

COMMONWEALTH OF KENTUCKY
HARDIN COUNTY CIRCUIT COURT
DIVISION NO. __
CIVIL ACTION NO. _____

COMMONWEALTH OF KENTUCKY, *ex rel.*,
ANDY BESHEAR, ATTORNEY GENERAL,

Plaintiff.

v.

INSYS THERAPEUTICS, Inc.;

Serve: CT Corporation System
306 W. Main Street
Suite 512
Frankfort, KY 40601;

And

JOHN N. KAPOOR

Serve: John N. Kapoor
121 Stone Gate Road
Lake Forest, IL 60045

Defendants.

COMPLAINT

JURY TRIAL DEMANDED

I. PRELIMINARY STATEMENT

1. Plaintiff, the Commonwealth of Kentucky, (“the Commonwealth, or Kentucky”), by and through its Attorney General, Andy Beshear, brings this action pursuant to his statutory and common law authority to redress Insys Therapeutics, Inc.’s and John N. Kapoor’s (collectively “Insys”) campaign to unlawfully promote and sell Insys’ opioid, Subsys, in Kentucky.

2. Prescription opioids are narcotics. They are derived from opium and possess properties similar to opium and heroin, are regulated as controlled substances, and cause addiction. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user’s breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience often prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e., the relief of pain), requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

3. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited both the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.¹ Consequently, the market for prescription opioids was sharply constrained.

4. Many opioid manufacturers, however, convinced prescribers that prescribing opioids for common, chronic pain conditions was necessary to compassionately treat their patients’

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

pain. By misrepresenting the risks and benefits of opioids and using other fraudulent schemes, they changed the medical community's beliefs about and use of opioids.

5. Upon information and belief, Insys exploited this expanding market for opioids as it aimed to sell more of its opioid, Subsys. Subsys is an extremely powerful fentanyl-based opioid, and is not approved for, nor has it been shown to be safe or effective for, treating chronic pain. The drug is approved solely for breakthrough cancer pain in patients who are tolerant to opioid therapy. Insys trained its sales representatives to convince doctors to prescribe high doses of Subsys for non-cancer chronic pain conditions. In addition, the company instituted a speaker program that operated as a kickback scheme to pay doctors to prescribe more and more Subsys in higher and higher doses, and to promote off-label use of Subsys to other doctors. Insys also instituted a fraudulent pre-authorization scheme which made misrepresentations to third party payors to procure coverage of non-cancer related prescriptions of Subsys.

6. Sales representative messaging, personal relationships with prescribers, kickbacks, and prior-authorization fraud were the keys to Insys' success and resulted in profit for the company. Insys Therapeutics, Inc. made approximately \$330 million in net revenue from Subsys in 2016. Between 2013 and 2016, the value of Insys stock rose 296%.

7. While Insys was reaping millions of dollars in profits from Subsys sales, the opioid epidemic was causing one of the deadliest drug crises in the history of the United States. Plaintiff, Commonwealth of Kentucky, has been hit especially hard, ranking fifth in the nation for opioid-related deaths in 2015. In 2015, 102 opioid prescriptions were written for every 100 Kentucky residents, 1.5 times the national average. In 2016, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month. Fentanyl was involved in 623 – approximately 47% -- of those

deaths. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which increased the average death rate to approximately 130 deaths per month.

8. Thus, rather than compassionately helping patients, this explosion in opioid use and Insys' profits has come at the expense of patients and has caused ongoing harm and damages to the Commonwealth. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."²

9. In addition to opioid-related fatalities, the Commonwealth has suffered other serious injuries. Kentucky has seen a dramatic increase in opioid addiction, reflected, in part, in the increase in Medicaid spending for medications to treat such addiction, which doubled in just two years—from \$56 million in 2014 to \$117 million in 2016.

10. The widespread use of opioids and corresponding increases in addiction and abuse have led to increased emergency room visits, emergency responses to overdoses, and emergency medical technicians' administration of naloxone—an antidote to opioid overdose. In Louisville, the police force administered 123 doses of naloxone in just the first six weeks of 2017—representing approximately three overdoses each day. It also has resulted in dramatic growth in drug-related crimes. In one Kentucky County, roughly 90% of prosecutions are related to prescription drug abuse or diversion. Across the Commonwealth, there have been increases in domestic violence, robberies, burglaries, and thefts, among other crimes.

11. Children are especially vulnerable to the opioid epidemic. In just one 12-month period, between August 1, 2014 and July 31, 2015, 1,234 infants in Kentucky were born addicted to opioids, more than 100 newborns per month. Many of these infants must be treated in neonatal

² Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 *New Eng. J. Med.* 1501-1504 (2016).

intensive care units while they painfully withdraw from the drugs. Children also suffer when removed from their homes due to their parents' opioid abuse and addiction.

12. Kentucky has had one of the highest rates of pregnant women using opioids in the country. In 2014, the Commonwealth had the third-highest rate of pregnant women with opioid use disorder. In 2017, the number of babies born with NAS in the Commonwealth had increased by 375% since 2007.

13. The burdens imposed on the Commonwealth are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Insys' illegal actions. Insys' conduct substantially contributed to and exacerbated the public nuisance and is a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

14. The Attorney General brings this lawsuit in the public interest to hold Insys accountable for its violations of the Consumer Protection Act ("KCPA"), KRS 367.110 *et seq.*; the Kentucky Medicaid Fraud Statute, KRS 205.8463; and the Kentucky Assistance Program Fraud Statute, KRS 194A.505. The Attorney General also seeks remedies for the creation and maintenance of a continuing public nuisance, fraud, unjust enrichment, and negligence. This action seeks repayment of the Commonwealth's Medicaid, workers' compensation, and other spending on Subsys, disgorgement of Insys' unjust profits, civil penalties for its egregious violations of law, compensatory and punitive damages, injunctive relief, and abatement of the public nuisance Insys helped create.

II. PARTIES

A. Plaintiff

15. The Plaintiff, Commonwealth of Kentucky, brings this action, by and through its Attorney General, Andy Beshear, in its sovereign capacity in order to protect the interests of the Commonwealth and its citizens. This suit concerns matters of statewide interest. Andy Beshear is the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law enforcement officer, with full authority to initiate and prosecute cases, including this one, in which the Commonwealth has an interest. The Attorney General is vested with specific constitutional, statutory and common law authority to commence proceedings to enforce KRS 194A.505, KRS 367.110 *et seq.*, and KRS 205.8451 through KRS 205.8483; to exercise all common law duties and authority pertaining to the office of the Attorney General under the common law pursuant to KRS 15.020, and pursuant to the Attorney General's authority to bring an action on behalf of the Commonwealth. The Attorney General has determined that these proceedings are in the public interest.

