue also offered savings cards (a/k/a prescription discount cards) to encourage long-term opioid use by creating low-cost or free trial periods for OxyContin, Butrans, and Hysingla.

27. **Section III** sets forth the injury to Indiana and its citizens. Purdue has profited immensely from its deceptive marketing campaign, at the expense of Indiana and its citizens, on whom Purdue's misconduct has imposed catastrophic harm.

28. The increased volume of opioid prescribing for chronic pain correlates directly to: skyrocketing addiction, overdose, and death; booming illegal markets for diverted prescription opioids as well as heroin, to which many addicts cross over when their prescription opioids prove

[2] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States*, 2016, MMWR Recomm. Rep. 2016;65(No. RR-1):1–49 (Mar. 18, 2016).

too expensive or unavailable; and the devastating social and economic consequences of each of these problems.

29. In October 2017, the federal government declared the opioid crisis a national public health emergency—the first such declaration under the Public Health Service Act not involving a natural disaster or infectious disease.

30. In 2016, the last year for which full data are available in Indiana, more people died from an opioid overdose than from car accidents. Opioid-related trips to emergency departments in Indiana hospitals rose by more than 54% between 2009 and 2014. The rise in opioid addiction has led to an increase of robberies and other crime in Indiana—requiring law enforcement to devote increasing resources to fighting the opioid epidemic.

31. Indiana's health care costs associated with opioid overprescribing are substantial.

- The State estimates that its Medicaid vendors have paid more than $101 million for opioids since 2012; and
- Since 2010, the State has directly paid more than $8 million under its Employee Plans.

32. The above costs are just a fraction of the consequential costs (past, present, and projected) associated with treating addiction, overdose, and other injuries caused by opioid overprescribing and misuse. There is an unprecedented demand for substance abuse treatment in Indiana—with opioids as a leading reason for treatment admissions.

33. While the State and its agencies have responded to the opioid crisis with urgency and vigor, much more remains to be done—and substantial funding will be necessary. The cost and effort of remediating the opioid crisis in Indiana will require tremendous resources. The State has brought this lawsuit in part because the burden of those costs should be shared by Purdue. These costs should not, and cannot, be borne by the State and its citizens alone.

34. **Section IV** sets forth Purdue's concealment of its culpability in causing the opioid crisis. Purdue attempts to portray itself as a responsible, compassionate corporate citizen by falsely depicting the opioid epidemic as a problem of illicit drug diversion and abuse. In fact, Purdue's misrepresentations have led to vast overprescribing and addiction.

35. Beginning in late 2017, Purdue has been running full-page, color advertisements on the pages of *The New York Times*, *The Washington Post*, and *The Wall Street Journal* to promote the purported safety of its abuse-deterrent formulations and its purported efforts to rein in diversion. The retail price for a single, full-page color advertisement in these national publications is hundreds of thousands of dollars. The millions that Purdue has spent on these newspaper advertisements to rehabilitate its reputation would have been better spent on the rehabilitation of lives damaged by addiction and overdose.

36. Notwithstanding Purdue's most recent, self-serving national advertising campaign, the company refuses to take responsibility for its part in creating this health crisis. In fact, Purdue continues to treat opioid addiction as a source of profit—just recently obtaining a patent to manufacture opioid treatment drugs.

37. The explosion of opioid prescribing and use was engineered by Purdue at the expense of chronic pain patients, many of whom would have been far better off with over-the-counter medications or alternative therapies. As explained below, Purdue has known all along that many of its marketing messages were, at best, misleading and, at worst, not supported by good evidence. Purdue had many opportunities to sound the alarm on indiscriminate opioid prescribing and potential diversion but did not. Purdue knew the identities, practices, and prescribing volumes of every health care provider the company visited, and therefore was well-situated to identify suspicious prescribing. Yet, Purdue did not use this information to protect patients and the public.

38. In 2018, with the writing on the wall and hundreds of lawsuits pending, Purdue finally announced that it would stop marketing opioids. This change was far too little, too late. Given the severity and far-reaching effects of opioid addiction, Purdue's greed and callousness in the way it expanded the market for opioids is morally reprehensible. Yet, despite mounting and inescapable evidence of Purdue's role in causing the opioid crisis, the company continues to deny its responsibility.

39. The family behind Purdue, moreover, is poised to profit from the public health crisis that it created. Purdue board member and former company president Richard Sackler was awarded a patent in January 2018 for a new formulation of buprenorphine—one of the most effective drugs used to treat opioid addiction. In his patent application, Sackler described the background of his new invention like this:

> Over the last decades, prejudices in the medical community as to the use of strong opioids for treating chronic pain in patients has significantly decreased. Many of these prejudices were due to some of the characteristics being inherent to opioids. While opioids have always been known to be useful in pain treatment, they also display an addictive potential in view of their euphorigenic activity. Thus, if opioids are taken by healthy human subjects with a drug seeking behavior, they may lead to psychological as well as physical dependence.

The application goes on to link addiction to crime before presenting his invention—in a shocking echo of OxyContin marketing—as less prone to diversion and abuse than other treatment drugs.

40. Buprenorphine sales in the United States topped $2.6 billion in 2017 and are expected to rise as the infrastructure and funding for addiction treatment expands to meet current and projected needs.

41. Purdue's conduct is illegal in Indiana and violates the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5 *et seq.* (DCSA); the Indiana False Claims Act, Ind. Code § 5-11-5.5 *et seq.* (FCA); and the Indiana Medicaid False Claims Act, Ind. Code § 5-11-5.7 (MFCA).

42. The State therefore seeks an order enjoining Purdue from unlawfully promoting opioids, requiring Purdue to correct its misrepresentations, and to compensate the State for false claims and related consequential costs to the State. The State further seeks a judgment requiring Purdue to pay civil penalties, disgorge ill-gotten gains, pay damages in connection with the false claims it caused to be submitted, and to reimburse Plaintiff's fees and costs.

PARTIES

43. The Attorney General of Indiana is charged with the responsibility of enforcing the State laws at issue, including the DCSA and all regulations promulgated thereunder, as well as the FCA and the MFCA. The Attorney General also has standing on behalf of the State as *parens patriae* to protect the health and well-being, both physical and economic, of its residents and its municipalities.

44. Defendant Purdue Pharma L.P. is a Delaware limited partnership. Defendant Purdue Pharma Inc. is a New York corporation that is the general partner of Purdue Pharma L.P. Defendant The Purdue Frederick Company is a New York corporation. Defendants operate as an integrated enterprise with its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901.

45. Purdue manufactures, promotes, and sells the opioids OxyContin, Butrans, and Hysingla ER, as well as MS Contin, Dilaudid, and Dilaudid HP in the United States and Indiana. OxyContin is Purdue's best-selling opioid. Purdue has generated sales estimated at more than $35 billion since it launched OxyContin in 1996.

JURISDICTION AND VENUE

46. The Court has personal jurisdiction over Purdue because it has regularly transacted business in Indiana, purposely directed business activities into Indiana, maintained employees in Indiana, and engaged in unlawful practices in Indiana against Indiana consumers.

47. As alleged here, Purdue has deceptively and otherwise unlawfully marketed its opioids in Indiana. From 2010 through 2018, Purdue employed at least 123 different Purdue sales representatives and sales managers who were assigned to a sales territory in or including Indiana. In that period, Purdue's Indiana sales force made more than 207,640 sales visits regarding OxyContin and other Purdue opioids to Indiana health care providers. On information and belief, Purdue has generated hundreds of millions of dollars in revenue from the sale of its opioid products in Indiana.

48. Venue in this Court is proper, pursuant to Indiana Trial Rule 75(A)(10), because Plaintiff's claims arose, in part, in Marion County, and Purdue conducts business there. Among other things, Purdue has made tens of thousands of sales visits regarding opioids to health care providers in Marion County. In addition, this case is brought by the State of Indiana, a governmental entity whose principal offices are located in Marion County, Indiana.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

I. THE FOUNDATION OF PURDUE'S CAMPAIGN OF DECEPTION: *Purdue Changed the Medical Consensus by Working Every Channel to Reach Prescribers and Indiana Patients.*

49. From the launch of OxyContin in 1996, Purdue knew its claims about the risks and benefits of long-term opioid use lacked scientific support. From the first OxyContin label in 1996 and up to today, in 2018, the only clinical study Purdue has relied upon for OxyContin's efficacy in adults is a two-week study of 133 patients. No clinical trials on efficacy have extended past 12 weeks.

50. Yet, Purdue sold OxyContin as the cure for chronic pain. Purdue promoted OxyContin, and opioids generally, with the understanding and expectation that health care providers would prescribe it to their chronic pain patients over periods of months and years.

51. Through marketing that was as pervasive as it was deceptive, Purdue convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits—in reduced pain and improved function and quality of life—were proven, even though Purdue had no good evidence to support these assertions.

52. Purdue changed the medical consensus on opioids through its campaign of deception. Purdue achieved this by ensuring that every channel a prescriber regularly consulted for information about opioids would deliver the same incomplete, misleading, and imbalanced information. Purdue effected this strategy through its sizeable sales force, through continuing medical education seminars and presentations, through academic literature, and through treatment guidelines.

A. Purdue Regularly Met Face-to-Face with Prescribers to Promote Its Opioid Drugs.

53. Purdue marketed its opioids directly to prescribers through its sales force—sales representatives, also known as "detailers," who made in-person sales visits to prescribers. By establishing frequent contact and personal relationships with health care providers, Purdue's detailers were able to disseminate key misrepresentations in largely unmonitored and unregulated settings.

54. In-person sales visits to prescribers are highly effective. Purdue's internal documents confirm that it was well-aware of the efficacy of detailing. For example, a 2012 report prepared by a research firm that Purdue hired to analyze trends in the pain market concluded that, even though physicians described sales visits as having only a small impact on prescribing habits, in reality, detailing had a high impact on levels of opioid prescribing. The report thus identified physician detailing as an "effort [that Purdue] … should maintain in order to maximize [market] share." The report also noted that, aside from medical journals, sales representatives were the top

source of new information for healthcare providers about medications for the treatment of chronic pain. Similarly, Purdue sales executives have confirmed during detailer training programs that "[a]nalysis has demonstrated that [local dinner] programs, when combined with regular sales visits, do increase the prescribing habits" of physicians. Of the $167 million that Purdue spent on promoting opioids nationwide in 2016, $156 million of that—93.4%—was spent in connection with its in-person sales force.

55. Purdue targeted generalists—primary care physicians, nurse practitioners, and physician assistants—who were likely to see patients with chronic pain conditions but unlikely to have the specialized training to evaluate Purdue's marketing and patients' pain conditions.

56. Purdue's internal marketing plans from 2013 reveal that Purdue targeted nurse practitioners and physician assistants as both the fastest growing specialty and particularly susceptible to marketing messages. In Purdue's words, "NPs and PAs desperately seek information, typically from sales representatives."

57. At least 123 different Purdue sales representatives and managers have detailed Indiana prescribers since 2010. Purdue's performance requirements included the expectation that every detailer make at least 7.5 in-person sales visits to prescribers, two to three in-person sales visits to pharmacies, and one in-person sales visit to a hospital or other institutional target *each day*.

58. Purdue's internal documents show that its sales representatives detailed at least 5,502 different Indiana prescribers between 2010 and 2017, and that these prescribers were visited by Purdue sales representatives in excess of 207,640 times. Most of these prescribers were visited regularly and repeatedly—according to one former Purdue sales representative in Indiana; offices housing multiple prescribers, including nurse practitioners and physician assistants, were visited

weekly. On average, Purdue's sales force in Indiana made a total of more than 22,000 prescriber visits per year.

59. Detailer compensation was not based on the number of sales visits or the strength of those relationships. Instead, compensation was tied to the number of prescriptions doctors wrote in a detailer's territory over quarterly periods. Bonuses were awarded to detailers quarterly based on their performance. At least one former Purdue detailer in Indiana had sales quotas of over 3,300 OxyContin prescriptions per month.

60. In fact, in 2012, at the peak of opioid prescribing, Purdue's highest achieving sales representative—nationwide—worked in Indiana. This detailer, who was assigned to the Fort Wayne area, was ranked No. 1 out of all 525 sales representatives in the country based on sales of OxyContin and Butrans.

61. Purdue used these rankings—as well as cash and prizes—to motivate sales representatives. In Purdue's words:

> Those colleagues who prevail will likely maximize available field time during these summer months, striving to implement our marketing strategies more effectively by focusing on Core and Super Core prescribers and using support materials to engage customers in an ongoing dialogue concerning the utilization of Purdue products, and always closing to increase usage with appropriate patients.

62. In just the first quarter of 2012, this Fort Wayne sales representative sold $2,031,666 of OxyContin in her district. Purdue rewarded her and other "winners" who secured the highest volume of Purdue opioid prescriptions with generous bonuses. The Fort Wayne sales representative received a first quarter bonus of $36,600 in 2012, plus a trip to Aruba.

63. The district managers who supervised Indiana detailers were evaluated and compensated on the expansion of opioid prescribing in their territory. Purdue trained its managers to encourage sales representatives to visit high-volume prescribers as frequently as 3x/week.

64. One Indiana district manager's performance evaluation from 2015 instructed, "[i]t is important to work with team members to ensure they are seeing their highest value doctors … with the suggested frequency. These HCPs [health care providers] provide us with the greatest opportunity to grow our business and achieve our sales results."

65. Purdue developed sophisticated plans to select prescribers for sales visits based on their prescribing habits. Purdue purchased prescription sales data from vendors like IMS (later IQVIA), which allowed Purdue to analyze and closely track prescribing of its opioids and those of its competitors. According to former Purdue employees in Indiana, any prescribing of an opioid—whether Purdue's or a competitor's—would cause a prescriber to be included on Purdue's target list for sales visits.

66. Purdue also recognized that the State's law enforcement efforts to halt overprescribing and diversion were affecting the prescribers Purdue was targeting. Following the highly-publicized closure of several practices that were essentially "pill mills," a Purdue Regional Manager wrote in his evaluation of an Indianapolis-area District Manager:

> During this review period, there were a number of things that took place that impacted your team: There were many representatives that had pain practices shut down by the Attorney General of Indiana. This contributed to many prescribers abandoning patients and the overall decline of the entire ERO [extended release opioids] market …. I am confident in your ability to help your team members continue to successfully launch Hysingla, protect OxyContin and grow Butrans for the remainder of 2015.

67. Through at least 2017, Purdue employed the same marketing tactics and messages in Indiana as it did nationwide, using uniform marketing materials and national and regional sales

training. Purdue carefully trained its sales representatives to deliver company-approved sales messages. The company exactingly directed and monitored its sales representatives—through detailed action plans, trainings, tests to review those trainings, scripts, role-plays, supervisor tag-alongs, and periodic reviews of representatives' written records of sales visits "call notes"—to ensure that individual detailers actually delivered the company's desired messages. Purdue likewise required its sales representatives to deploy sales aids that were reviewed, approved, and supplied by the company.

B. Purdue Co-opted and Exploited Seemingly-Independent Channels to Reach Prescribers.

68. In addition to its branded marketing efforts that showcased Purdue opioids, Purdue also undertook, or financially supported, a number of unbranded marketing initiatives that were designed to promote opioids generally, and to convey Purdue's key messages about opioids without properly disclosing that Purdue had created, funded, directed, or was otherwise influencing these endeavors. Purdue intended prescribers and patients to receive these materials and to perceive (incorrectly) that they were coming from neutral researchers, clinicians, and independent patient advocacy groups.

69. As part of its unbranded marketing scheme, Purdue recruited and paid physician speakers to present talks on opioids to their peers at lunch and dinner events. It funded biased research and sponsored continuing medical education ("CME") activities that misleadingly portrayed the risks and benefits of chronic opioid therapy. Purdue collaborated with professional associations and pain advocacy organizations, such as the American Pain Foundation, to develop and disseminate pro-opioid educational materials and guidelines for prescribing opioids.

70. Purdue's relationship with the American Pain Foundation (APF) is particularly instructive of its relationship with advocacy and professional groups. Purdue was APF's second

biggest donor, with donations totaling over $3.6 million between 1999 and 2012. As early as 2001, Purdue grant letters informed APF that the contributions reflected Purdue's effort to "strategically align our investments in nonprofit organizations that share our business interests," making clear that funding depended on APF continuing to support Purdue's objectives. Purdue also engaged APF as a paid consultant on various initiatives.

71. The American Pain Foundation used funding from Purdue and others to distribute false and misleading information about the addiction risks associated with opioids.

(a) *Exit Wounds*, an APF book styled as the personal narrative of a veteran recovering from war injuries, described opioids as the "'gold standard' of pain medications" and minimized the risk of addiction, emphasizing that physical dependence often is mistaken for addiction and claiming that "[l]ong experience with opioids shows that … people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." With Purdue's financial support, APF promoted and distributed *Exit Wounds* to veterans throughout the country, including, on information and belief, veterans in Indiana.

(b) *A Policymaker's Guide to Understanding Pain & Its Management* claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction" and asserted, without support, that "less than 1 percent of children treated with opioids become addicted." In addition to mischaracterizing the risk of addiction, *A Policymaker's Guide* perpetuated misleading information regarding a bogus phenomenon called "pseudoaddiction." Purdue provided a grant for the development and distribution of *A Policymaker's Guide* and kept abreast of the content of the guide as it was formulated. On information and belief, Purdue had editorial input into *A Policymaker's Guide*.

72. Purdue also created a portfolio of unbranded materials—from websites to glossy brochures—that were copyrighted by Purdue but were designed to look like the work of independent organizations—with names like *Partners Against Pain* and *In the Face of Pain*.

73. Among these tactics, all of which originated in the late 1990s and early 2000s, three stand out for their lasting influence on opioid prescribing nationwide and in Indiana: (1) Purdue's capture, for its own ends, of physicians' increased focus on pain treatment; (2) Purdue's efforts to

skew the scientific literature on chronic opioid therapy with biased studies; and (3) Purdue's corrupting influence on authoritative treatment guidelines issued by professional associations.

1. Purdue Co-opted the Medical Community's Focus on Pain.

74. As Purdue marketed OxyContin in the late 1990s, it both capitalized on and co-opted a movement in the medical community to make pain identification and treatment a priority for all patients. Purdue provided financial support to the organizations and individuals leading the movement, and, in turn, they promoted the aggressive treatment of chronic pain, especially with opioids.

75. Purdue had already laid the groundwork for this strategy by financially supporting researchers who were willing to advocate for expanded use of opioids without adequate scientific support. Chief among these was Dr. Russell Portenoy, who wrote a seminal paper supporting chronic opioid therapy while receiving Purdue funding and serving as Purdue's consultant. Dr. Portenoy concluded—based on a review of just 38 patients—that "opioid maintenance therapy can be a safe, salutary and more humane alternative" to not treating patients with chronic pain.

76. Beginning in 1995, the American Pain Society ("APS"), of which Dr. Portenoy later would become president, launched a national campaign to make pain a "vital sign"—an objectively measured indicator—that doctors should monitor alongside blood pressure, temperature, heartbeat, and breathing. Purdue provided substantial funding to APS both to promote pain awareness generally and, on information and belief, to support the group's "Pain as the 5th Vital Sign" campaign. The Veterans Health Administration adopted this concept in its facilities nationwide in 1999, and "Pain as the 5th Vital Sign" spread from there to the private sector.

77. In 2001, the Joint Commission on the Accreditation of Healthcare Organizations ("JCAHO") issued pain treatment standards requiring assessment of pain in all patients during

every physician-patient interaction and made hospital accreditation decisions contingent on adherence to those standards. Purdue worked closely with JCAHO to promote the pain standards, and JCAHO licensed Purdue—exclusively—to distribute educational videos about how to comply with the new pain management standards. Purdue also sponsored various guides for implementing the JCAHO standards, such as *Pain Assessment and Management: An Organizational Approach*. This book promoted the use of opioids, claiming that "[s]ome clinicians have inaccurate and exaggerated concerns about addiction, tolerance, respiratory depression, and other opioid side effects … despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." JCAHO distributed the book to hospital officials and physicians nationwide at a series of Purdue-sponsored "leadership summits" on pain management.

78. Both the APS "Pain as the 5th Vital Sign" campaign and the JCAHO pain standards were widely integrated into medical practice. Although the JCAHO standards strictly applied only to pain management in hospitals, they influenced the entire medical profession through hospital-based residency training. Indiana health care providers interviewed by the State credit these initiatives with increasing the prescribing of opioids by requiring that doctors be aggressive in treating pain but did not know that Purdue had played a key role in launching these initiatives.

2. Purdue Corrupted the Science Regarding Opioids with Flawed and Biased Research.

79. Rather than rigorously test the safety and efficacy of opioids for long-term use, Purdue created scientific support for its marketing claims by sponsoring studies that were methodologically flawed and biased, and drew inappropriate conclusions from prior evidence. Purdue selectively promoted studies with favorable outcomes and relegated the problematic ones to obscure journals. The result was an incomplete, inaccurate, and deceptive body of literature that was then cited by other researchers.

80. Some of these methodologically flawed studies made unsubstantiated claims that the risk of psychological dependence or addiction is low absent a history of substance abuse. One such study making this claim, published in the journal *Pain* in 2003 and widely referenced since (with nearly 600 citations in Google Scholar), ignored existing research showing actual addiction rates between 8% and 13% and instead relied heavily on a 1980 letter to the editor—not a peer-reviewed study or in-depth article but a letter—in the *New England Journal of Medicine*. That letter, J. Porter & H. Jick, "Addiction Rare in Patients Treated with Narcotics," 302(2) *New Eng. J. Med.*, 123 (1980) ("Porter-Jick Letter"), is reproduced below:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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

81. The Porter-Jick Letter does not reflect any study, but simply describes a review of the charts of hospitalized patients who had received opioids. One of the authors of the letter and the *New England Journal of Medicine* have since repudiated this misuse of the Porter-Jick Letter. Yet, the Porter-Jick "study" has become a mainstay in scientific literature due, in large measure, to Purdue's efforts, with more than 1,000 citations in Google Scholar.

3. Purdue Funded and Influenced Treatment Guidelines.

82. Treatment guidelines inform health care providers' prescribing practices, are cited throughout the scientific literature, and are referenced by third-party payors when determining whether prescriptions should be covered by insurance. Purdue financed and collaborated with three groups on guidelines that have been, and continue to be, broadly influential in Indiana and nationwide: (i) the American Academy of Pain Medicine (AAPM); (ii) the American Pain Society (APS); and (iii) the Federation of State Medical Boards (FSMB).

The AAPM/APS Guidelines

83. The AAPM and APS each received substantial funding from Purdue. From 2009 to 2012, Purdue gave APS nearly $500,000 and AAPM more than $400,000. Purdue gave APS another $500,000 and AAPM more than $700,000 between 2012 and 2017. An internal Purdue request to its CEO for approval of "2009 funds for AAPM and APS proposals" described each group as "one of our top tier organizations."

84. In 1997, AAPM and APS issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," that endorsed using opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. J. David Haddox, was a paid speaker for Purdue at the time. Shortly after issuing this statement, he became a senior executive for the company. Dr. Portenoy was the sole consultant for the consensus statement, which remained on AAPM's website until 2011.

85. AAPM and APS also issued a 2001 set of recommendations, titled "Definitions Related to the Use of Opioids for the Treatment of Pain," that advanced the unsubstantiated concept of "pseudoaddiction." The term, coined by Dr. Haddox in a 1989 journal article, reflects the idea that signs of addiction may actually be the manifestation of undertreated pain and will resolve once the pain is effectively treated—*i.e.*, with more or higher doses of opioids. The 2001

AAPM/APS recommendations claimed "clock-watch[ing]," "drug seeking," and "[e]ven such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain [pain] relief." The lack of evidentiary support for this definition has since been exposed and the treatment approach discredited.

86. In 2009, AAPM and APS issued comprehensive opioid prescribing guidelines ("2009 AAPM/APS Guidelines"), drafted by a 21-member panel, that promoted opioids for treating chronic pain. The panel made "strong recommendation[s]" regarding management of chronic opioid therapy even while acknowledging "low-quality evidence" to support its positions and concluded that the risk of addiction is manageable for patients, even patients with a prior history of drug abuse. Six of the panel members, including Dr. Portenoy, received financial backing from Purdue, and another eight received funding from other opioid manufacturers.

87. The 2009 AAPM/APS Guidelines reprinted in *The Journal of Pain* were distributed by Purdue sales representatives to Indiana prescribers. These guidelines, in addition to influencing physicians, have now been cited nearly 1,700 times in academic literature.

FSMB Guidelines

88. The Federation of State Medical Boards (FSMB) is an association of the various state medical boards in the United States. The state boards that comprise the FSMB membership, including Indiana's, have the power to license doctors, investigate complaints, and discipline physicians. The FSMB has financed opioid- and pain-specific programs through grants from pharmaceutical manufacturers, including more than $800,000 from Purdue between 2001 and 2008.

89. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which the FSMB acknowledged were

produced "in collaboration with" pharmaceutical companies and allied groups such as the APS. The FSMB Guidelines stated that opioids "may be essential" for treatment of chronic pain but failed to mention risks of respiratory depression and overdose. Further, the FSMB Guidelines addressed addiction only to define the term as separate from physical dependence and state that an "inadequate understanding" of addiction can lead to "inadequate pain control." Purdue sales representatives distributed the FSMB Guidelines to health care providers in Indiana.

90. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from them, *Responsible Opioid Prescribing*, repeated the 1998 version's claims. The book also claimed that opioids would improve patients' function and endorsed the dangerous, now-discredited concept of pseudoaddiction, suggesting that signs of addiction may actually reflect undertreated pain that should be addressed with more opioids.

91. *Responsible Opioid Prescribing* was sponsored by Purdue, among other opioid manufacturers, and Purdue had editorial input into its contents. In particular, Dr. Haddox, by then employed by Purdue, made edits to the book to ensure that pseudoaddiction was falsely presented as an accepted medical concept.

92. Through at least 2015, the FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationwide through state medical boards and non-profit organizations. On information and belief, copies were distributed in Indiana.

II. PURDUE'S ACTIONABLE MISREPRESENTATIONS AND PRACTICES: *From 2010 Through 2017, Purdue Misrepresented the Risks and Benefits of Opioids to Indiana Prescribers and Consumers*.

A. Purdue Failed to Correct Its Previous False and Misleading Marketing Messages.

93. In the 2007 Settlements, Purdue entered into consent decrees with the federal government and numerous states to resolve investigations into its marketing of OxyContin between 1996 and 2007. As part of these settlements, Purdue admitted that it had misrepresented key facts about the safety of its opioids—particularly about the risk of addiction. The Purdue Frederick Company and its top representatives plead guilty to federal crimes related to these misrepresentations. Purdue admitted that its sales representatives, as a matter of course:

- falsely told some health care providers that OxyContin had "less euphoric effect, and less abuse potential than short-acting opioids."
- falsely told prescribers that OxyContin—the first "extended release" a/k/a "long-acting" ("ER/LA") opioid—had fewer "peak and trough" effects than short-acting opioids, also known as immediate release (IR) opioids;
- falsely told prescribers that patients could discontinue OxyContin therapy without experiencing withdrawal symptoms; and
- falsely told prescribers that OxyContin was more difficult to intravenously abuse than generic oxycodone.

94. In addition to making these deceptive claims through its sales force, Purdue also deceptively advertised OxyContin in print advertisements in medical journals and in videos distributed directly to physicians:

- In 1998 and 2000, Purdue distributed to doctors thousands of copies of videos, titled "I Got My Life Back," which made the unsubstantiated claim that opioid addiction occurred in less than 1% of patients; and
- Purdue print advertising claimed that OxyContin provides "Consistent Plasma Levels Over 12 Hours" and depicted plasma levels on a logarithmic scale. The graph however, visually distorted and intentionally obscured the steep decline in OxyContin's efficacy over 12 hours, falsely making the absorption rate appear more steady or consistent over 12 hours. In fact, OxyContin works by releasing a

greater proportion of oxycodone (about 40%) into the body upon administration, followed by a steep decline over those hours.

95. The 2007 Settlements required Purdue to cease all deceptive marketing—including any misrepresentations regarding OxyContin's potential for abuse, addiction, or physical dependence—and to provide a fair balance of risk and benefit information as required by FDA regulations.

96. Had Purdue ceased its marketing efforts after the 2007 Settlements, it may not have had a duty to affirmatively correct these past misrepresentations. But Purdue neither ceased its deceptive marketing nor corrected its past misrepresentations. Instead, Purdue intensified its marketing efforts and built upon the deceptive messaging that had established chronic opioid therapy as a first-line option for treatment of routine, moderate pain. In failing to affirmatively correct the statements already deemed—and in some cases admitted—to be false and misleading, Purdue engaged in material omissions.

97. Through its sales force and deceptive promotional materials, Purdue continued, from 2010 through at least 2017, to omit, understate, and misrepresent the serious risks posed by opioids and to overstate the benefits of chronic opioid therapy, while failing to disclose the lack of evidence supporting long-term use.

B. Purdue Minimized or Omitted the Known and Serious Risks of Addiction and Overdose.

98. To convince Indiana prescribers and patients that opioids are safe, Purdue has deceptively minimized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction. Purdue trained its sales representatives to overemphasize the technical distinctions between dependence and addiction in order to convey the deceptive message that "dependence" was a benign consequence of opioid use and that "addiction" was a rare outcome of opioid use that could be easily anticipated and prevented.

99. Purdue's misrepresentations and omissions, which are described below, have reinforced each other to create the dangerously misleading impressions that:

- Purdue's ER/LA opioids present a reduced risk of addiction, and even patients who seem addicted may simply be physically dependent on the drug or have pain that requires more or higher doses of opioids;
- Patients at greatest risk of addiction can be identified, allowing doctors to confidently prescribe opioids to all other patients, and even prescribe to high-risk patients, provided they are closely managed;
- The abuse-deterrent formulations of Purdue's opioids both prevent abuse and are inherently less addictive; and
- Physicians can prescribe steadily higher doses of opioids without added risk of dependence or addiction.

Each of these misrepresentations is contrary to FDA and CDC scientific conclusions, as well as a substantial body of scientific literature regarding the limitations, disadvantages, and risks of long-term opioid use.

1. Omitting, Trivializing, and Mischaracterizing Addiction Risk.

100. Throughout the time period covered by this Complaint, Purdue's Indiana sales representatives regularly omitted from their sales conversations any discussion of the risk of addiction from long-term use of opioids. These omissions are material and rendered even facially truthful statements about opioids false and misleading because they were incomplete in light of Purdue's prior misrepresentations regarding the risk of addiction. By failing to correct earlier false statements, Purdue's sales representatives let stand the dangerous and incorrect impression that patients who receive chronic opioid therapy for legitimate pain conditions are unlikely to become addicted.

101. Even when Purdue's sales representatives mentioned addiction, they emphasized that Purdue's ER/LA opioids (OxyContin, Butrans, and Hysingla) provide a slow-onset, stable dose with "steady-state" blood plasma levels—encouraging Indiana prescribers to take away the

misleading message that these particular opioids were safer because they do not produce the euphoric high that fosters addiction.

102. One Indiana prescriber recalls a Purdue employee telling her—within the last two years—that extended release opioids [*e.g.*, OxyContin, Butrans, and Hysingla] were less addictive because they provide a more steady, stable relief without an immediate rush.

103. Another Indiana prescriber remembers that the Purdue sales representative who visited him within the last two years explained that extended release opioids do not provide the highs that can cause people to become addicted.

104. Yet another Indiana prescriber was told by a Purdue detailer—within the last three to five years—that continuous release opioids have no peaks and valleys.

105. Promotional materials and other publications Purdue disseminated or made available in Indiana during the relevant time period have included similar, mutually reinforcing messages minimizing the risk of addiction.

106. In 2011, for example, Purdue published an unbranded pamphlet, *Providing Relief, Preventing Abuse*, for prescribers that misleadingly depicted the signs of addiction. The pamphlet shows graphic pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—and promoted the scientifically discredited concept of pseudoaddiction. Purdue sales representatives regularly distributed *Providing Relief, Preventing Abuse* to Indiana prescribers for years. At least one former Purdue sales representative in Indiana was handing this pamphlet out "on a daily basis" in 2015. She described the indications that someone may be abusing opioids identified in *Providing Relief, Preventing Abuse* as "pictures of like pupils and things, if a patient is, I guess, abusing, how their pupils might look … track marks, just behavior that seemed a little erratic, like calling the doctor 20 times in a two-hour period."

107. Purdue created and promoted an unbranded campaign, *Partners Against Pain*, to distribute medical education resources and information, which included a website styled as an "advocacy community" for better pain care. Purdue sales representatives widely showed and disseminated *Partners Against Pain* materials to Indiana prescribers and encouraged prescribers to use the *Partners Against Pain* website as a resource as recently as 2015. Indiana residents accessed the *Partners Against Pain* website 10,093 times between 2012 and 2016.