B. Defendants

16. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys' principal product and source of revenue is Subsys, a transmucosal immediate-release formulation ("TIRF") of fentanyl, contained in a single-dose spray device. Subsys was approved by the Food and Drug Administration ("FDA") solely for the treatment of breakthrough cancer pain. From 2012, the year that Subsys was approved by the FDA, to 2013, Insys' net revenue increased by more than 1,000% from Subsys sales. Insys promotes, sells, and distributes Subsys throughout the United States and in Kentucky. Several Insys executives and sales directors have been indicted, including Insys founder and former CEO,

John N. Kapoor.

17. John N. Kapoor is a resident of Lake Forest, Illinois and was the founder and owner of Insys Therapeutics, Inc. He held various executive positions at Insys including Chairman of the Board of Directors and CEO. In 2013, *Forbes Magazine* listed him as a billionaire following the success of Insys' initial public offering. In 2017, Kapoor, along with other Insys executives, was arrested and charged by the Office of the United States Attorney for the District of Massachusetts, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies.. He at all times personally directed the activities of Insys, including, upon information and belief, the payment of fraudulent kickbacks to prescribers in Kentucky, and directed the misrepresentations made to third party payors to obtain off-label coverage of Subsys.³

III. JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction over the Commonwealth's claims pursuant to KRS 23A.010, KRS 194A.505(8), KRS 205.8469, and KRS 367.190, as the claims enumerated herein arise exclusively under Kentucky statutory and common law and from the *parens patriae* authority of the Attorney General to protect the health and welfare of its citizens under the common law. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of this Court.

19. This Court has personal jurisdiction over Insys pursuant to KRS 454.210 because Insys has regularly transacted and/or solicited business in the Commonwealth and/or derived substantial revenue from goods used or consumed or services rendered in the Commonwealth

³ *United States v. Michael Babich, et al.*, 1:16-cr-10343-ABD, Second Superseding Indictment, Doc#419 (D. Mass. September 11, 2018) ("Second Superseding Indictment").

and/or contracted to supply good or services in the Commonwealth and/or caused injury by an act or omission in the Commonwealth and/or caused injury in the Commonwealth by an act or omission outside the Commonwealth.

20. This Court has personal jurisdiction over Defendant Kapoor because he personally directed the commission of tortious acts in Kentucky, including, upon information and belief, payments to prescribers in Kentucky to induce them to prescribe Subsys, and misrepresentations to third party payors to obtain off-label coverage of Subsys and increase prescribing and use of Subsys in the Commonwealth.

21. The Complaint herein sets forth exclusively state law claims against Insys. Nowhere does the Commonwealth plead, expressly or implicitly, any cause of action or request any remedy that arises under or is based on federal law. The Commonwealth expressly asserts that the only causes of action claimed and the only remedies sought herein are founded upon the statutory, regulatory, common, and decisional laws of the Commonwealth of Kentucky.

22. The claims asserted herein by the Commonwealth of Kentucky consist of common law and statutory claims on behalf of the Commonwealth of Kentucky for its own injuries, and common law claims brought pursuant to the Commonwealth's *parens patriae* authority to protect the health and welfare of its citizens. The Commonwealth does not assert any cause of action herein on behalf of any individual or any purported class of individuals.

23. Venue is proper in Hardin County pursuant to KRS 452.450 and 452.460 because injuries to the Commonwealth occurred in Hardin County and pursuant to KRS 367.190(1) because unlawful methods, acts and/or practices of Insys were committed in Hardin County.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

A. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

24. Insys' opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

25. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Teva's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" and to "ensure safe use and access to these drugs for patients who need them."⁴ Prescribers must enroll in TIRF REMS before writing a prescription for Subsys.

26. Despite the limited FDA approval for Subsys and the TIRF REMS program, Insys promoted and marketed Subsys for off-label, non-cancer use, and used its Insys Reimbursement Center, discussed further below, to increase prescriptions of Subsys. Furthermore, according to publicly available information, Insys promoted Subsys to non-oncologist doctors in Kentucky, including family practitioners, pediatric doctors, and doctors who specialized in internal medicine.

B. Insys Pressured its Sales Representatives into Boosting Sales of Subsys for Off-Label Use

⁴ Press Release, FDA, FDA Approves Shared System REMS for TIRF Products, December 29, 2011.

27. Insys sales representatives were trained on how to effectively market Insys to prescribers. According to internal training documents from February and October of 2014, Insys sales representatives were provided with a “Role Playing Checklist” which trained them on how to “Sell Subsys Clinical Benefits,” explain “REMS Enrollment,” discuss the “Free product trial” in which a patient could receive up to 40 free doses of Subsys, explain “IRC Support,” and provide a “Free Interim Product.” As is discussed in Section E, *infra*. Insys prescriptions require prior-authorization in order to receive reimbursement from third-party payors. If a patient’s insurance approved Subsys the sales representatives were told to push Insys’ co-pay assistance which provided a patient with up to \$500 off a prescription. If the insurance denied coverage, the sales representative would provide a patient with a free product voucher. The sales representatives were also trained on how to overcome objections by doctors as well as how to discuss the efficacy of Subsys. Upon information and belief, these tactics were used to induce Kentucky prescribers into prescribing Subsys.

28. Insys incentivized its sales force to engage in illegal and fraudulent conduct in order to increase sales of Subsys. In October 2013, the National Director Sales, Richard Simon, wrote to the District Sales Managers and stated, “[w]hat drives us all? COMPENSATION.”⁵ Instead of looking to assist those who suffered from cancer-related pain, Insys chose to place profits over the health of patients. In order to motivate sales representatives, Insys created a compensation structure with a low base salary and high commission to “increase the off-label Subsys prescriptions.”⁶ The compensation structure was heavily weighted towards commissions, and rewarded reps for selling higher (and more expensive) doses of Subsys, a highly unusual practice

⁵ Staff Report, *Fueling an Epidemic, Inside the Insys Strategy for Boosting Fentanyl Sales*.

⁶ *Id.*

because most companies consider dosing a patient-specific decision that should be made by a doctor. In 2016, an external consulting firm explained to Insys that the incentive compensation was problematic because it encouraged non-complaint behavior. Former Sales representatives acknowledge that the compensation structure encouraged inappropriate behavior, which one executive assumed to mean “off label promotion.”⁷

29. The FDA expressly prohibited Insys from marketing Subsys for anything but cancer pain due to the high risk of “serious or life-threatening” events and abuse, which are greatest in non-cancer patients. Upon information and belief, Insys sales representatives located in Kentucky were encouraged to promote Subsys for off-label use for non-cancer chronic pain conditions.

30. Internal emails demonstrate the pressure Insys executives put on sales representatives. Insys Vice President of Sales, Alec Burlakoff, described the financial incentives for sales representatives in an email sent in March 2013. He stated, “[w]e expect at minimum we each grow our territory by 25 percent in the uncapped bonus plan I just sent. The faster you get to 100K, the faster your earnings will grow...The top rep earned over 90k this quarter, who else wants some of that???” In an additional email that he sent in March 2014, he stated that the lowest-ranked sales representatives made, “20k a quarter plus a 40k base which equals 140K for only maintaining the base of business.”⁸

31. Insys’ pressure on sales representatives was evident in Kentucky. Publicly available data shows that Insys sales representatives visited prescribers 624 times between the third quarter of 2013 and 2016 and spent \$229,852 on these visits. This number understates the amount

⁷ *Id.*

⁸ *Id.*

of “detailing” by each Insys’ sales representatives, as it only reflects visits in which some sort of payment was provided to the prescriber. Many of these doctors were family and pediatric doctors who lacked specialized training in prescribing opioids, not oncologists. Sales representatives were unrelenting in their pursuit of prescribers. For example, according to internal documents, one Insys sales representative visited or called Kentucky prescribers 149 times between December 12, 2016 and January 20, 2017.

32. The Congressional Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, noted the link between drug maker payments to prescribers and physician prescribing practices. It found that “a clear link exists between even minimal manufacturer payments and physician prescribing practices.”⁹ The Report quotes ProPublica findings that “doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty.”

33. The effects of sales calls on prescribers’ behavior is also well-documented in the literature. A study which involved research on different marketing practices -- including visits by sales representatives, medical journal advertisements, and direct-to-consumer advertising -- found that visits by sales representatives have the strongest impact on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the sales representatives’ drugs to hospitals’ formularies.

34. Sales representatives conformed their behavior to Insys’ demands, forming personal bonds with prescribers. According to an email that was sent from a sales representative

⁹ Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

to Alec Burlakoff, the sales rep met with a physician and potential Subsys prescriber and “made plans with him to run together every Monday night at 5 pm. He is looking to get back in shape so I told him that I promised I [sic] could help him get to his goal. I am sure he will help me get to mine as well...” In order to convince a prescriber to prescribe Subsys, another sales representative stated that she visited the physician twice a month on Saturday evening at the doctor’s night clinic. Additionally, she stated, “I can tell you everything about his family and personal life.”¹⁰

35. Insys also created punishments for sales representatives who did not meet their sales goals. Sales representatives were threatened with termination in order to get doctors to write prescriptions of Subsys and encourage prescribers to increase their doses for off-label use such as neck pain, migraines and other chronic pain conditions.

36. Insys sales executives noticed that Fridays were a low day for Subsys sales, and aimed to increase sales on this day. In July 2013, Mr. Burlakoff sent an email to Insys regional sales managers and stated, “Fridays, we literally do half in sales as the other 4 days. Every rep that does not produce a script two consecutive Fridays will be placed on a [performance improvement plan]...Below is the list that failed to produce this past Friday, if you are on the list you must produce 1 single script this Friday to avoid a [performance improvement plan.] All of you are saying ‘what’s with the scare tactics,’ that’s no way to motivate a sales force! LET ME BE CRYSTAL CLEAR[.] I’m not trying to motivate anyone. I am truly trying to get rid of those reps whom [sic] choose or simply can’t follow direction.”¹¹ Insys’ sales demands inevitably resulted in sales representatives’ promotion of Insys to non-oncologists for off-label use. Upon information and belief, Insys used these tactics on Kentucky sales representatives in order to

¹⁰ Staff Report, *Fueling an Epidemic, Inside the Insys Strategy for Boosting Fentanyl Sales*.

¹¹ *Id.*

encourage them to aggressively sell Subsys to Kentucky prescribers for non-cancer, chronic pain conditions.

C. Insys' Sales Representatives were Instructed to Encourage Prescribers to Titrate Up Doses of Subsys to Boost Subsys Sales

37. Insys sales executives pressured their sales representatives to encourage doctors to prescribe higher doses of Subsys to increase revenue from Subsys sales. According to a Subsys Incentive Compensation Plan for the Second Quarter of 2013, “[high dose (1200 and 1600 MCG) still get the highest payout rate.”¹² Additionally, a slide presentation titled “Subsys Incentive Compensation Plan Q4 2013”, stated that specialty sales professionals who began with Insys before the second quarter of 2013 would receive bonus payouts of 5% to prescriptions with doses of 100-800 mcg and 7.5% bonus payouts for prescriptions with doses of 1200 to 1600 mcg.

38. According to a September 2012 email sent from Alec Burlakoff to Insys sales personnel, the sales representatives would receive an email “each and every time a prescriber in [their] territory writes for a Subsys prescription at 100mcg or 200mcg.” After receiving a notice of a low dose, a sales representative was then required to “report back within 24 hours on WHY the low dose was used and HOW the doctor plans to titrate the patient to effective dose.”¹³

39. Insys trained sales representatives to manipulate prescribers by suggesting that they were not providing patients with adequate pain relief by prescribing lower doses of Subsys. In 2012, Insys CEO Michael Babich sent an email to Insys sales personnel stating “you will make more money the more units and higher dose you sell. This is never changing so continue with you [sic] writes how to ensure the patient is getting the proper pain relief.” The following month, Mr. Babich sent an email to sales representatives with a contest for the top five sales representatives in

¹² *Id.*

¹³ *Id.*

July and August 2012. According to the email, the top five sales representatives who had “the highest number of UNITS written for 600 mcg or higher will receive an extra \$1500 and the overall winner will be \$2000.”