(a) One early *Partners Against Pain* pamphlet answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

(b) Through 2013, the *Partners Against Pain* website relied on and directed users to the 2001 guideline from AAPM and APS, which endorsed the concept of pseudoaddiction and claimed that patients who engage in drug-seeking behaviors may not be addicted but simply have undertreated pain.

(c) Purdue sales representatives also distributed a pamphlet called "Clinical Issues in Opioid Prescribing," which made similar claims about drug-seeking behaviors. It claimed that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated," again suggesting that the solution to the behavior was to prescribe more opioids. This document was available on the *Partners Against Pain* website until at least 2016.

(d) A *Partners Against Pain* "Pain Management Kit" likewise promoted the pseudoaddiction concept, referring prescribers to the 2001 AAPM/APS "Definitions Related to the Use of Opioids for the Treatment of Pain." The *Partners Against Pain* "Pain Management Kit" was distributed in Indiana from at least 2006 through 2012.

108. Purdue also created, funded, and controlled a website targeted at patients, caregivers, and prescribers: *In the Face of Pain* (www.inthefaceofpain.com), which was publicly accessible until it was deactivated in October 2015, following an investigation by the New York Attorney General. Upon information and belief, this website was promoted to Indiana prescribers and patients. Indiana residents accessed the *In the Face of Pain* website 7,913 times between 2010 and October 2015.

109. The *In the Face of Pain* website is another example of Purdue's "unbranded" marketing; although it featured the Purdue copyright at the bottom of each page, the site was designed to cultivate the "impression that it [was] neutral and unbiased."

(a) The *In the Face of Pain* website asserted that policies limiting access to opioids are "at odds" with best medical practices, and encouraged patients to be "persistent" in finding doctors who will treat their pain—but contained no mention of the risk of addiction. Instead, the website contained a single link, that if followed, took the consumer to a separate document that briefly mentioned opioid abuse, but not addiction.

(b) At the same time, *In the Face of Pain* contained testimonials from several dozen physician "advocates" speaking positively about opioids but failed to disclose that from 2008 to 2013 (the years for which this partial financial information is available), Purdue paid 11 of these advocates a total of $231,000.

110. Purdue's misrepresentations regarding the addictive properties of OxyContin and the risk of addiction are contrary to longstanding scientific evidence, and its failures to disclose the risk of addiction are material given both the magnitude of the risk and the grave consequences of addiction.

111. Purdue pled guilty to federal charges of misbranding under the Federal Food, Drug, and Cosmetic Act for deceptively claiming that patients taking OxyContin would not experience peaks and valleys. Moreover, Purdue was aware that for many patients, OxyContin does not provide even 12 hours of pain relief and will cause patients to experience a crash (or valley) hours before they are due to take their next pill.

112. Purdue's other statements regarding addiction are also indefensible. Studies have shown that at least 8-12%—and as many as 30% or even 40%—of patients on long-term opioid therapy experience problems with addiction. At the conclusion of its evidence review in 2016, the CDC found that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder," the diagnostic term for addiction. The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

113. Purdue's depiction of opioid addiction as manifesting in only the most extreme methods of abuse—methods associated with illegal street drugs—is also contrary to fact. Opioid addicts who snort and inject crushed prescription pills are uncommon; the far more typical reality is that patients become addicted and maintain that addiction through oral use. These depictions were harmful because they reassured doctors that as long as they were not observing those more extreme signs of abuse, they did not need to worry that their patients were abusing or addicted to opioids.

2. Exaggerating the Efficacy of "Abuse-deterrent" Properties.

114. In 2010, Purdue developed an abuse-deterrent formulation for OxyContin and Hysingla ER—a new coating and elements to make these pills more difficult to crush or inject.

115. Purdue regularly cites its introduction of abuse-deterrent opioids as evidence of its commitment to addressing the opioid crisis, as described in Section IV. In fact, the reformulation and the change in labeling solved an important business problem for Purdue: how to keep the money flowing after April 2013, when OxyContin's original patent was set to expire.

116. Purdue used the abuse-deterrent reformulation of its opioids as a primary selling point to differentiate its products from its competitors, especially generic opioids. In delivering this sales message, Purdue sales representatives falsely claimed or implied to Indiana prescribers that Purdue's abuse-deterrent formulations (a) prevent tampering and that these products cannot be crushed or snorted; (b) prevent or reduce opioid abuse, diversion, and addiction overall; and (c) are safer than other opioids.

117. Multiple Indiana prescribers recall Purdue sales representatives telling them that the abuse-deterrent properties of Purdue drugs made them safer than generics, that abuse potential was greatly decreased, and—as recently as late 2017—that the way to prevent addiction was to use an abuse-deterrent formulation.

118. An Indiana doctor specifically recalled that, between 2012 and 2015, a Purdue representative told him that when drugs were diverted to the streets, they were only taken in crushed form, not swallowed whole.

119. Another Indiana doctor recalled being told by a Purdue sales representative in the last two years that the ER formulation was less addictive because it did not offer the same immediate high as the IR products, and the formulation changes for OxyContin ER made it more difficult to abuse and therefore less subject to abuse or diversion.

120. Purdue's internal documents confirm that it was well-aware that prescribers who were detailed about the abuse-deterrent properties of Purdue's opioids were likely to come away with the misimpression that those opioids had a "safer formulation," were reformulated in a manner that would "prevent abuse," and had less potential for "abuse and diversion." The majority of those prescribers considered abuse-deterrent technology to be "an advantage" and said it had "a favorable impact on their perception of opioids." Purdue also knew that prescribers detailed on the abuse-deterrent properties of OxyContin were significantly more likely to increase their prescribing of that drug compared to prescribers who had not been detailed with that message.

121. Data from inVentiv Health, a market research and analytics company that tracks promotional messaging in the pharmaceutical industry, further demonstrate that Purdue's sales representatives made these deceptive statements to prescribers. Practitioners in the Midwest Region—which includes Indiana—received messages from Purdue sales representatives that OxyContin has "less potential for abuse," has been found "abuse preventative in clinical trials," and that the drug is abused "only when used incorrectly."

122. Indiana prescribers' recollections are also consistent with a 2014 national survey of 1,000 primary care physicians—in which nearly half reported that they believed abuse-deterrent

formulations of opioids are inherently less addictive. One-third of the doctors in that same study had the mistaken impression that most prescription drug abuse is by means other than swallowing the pills as intended.

123. Purdue's misrepresentations were deceptive and misleading for several reasons:

- **First**, they were inconsistent with the FDA-approved labels for OxyContin and Hysingla ER, which affirmatively indicate that their abuse-deterrent properties can be defeated, state that the drugs can be abused orally notwithstanding the abuse-deterrent properties, and do not indicate that the drugs prevent or reduce abuse, misuse, or diversion.

- **Second**, prescription opioid abuse takes several forms, the most common of which is oral abuse, which includes not only using the drugs without a prescription, but also taking higher or more frequent doses than prescribed. When the FDA reviewed Purdue's application for approval of the abuse-deterrent reformulation, the agency found that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)" and that "[w]hile the reformulation is harder to crush or chew, possibly mitigating some accidental misuse, oxycodone HCI is still relatively easily extracted" (emphasis added).

- **Third**, Purdue knew or should have known that its abuse-deterrent drugs still are regularly tampered with and abused. In online forums such as bluelight.org and Reddit, drug abusers discuss a variety of ways to tamper with OxyContin and Hysingla ER, including by grinding the pills, microwaving then freezing them, or dissolving them in soda or lemon juice. Indeed, a still-pending citizen petition submitted by another pharmaceutical firm in 2016 challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily process OxyContin for snorting or injection. And a 2015 study by researchers at Washington University in St. Louis found that many addicts continued to abuse reformulated OxyContin. Of the survey respondents who continued to abuse the drug, most either continued with or switched to oral abuse, while about a third found various methods to continue snorting or injecting the drug.

124. Purdue knew that its marketing should not go beyond the words "abuse-deterrent properties" to claim that OxyContin and Hysingla actually deter abuse. The FDA was aware that the abuse-deterrent formulation of OxyContin required more "effort, time, experience and tools to create a fine powder for intranasal abuse," but could still be crushed and abused in this manner.

125. Purdue's deceptive marketing of the benefits of its abuse-deterrent formulations was particularly dangerous because it overcomes the very risk that doctors and patients are

concerned about. It persuaded doctors—who might otherwise have curtailed their opioid prescribing—to continue prescribing Purdue's opioids in the mistaken belief they were safer. It also allowed prescribers and patients to discount evidence of opioid addiction, and attribute it to other, less safe opioids—*i.e.*, to believe that while patients might abuse or overdose on non-abuse-deterrent opioids, Purdue's opioids did not carry that risk.

3. Failing to Disclose the Increased Risks of Higher Doses of Opioids.

126. Purdue falsely told Indiana prescribers and consumers that opioids can be taken at ever-increasing doses for better pain relief, without disclosing that higher doses carry greater risk of addiction and overdose.

127. The ability to escalate doses was critical to Purdue's efforts to market opioids for long-term use to treat chronic pain. Unless doctors felt comfortable prescribing increasingly higher doses of opioids to counter tolerance to the drugs' effects, they may not have chosen to initiate opioid therapy at all—because chronic opioid patients develop a tolerance to the drugs, requiring the dose to be increased over time. Numerous Purdue marketing materials depict the seven OxyContin tablet strengths—in a line or even a series of steps—and instruct prescribers that they can "titrate," *i.e.*, increase the dose, "as clinical need dictates."

128. Purdue's sales representatives omitted from their sales conversations any discussion of increased risks associated with higher doses of opioids, despite knowing that dose escalation—"titrating up," in Purdue's parlance—was virtually inevitable. A key sales strategy was to persuade prescribers to convert patients from other, non-opioid pain relievers to the lowest dose of OxyContin, without discussing that the dose would need to be increased over time. Indiana sales representatives used the patient vignette of Sam, an elderly patient on non-steroidal anti-inflammatory drugs ("NSAIDs") to gain a prescriber's commitment to convert patients from non-opioid medications to the lowest dose of OxyContin:

> I mentioned Oxycontin to physician with indication and the seven tablet strengths. I mentioned Sam in Sales Aid (0P0560) who has osteoarthritis of the knee and has taken different NSAIDS and he was having a hard time tolerating them. I discussed with physiciasn [sic] would prescribe after this scenario for Sam and physician mentioned if he has insurance could prescribe low dose Oxycontin as 10mgs. Q12H. I mentioned good answer and that Oxycontin would be appropriate for this patient and can increase the Q12H doseif [sic] needed.

129. Purdue and Purdue-sponsored publications and CMEs available in Indiana also misleadingly suggested that higher opioid doses carried no added risk. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe what—in the patient's view—was a sufficient dose of opioids, the patient should find another doctor who would. *A Policymaker's Guide*, the 2011 publication on which Purdue collaborated with the American Pain Foundation, asserted that dose escalations—even unlimited ones—are "sometimes necessary," but did not disclose the risks from high doses of opioids.

130. Even where Purdue marketing pieces acknowledged that certain serious risks rose with increasing the opioids' dose, they failed to disclose the dramatically increased risk of addiction. For example, a 2009 brochure for prescribers stated that "there is no defined maximum daily dose" and "[t]he ceiling to analgesic effectiveness is imposed only by side effects." Side effects were defined to include respiratory depression and various non-serious events such as constipation, but not addiction or opioid abuse.

131. There is no substantial scientific evidence that doses of opioids can be continuously titrated upward without significant added risk. On the contrary, patients develop a tolerance to opioids' analgesic effects quicker than they develop a tolerance to opioids' depressive effects on respiration. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. Patients receiving

high doses of opioids as part of long-term opioid therapy are 3 times to 9 times more likely to suffer overdose from opioid-related causes than those on low doses.

132. As confirmed by the CDC in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established," while the risks for serious harms are clear and dose-dependent. The CDC has published that "higher dosages haven't been shown to reduce pain over the long term. One randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME)."

133. 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 are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

134. Because of these risks, the 2016 CDC Guideline advises doctors to "avoid increasing dosage" above 90 morphine milligram equivalents (MME) per day. Of the seven available OxyContin tablet strengths, the three strongest—40 milligrams (120 MME), 60 milligrams (180 MME), and 80 milligrams (240 MME)—all exceed the CDC limit when taken (as directed) twice daily, and the 30 milligram dose equals the 90 MME limit when taken twice daily as directed. Yet, many patients have continued to receive dangerously high doses of opioids. Among Indiana patients insured by Medicaid, for example, 49% of patients taking OxyContin between 2012 and July 2018 ultimately were prescribed doses exceeding the CDC's recommended limit of 90 MME.

C. Purdue Grossly Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use.

135. To convince Indiana prescribers and patients that opioids should be used to treat chronic pain despite the unavoidable risk of addiction, Purdue had to persuade them that there were significant benefits to long-term opioid use.

1. Overstating Pain Control and Improvement in Function.

136. Purdue promoted the purported benefits of long-term opioid use—pain control and improved function—while falsely and misleadingly implying that these benefits are supported by scientific evidence. In their sales conversations with Indiana prescribers, Purdue sales representatives who worked in Indiana between 1997 and 2016 failed to disclose the lack of evidence supporting long-term use. Purdue promotional materials shown and distributed to Indiana prescribers by Purdue detailers likewise promoted long-term use without disclosing the absence of long-term studies.

137. For example, the OxyContin "Conversion and Titration Guide," which sales representatives widely distributed in Indiana, recommended that "the need for around-the-clock opioid therapy should be reassessed periodically (*e.g.*, every 6 to 12 months) as appropriate for patients on chronic therapy"—implying that use for a period of years was appropriate without disclosing the absence of any evidence showing that therapeutic benefits existed for use lasting 6 months, 12 months, or longer. Purdue detailers showed this guide to prescribers across the country, including in Indiana, for years. Even after removing the specific references to periodic annual and semi-annual reviews, Purdue still trained its detailers to recommend semi-annual or annual medication reviews.

138. Purdue specifically has claimed—also without evidence—that long-term opioid use will improve patients' daily function and quality of life. Purdue's sales representatives active in

Indiana between at least 1992 and 2013 have delivered this unsubstantiated and deceptive message in their Indiana sales visits, and Indiana prescribers recall hearing this deceptive marketing message as recently as 2015.

139. On information and belief, materials written or sponsored and influenced by Purdue were distributed or available in Indiana to reinforce this message. The APF book *Exit Wounds* asserted unequivocally: "The bottom line with opioids is that these are very valuable pain-relievers when used correctly and responsibly and can really help improve your functioning in daily life." APF's *A Policymaker's Guide* erroneously claimed that "multiple clinical studies have shown that long-acting opioids, in particular, are effective in improving [d]aily function … [and] quality of life for people with chronic pain."

140. Purdue knew better. The FDA has cautioned for years that opioid manufacturers should not make claims regarding functional improvement and ability to perform daily activities, warning Purdue competitors in public letters that such claims lacked substantial scientific evidence.

141. In internal correspondence from 2011, Purdue acknowledged that it needed evidence to support these claims. It is impossible to believe that Purdue was not aware of available and growing evidence indicating that opioids do not improve patient function, and, in fact, may worsen patients' health over a long-term course of therapy.

- A 2006 academic review of studies found that "[f]or functional outcomes, … other [non-addictive] analgesics were significantly more effective than were opioids."[3]
- A 2011 study concluded that increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety,

[3] Andrea D. Furlan et al., "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," 174(11) *Can. Med. Ass'n J.*, 1589-1594 (2006).

post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.[4]

- Studies from 2007, 2008, 2012, 2013, and 2014 of patients using opioids to treat lower back pain and migraine headaches, for example, consistently showed that patients experienced deteriorating function over time, as measured by ability to return to work or physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[5]

- Studies analyzing workers' compensation claims in 2008 and 2012 found that (a) workers who take opioids are almost four times more likely to reach costs over $100,000, owing to greater side effects and slower returns to work;[6] (b) receiving an opioid for more than seven days increased patients' risk of being on work disability one year later;[7] and (c) an opioid prescription as the first treatment for a workplace injury doubled the average length of the claim.[8]

142. These findings are consistent with the CDC's exhaustive review of the literature, concluded in 2016. The CDC summarized: "there is no good evidence that opioids improve pain or function with long-term use." Specifically, the CDC noted that "evidence is limited or

[4] Richard A. Deyo et al., "Opioids for Back Pain Patients: Primary Care Prescribing Patterns and Use of Services," 24 *J. Am. Bd. Fam. Prac*., 717-27 (2011).

[5] Luis E. Chaparro et al., "Opioids Compared to Placebo or Other Treatments for Chronic Low-Back Pain," 8 *Cochrane Database of Systematic Reviews* (Aug. 27, 2013); Jeffrey Dersh et al., "Prescription opioid dependence is associated with poorer outcomes in disabling spinal disorders," 33(20) *Spine*, 2219-27 (Sept. 15, 2008); Dawn C. Buse, "Opioid Use and Dependence Among Persons With Migraine: Results of the AMPP Study," 52 *Headache: The J. of Head & Face Pain*, 18-36 (Jan. 2012); Nat'l Headache Found., *Opioid Treatment of Migraine is Associated with Multiple Risks*, News Briefs, June 15, 2012, http://www.headaches.org/2012/06/15/opioid-treatment-of-migraine-is-associated-with-multiple-risks/; Nat'l Headache Found., "Migraine Patients Taking Addictive Or Non Approved FDA Migraine Treatment, Press Kits," May 15, 2007, http://www.headaches.org/press/NHF Press_Kits/Press Press_Kits/Press_Kits_Migraine_Patients_Taking_Addictive_Or_Non_ Approved_FDA_Migraine_Treatments (last visited Apr. 15, 2014).

[6] Jeffrey A. White et al., "The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan," 54(8) *J. of Occupational & Environ. Med*., 948-953 (2012).

[7] Gary M. Franklin et al., "Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort," 33(2) *Spine*, 199-204 (2008).

[8] Dongchun Wang et al., "Longer-Term Use of Opioids," Workers Comp. Res. Inst. (Oct. 2012).

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." In addition, the CDC observed that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." Purdue's claims that patients will experience functional improvement, in addition to lacking evidence, also ignore these very serious consequences.

2. Equating 12-hour Dosing with 12-hour Pain Relief.

143. To convince Indiana prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. While the product labeling specifies 12-hour dosing, Purdue's marketing went well beyond the label's limited instructions to take OxyContin every 12 hours by (1) affirmatively claiming that OxyContin lasts for 12 hours; and (2) by failing to disclose the material fact that OxyContin does not provide 12 hours of pain relief for a significant percentage of patients. Purdue has known this since 1996. There is even a name for it: "end-of-dose failure."

144. Purdue's decision to seek FDA approval for 12-hour dosing ("Q12") when the drug was introduced in 1996 was a business decision. Internal Purdue marketing documents show that Purdue considered 12-hour dosing the key to distinguishing OxyContin from its competition—short-acting, generic opioids (like Percocet and Vicodin) that require patients to wake in the middle of the night to take the next dose in order to maintain adequate pain control. Purdue has held tight to this perceived market advantage, which explains why Purdue has never pursued FDA approval for more frequent dosing on the OxyContin label (*e.g.*, every 8 hours). In Purdue's own words, 12-hour dosing was "a significant competitive advantage."

145. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake in

the middle of the night to take another dose. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved this marketing claim.

146. 12-hour dosing has remained a principal feature of Purdue's marketing and has been featured in most OxyContin promotional pieces.

- A 2012 version of Purdue's Conversion and Titration Guide—which was distributed nationally (including in Indiana) through 2017—for example, contains the tag line: "Because each patient's treatment is personal / Individualize the dose / Q12 OxyContin Tablets."
- A 2014 visual aid used by sales representatives refers not merely to OxyContin, but to "every 12-hour OxyContin" and "Every-12-Hour OxyContin Tablets."
- The 2017 Conversion and Titration Guide advises prescribers that they can increase the dosage to achieve adequate pain relief "as clinical need dictates, while maintaining every 12-hour dosing."

None of these pieces discloses that the pain relief from each 12-hour dose will not last 12 hours for many patients, thereby leaving prescribers and patients unprepared for end-of-dose failure and the craving for more opioids that it creates. This is both an affirmative misrepresentation and a material omission.

147. Indiana health care providers complained to Purdue sales representatives that OxyContin was not giving 12 hours of pain relief to a significant number of their patients. One Indiana doctor told the State that he complained to Purdue for years about the fact that a 12-hour dose only lasts for eight hours. He said that he repeatedly brought this up with the Purdue sales representative who visited him over the past 6 years, and the representative's response was to encourage higher dosing of OxyContin.

148. When Purdue sales representatives were asked whether Indiana doctors raised this concern, a district manager who worked in Indiana until 2016 replied, "[w]e heard it all the time."

149. Instead of addressing the real problem, Purdue trained sales representatives who worked in Indiana between 1997 and 2016 to tell prescribers to increase the patient's OxyContin dose as a way to compensate for end-of-dose failure. As one district manager explained, "Our FDA approved labeling was only for q12 hour dosing, so that's all we could talk about." Thus, she trained her Indiana detailers to "encourage the doctor to maybe titrate the patient [increase the dose] instead of adding a third dose." Purdue's constant suggestion to increase the dose was not accompanied by appropriate warnings regarding increased risk of addiction associated with increased doses, as discussed in Section II.B.4. During the State's investigation of Purdue, an Indiana district manager confirmed that she reported to her superiors at Purdue—multiple times and over a span of years—that she was frequently hearing that 12-hour OxyContin dosing did not work.

150. Despite their training to give a non-responsive, scripted answer to prescriber concerns about OxyContin's 12-hour duration, Purdue sales representatives also hinted at or outright told Indiana prescribers that prescribing OxyContin 3 times a day was an option. According to one Indiana health care provider, when she informed a Purdue detailer that her patients were not getting 12 hours of relief from OxyContin, the detailer told her that she had heard this from other doctors' offices, and that those other offices were writing the prescription for 8-hour (3 times a day) dosing. The prescriber inferred that the detailer was implicitly encouraging her to write the prescription for 8-hour dosing. Another prescriber also told Purdue sales representatives that "lots" of her patients were not getting 12 hours of relief from OxyContin. The sales representative acknowledged that they heard the same thing from other doctors and told her to try prescribing every 8 hours (3 times a day).

151. According to a 2016 *Los Angeles Times* investigation, Purdue's own early studies showed many patients asking for more medication before their next scheduled dose. In one clinical trial, one-third of the patients dropped out because the treatment was ineffective. Purdue's researchers changed the rules to allow patients to take supplemental immediate release/short-acting opioids—referred to as "rescue medication"—between OxyContin twice-daily doses. In another OxyContin study conducted by Purdue, the majority of patients used rescue medication, and 95% resorted to it at least once.

152. Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction." End-of-dose failure causes patients to experience the early stages of psychological and physical withdrawal symptoms on a daily basis, followed by a euphoric rush when they take their next dose—leading to a cycle that fuels a craving for OxyContin. This exacerbates the risks of addiction, overdose, and death. With a higher dose, the pain relief does not last 12 hours—patients experiencing end-of-dose failure will simply experience higher highs and lower lows, increasing their craving for their next pill.

153. "Titrating up" to cover the end-of-dose failure also means that health care providers routinely prescribe OxyContin in doses that exceed the maximum recommended daily limit of 60mg (90 MME). Based on a nationwide analysis by the *Los Angeles Times* in 2014, more than 52% of patients taking OxyContin longer than three months were on doses greater than the 60mg that the 2016 CDC Guideline urges prescribers to "avoid" or "carefully justify."

154. These high doses of OxyContin are similarly prevalent in Indiana. About 59% of OxyContin and Hysingla prescriptions covered by Medicaid in Indiana in the last decade exceeded the CDC threshold.

3. Pitching Ineffective Low Doses.

155. Purdue long-ago recognized that it would need to overcome the reservations of prescribers who preferred to treat chronic pain with NSAIDs, combination acetaminophen-low dose opioid products (such as Percocet), and non-pharmacologic therapies (*e.g.*, exercise, improved ergonomics, and physical therapy) rather than expose their patients to the risks of addiction and overdose associated with opioids. Purdue marketed the lowest doses of OxyContin—the 10mg and 15mg pills— as safe *and* effective for treating pain to assuage concerns about opioid side effects and addiction risks when Purdue had no scientific evidence demonstrating that those low doses provide any analgesic relief.

156. Purdue call notes from Indiana detailers show that sales representatives regularly promoted the 10mg and 15mg doses of OxyContin to Indiana prescribers until at least 2015—without disclosing the lack of evidence of efficacy or distinguishing them as merely "starter doses" that would require escalation for effective analgesia. Compensation documents for Indiana detailers show that Purdue specifically encouraged promotion of these doses, by using a multiplier for any growth in sales of the 10mg and 15mg doses when calculating bonus compensation. Sales of these low doses were worth 20% more than sales of the 20mg, 30mg, or 40mg tablets. Nothing in the call notes from Indiana detailers suggests that sales representatives advised prescribers that clinical research showed that 10mg OxyContin was ineffective. Interviews of Indiana prescribers and depositions of former Purdue sales representatives confirm that this critical information was neither delivered nor received.

157. In fact, Purdue has never established the efficacy of the 10mg and 15mg pills, which were always intended as "starter" doses or means to fine-tune the strength of doses between 20 and 80 milligrams. At the same time, Purdue had to know that once patients started on OxyContin,

dose escalation ("titrating up")—with the attendant increased risks of dependence and addiction—was likely, if not inevitable.

158. The OxyContin package insert lists only one study about the efficacy of the 10mg dose in adults—and the results showed that the 10mg dose was not effective. As printed on the OxyContin package insert, this study concluded that "OxyContin 20 mg, but not 10mg, was statistically significant in pain reduction compared with placebo."

159. The 10mg pills (and later, 15mg pills) should only have been marketed for limited purposes: (a) to allow precise doses with a minimum combination of pills, something Purdue markets as "dosing convenience"; and (b) to permit physicians to manage the most serious side effects (like respiratory depression) by starting patients on a very low dose and allowing the body to adjust to the drug, with the expectation that the dose would soon be increased to a therapeutic pain-relief level. Reflecting that latter purpose, the package insert instructs prescribers that "The starting dosage for patients who are not opioid tolerant is OxyContin 10mg orally every 12 hours. Use of higher starting doses in patients who are not opioid tolerant may cause fatal respiratory depression," but that thereafter "Close observation and frequent titration are warranted until pain management is stable on the new opioid."

160. In 2000, the FDA warned Purdue that an advertisement showing an image of the 10mg OxyContin pill placed beneath statements about the drug's efficacy misleadingly implied that the drug was effective at this dose. From the FDA:

> You present the headline, "IN A STUDY OF 133 PATIENTS WITH MODERATE TO SEVERE OSTEOARTHRITIS PAIN*," followed by bulleted claims about this study. This presentation is followed by the product logo for OxyContin along with various doses of OxyContin that are available. This presentation suggests that any dose of OxyContin can be used for the treatment of moderate to severe osteoarthritis pain. However, the study only demonstrated OxyContin 20mg given twice daily to be significantly

> more effective than placebo at day 7 and 14. In fact, Oxycontin 10mg given twice daily was no better than placebo in reducing pain intensity. Therefore, your suggestion that any dose of OxyContin can be used in the treatment of moderate to severe osteoarthritis pain is unsubstantiated, and consequently misleading.

161. Despite this FDA warning, Purdue made similar misrepresentations in 2012 and later as to the efficacy of the 10mg and 15mg doses for the treatment of pain. Purdue made these representations directly to prescribers, through a visual aid used by detailers during in-office visits that were specifically labeled as "retained" and "not for distribution." On information and belief, this visual aid was sent by Purdue to sales representatives in Indiana.

162. Even worse than the lack of scientific evidence for these low doses, Purdue knew that even the 10mg and 15mg doses still carried significant risks. In 2007, Purdue admitted that as early as 2000, it had received numerous complaints about physical dependence and withdrawal symptoms occurring with usage of 10mg pills. Moreover, low-dose OxyContin had the same potential for diversion, misuse, and abuse as higher dosages.

163. Purdue's 10mg and 15mg OxyContin marketing strategy has not simply exposed patients to short-term inconvenience and discomfort for little or no therapeutic benefit. The misleading and dangerous implication of marketing 10mg and 15mg doses as effective for treating pain is that doctors can reduce the risks of addiction and overdose to acceptably safe levels while still providing their patients the pain-relief benefits of OxyContin.

164. Purdue knew that patients were highly likely to require increases of their doses of opioids over time—*i.e.*, "titrating up"—to obtain adequate pain relief. In fact, that is what the label itself described. Indeed, Purdue trained its detailers to *recommend* titrating up as the solution to a variety of complaints about inadequate pain control. But Purdue did not train its detailers to advise or discuss with doctors the complete lack of evidence that the 10mg and 15mg doses were effective at treating pain.

165. Purdue also knew that the risks of dependence, overdose, and addiction rise with the dose. By promoting low-dose OxyContin over other treatments, Purdue purposefully opened a gateway to dependence, addiction, misuse, and abuse—building a captive market of patients who it exposed to escalating risks over time. This consequence is particularly disturbing when many of the patients targeted for 10mg and 15mg OxyContin were, as explained below, prime candidates for safer and more effective non-opioid therapies.

4. Overstating the Efficacy of Screening Tools.

166. Purdue falsely instructed Indiana prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to reliably identify and safely prescribe opioids to patients, including patients predisposed to addiction.

167. Purdue conveyed these messages in its in-person detailer visits in Indiana, where sales representatives discussed with health care providers ways to screen patients at high risk for addiction through urine tests and patient contracts. When Indiana prescribers expressed hesitance about prescribing a Purdue opioid for fear of attracting drug seekers, internal Purdue records from 2011 and 2012 reflect that the sales representative did not address the concern, but rather parroted inapplicable responses like, "prescribe[e] for appropiate [sic] patients within guidelines, using INSPECT, and urine drug screens" or only give the drug "to patients she knows and trusts"—advice that relates to diversion, not to dependence or addiction. These prescribers told the Purdue representative they would consider prescribing the drug.

168. Sales representatives in Indiana used and disseminated the *Partners Against Pain* "Pain Management Kit," which contained several drug abuse screening tools. The Pain Management Kit included the "Opioid Risk Tool" created by opioid advocate Dr. Lynn Webster, who received research funding from Purdue. The Opioid Risk Tool is a five-question, one-minute screening tool that assumes honest and accurate patient self-reporting (particularly unlikely given the sensitive topic and the nature of addiction) to purportedly allow doctors to manage the risk that their patients will become addicted to or abuse opioids.

169. One former Purdue sales representative who detailed Indiana prescribers from 2009 until 2015 described the *Partners Against Pain* material (including the kit and screening tool) as

something she used with Indiana prescribers because it contained "tools and resources for physicians … [to] help identify appropriate [opioid] patients."

170. Purdue also deceptively promoted screening tools in CMEs and at scientific conferences as reliable means for predicting and managing addiction risk. For example, Purdue sponsored a 2011 web-based CME taught by Dr. Lynn Webster titled "Managing Patient's Opioid Use: Balancing the Need and Risk." Upon information and belief, this webinar was available to Indiana prescribers. Dr. Webster's webinar deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths"—providing the type of false assurance designed to encourage opioid prescribing. This CME was offered online as late as 2017.

171. Purdue also funded a deceptive 2012 symposium titled "Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes," which taught doctors that through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be safely treated with opioids.

172. The 2016 CDC Guideline confirms the lack of substantial scientific evidence to support Purdue's claims regarding the utility of screening tools and patient management strategies in managing addiction risk. The 2016 CDC 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—all widely believed by doctors to detect and deter abuse. As a result, the 2016 CDC 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."

173. Such misrepresentations made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting on chronic opioid therapy. Purdue's misrepresentations were critical to assuring doctors—who were beginning to see or hear about rising opioid addiction—that they could safely prescribe opioids in their own practices and that addiction was not unavoidable, but the result of other prescribers' failing to rigorously manage and weed out problem patients.

5. Promoting OxyContin as Safer than NSAIDs and Other OTCs.

174. One of Purdue's main selling points for its opioids—including but not limited to OxyContin—was that unlike NSAIDs and other pain relievers (*e.g.*, Advil or Tylenol), there is no maximum dose for opioids. This gave the false impression that opioids were safer than Advil or Tylenol. Purdue also deceptively presented the risks of opioids in comparison to the risks presented by over-the-counter pain relievers like NSAIDs—containing ibuprofen (*e.g.*, Advil or Motrin), which can cause gastrointestinal bleeding at high doses—and acetaminophen (*e.g.*, Tylenol), which can cause liver toxicity at high doses.