40. The pressure to get prescribers to write higher prescriptions continued throughout 2012. In November 2012, the Northeast Regional Sales Manager, Frank Serra, urged Insys sales representatives to push prescribers towards higher doses by stating, “[l]ook at the attached spreadsheet that shows an approximate cash [sic] you’ll make when making sure to have the effective dose conversation with each target. Note that at 120 units, there is serious money to be made...Every time a doc tells you how they prescribed, the very next question should be, ‘How Many Units? And what Dose?’” The accompanying slide to his email, titled “Strength Makes the Difference,” shows the payouts for the doses. For example, a dose of 100 mcg would create a payout of \$283, while a dose of 1600mcg would create a much higher payout of \$1,830. In a similar slide titled, “Don’t Forget the Doses,” demonstrated how bonuses ranged from \$340 per quarter for the 100mcg dose of Subsys to \$2,352 for the 1200 mcg dosage. In a December 2012 email which included the slide, Mr. Serra stated, “the bigger the script the more money you make.”¹⁴

41. Insys executives also pressured sales representatives to push doctors to increase doses for existing Subsys patients. According to an email from March 2013, Mr. Burlakoff stated that it is “infinitely easier to get somebody who is Writing to Write MORE.” In the same email, he praised a sales representative who was able to switch a prescriber from a competing fentanyl product to Subsys and stated, “[t]he physician has every intention of increasing the dose slowly

¹⁴ *Id.*

but surely to 1200mcg in an effort to ensure the patient is being titrated effectively. Cha Ching again!”¹⁵ Upon information and belief, sales representatives who visited Kentucky prescribers received such messages and were encouraged to push doctors to prescribe higher doses of Subsys, despite the dangers of doing so.

42. Additionally, Mr. Serra also urged sales representatives to encourage prescribers to titrate their doses of Subsys. According to an email, Mr. Serra stated, “take specific notice of the number of units per prescription your doctor is prescribing. If it is less than 60 per day, your message to this doctor should be built around increasing the number of units per day by just 1 unit.”¹⁶

43. Mr. Burlakoff later explained that the intention of the titration policy was to “help you to maintain these newly generated Subsys patients by rapidly informing you of the fact that they wrote for a dose and number of units that is simply NOT effective. We are 100 percent sure that those patients who [sic] are prescribed 60 units of 100mcg do not end up filing a prescription for Subsys the following month.”¹⁷ He further stated that “[t]he goal is to generate Subsys patients who [sic] believe in the safety and efficacy behind this product, hence these patients will continuously refill their monthly prescriptions indefinitely. This of course equates to residual income for you!”¹⁸

44. Insys’ push to increase patient doses of Subsys conflicts with science. Nowhere in the CDC Guideline is it recommended that opioid doses be increased if a patient is not experiencing

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷*Id.*

¹⁸ *Id.*

pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,”¹⁹ and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”²⁰

45. Furthermore, patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids’ analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the “[b]enefits of high-dose opioids for chronic pain are not established” while “there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent.”²¹ That is why the CDC advises doctors to “avoid increasing doses” above 90 mg the morphine equivalent dose.²²

D. Insys Utilized its Speakers Program to Increase Subsys Prescriptions

46. The Insys “speakers program” was perhaps its most widespread and damaging

¹⁹ CDC Guideline at 13.

²⁰ *Id.* at 25.

²¹ CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.”

²² CDC Guideline at 16.

scheme. Through this program, Insys paid doctors to discuss Subsys with colleagues in order to boost Subsys sales. According to a 2013 email from an Insys executive to district and regional sales managers, the speaker programs were “the single most important thing we have the luxury of doing here in order to promote [Subsys]...”²³ and that when interviewing prospective sales representatives, they needed to explain that the “single most important function will be facilitating speaker programs.” Insys executives stressed the importance of “owning” doctors, which meant that sales representatives monitored and controlled of doctors’ prescribing behaviors.²⁴ An Insys executive sent an email to sales representatives stating that the top representatives had their business driven by one doctor, who they were able to “own.” Insys expected a “return on investment” made in doctors who participated in the speakers program, meaning the company expected the participating doctors’ prescribing to increase.

47. According to a 2013 Insys presentation titled, “2013 Proposed Marketing Budget,” Subsys prescriptions increased at the same time that the speakers program. According to the presentation, the speakers program created six times more revenue per prescriber compared to those who did not participate in the programs, and that the revenue from the programs created a five to one return on investment based on a comparison of the total speaker program expenses to net revenue.

48. An Insys presentation titled “2014 Proposed Marketing Budget,” showed the prescribing habits of doctors who attended multiple speakers programs. These doctors tended to prescribe more Subsys than those who attended only one program. According the presentation, doctors “who attend multiple [Insys speakers programs] are more prolific” prescribers, averaging

²³ *Fueling an Epidemic Part 4: Inside the Insys Strategy for Boosting Fentanyl Sales.*

²⁴ *Id.*

17.63 prescriptions, compared to an average of 8.61 prescriptions from physicians who attended one program.

49. According to a report by the Southern Investigative Reporting Foundation (“SIRF”) a former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of the speakers program was “in the words of his then supervisor Alec Burlakoff, ‘to get money in the doctor’s pocket.’” Furchak went on to explain that “[t]he catch... was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program – and the checks.”²⁵

50. The Insys speakers program was utilized in Kentucky. For example, according to publicly available documents, one Kentucky doctor received nearly \$40,900 in fees from Insys in 2015, and \$52,727 in fees in 2016. The majority of these fees, totaling nearly \$100,000, were for his participation in the Insys speakers program.

51. In November 2014, Insys held a speaker-training program in Phoenix, Arizona, which was attended by 17 Insys executives and 42 health care providers. One provider from Kentucky attended the program. According to publicly available information, this provider received over \$25,000 in payments from Insys, including \$19,200 in payments for promotional speaking. This provider held at least two talks for Insys, both in 2014, both of which were only attended by two other prescribers.

52. Insys’ corporate office was aware that the speakers program had several problems, including fraud. According to an internal document, an Insys employee had scheduled a speaker program dinner for a doctor, but advised her supervisor that the doctor had to leave the country

²⁵ Roddy Boyd, *Insys Therapeutics and the New ‘Killing It’*, Southern Investigative Reporting Foundation, The Investigator, April 24, 2015.

and would be absent for the dinner. Although the employee was uncomfortable continuing with the program, her supervisor advised her to hold the program despite the doctor's absence, and directed her to have the doctor sign the sign-in sheet upon his return to show the corporate office that he was present for the dinner. The employee advised the Insys Human Resources Department of the incident, which then escalated the issue to the Vice President of Sales. Although the supervisor was reprimanded, she was not terminated despite the fact she felt comfortable holding a speaker program that would have resulted in a sham. Upon information and belief, Insys employees took similar action in Kentucky supporting a sham speaker program.