175. Purdue sponsored a 2013 CME titled "Overview of Management Options" that highlighted the evidence of adverse effects from high doses of NSAIDs but did not address the increased risk from using high doses of opioids. The CME was edited by Dr. Russell Portenoy, who received research support, honoraria, and consulting fees from Purdue. Issued by the American Medical Association (AMA) in 2013, the CME remains available online to Indiana prescribers from the AMA. Purdue also sponsored a pain pamphlet for physician assistants that similarly emphasized the risk of liver damage from acetaminophen at higher doses, while omitting any comparable discussion of the risks of opioids at high doses.

176. Former Purdue sales representatives who were detailing Indiana prescribers as recently as 2015 confirmed that they told Indiana prescribers that acetaminophen and ibuprofen

posed risks to patients, while simultaneously explaining that Purdue's opioids do not contain the allegedly dangerous chemical compounds found in Advil and Tylenol. They also promoted Purdue's opioids in comparison with popular, short-acting "combination opioids" like Vicodin. As one former Indiana Purdue sales representative explained, because short-acting opioids often contain acetaminophen, there was a ceiling dose, "strictly because of the acetaminophen … the ceiling dose really comes into play when you have the acetaminophen." The sales representative went on to say, "Probably one of the biggest as far as deaths is liver toxicity with acetaminophen."

D. Purdue Targeted the Elderly and Opioid-Naïve Patients to Expand Its Market.

177. Part of Purdue's strategy to continue expanding its market share, and hence its revenue, has been to target two overlapping markets: the elderly, a demographic that has seen an explosion in opioid prescribing in recent years, and opioid-naïve patients, those who previously had not taken opioids.

178. Training materials and sales goals for Purdue's sales representatives, as well as Indiana detailer call notes and sales manager "ride-along" reports from 2011 through 2014, include multiple references to Purdue's efforts to persuade doctors to start prescribing OxyContin and Purdue's other ER/LA opioids to elderly patients. As one former Indiana sales representative stated, Purdue encouraged its representatives to remind all Indiana prescribers that OxyContin was covered for Medicare part D patients: "[the elderly was] an approved … patient population to go after." Call notes from Indiana also show that detailers told prescribers that OxyContin was "safe in the elderly" while simultaneously reminding them of all OxyContin dosage levels available. Managers evaluating the performance of sales representatives in Indiana noted favorably when sales representatives "Bridged to Oxycontin and asked for those med d pts [Medicare part D patients]."

179. There is ample evidence from former Indiana detailers to demonstrate the extent of Purdue's efforts to persuade doctors who were prescribing immediate release opioids such as Percocet (a Schedule II opioid that combines oxycodone and acetaminophen) to prescribe OxyContin instead, by emphasizing the dangers of liver toxicity from acetaminophen. This practice of using ER rather than IR opioids increases patients' risk for addiction and overdose, since the risks are dose-dependent. As the CDC has explained, use of ER/LA opioids such as OxyContin, which are indicated only for round-the-clock use, tends to be associated with higher daily dosages than use of as-needed IR opioids.

180. When Indiana sales representatives were confronted by a reluctant prescriber, they were trained to promote (and did, in fact, promote) 10mg and 15mg OxyContin to allay the prescriber's concerns. As one Indiana detailer recorded in her call notes, "Shared the Oxycontin med D grid and asked for consideration for 65+ patients with chronic pain. Discussed Nursing home patients too. Noel said she shy [sic] away from C2 products. But she likes the idea of Oxycontin lower doses with Q12h control."

181. Purdue detailers in Indiana also specifically targeted nursing home residents through their physicians. In 2016, one-third of enrollees in Medicare Part D received at least one opioid prescription. And more than 500,000 enrollees nationwide were on a high dose of at least 120 MME—well above the 90 MME maximum threshold that the CDC has set. These high doses underscore the reality that even elderly patients do not simply remain on OxyContin 10mg—their doses escalate too, along with the concomitant increased risks.

182. Purdue's targeting of elderly patients overlapped with Purdue's broad marketing push to persuade doctors to prescribe OxyContin and Butrans to opioid-naïve patients—even when faced with reluctant practitioners. For example, an October 2012 sales representative training

bulletin provided suggested questions for prescribers designed to elicit their commitment to converting opioid-naïve patients to OxyContin. Manager ride-along notes from detailing visits made in Indiana during 2014 reflect Purdue's focus on expanding prescriptions through the conversion of opioid-naïve patients to OxyContin. One manager praised a sales representative for getting a prescriber to try Butrans for a particular patient after challenging the prescriber with: "when was the last time you initiated a new start for an opioid?" Another manager praised his detailer in 2012 when he "positioned Butrans for the opioid naïve," and obtained the Indiana doctor's prescribing "commitment for these types of patients."

183. Purdue's decisions to target the elderly and opioid-naïve patients reflect a business strategy that placed little value on the well-being and safety of consumers. Elderly patients are at higher risk for the most dangerous side effect of opioids—respiratory depression. They also are likely to experience more severe consequences from falls (fractures and hospitalizations) caused by the cognitive impairment that is associated with opioid use.[9] A 2010 paper reported that elderly patients who used opioids had a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.[10]

184. For "opioid-naïve" patients, the unproven benefits of long-term opioid therapy are not justified by the known and serious risks—particularly when safe and effective alternative treatments for their conditions exist. As the CDC summarized in 2016, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits" of opioids for chronic pain. Purdue targeted this population to enrich itself.

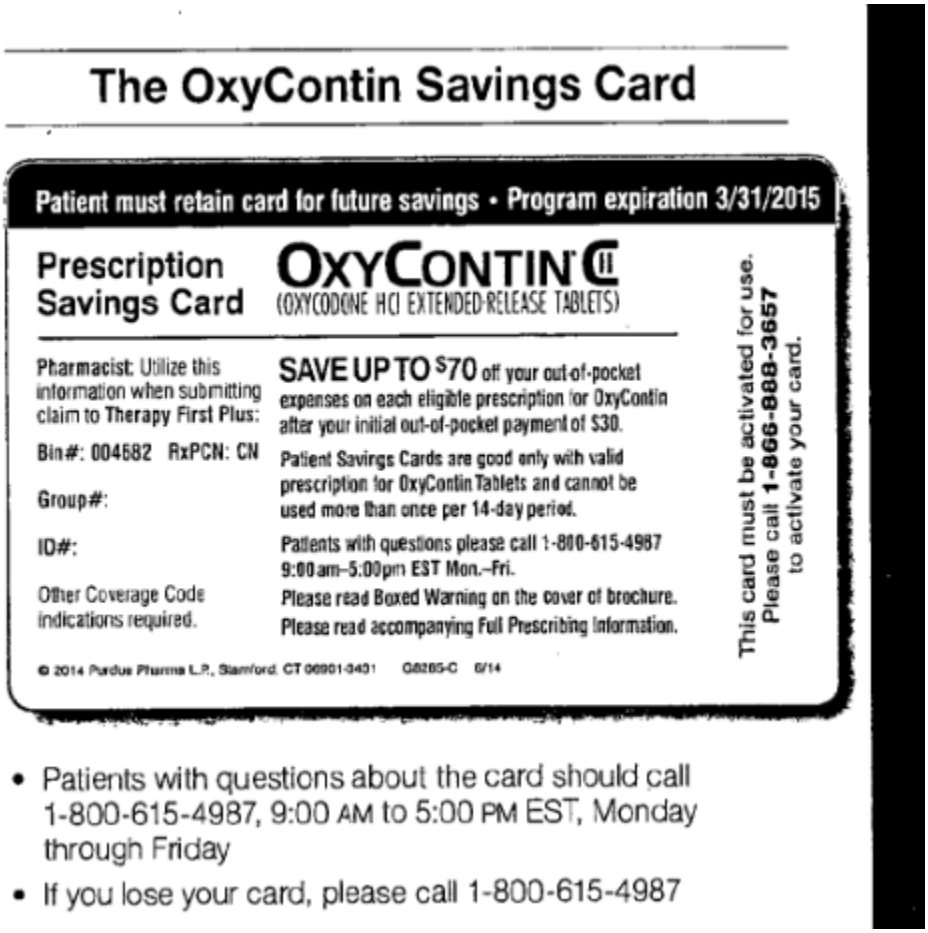
[9] Saunders, Dunn et al., "Relationship of opioid use and dosage levels to fractures in older chronic pain patients," *J. Gen. Intern. Med*., 2010;25:310-5.

[10] Kathleen W. Saunders et al., "Relationship of opioid use and dosage levels to fractures in older chronic pain patients," 2010(25) *J. Gen. Intern. Med*., 310-315 (Jan. 2009).

E. Purdue Used Savings Cards to Initiate and Encourage Long-term Use of Opioids.

185. Purdue's distribution of prescription discount "Savings Cards" for OxyContin, Butrans, and Hysingla was part of its deliberate marketing strategy to encourage, initiate, and extend long-term use of these drugs.

186. Purdue promoted, marketed, advertised, or distributed Savings Cards in Indiana that offered patients discounts on their out-of-pocket costs for OxyContin, Butrans, and Hysingla and encouraged long-term use of these drugs. Examples of the Savings Cards that Purdue promoted, marketed, advertised, or distributed include:



The OxyContin Savings Card

Patient must retain card for future savings • Program expiration 3/31/2015

Prescription Savings Card

OXYCONTIN® CII
(OXYCODONE HCl EXTENDED-RELEASE TABLETS)

Pharmacist: Utilize this information when submitting claim to Therapy First Plus:

Bin#: 004682 RxPCN: CN

Group#:

ID#:

Other Coverage Code indications required.

SAVE UP TO $70 off your out-of-pocket expenses on each eligible prescription for OxyContin after your initial out-of-pocket payment of $30.

Patient Savings Cards are good only with valid prescription for OxyContin Tablets and cannot be used more than once per 14-day period.

Patients with questions please call 1-800-615-4987 9:00 am–5:00 pm EST Mon.–Fri.

Please read Boxed Warning on the cover of brochure.

Please read accompanying Full Prescribing Information.

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This card must be activated for use. Please call 1-866-888-3657 to activate your card.

- Patients with questions about the card should call 1-800-615-4987, 9:00 AM to 5:00 PM EST, Monday through Friday
- If you lose your card, please call 1-800-615-4987

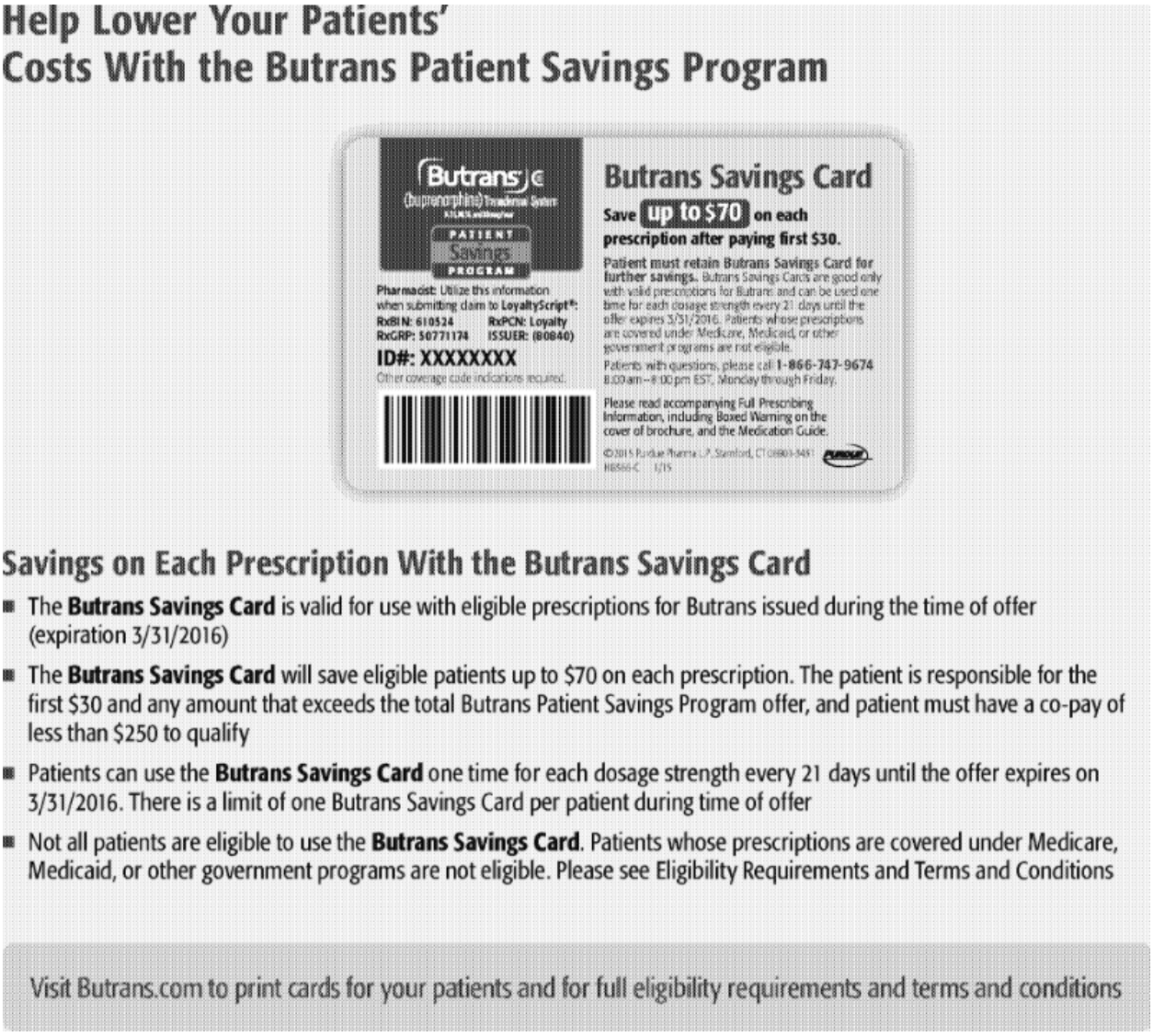
Help Lower Patients' Costs With the Hysingla ER Patient Savings Program*

To learn more and download cards visit Hysingla ER.com

***ELIGIBILITY REQUIREMENTS:**
This card cannot be used if prescriptions are covered by: (i) any federal or state healthcare program, including a state medical or pharmaceutical assistance program (Medicare, Medicaid, Medigap, VA, DOD, TRICARE, etc); (ii) Medicare Prescription Drug Program (Part D Program); (iii) insurance in states that have an "all payor" anti-kickback law or insurance that is paying the entire cost of the prescription. Card use must comply with all Terms and Conditions. Patients must meet eligibility requirements. Void where prohibited by law. Patients in VT are not eligible. Patients must meet eligibility requirements. Other restrictions may apply.

TERMS AND CONDITIONS:
Patients must meet eligibility requirements. Patient agrees to report their use of this card to any third party that reimburses them or pays for any part of the prescription price. Patient additionally agrees to not submit any portion of the product dispensed pursuant to this card to a federal or state healthcare program for purposes of counting it toward their out-of-pocket expenses (such as TrOOP under Medicare Part D or Medicaid). This card is not valid with any other program, discount, or incentive involving the covered medication. This offer is not contingent upon any past, present, or future purchases of the covered drug or any other product, and this offer may be rescinded, revoked, or amended without notice. No reproductions. This card is not insurance. This card is void where prohibited or where restricted beyond the terms herein.

RelayHealth eVoucherRx™ Purdue has partnered with RelayHealth to provide automatic savings at the pharmacy on qualified claims with commercial insurance coverage. For convenience, patients who have third-party insurance and visit a participating eVoucher pharmacy will have savings applied automatically for qualified claims—no Savings Card Required. At participating pharmacies, simply submit the patient's prescription and the patient will automatically receive the co-pay savings on qualified claims. For information, please call RelayHealth Customer Support at 1-800-388-2316.



187. The State alleges, on information and belief, that the Savings Cards for OxyContin, Butrans, and Hysingla that Purdue promoted, marketed, advertised, or distributed in Indiana do not bear prominent disclosures—as required by Indiana law—that the benefits offered are not insurance. A disclaimer sometimes appeared in the "terms and conditions" language in pamphlets or other material accompanying Savings Cards, but it did not appear on the Savings Cards themselves, nor did it appear in a prominent place in bold and prominent type.

188. Purdue trained sales representatives to discuss Savings Cards on every sales call. Purdue tracked the redemption of these cards and evaluated detailers' "sales skills" based, in part, on how many Savings Cards were redeemed in their territory.

189. Purdue's emphasis on Savings Cards helped to boost the "continuing prescriptions" group of patients—which constituted 80% of its OxyContin sales—beyond 90 days of use. In 2013, Purdue identified the need to "drive appropriate titration and length of therapy … with continuing patients" as a "critical success factor[]" for the OxyContin brand.

190. The Savings Card Program was a key tool that Purdue used to capture a long-term, dependable customer base. A 2012 Purdue sales training document asserted that "market research has shown that ~60% more patients stay on therapy >90 days if a savings card is redeemed." Internal Purdue business plan documents separately confirm that the Savings Card Program "has consistently shown a positive [return on investment]" and that "patients who receive these cards have up to a 49% increase in their likelihood to remain on OxyContin after 90 days."

191. Purdue also used Savings Cards to encourage new patients to try its opioids, by making the drugs significantly cheaper. In a 2012 sales training presentation, Purdue described its rationale for subsidizing a $0 (*i.e.*, free) Butrans copayment through Savings Cards for new patients: that a Savings Card was "effectively acting as a sample."

192. Purdue marketed, promoted, advertised, or distributed Savings Cards to Indiana prescribers and pharmacies for use by Indiana patients, who could present the cards at participating pharmacies for discounts on out-of-pocket pharmacy costs. Detailers met with prescribers and pharmacists and advised them to inform their opioid patients / customers about available discounts that would reduce the out-of-pocket price.

193. In 2012, Purdue introduced what it described in internal documents as "new channels to broaden access to Patient Savings Card Program": Relay Health, which provided automatic rebates at pharmacies, and downloadable savings cards on PurdueHCP.com. This training document identified the Savings Cards as being downloadable by "HCP" (healthcare providers), and Purdue call notes show that detailers in Indiana instructed prescribers on how to download savings cards. Purdue sales representatives in Indiana also discussed downloadable savings cards with pharmacists, informing them that *patients* could download the cards directly from Purdue websites—a workaround when prescribers chose not to offer them.

194. In the 2007 Settlements, Purdue expressly agreed to stop distributing samples of OxyContin. Indiana, moreover, strictly regulates the distribution of free narcotic samples. Nonetheless, Purdue used the promotion of Savings Cards to eliminate or steeply discount patient co-payments—effectively making these drugs free (or very inexpensive) to patients—as a way to drive long-term use.

III. THE INJURY TO INDIANA AND ITS CITIZENS: *Purdue Has Caused Significant Harm to Public Health, Welfare, and Finances in Indiana.*

195. Indiana and its citizens are suffering an epidemic of opioid addiction, abuse, overdose, and other injuries—with their attendant societal costs—as a result of the Purdue-driven overprescribing of, and increased patient demand for, opioids. Through State-funded health programs, more than two hundred million dollars has been spent for opioid prescriptions and related treatment. Many of these opioid prescriptions were not medically necessary or appropriate and would not have been written but for Purdue's fraudulent scheme.

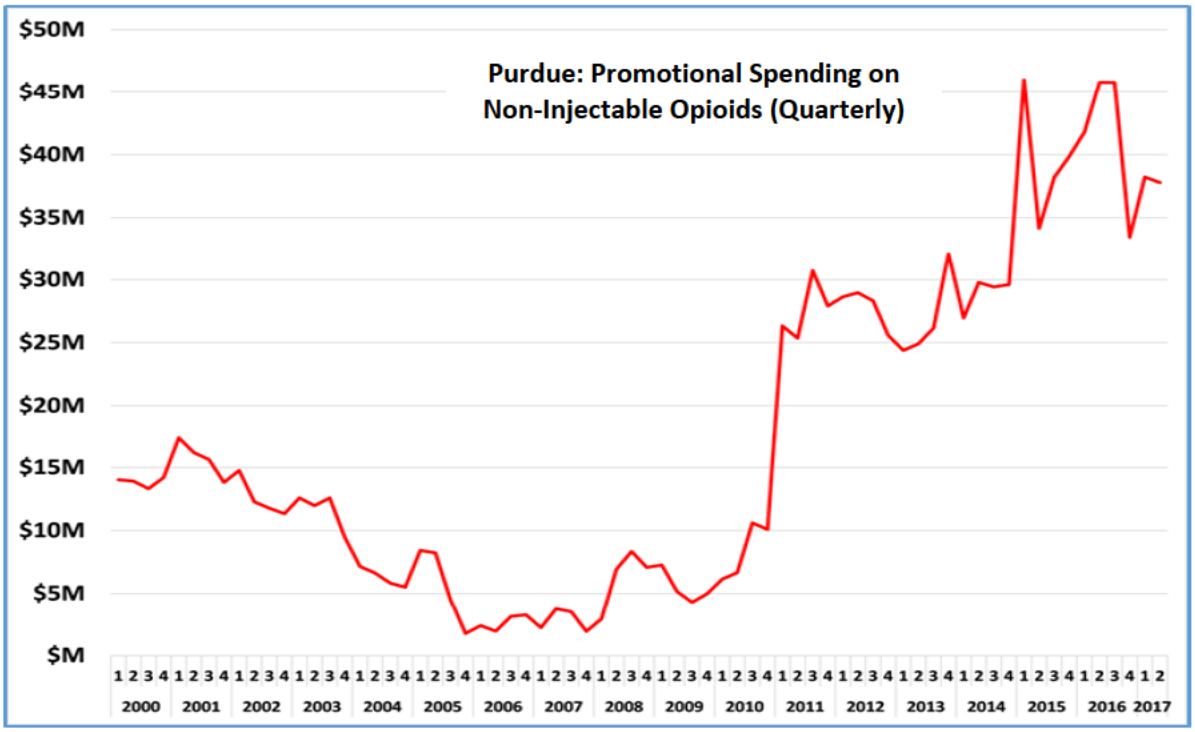
A. Purdue's Deceptive Marketing Has Fueled Opioid Prescribing in Indiana.

196. Purdue's misrepresentations have prompted Indiana health care providers to prescribe, patients to take, and the State to reimburse the cost of opioid prescriptions for the

treatment of chronic pain—directly contributing to an explosion in opioid use. Opioids are the most common treatment for chronic pain in the United States. The CDC has reported that, by 2012, healthcare providers were writing 259 million opioid prescriptions annually—"enough for every adult in the United States to have a bottle of pills."

197. Purdue accounts for the lion's share of these prescriptions. Nationwide in 2013, there were 6 million prescriptions of OxyContin, resulting in $2.6 billion in sales—giving Purdue 44% of the ER/LA opioid market and 24% of the overall opioid market (which includes generics). In Indiana, from 2012 to the present, Purdue accounted for 53.93% of branded opioid prescriptions paid by the State's Medicaid programs, and 50.31% of those paid by the State's Employee Health Plans and Workers' Compensation Program.

198. Nationwide, opioid prescribing has quadrupled since 2000, a gigantic increase that corresponds to Purdue's equally massive marketing push. As depicted below, Purdue's national spending on opioid marketing stood at $15 million per quarter in 2000. Its spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and state attorneys general. But by 2010, with the introduction of Butrans and the reformulated "abuse-deterrent" OxyContin, Purdue redoubled its marketing investment, spiking to $25 million per quarter in 2011. By 2016, with the introduction of Hysingla, it soared to more than $40 million per quarter.



199. The largest component of this spending was the cost of sales representatives who were responsible for meeting with prescribers. Annual detailing expenditures nationwide rose from $45 million in 2000 to $156 million in 2014.

200. While many physicians may not readily acknowledge the significant impact of pharmaceutical detailing on their prescribing, companies like Purdue know that detailing is a powerful way to influence prescribing. The vast budget Purdue has devoted to detailing—hundreds of millions of dollars since the launch of "abuse-deterrent" OxyContin in 2010—is a testament to the success of this model.

201. The effects of detailer sales calls on prescribing are well-documented. A 2009 study correlates the nearly 10-fold increase in OxyContin prescriptions between 1997 and 2002

with Purdue's doubling of its sales force and trebling of sales calls.[11] Over a long period of time, the lockstep pattern is apparent, with spending and prescribing rising together: between 2007 and 2016, Purdue's spending quadrupled while prescribing trebled.

202. Purdue's aggressive marketing has affected even those health care providers whom Purdue did not aggressively target directly. Purdue's long-running marketing scheme entrenched opioids as a routine treatment for chronic pain, despite their serious risks and the absence of evidence that they improve patients' pain and quality of life over the long term. Purdue's marketing of opioids as the best, first-choice answer to chronic pain reinforces the psychological incentives for doctors who want to make their patients feel better: if they provide opioids, the patient is satisfied; if they do not, the patient feels underserved and may, with Purdue's encouragement, seek another doctor who will.

B. The Purdue-Driven Increase in Opioid Prescribing Has Placed Devastating Social and Economic Burdens on Indiana.

203. Purdue's success in expanding the market for opioids has fueled the opioid epidemic in Indiana and nationally. In August 2016, the U.S. Surgeon General published an open letter to physicians, 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."

204. The leading cause of drug overdoses in Indiana is prescription opioids: "Indiana loses more citizens to prescription opioid overdoses annually than to cocaine and heroin

[11] Art Van Zee, "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy," 99(2) *Am. J. Pub. Health*, 221 (2009).

combined." In Indiana, there were 757 opioid-overdose deaths in 2016—reflecting a 73% rise since just 2014. Year-over-year increases are continuing despite efforts by the State and the CDC to reduce prescribing and educate consumers.

205. Scientific evidence demonstrates the close link between opioid prescriptions and opioid abuse. A 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse," with compelling data for extended release oxycodone (*i.e.*, OxyContin).[12] An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.[13]

206. Opioid prescribing and opioid related overdoses have risen in tandem since 1999. Both have quadrupled. According to the CDC, patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC has 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."

207. Opioid overdose deaths are only the tip of the iceberg, according to national data analyzed by the National Institute on Drug Abuse. For every overdose death in 2009, for example, there were 9 abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users of opioids.

208. The number of people in Indiana seeking treatment for opioid addiction also has risen. In 2000, of all Indiana admissions for substance abuse and addiction treatment, 5.5%

[12] Theodore J. Cicero et al., "Relationship between therapeutic use and abuse of opioid analgesics in rural, suburban, and urban locations in the United States," 16 (8) *Pharmacoepidemiology and Drug Safety*, 827-840 (Aug. 2007).

[13] N. Katz, "Prescription Opioid Abuse: Challenges and Opportunities for Payers," *Am. J. Manag. Care*, Apr. 19, 2013, p. 5 , http://www.ajmc.com/publications/issue/2013/ 2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

reported prescription opioid misuse or abuse; by 2012, this number rose to 22%. According to public health experts' estimates, as many as 89,000 people in Indiana are currently struggling with opioid use, misuse, and addiction.

209. Opioids harm not only those who take them. Infants exposed to opioids in utero are at increased risk for NAS—with 60–80% experiencing withdrawal symptoms upon birth including tremors, difficulty eating, vomiting, seizures, and respiratory distress. When untreated, NAS can be life-threatening. Research shows these children are likely to suffer serious neurologic and cognitive impacts.

210. Infants with NAS face more difficult and more expensive hospital stays. In 2014, the average length of a hospital stay in Indiana for infants without NAS was 2.24 days at an average cost of $4,167, compared to 17.88 days at an average cost of $97,555 for an infant with NAS. The total hospital cost for 657 infants with NAS in Indiana in 2014 was $64 million.

211. Opioid abuse has impacted hospital emergency departments. An Indiana University report identified 641,940 visits to Indiana emergency departments due to non-fatal poisonings in 2010 alone, 90% of which were due to drug abuse. Non-fatal emergency room visits due to opioid overdoses increased 60% from 2011 to 2015, per the State Department of Health. These visits represent not simply a health care cost, but a diversion of resources that affects the ability of emergency departments to deliver timely care.

212. More than 7,000 naloxone kits were distributed in 2016 and 2017 by treatment facilities, local health departments, schools, prisons, and jails through a State initiative to broaden the availability of this overdose-reversal drug.

213. Indiana's health care costs attributable to opioids totaled $650 million in 2007 according to a Matrix Global Advisors report. This figure is 12th highest among all U.S. states

and places Indiana even higher—8th—among all 50 states on a per capita basis with a cost of $99 per citizen. No doubt this figure is certain to have risen as the opioid crisis has worsened.

214. In addition to its impact on Indiana's health care system, Purdue's conduct has led to other substantial costs for the State, in the form of social welfare spending, law enforcement costs, and lost productivity.

215. More than 60% of children removed from homes by Indiana's Department of Child Services come from families with parental drug use. Roughly one in four teenagers has abused prescription drugs, according to 2012 data. In 2015, 16.8% of Indiana teens had abused prescription drugs, including prescription opioids.

216. The proliferation of opioids has increased drug-related crime, requiring additional law enforcement resources. From 2013 through May 2016, Indiana led the nation in pharmacy robberies, with 367 reported. By contrast, California—with a population six times as large—had 47 fewer robberies during the same time period.

217. Prescription opioid addiction functions as a gateway to heroin addiction. Those addicted to prescription opioids are 40 times more likely to be addicted to heroin, and 45% of heroin users were also addicted to prescription opioids. Studies report that as many as 80% of heroin addicts used prescription opioids before turning to heroin. Heroin overdose deaths in Indiana have risen dramatically, by more than 300%, from 54 in 2010 to 239 in 2015. And the rates of heroin dependence reported by people seeking treatment in Indiana have risen from 1.8% in 2001 to 7.9% in 2012.

218. A litany of adverse health outcomes is associated with heroin, including spontaneous abortions, chronic infections, liver disease, pulmonary complication, and death. When heroin is administered by injection, needle-sharing puts users at increased risk for HIV and

Hepatitis B and C.[14] Ten Indiana counties have been recognized by CDC as among the U.S. counties most vulnerable to HIV outbreaks due to injection drug use.

219. Fentanyl, an opioid even more dangerous than heroin because it is more potent, is becoming more prevalent. Indiana forensics labs recorded 600 cases of seized fentanyl in 2016, compared to 27 in 2013.

220. The severity of the epidemic is also reflected in the State's prison population. More than 50% of the state's prison population have reported substance use disorders. Of those incarcerated two or more times, 75% have substance abuse disorders.

221. Finally, the impact of opioid over-prescribing and misuse has seeped into Indiana businesses. As many as 80% of Indiana's employers have observed prescription drug misuse by their employees, according to a survey by the National Safety Council and the Indiana Attorney General. Almost two-thirds of Indiana employers surveyed perceived that prescription drugs present bigger problems in the workplace than illegal substances.

222. Not surprisingly, drug overdoses are harming Indiana in terms of work loss. Data from the CDC show that the estimated lifetime medical and work loss costs in Indiana of drug overdose fatalities occurring in 2014 were $1.4 billion, while costs incurred for non-fatal drug overdose emergency room visits were $31.9 million. Over a four-year period from 2007 to 2010, hospitalizations for all non-fatal poisonings led to lifetime medical and work loss costs totaling $350 million.

[14] Increased risk of HIV and Hepatitis is not limited to heroin users. In fact, one of the worst recent outbreaks of these diseases is attributable to prescription opioid abuse *via* needle injections. In Austin, Indiana, there were only five reported cases of HIV between 2004 and 2014. In late 2014, three individuals were diagnosed with HIV. By April 2016, there were 191 cases, half of which were located within a half-square-mile area. Ninety-percent of those infected with HIV were also infected with Hepatitis C

223. Indiana has taken numerous steps to stop over-prescribing in the State and reduce the harms caused by opioids:

- Setting restrictions on opioid coverage under the Medicaid program;
- Setting a new, seven-day supply limit on all initial opioid prescriptions;
- Improving INSPECT, the State's prescription drug monitoring program, to help providers determine what other opioids a patient has been prescribed;
- Requiring State health care professional licensing boards to review and revise their prescribing guidelines;
- Funding OB/GYN training on medication-assisted treatment (MAT) for opioid addiction to improve maternal health and reduce the incidence of NAS; and
- Passing legislation that provides funding and authority for first responders and laypersons to obtain and administer overdose-reversal drugs.

C. Purdue's Conduct Has Burdened Indiana's Health Insurance and Workers' Compensation Programs with Substantial Direct Costs.

224. Indiana has incurred significant costs due to the payment of false claims for chronic opioid therapy under the State's (a) Medicaid programs; (b) Employee Health Plans; and (c) Workers' Compensation Program. The State has also been damaged by the payment of additional claims for drugs and medical services to treat conditions and injuries caused by chronic opioid use.