53. Through its speakers program, Insys bribed and provided kickbacks to doctors in exchange for their increasing the number of new Subsys prescriptions, and increasing the dosage and number of Subsys prescriptions overall. In some cases, Insys required prescribers to write a minimum number of Subsys prescriptions, and write a minimum dosage to receive the bribes and kickbacks. In all cases, Insys measured the effect on the bribes and kickbacks on the doctors' prescribing habits, and the revenue that these habits brought into Insys.

54. The bribes and kickbacks that were given to Insys prescribers came in different forms. For example, Insys paid doctors bribes that were described as honoraria for speaking at different education events regarding Subsys. Insys also paid the salaries for targeted doctors' office staff, and directed Insys employees to perform administrative tasks for which the doctors would otherwise have to have paid an employee.

55. Defendant Kapoor and other executives targeted prescribers for speaker program bribes and arranged for the payment of bribes and kickbacks to these prescribers including, upon information and belief, prescribers in Kentucky. Defendant Kapoor personally participated in meetings to monitor the effectiveness of the bribes and kickbacks on prescribers. If Defendant

Kapoor and other participating executives determined that Insys was not receiving sufficient “return on investment” from the prescribers, they directed the reduction or discontinuance of the payments to the prescriber.

56. In February 2014, Insys hired an outside consulting company, Compliance Implementation Services, LLC to review 15 speakers programs and to “provide assistance in meeting the on-going challenge in sustaining compliance” with the program.²⁶ After reviewing nine speaker programs, Compliance Implementation Services, LLC noticed several problems with the program. According to one summary, the company noticed that that one presentation was “severely lacking in content delivery of safety information.”²⁷ In another presentation, the company noted that “[s]afety information was not discussed at all during the presentation,” and that there was “no clear disclosure to the attendees that the program was sponsored by Insys.”²⁸ During another program, the Insys sales representative informed the attendees that the speaker would be providing information on Subsys, “[h]owever, there was no clear disclosure [that the program was sponsored by Insys] to the attendees.”²⁹ Even more troubling, the speaker discussed Subsys for possible off-label use. According to the report, the discussion included “anecdotal information regarding patient with back pain for which Subsys was effective; however, it is unclear if the patient is an adult cancer patient.”³⁰ Review by Compliance Implementation Services, LLC demonstrated further program deficiencies, such as certain programs lacking a true educational

²⁶ Staff Report, *Fueling an Epidemic, Inside the Insys Strategy for Boosting Fentanyl Sales*.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

purpose, and according to one program checklist, other than Compliance Implementation Services, LLC and the Insys sales representative, “all attendees were from the speakers’ office.”³¹

57. Insys’ sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country.

58. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys in Alabama, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In May of 2017, one of the doctors was sentenced to 20 years in prison.³²

59. In June of 2015, a nurse practitioner in Connecticut, described as the state’s highest Medicare prescriber of narcotics, plead guilty to receiving \$83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at a rate of approximately \$1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted that she was receiving the speaker fees in exchange for writing prescriptions for Subsys.³³

60. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of the

³¹ *Id.*

³² Nate Raymond, *Alabama Doctor Tied to Insys Gets 20 Years for Illegal Prescriptions*, Reuters, May 25, 2017.

³³ Lisa Chedekel, *High-Prescribing Nurse Charged with Accepting Drug Company Kickbacks*, Connecticut Health I-Team, June 23, 2015. Katie Thomas, *Nurse Pleads Guilty to Taking Kickbacks From Drug Maker*, New York Times, June 25, 2015.

Alabama prescribers discussed above to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients.

61. In December of 2016, six Insys executives and managers were indicted. The indictment alleged that the former Insys employees conspired to bribe prescribers, many of whom operated pain clinics, in order to induce them to prescribe Subsys. According to the indictment, in exchange for bribes and kickbacks, the prescribers wrote large numbers of prescriptions for their patients, though most were not diagnosed with cancer.³⁴ In announcing the indictments, the Special Agent in charge of the Boston Division of the FBI noted that this scheme “contributed to the growing opioid epidemic and placed profit before patient safety.”³⁵ In October of 2017, federal prosecutors indicted and arrested Defendant Kapoor, adding him to the case filed against the other Insys executives in December of 2016. The indictment alleged that he devised a scheme to profit by using bribes to cause the distribution of opioids. Only after these indictments were handed down in 2017 did Insys end its speaker program.

62. Federal prosecutors filed a Second Superseding Indictment against Defendant Kapoor and the other Insys executives in September of 2018, narrowing the charges against them, but maintaining the allegations that Defendant Kapoor and others bribed prescribers and, as discussed below, made misrepresentations to insurers, in order to increase prescriptions of Subsys.

E. Insys relied on the Insys Reimbursement Center to Increase Subsys Prescriptions

63. Subsys is an extremely expensive medication. A month’s supply of Subsys could cost in the thousands of dollars, depending on a patient’s dosage and frequency of use. Due to the high cost of Subsys, in most instances Subsys prescriptions must be submitted to insurance

³⁴ Press Release, United States Attorney’s Office District of Massachusetts, *Pharmaceutical Executives Charged in Racketeering Scheme*, December 8, 2016.

³⁵ *Id.*

companies or health benefit payers for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report (“Staff Report”), the prior authorization process for Subsys includes “confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied ... meaning no reimbursement would be due.”³⁶

64. These prior authorization requirements proved to be daunting, as they significantly reduced the number of Subsys prescriptions that would be approved for payment. Even when Insys sales representatives were able to persuade prescribers to prescribe Subsys for non-cancer chronic pain conditions, their sales were thwarted by the prior-authorization requirements. Subsys received reimbursement approval in only approximately 30% of submitted claims. According to an internal presentation titled, “2013 Subsys Brand Plan,” Insys identified ways to overcome authorization barriers, which included building a pre-authorization infrastructure, creating an internal reimbursement assistance hotline, and education on the on prior authorization.

65. Defendant Kapoor and other executives “planned and created” a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys prescriptions.³⁷ This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and

³⁶ Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

³⁷ Second Superseding Indictment, ¶16.

providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions. This practice occurred on a nationwide and corporate level, including in Kentucky.

66. According to the Congressional Staff Report, employees of the IRC received large financial incentives and pressure from management, which included group and individual bonuses, in order to increase the number of Subsys authorizations. In order to boost these numbers, IRC employees falsified medical histories of potential Subsys patients by asserting that the patient had a "cancer diagnosis regardless of the patient's history and regardless of whether the prescriber had prescribed Subsys for a prior diagnosis."³⁸

67. After receiving scrutiny from the U.S. Department of Health and pharmacy benefit managers ("PBMS"), Insys created a canned response to be used for questions regarding whether a patient had breakthrough cancer pain. The response that the Insys employees provided was "[t]he physician is aware that the medication is intended for the management of breakthrough pain in cancer patients [and] [t]he physician is treating the patient for their pain."³⁹ According to an affidavit filed in support of criminal charges against the head of the IRC, the employee script, "deliberately omitted the word 'cancer' in order to mislead agents of insurers and PBMs."⁴⁰

68. Additionally, Insys used manipulative tactics to lead PMBs into believing that the IRC worked on behalf of prescribers. In order to prevent a PBM from tracing calls to Insys, Insys employees provided a 1-800 number for return calls, which was answered by an Insys representative, as opposed to providing the contact information for the patient's prescriber. Insys

³⁸ *Staff Report, Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*

³⁹ *Id.*

⁴⁰ *Id.*

executives allegedly told IRC employees to state that they were calling “from” a doctor’s office, but were later told to tell agents and PBMs that they were calling “on behalf” of a doctor, and that they were “with” a doctor’s office.⁴¹

69. Insys was aware that the majority of the submissions to the IRC were for non-cancer, off-label, non-FDA approved uses. A class action lawsuit filed in Arizona against Insys discusses that Insys management “was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients.”⁴² Additionally, the Oregon Department of Justice determined that 78% of the preauthorization forms submitted on behalf of Oregon patients were for non-cancer use.

70. The IRC maintained an active role in Kentucky. From March 2015 to April 2017, the IRC had 2,112 call notes for Kentucky patients. Many of these call notes involved the reimbursement approval of Subsys for patients with chronic, non-cancer pain. For example, these non-cancer diagnoses include arthritis, herniated discs, migraines, cervical disc degeneration, and chronic pain syndrome. These examples demonstrate the IRC’s skill in deceptively obtaining authorization for reimbursement for Subsys for uses that were not FDA-approved or safe and effective.

71. According to the 2018 indictment, Defendant Kapoor tracked the ability of the IRC to obtain authorization for Subsys prescriptions and instructed IRC employees to make misrepresentations to third-party payors in order to obtain authorization for Subsys prescriptions. Indeed, the IRC manager told IRC employees that they needed to do a better job obtaining

⁴¹ *Id.*

⁴² *Id.*

prescription approvals because “Dr. Kapoor’s not happy, we have to get these approvals up.”⁴³ In 2017, this manager plead guilty to conspiring to “defraud insurers.”⁴⁴

72. Senior executives were heavily involved with other means to get patients Subsys prescriptions. According to an internal document, Defendant Kapoor authored a power point presentation for a 2016 training. The presentation discussed a co-pay assistance program which offered a free trial of Subsys for commercially insured patients in order for patients to receive 30 units of any strength Subsys and vouchers to accommodate extended product trial and insurance delays. The program also offered free monthly and weekly product vouchers for commercial or government insurance denial. Thus, patients were taking and, consequently, becoming addicted to Subsys regardless of whether the third-party payor approved the prescription or not. The presentation also included information regarding specialty pharmacies “who can do it all,” and listed information on Mullaney’s specialty pharmacy in Kentucky and other states.

73. Through the IRC, Insys defrauded third-party payors, including the Commonwealth into paying for improper prescriptions of Subsys. The fraudulent and misleading scheme had the effect of pushing Insys’ highly potent and dangerous opioid onto patients who did not need it, further exacerbating the opioid epidemic.⁴⁵

F. By Increasing Opioid Prescriptions and Use, Insys Contributed to the Opioid Epidemic And Significantly Harmed Kentucky and its Residents

74. Insys devoted substantial resources to its marketing efforts. In 2013, Insys spent \$29.2 million on sales and marketing of Subsys. By 2015, the company was spending \$329 million

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ German Lopez, Want to Understand How Big Pharma Helped Create the Opioid Epidemic? Read This Report, Vox, September 6, 2017.

on marketing of the drug.⁴⁶ In Kentucky, publicly available data shows that Insys sales representatives visited prescribers 624 times between the third quarter of 2013 and 2016 and that Insys spent \$229,852 on these visits.

75. Overall sales of prescription opioids in Kentucky have skyrocketed. From 2006 to 2015, the Commonwealth had more opioid prescriptions than people. In 2015, Kentucky ranked sixth in the nation in opioid-related deaths. In 2016, 102 opioid prescriptions were written for every 100 Kentucky residents.

76. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are now the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

77. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

78. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."⁴⁷ In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Prescription opioids and heroin account for the majority of overdoses. For these reasons, the CDC concluded that efforts to improve the safer

⁴⁶ Letter from Congressional Committee on Energy and Commerce to Saeed Motahari, August 2, 2018.

⁴⁷ 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*, 827-40 (2007).

prescribing of opioids must be intensified “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

79. Most opioid addiction begins with legitimately prescribed opioids. An estimated 60% of the opioids that are abused come, directly or indirectly, through physicians’ prescriptions. A study of 254 accidental opioid overdose deaths in Utah found that 92% of the decedents had been receiving prescriptions from health care providers for chronic pain. Sales to patients who doctor-shop (or visit multiple doctors to hide illicit or over-use) constitute only approximately 1% to 2% of opioid volume. This study is consistent with the observations of a Kentucky law enforcement officer, who perceived prescription opioids and heroin as among the most abused drugs in his region of Kentucky. In his experience, which was confirmed by addiction treatment providers in Kentucky, prescription opioid abuse stemmed from overprescribing opioids, and almost all heroin abuse begins with prescription opioid abuse.

80. Upon information and belief, the escalating number of opioid prescriptions written by doctors who were deceived by Insys’ deceptive and fraudulent marketing schemes, caused a correspondingly dramatic increase in opioid addiction, overdose, and death throughout Kentucky.

81. Addiction has consumed the lives of countless Kentuckians exposed to opioids prescribed by doctors either directly from their own prescriptions, or indirectly from prescription drugs obtained by others and found in family medicine cabinets. It is difficult to describe the lifelong struggle individuals addicted to opioids will face. The desire to get drugs becomes so consuming that addicts can no longer work or care for their children, and will resort to desperate means to persuade doctors to provide their next prescription—even pulling their own teeth.