1. State's Medicaid Programs.

225. The State provides comprehensive health care benefits—including prescription drug coverage—to low- and moderate-income residents through its Medicaid programs. These programs, which include Traditional Medicaid, the Healthy Indiana Plan, Hoosier Healthwise, and others, operate under the Indiana Health Coverage Programs—the single State agency designated to administer the Medicaid program in Indiana under Title XIX of the Social Security Act (collectively with its vendors, agents, and contractors, "IHCP"). Approximately 1.44 million Indiana residents are enrolled in these programs, which are administered through four managed

care entities: Anthem, MDwise, MHS, and CareSource ("Medicaid Contractors"). The State pays the Medicaid Contractors a capitated rate—per beneficiary, per month—to provide the services covered under the IHCP.

226. The Medicaid Contractors enlist health care providers ("Medicaid Providers")—including doctors and pharmacies—to provide services to beneficiaries. To uphold their responsibilities to the State, each Medicaid Contractor requires its Medicaid Providers to deliver medically necessary services. The Indiana Administrative Code defines a "medically reasonable and necessary service" as "a covered service … that is required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice."

227. Separately, each Medicaid Provider enters a Provider Agreement with the State, under which they agree to provide covered services to program beneficiaries and to only submit claims for reimbursement "that can be documented by Provider as being strictly for medically necessary medical assistance services." Each of the four Medicaid Contractors' policies substantially reflects the Indiana Administrative Code's definition of medical necessity.

228. Opioids are only dispensed based on a licensed medical practitioner's prescription, which a practitioner will not write without first examining and diagnosing a patient. Medicaid Providers are required to submit information regarding the specific services provided to their patients to their corresponding Medicaid Contractor in order to be compensated. In submitting such information, Medicaid Providers certify the medical necessity of the services for which they seek reimbursement. The Medicaid Contractor audits and monitors these submissions for accuracy, completeness, and timeliness, and provides the data to the State. Pharmacy data is likewise provided to the State by the Medicaid Contractors. The State uses this to calculate and

adjust, on an annual basis, the capitated rates that the State pays its Medicaid Contractors. Where utilization rates or costs rise, the State's capitated rates rise, too.

229. A small percentage of the State's Medicaid recipients are enrolled in a fee-for-service plan. The only pertinent difference between the Medicaid Contractor plans and the fee-for-service plan is that, for the latter, the State reimburses Medicaid Providers and pharmacies directly.

2. State's Employee Health Plans.

230. The State provides comprehensive health care benefits ("Employee Health Plans")—including prescription drug coverage—to its active, full-time employees and their dependents. These Employee Health Plans are self-funded, meaning the State bears the charges for all services and products used by beneficiaries.

231. The State's four Employee Health Plans all offer a variety of premium costs, deductibles, and out of pocket maximums, but coverage under each plan is restricted to medically necessary care. Each plan defines "medically necessary" as an intervention determined to be, among other things:

- Medically appropriate for and consistent with the symptoms and proper diagnosis or treatment of the beneficiary's condition, illness, disease, or injury;
- Provided in accordance with applicable medical and/or professional standards;
- Known to be effective, as proven by scientific evidence, in materially improving health outcomes; or
- Not more costly than an alternative service that is medically appropriate, or the service is performed in the least costly setting that is medically appropriate.

232. As of 2018, State employees' drug benefits are administered by CVS/Caremark. In order for prescription drugs to be covered by CVS/Caremark, they must be "medically necessary and not experimental or investigative." Prior to 2018, State employees' drug benefits were

administered by Express Scripts and its predecessor Medco, which applied identical requirements and limitations to its prescription drug coverage.

3. State's Workers' Compensation Program.

233. When a State employee is injured on the job, he or she may file a claim for workers' compensation; if the injury is deemed work-related, the State is responsible for covering the employee's medical costs and lost wages. Indiana law prohibits the State from purchasing workers' compensation insurance, so its liability is covered through self-insurance.

234. The purpose of providing medical care as part of workers' compensation is "to treat the injury and bring the employee to" the point at which his or her condition "will no longer improve." The State is required to provide the employee with a "physician for the treatment of the employee's injuries, and in addition thereto, such services and products as the attending physician or the workers' compensation board may deem necessary."

4. False and Material Claims Against the Above State-funded Programs.

235. Coverage under each of the above State-funded programs includes opioids, when prescribed by a doctor as medically necessary, as well as office visits for pain management (including toxicology screens), and treatments related to any adverse outcomes from chronic opioid therapy (such as overdose or addiction).

236. Most long-term use of opioids to treat chronic pain is not medically necessary or appropriate, as defined by the programs above. As set forth in Section II.C, long-term opioid therapy for chronic moderate pain is not medically appropriate because the risks of long-term use generally outweigh the benefits. In fact, long-term use can cause hyperalgesia (increased sensitivity to pain), and cognitive impairment without improving physiological function. Yet, Purdue undertook a systematic marketing campaign to encourage prescribers to use opioids as the first line of treatment for chronic pain. In doing so, Purdue caused prescribers and pharmacies to

submit, and the State to pay, claims to the State's Medicaid program, Employee Health Plans, and Workers' Compensation Program that were false by:

(a) causing prescribers to write, and pharmacies to fill, prescriptions for chronic opioid therapy supported by Purdue's deceptive, false, and incomplete representations regarding the risks, benefits, and superiority of those drugs; and

(b) causing prescribers to certify that these prescriptions were "medically necessary" and causing pharmacies to fill such prescriptions when, in fact, the prescriptions were not supported by substantial scientific evidence showing either that the risks associated with the drugs were outweighed by benefits or that the drugs were medically appropriate for long-term, chronic use.

These false claims subsequently caused prescribers to write continuing opioid prescriptions when long-term opioid use renders patients dependent upon the continued and increased use of the drugs.

237. Alternatively, to the extent that chronic opioid therapy was considered "medically necessary" because it was consistent with the generally-accepted professional and community standards that prevailed from the late 1990s onward, that medical consensus existed only because standards of practice had been re-written to conform to the false reality created by Purdue. Purdue engineered that medical consensus, causing prescribers to believe that long-term use of opioids to treat chronic pain was not simply permissible or appropriate but required.

238. The State would not have knowingly reimbursed claims for prescription drugs that were not eligible for coverage. For example, the State paid the following claims:

(a) Indiana Medicaid Patient A was diagnosed with unspecified joint pain and osteoarthritis. Patient A received 59 opioid prescriptions (38 OxyContin prescriptions, 6 oxycodone prescriptions, 6 Nucynta ER prescriptions, 8 morphine sulfate prescriptions, and 1 methadone prescription)—totaling a 1,626 day supply—between January of 2012 and April of 2018. These prescriptions resulted in $26,589.73 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 360 visits from Purdue detailers from 2006 to 2017. Five of those visits (including one at which the Purdue representative provided lunch to the practitioner) occurred in the two months prior to writing Patient A's first opioid prescription, including one at which the Purdue detailer explicitly discussed Medicaid coverage for OxyContin with the practitioner.

(b) Indiana Medicaid Patient B was diagnosed with abdominal pain, a backache, and a diaphragmatic hernia. Patient B received 62 opioid prescriptions (35 OxyContin prescriptions, 19 oxycodone prescriptions, 5 morphine sulfate ER prescriptions, and 3 Tramadol prescriptions) ―totaling a 1,783 day supply―between August of 2013 and April of 2017. These prescriptions resulted in $26,419.80 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 140 visits from Purdue detailers from 2007 to 2017. Two of those visits occurred in the two months prior to writing Patient B's first opioid prescription. At one visit, which occurred two days prior to Patient B's first prescription, the Purdue detailer reviewed the abuse deterrent properties of OxyContin and went over the appropriate patient profile for the drug, and the practitioner responded that he would make an effort to try OxyContin with his patients.

(c) Indiana Medicaid Patient C was diagnosed with myalgia and myositis (muscle pain and inflammation) and central pain syndrome. Patient C received 53 opioid prescriptions (34 OxyContin prescriptions and 19 Opana ER prescriptions) ―totaling a 1,589 day supply―between January of 2012 and February of 2017. These prescriptions resulted in $34,360 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 159 visits from Purdue detailers from 2011 to 2017. Three of those visits occurred in the two months prior to writing Patient C's first opioid prescription, and the Purdue detailer noted that he encouraged the practitioner multiple times during those visits to start new patients on OxyContin.

(d) Indiana Medicaid Patient D was diagnosed with acute cholecystitis (gallbladder inflammation). Patient D received 74 opioid prescriptions (37 OxyContin prescriptions and 37 oxycodone prescriptions)―totaling a 2,220 day supply―between June of 2015 and June of 2018. These prescriptions resulted in $17,796.69 in claims paid through the IHCP. The prescriptions were written by a practitioner who received 243 visits from Purdue detailers between 2006 and 2017. Seven of those visits (including one at which the Purdue detailer provided lunch to the practitioner) occurred in the two months prior to writing Patient D's first opioid prescription. The Purdue detailer noted that, at the lunch visit that occurred 10 days prior to the prescription, the practitioner committed to continue trying OxyContin with patients.

(e) Indiana Employee Plan Patient E was diagnosed with an ankle fracture and ankle, foot, and joint pain. Patient E received 9 OxyContin prescriptions―totaling a 270 day supply―between March of 2014 and November of 2014. These prescriptions resulted in $2,356.63 in claims paid through the State Employee Health Plans. The prescriptions were written by a practitioner who received 159 visits from Purdue detailers between 2011 and 2017, including one visit (at which the Purdue detailer provided lunch to the practitioner) that occurred in the two months prior to writing Patient E's first opioid prescription.

(f) Indiana Employee Plan Patient F was diagnosed with osteoarthritis and received a hip joint replacement. Patient F received 34 OxyContin prescriptions―totaling a

954 day supply—between September of 2011 and December of 2017. These prescriptions resulted in $12,147.65 in claims paid through the State Employee Health Plans. The prescriptions were written by a practitioner who received 232 visits from Purdue detailers between 2001 and 2017. Two of those visits (including one at which the Purdue detailer provided lunch to the practitioner) occurred in the two months prior to writing Patient F's first opioid prescription.

(g) Indiana Employee Plan Patient G was a passenger in a van that collided with a fixed object and was diagnosed with pain in the soft tissues of the limbs. Patient G received 8 OxyContin prescriptions—totaling a 240 day supply—between June of 2010 and November of 2010. These prescriptions resulted in $9,140.28 in claims paid through the State Employee Health Plans. The prescriptions were written by a practitioner who received 427 visits from Purdue detailers between 2006 and 2017. Five of those visits (including one at which the Purdue detailer provided lunch to the practitioner) occurred in the two months prior to writing Patient G's first opioid prescription.

239. During the years 2012-2018, the State paid substantial funds for prescription opioids: more than $100 million for opioids covered through Medicaid; more than $8 million for opioids covered by State employee insurance programs, and workers' compensation for State employees. For the reasons stated above, the State believes that a significant percentage of these prescriptions were not medically necessary or appropriate as defined by the relevant plans and should not have been covered because they were for opioids prescribed for a period longer than 90 days and were prescribed: (a) at a strength of 90 MME or more; or (b) to treat pain less severe than indicated in the package insert; or (c) without exploration of alternative therapies like non-opioid medication and physical therapy.

240. As described above, Purdue set out to change the medical consensus supporting chronic opioid therapy so that prescribers would prescribe—and so that government payors such as the State would pay for—long-term prescriptions to treat moderate, chronic pain in the absence of scientific evidence showing that the benefits outweigh the risks.

241. In addition to these prescription costs, the State has paid for services and supplies necessitated by long-term opioid use abuse—office visits, toxicology screens, hospitalization for overdoses and infection, rehabilitation and addiction-related therapy, and other treatments.

242. Purdue's misrepresentations were material to and influenced the State's decisions to pay claims for opioids for chronic pain and, subsequently, to bear consequential costs in treating overdose, addiction, and other side effects. But for Purdue's unfair and deceptive marketing campaign, the State would not have been presented with, or paid, claims for opioids to treat chronic, moderate pain. That the State would pay for these ineligible prescriptions was a foreseeable and intended consequence of Purdue's intentionally misleading marketing scheme.

243. Purdue's misrepresentations related to the State's requirement that medical treatments be medically necessary—a condition of coverage for any medical treatment under the above State-funded programs. Misrepresentations as to, for example, whether patients were likely to become addicted, would be able to resume life activities, and would experience long-term relief were not minor; they went to the core of a prescriber's decision-making.

IV. PURDUE'S EFFORTS TO CONCEAL ITS MISCONDUCT FROM LAW ENFORCEMENT: *Purdue Fraudulently Concealed Evidence of Its Deceptive Business Practices.*

244. As explained above, Purdue knowingly made deceptive and misleading statements about OxyContin—and opioids generally—for more than two decades. Under the terms of the 2007 Settlements, Purdue publicly agreed that it would stop all deceptive and misleading marketing related to OxyContin's potential for abuse, addiction, and physical dependence. Purdue publicly committed to marketing its drugs in a manner consistent with the "Indication and Usage" section of the Package Insert and to providing "fair balance" in its marketing of OxyContin and other opioids.

245. Notwithstanding these commitments, Purdue continued to deceive and mislead prescribers and patients. In addition, Purdue has taken steps to avoid detection of—and to fraudulently conceal—its deceptive marketing and unlawful and deceptive conduct from regulators and law enforcement.

246. After 2007, Purdue continued to disguise its own role in the deceptive marketing of chronic opioid therapy by funding and promoting unbranded marketing, third-party advocates, and professional associations. Purdue purposefully hid behind the assumed credibility of these sources and relied on them to disseminate and establish Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed its role in shaping, editing, and approving the content of this information. Purdue also distorted the conclusions of the studies it cited and deceptively offered them as evidence for propositions the studies did not support.

247. Despite the intensity of in-person sales visits throughout the relevant period and the pervasive promotion of alleged benefits of long-term opioid use, Purdue's internal records do not reflect many discussions of the serious risks associated with opioids: addiction and overdose. As part of the State's investigation, Purdue produced a total of 270,071 Indiana call notes (each representing a single sales representative visit to an Indiana prescriber), dated January 3, 2006 through December 22, 2017. Of the 270,071 call notes memorializing Purdue sales representative visits to Indiana prescribers over this 10-year period, there are only 416 instances—approximately 0.1% (one-tenth of one percent)—mentioning "addiction," "addicted," or any variation thereof. Given the real and serious risk of addiction, the utter failure of Purdue to discuss it was not accidental. The logical conclusion is either that Purdue fraudulently concealed and

underrepresented prescriber questions about addiction, or expressly instructed its detailers not to raise the topic of addiction. These conclusions are not mutually exclusive.

248. Further, Purdue failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse" and "strong record of coordination with law enforcement."

249. Purdue has worked hard to obfuscate the origin of the opioid crisis—unprecedented overprescribing in response to Purdue's assurances that opioids are the proper treatment for routine, moderate pain because their benefits vastly outweigh their risks. Instead, Purdue has spent considerable resources to publicly ascribe widespread abuse, addiction, and death to patients who deliberately misuse opioids and the diversion of pills to illicit secondary channels.

250. Purdue has engaged in a public relations campaign to publicize its purported efforts to work with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation features in virtually all of Purdue's recent pronouncements in response to public scrutiny of opioid abuse.

251. These public pronouncements have created the impression that Purdue is proactively working with law enforcement and government authorities, nationwide and in Indiana, to root out drug diversion, including the illicit prescribing that can lead to diversion. They aimed to distance Purdue from its past publicly admonished conduct in deceptively marketing opioids—which gave rise to its 2007 criminal pleas—and to make its current marketing seem more trustworthy and truthful. In fact, Purdue consistently failed to report suspicious prescribing to authorities, despite having all the necessary tools—detailed prescribing data and the eyes and ears of its sales force—to observe such practices.

252. For almost 20 years, Purdue has maintained a database of health care providers that Purdue itself has flagged as inappropriately prescribing OxyContin or other opioids. According to Purdue, providers could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing volume. Purdue has said publicly that "[o]ur procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation." According to Purdue, health care providers added to the database no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

253. Yet, Purdue did not report suspicious prescribing or suspicious prescribers to law enforcement agencies. Despite its knowledge of illicit prescribing in other jurisdictions, Purdue did not report its suspicions, for example, until years after law enforcement shut down a Los Angeles clinic that Purdue's district manager described internally as "an organized drug ring" and that had prescribed more than 1.1 million OxyContin tablets. The New York Attorney General's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Purdue did not report any suspicious prescribing or suspicious prescribers to the Indiana Attorney General's Office, the Professional Licensing Agency, or the Medical Licensing Board.