82. Opioids have contributed to a significant labor shortage in Eastern Kentucky. Recent research has demonstrated that the Commonwealth’s high rate of opioid usage

has reduced the work force, created high turnover, increased employers' costs to train new employees, and caused an increase in employee thefts. Additionally, according to a study conducted by the Appalachian Regional Commission, small businesses and large manufacturing firms are having difficulties hiring employees who are able to pass drug screening tests. For example, convenience stores that are open 24 hours per day are having difficulties operating with fewer employees. The shortage in work force impacts customer service, and requires managers to work extra shifts, which increases overtime costs. According to a Commonwealth resident who owns convenience stores in London and Manchester, Kentucky, "[t]his is the hardest I've ever seen getting workers and keeping workers."⁴⁸

83. The Commonwealth has incurred considerable costs in treating opioid addiction. At the beginning of 2014, the Medicaid program spent roughly \$56 million on behavioral health and substance abuse treatment. By the end of 2016, Kentucky was spending about \$117 million in Medicaid money on those treatments. In addition, the Commonwealth is also providing funding to treat addiction among inmates in its corrections system.

84. In 2016, there were 1,404 reported fatal drug overdoses in Kentucky—117 per month. This was a 12.4% increase from 2015, a year which, in turn, had seen in a 23.6% increase in fatalities from drug overdoses as compared to 2013. Altogether, between 2012 and 2016, drug overdoses claimed a total of 5,822 Kentuckians. In 2017, there were 1,565 fatal drug overdoses in Kentucky, which is approximately 130 deaths per month.

85. In the first month of 2017 alone, Louisville saw 695 overdoses (a figure which includes prescription drugs, illicit drugs, and alcohol). Louisville Metro Emergency Medical

⁴⁸ Lexington Herald Leader, 'Nobody to pick from.' How opioids are devastating the workforce in Eastern Kentucky, available at <https://www.kentucky.com/news/state/article213189309.html>, last accessed June 28, 2018.

Services received 151 of these overdose calls within just four days.

86. The increase in opioid-related deaths has created a shortage of forensic pathologists within the Commonwealth qualified to perform autopsies and post mortem toxicology tests. Currently, the Commonwealth's medical examiner office only has nine doctors, and the demand for coroners has only increased due to growth in opioid-related deaths. The Kentucky Justice Cabinet recently announced a collaboration with the University of Kentucky to contract for forensic pathology services, which will increase training for medical students and strengthen salaries for doctors by combining resources for medical education and autopsies. The University of Kentucky will provide up to four pathologists and the University of Louisville will provide up to six in the Commonwealth's Medical Examiner Office in order to keep up with the surge in opioid-related deaths.

87. Because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin when they can no longer get access to or afford their prescription. Insys knew or should have known that users who become addicted to a particular prescription opioid, such as Subsys, would migrate to another drug (including heroin) if those drugs become less expensive or more readily available. In fact, some users migrate to heroin (sometimes with fentanyl) they buy on the street. One Kentucky treatment provider confirmed that, in his experience, most heroin users started with prescription opioids.

88. Nationally, roughly 80% of heroin users previously used prescription opioids. In Kentucky, toxicology reports showed that 34% of fatal overdoses in Kentucky in 2016 involved the use of heroin. Fentanyl which, in synthetic form, has made its way into Kentucky communities through trafficking, was involved in 763 over-dose deaths in Kentucky, accounting for more than

half of all drug-related deaths in 2017. This was an increase from 2016, where fentanyl-related deaths accounted for 47% of all fatal drug overdoses in the Commonwealth.

89. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone—an antidote to opioid overdose. For example, Louisville Metro Police Major, Eric Johnson, said that the police force administered 123 doses of naloxone in one six-week period between January 1st and February 15th, 2017. One opioid addiction treatment center in Paducah, Kentucky doubled in size to meet the growing needs of the community. The center reports seeing as many 300 patients, of all ages and from all backgrounds, for addiction to prescription opioids, heroin, and fentanyl. A law enforcement officer in Kentucky similarly observed opioid addiction and abuse affecting people across varying ages and demographics.

90. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. Prescription drug abuse causes an increase in crimes such as domestic violence, burglaries, and thefts. One corrections officer estimated that nearly all of the inmates in a Woodford County jail were struggling with addiction, that almost all of the inmates with drug problems started with abusing opioids, and that 90% of the crimes for which they were convicted were drug related.

91. The abuse of opioids, including Subsys, and the resulting increase in heroin use and addiction have caused outbreaks of HIV, chronic Hepatitis C, and TTP.

92. In 2016 the CDC published a report which listed the top counties in the nation that are at risk of spreading HIV and Hepatitis C due to injecting drugs. Of the top 220 counties, 54 were located in Kentucky, including Wolfe County, which had the greatest risk in the United

States. St. Elizabeth Healthcare in Edgewood reports that it sees up to ten new cases of Hepatitis C daily.

93. Additionally, according to an infectious-disease physician at the University of Kentucky College of Medicine, the opioid epidemic is quickly spreading infectious diseases in the Commonwealth. The doctor stated that “[o]ne IV drug user who might be infected with Hepatitis C is likely to infect up to another 20 people.”⁴⁹ The doctor also noted that the individual using the drugs is not the only one affected by infectious diseases. The doctor also said “[t]hat individual who may acquire HIV disease from injecting drugs has the potential for passing it on to someone else—a spouse, a partner-or a women who becomes pregnant passing it on to her unborn child.”⁵⁰

94. In 2016, the Commonwealth spent \$69.7 million on pharmacy claims to provide Hepatitis C drugs to 833 patients (which does not include the costs of testing for the infection or other treatment-related costs). The list price for a course of treatment ranges from \$84,000 to close to \$100,000. The total number of Kentucky Medicaid enrollees with a diagnosis of Hepatitis C increased from 8,000 in 2013 to 16,000 in 2014, though the CDC estimates that 90% of infections are unreported because the patients are still not symptomatic. If untreated, Hepatitis C continues to be transmitted, including in childbirth.

95. Children have not been spared by the opioid crisis. As of June 2017, there were over 8,000 children in foster care in Kentucky, compared to 6,000 in 2012, most commonly because of parent’s abuse of drugs or alcohol. According to one foster-parent recruiter, the increasing number of children in foster care in Ashland, Kentucky has reached a “crisis point” as

⁴⁹ Kuhlman, Mary, *Experts Take a Deeper Dive Into the KY Opioid Epidemic*, Public News Service, September 24, 2018, available at <https://www.publicnewsservice.org/2018-09-20/health-issues/experts-take-a-deeper-dive-into-ky-opioid-epidemic/a64024-1>.