254. In Indiana, Purdue seemed to see law enforcement as an obstacle to its mission to expanding the opioids market. One of the most notorious pill mills in the country—the Wagoner Clinic located in Kokomo, Indiana—operated for years under Purdue's indulgent gaze. Purdue's sales representatives visited this family practice clinic frequently—at times as often as twice a week. For a number of years, the clinic was within the territory of one of Purdue's top salespeople

nationwide. No wonder: The Wagoner Clinic—a small family medicine practice with only four doctors on staff—was writing hundreds of opioid prescriptions weekly. By the time these doctors were arrested in 2013, more than 125,000 prescriptions had been written and the overdose deaths of more than two dozen patients had been traced to the reckless prescribing at this clinic.

255. Purdue detailers, despite their regular visits, did not report any suspicious activity to the State.

256. Purdue did not instruct its detailers to stop visiting the Wagoner Clinic even after the Attorney General's Office suspended the licenses of four physicians in the practice on March 18, 2013. Instead, more than a week later, Purdue informed its sales representatives not to visit specific prescribers at that clinic, while continuing to allow them to visit others. Purdue did not instruct its sales representatives to stop visiting one prescriber who had been arrested and charged with dealing narcotics until six months later.

257. Purdue similarly turned a blind eye to misconduct by Dr. Tristan Stonger, who was indicted by the State in 2016 for improperly prescribing vast quantities of opioids through three pain clinics he operated in Indiana. In just four years (2012-2015), Dr. Stonger wrote at least 48,000 prescriptions for controlled substances. Stonger was routinely "seeing" as many as 100 patients a day; his waiting rooms were filled beyond seating capacity, and large numbers of vehicles and people gathered in the clinic parking lots. Despite all of these questionable signs, Purdue detailers visited Dr. Stonger, listed in Purdue call notes as a plastic surgeon, 86 times between December 2010 and January 2015. Purdue never reported any suspicious conduct to the appropriate state licensing authorities.

258. Nor did Purdue cut off improper prescribing at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions. Purdue's former senior

compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue consistently failed to report suspicious dispensing or to stop supplies to the pharmacy, even where Purdue employees personally witnessed conduct emblematic of illicit prescribing and drug diversion.

259. Purdue thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that the State now asserts. The State did not know of the existence or scope of Purdue's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

CAUSES OF ACTION

COUNT ONE
VIOLATIONS OF THE DECEPTIVE CONSUMER SALES ACT

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

261. The Deceptive Consumer Sales Act makes it unlawful for a supplier to engage in an "unfair, abusive, or deceptive act, omission, or practice" in connection with a consumer transaction. Ind. Code § 24-5-0.5-3(a).

262. The Defendants are "suppliers" as defined by Ind. Code § 24-5-0.5-2(3).

263. The purchase and sale of opioid products are "consumer transactions" as defined by Ind. Code § 24-5-0.5-2(1).

264. Pharmaceutical manufacturers are required to comply with the provisions of the DCSA in their marketing, promotion, sale, and distribution of prescription drugs.

265. The Defendants, by making or disseminating false or misleading statements about the long-term use of opioids to treat chronic pain, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in

connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

266. The Defendants, by causing false or misleading statements about opioids to be made or disseminated, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

267. The Defendants, by making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

268. The Defendants, by failing to correct prior misrepresentations and omissions about the risks and benefits of opioids, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

269. The Defendants, by claiming or implying that long-term use of opioids would improve patients' function and quality of life, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-

3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

270. The Defendants, by mischaracterizing the risk of opioid addiction and abuse, including by stating or implying that "steady state" and abuse-deterrent properties meant the drugs were less likely to be addictive or abused, and that specific opioid drugs were less addictive or less likely to be abused than other opioids, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

271. The Defendants, by claiming or implying that addiction can be avoided or successfully managed through the use of screening and other tools, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

272. The Defendants, by promoting the misleading and discredited concept of pseudoaddiction and emphasizing the prevalence of dependence to conceal and distract from the true risk of addiction, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

273. The Defendants, by claiming or implying that increasing the dose of opioids (titrating up) poses no significant additional risk, violated Ind. Code § 24-5-0.5-3(a) by committing

unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

274. The Defendants, by misleadingly depicting the safety profile of opioids by minimizing their risks and adverse effects while emphasizing the risks of competing products, including NSAIDs and acetaminophen, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

275. The Defendants, by mischaracterizing OxyContin's onset of action and duration of efficacy to imply that the drug provides a full 12 hours of pain relief, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

276. The Defendants, by misleadingly marketing 10mg and 15mg doses of OxyContin for the treatment of pain when Purdue knew that those dosages provide no therapeutic benefit, violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

277. The Defendants, by engaging in deceptive, false, and misleading marketing that was unsupported by substantial scientific evidence to support its product claims as required by 21 C.F.R. § 202.1(e), violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions,

and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

278. The Defendants, by engaging in a marketing campaign that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in its promotion of opioids, contravening FDA regulations, including 21 C.F.R. § 202.1(e), violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

279. The Defendants, by promoting the purported advantages of opioids over other pain relief products, including but not limited to the risks and/or benefits of opioids in comparison to NSAIDs, acetaminophen, or ibuprofen without substantial scientific evidence to support those claims, contravening FDA regulations, including 21 C.F.R. § 202.1(e), violated Ind. Code § 24-5-0.5-3(a) and § 24-5-0.5-3(b)(1) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions, and by misrepresenting that such subject of a consumer transaction had uses, or benefits, that it did not have which the Defendants knew or reasonably should have known that it does not have.

280. The Defendants, by promoting high doses for extended periods of time, in contravention of longstanding public policy to avoid and minimize the risk of addiction and abuse of controlled substances, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

281. The Defendants, by targeting a vulnerable population—senior consumers, as defined by Ind. Code § 24-5-0.5-2(a)(9)—for promotion of opioids to treat chronic pain in the face of the known, heightened risks of opioid use to that population, including risks of addiction,

adverse effects, hospitalization, and death violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

282. The Defendants, by targeting opioid naïve patients and patients using IR or weaker (Schedule III) opioids for conversion to Purdue's ER/LA opioid products, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

283. The Defendants, by using unbranded marketing, front groups, and key opinion leaders to evade FDA oversight and rules prohibiting deceptive marketing and to deceive prescribers and consumers regarding the impartiality of the information conveyed, violated Ind. Code § 24-5-0.5-3(a) by committing unfair, abusive, and deceptive acts, omissions, and practices in connection with consumer transactions.

284. The Defendants, by marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drugs OxyContin, Butrans, and Hysingla—where the card did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance—violated the Prescription Drug Discount and Benefit Cards Statute (Ind. Code § 24-5-21) and thereby violated Ind. Code § 24-5-0.5-3(b)(32).

285. **WHEREFORE** the State requests an order under Ind. Code § 24-5-0.5-4: permanently enjoining Purdue from engaging in these unfair and abusive acts and practices; directing disgorgement of any ill-gotten gains; directing the payment of civil penalties for each violation of the DCSA; awarding attorneys' fees and costs to the State, and any other just and proper relief.

COUNT TWO
KNOWING VIOLATIONS OF THE DECEPTIVE CONSUMER SALES ACT

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

287. The deceptive acts asserted in Paragraphs 260 through 284 were committed by the Defendants with knowledge of their deceptive acts.

COUNT THREE
INCURABLE DECEPTIVE ACTS

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

289. The deceptive acts asserted in Paragraphs 260 through 284 are incurable deceptive acts and were committed by the Defendants as part of a scheme, artifice, or device with intent to defraud or mislead.

COUNT FOUR
VIOLATIONS OF
THE PRESCRIPTION DRUG DISCOUNT AND BENEFIT CARDS STATUTE, IND. CODE § 24-5-21, *ET SEQ*.

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

291. The Prescription Drug Discount and Benefit Cards Statute makes it unlawful for a non-exempt business to sell, market, promote, advertise, or distribute a card that purports to offer discounts or access to discounts from a pharmacy for prescription drug purchases where the card does not expressly state in bold and prominent type, which is prominently placed, that the discounts are not insurance. Ind. Code § 24-5-21-3.

292. At all times relevant to this Complaint, Purdue violated Ind. Code § 24-5-21-3 by engaging in the following acts and practices:

(a) Marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drug OxyContin where the card did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance;

(b) Marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drug Butrans where the card did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance; and

(c) Marketing, promoting, advertising, or distributing in Indiana savings cards that purported to offer discounts or access to discounts from a pharmacy for the prescription drug Hysingla where the cards did not expressly state in bold and prominent type, which was prominently placed, that the discounts were not insurance.

293. **WHEREFORE** the State requests an order under Ind. Code § 24-5-21-6 permanently enjoining Purdue from marketing, promoting, advertising, or distributing savings cards in Indiana in violation of Ind. Code § 24-5-21-3; directing the payment of civil penalties of a sum equal to one hundred dollars ($100) per card distributed in Indiana or ten thousand dollars ($10,000), whichever is greater; awarding attorneys' fees and costs to the State; and providing any other relief that the Court considers proper.

COUNT FIVE
FALSE CLAIMS
IN VIOLATION OF THE INDIANA FALSE CLAIMS ACT,
IND. CODE § 5-11-5.5, *ET SEQ.*

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

295. A person is liable under the Indiana False Claims Act, Ind. Code § 5-11-5.5-2(b)(8), when that person knowingly or intentionally causes or induces another person to present a false claim to the State for payment or approval *or* to make or use a false record or statement to obtain payment or approval of a false claim from the State.

296. Ind. Code § 5-11-5.5-1(1) defines a "claim" as:

> a request or demand for money or property that is made to a contractor, grantee, or other recipient if the state (a) provides any part of the money or property that is requested or demanded; or (b) will reimburse the contractor, grantee, or other recipient for any part of the money or property that is requested or demanded.

297. Purdue is a "person" within the meaning of the Indiana False Claims Act. Purdue's practices, as described in the Complaint, violated Ind. Code § 5-11-5.5-2(b). Purdue, through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the State.

298. Purdue knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, misleading, or unsupported by substantial scientific evidence, and were made for the purpose of inducing the State, through its employees and contractors, to pay for opioids for long-term treatment of chronic pain. In addition, Purdue knew or should have known that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

299. Purdue's scheme caused doctors and other prescribers to write prescriptions for opioids to treat chronic pain, resulting in claims paid through the IHCP or "Medicaid," and the State employee health and workers' compensation plans. Doctors, pharmacists, other health care providers, and/or other agents participating in these programs expressly or impliedly certified to the State that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Purdue through the marketing campaign described in Sections I and II above. To the extent that such

prescribing was considered customary or consistent with generally accepted medical standards, those standards were influenced and ultimately corrupted by Purdue's deceptive marketing as well.

300. Purdue knew or should have known that, as a foreseeable consequence of its actions, governments such as the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Purdue's deceptions. The misrepresentations Purdue made and caused to be made were material to the State's decisions to pay the costs of long-term opioid use because they falsely suggested that such treatment was medically necessary.

301. Through the IHCP, State employee health and workers' compensation plans, more than a hundred million dollars has been paid for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed or covered but for Purdue's deceptive, fraudulent, and unlawful marketing practices.

302. The State has paid and will continue to pay consequential health care costs necessitated by Purdue's deceptive, fraudulent, and unlawful marketing practices: drugs for persons dependent upon and addicted to opioids and treatment costs for those dealing with addiction, overdose, and other adverse effects.

WHEREFORE Plaintiff, the State of Indiana, respectfully requests that this Court enter an order enjoining Purdue from engaging in conduct that violates Ind. Code § 5-11-5.5; requiring Purdue to pay the maximum civil penalty for each false or fraudulent claim Purdue caused to be presented to an official, employee, or contractor of the State for payment or approval; requiring Purdue to pay three times the amount of damages, including consequential damages, sustained by the State for each violation of this section; compelling Purdue to pay the cost of the suit, including

attorneys' fees under Ind. Code § 5-11-5.5-2(b)(8); and awarding the State such other, further, and different relief as this Court may deem just.

COUNT SIX
FALSE CLAIMS
IN VIOLATION OF THE INDIANA MEDICAID FALSE CLAIMS ACT,
IND. CODE § 5-11-5.7, *ET SEQ.*

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

304. A person is liable under the Indiana Medicaid False Claims Act, Ind. Code § 5-11-5.7-2(a)(8), when that person knowingly or intentionally causes or induces another person to present a false claim to the State for payment or approval *or* to make or use a false record or statement to obtain payment or approval of a false claim from the State.

305. Ind. Code § 5-11-5.7-1(b)(1) defines a "claim" as:

> [A] request or demand for money or property, whether under a contract or otherwise, and whether the state has title to the money or property that: (A) is presented to an officer, employee, or agent of the state; or (B) is made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the state's behalf or to advance a state program or interest, and if the state: (i) provides or has provided any part of the money or property that is requested or demanded; or, (ii) will reimburse the contractor, grantee, or other recipient for any part of the money or property that is requested or demanded.

306. Purdue's practices, as described in the Complaint, violated Ind. Code § 5-11-5.7-2. Purdue, through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the State.

307. Purdue knew, deliberately ignored, or recklessly disregarded, at the time of making or disseminating these statements, or causing these statements to be made or disseminated, that such statements were untrue, false, misleading, or unsupported by substantial scientific evidence,

and were made for the purpose of inducing the State, through its employees and contractors, to pay for opioids for long-term treatment of chronic pain. In addition, Purdue knew or should have known that its marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain.

308. Purdue's scheme caused doctors and other prescribers to write prescriptions for opioids to treat chronic pain, resulting in claims paid through the IHCP. Doctors, pharmacists, other health care providers, and/or other agents participating in the IHCP expressly or impliedly certified to the State that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Purdue through the marketing campaign described in Sections I and II above. To the extent that such prescribing was considered customary or consistent with generally accepted medical standards, those standards were influenced and ultimately corrupted by Purdue's deceptive marketing as well.

309. Purdue knew or should have known that, as a foreseeable consequence of its actions, governments such as the State would necessarily be paying for long-term prescriptions of opioids to treat chronic pain, which were dispensed as a consequence of Purdue's deceptions. The misrepresentations Purdue made and caused to be made were material to the State's decisions to pay the costs of long-term opioid use because they falsely suggested that such treatment was medically necessary.

310. Through the IHCP, more than a hundred million dollars has been paid for opioid prescriptions that were represented to the State as medically necessary. These prescriptions would not have been prescribed or covered but for Purdue's deceptive, fraudulent, and unlawful marketing practices.

311. The State has paid and will continue to pay consequential health care costs necessitated by Purdue's deceptive, fraudulent, and unlawful marketing practices including drugs for persons dependent upon and addicted to opioids, and treatment costs for those dealing with addiction, overdose, and other adverse effects.

WHEREFORE Plaintiff, the State of Indiana, respectfully requests that this Court enter an order enjoining Purdue from engaging in conduct that violates Ind. Code § 5-11-5.7; requiring Purdue to pay the maximum civil penalty for each false or fraudulent claim Purdue caused to be presented to an official, employee, or contractor of the State for payment or approval; requiring Purdue to pay three times the amount of damages, including consequential damages, sustained by the State for each violation of this section; compelling Purdue to pay the cost of the suit, including attorneys' fees under Ind. Code § 5-11-5.7-2(a)(8); and awarding the State such other, further, and different relief as this Court may deem just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the Court enter judgment against Purdue:

(a) awarding judgment in its favor and against Purdue on each cause of action asserted in the Complaint;

(b) assessing treble damages for the payments made by or on behalf of the State for opioid prescriptions covered by the IHCP, the State Employee Health Plans, and the State Workers' Compensation Program;

(c) assessing the maximum statutory civil penalties for each violation of the Indiana False Claims Act and the Indiana Medicaid False Claims Act;

(d) permanently enjoining Purdue from engaging in the deceptive, unfair, and abusive acts and practices described in the Complaint, including by directing Purdue to disgorge any ill-gotten gains acquired by virtue of the conduct described in the Complaint;

(e) assessing maximum statutory civil penalties for each violation of the Deceptive Consumer Sales Act;

(f) assessing maximum statutory civil penalties for each violation of the Prescription Drug Discount and Benefit Cards Statute;

(g) requiring Purdue to pay the costs of the suit, including attorneys' fees; and

(h) awarding such other, further, and different relief as this Court may deem just.

Dated: November 14, 2018
Indianapolis, IN

Respectfully submitted,

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