⁵⁰ *Id.*

a result of the opioid epidemic.⁵¹ Additionally, there has been a recent increase in the number of Commonwealth children who are living with relatives other than their parents due to the opioid crisis. For example, from 2013 until 2015, more than 50,000 children in the Commonwealth were raised by a relative other than their parents. From 2016 to 2018, this number increased to 96,000 children—nearly double, and 9% of all children in the Commonwealth. Furthermore, these statistics demonstrate that Kentucky’s number of children living with family members other than their parents are nearly two times higher than the national average. According to Dr. Terry Brooks of the Kentucky Youth Advocates, the “opioid epidemic” is the “catalyst” of the growth of number of children who are living with family members other than their parents.⁵²

96. School districts also have seen a dramatic increase in suspensions of high school students found possessing, distributing, or under the influence of prescription drugs. According to a 2017 CDC study, one in seven high school students in the U.S. has misused opioids. In 2016, 90 Kentucky residents ages 15-24 years-old died of fatal drug overdoses. In 2017, 2 children ages 5-14 died in the Commonwealth due to fatal drug overdoses. Drug use is also having an effect on local schools and playgrounds. In one school year, elementary schools in Boyd County found a total of 18 syringe needles in their playgrounds. To fight the epidemic, students from Ashland Middle school created a prototype to safely pick up and dispose of syringes and created a database enabling residents to see where the needles were found.

97. Even infants have not been immune to the impact of opioid abuse. There has been

⁵¹ States hit hard by opioid crisis see increase in foster care kids, North Jefferson News, Jan. 19, 2017.

⁵² Mountain News WYMT, “Number of Children Living with Relatives Due to Opioids is Increasing in Kentucky,” available at <https://www.wyvt.com/content/news/Number-of-children-living-with-relatives-due-to-opioids-increasing-in-Kentucky-498590891.html>, last accessed October 31, 2018.

a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from Neonatal Abstinence Syndrome (“NAS”). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, babies who suffer from NAS are at risk of life-threatening illnesses.

98. NAS has become a great source of concern within the Commonwealth. Kentucky has one of the highest rates of pregnant women using opioids in the country. In 2014, the Commonwealth had the third-highest rate of pregnant women with opioid use disorder in the United States. In Kentucky, from August 1, 2014 until July 31, 2015, there were 1,234 cases of NAS reported to the Kentucky Department of Public Health. This translates to about 100 newborns per month. In 2017, the number of babies born with NAS in the Commonwealth increased by 375% from 2007. In March 2018, Madison County officials, including healthcare providers and social workers held a conference in order to solve the increasing problem of pregnant women being addicted to opioids. The goal of the conference was to create a plan that would provide support to mothers and families after giving birth, and the motive of the program is to help families plan for the future.

99. Andy Beshear, the Attorney General of the Commonwealth, has taken initiatives to combat the opioid epidemic in Kentucky. As recently as August 2018, the Attorney General Beshear delivered pouches to Muhlenberg County that allow for the proper disposal of unwanted or outdated prescription medications, including opioids. According to Attorney General Beshear, a Kentucky resident is able to dispose of up to 45 prescription opioids in one pouch. The pouches were created in order to prevent the diversion of opioids within the Commonwealth. Attorney

General Beshear intends on distributing 50,000 pouches throughout the Commonwealth, which allow for up to 2.2 million pills, including opioids, to be properly disposed.

100. While the use of opioids has taken an enormous toll on the Commonwealth and its residents, Insys has realized millions of dollars in revenue from use of its opioids for chronic pain as a result of its deceptive, unfair, and unlawful conduct.

G. Insys Fraudulently Concealed Its Misconduct

101. Insys made, promoted, and profited from its fraudulent and deceptive promotion of Subsys and concealed its misconduct. For example, Insys concealed the fraud and deception of its IRC program, which resulted in the increased use of Subsys across the nation and in the Commonwealth. In addition, Insys concealed the fact that many doctors prescribing Subsys were doing so not because it was safe, effective, or appropriate, but because Insys was paying kickbacks to the prescribers.

102. At all times relevant to this Complaint, Insys took steps to avoid detection of and to fraudulently conceal its deceptive and fraudulent conduct.

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

V. CAUSES OF ACTION

COUNT I

Deceptive Acts and Practices in Violation of Kentucky Consumer Protection Act

(KRS 367.110 et seq.)

104. The Commonwealth 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.

105. Kentucky’s Consumer Protection Act (“KCPA”), KRS 367.110 *et seq.* prohibits “unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce.” KRS 367.170.

106. Under KRS 367.190, “[w]henver the Attorney General has reason to believe that any person is using, has used, or is about to use any method, act or practice declared by KRS 367.170 to be unlawful, and that proceedings would be in the public interest,” he may seek injunctive relief.

107. At all times relevant to this Complaint, Insys violated the KCPA by making or causing to be made, and by disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions, to Kentucky prescribers and consumers to promote the sale and use of Subsys. These unfair, false, deceptive, and misleading statements and omissions included, but were not limited to:

- a. Statements or omissions indicating that Subsys was safe, effective, and appropriate for non-cancer chronic pain;
- b. Statements or omissions indicating that Subsys was selected by prescribers as medically necessary or appropriate, or because of the prescriber’s independent medical judgment when it was actually selected due to kickbacks, bribes, or other illegal inducements from Insys;
- c. Failing to disclose marketing practices that induced prescribers to prescribe Subsys notwithstanding the fact that it was not safe, effective, or appropriate for the prescribed use;
- d. Claiming that prescribers should prescribe Insys in higher and higher doses without evidence that doing so was safe or effective; and
- e. Failing to disclose that prior-authorization decisions were based on fraud and deception, not on the medical necessity or appropriateness of the Subsys prescription for the patient’s condition.

108. Insys knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions to be made or disseminated, that they were unfair, false, deceptive, and misleading and therefore likely to deceive the public. In addition, Insys knew that its marketing and promotional efforts created an unfair, false, deceptive, and misleading impression of the risks and benefits of Subsys.

109. At all times relevant to this Complaint, Insys directly violated the KCPA by engaging in unfair acts or practices to promote the sale and use of Subsys. These acts or practices are unfair in that they are unconscionable, offend public policy, and are immoral, unethical, oppressive, or unscrupulous.

110. Insys' unfair acts or practices include, but are not limited to:

- a. Promoting Subsys for non-cancer chronic pain conditions for which it was not FDA approved and for which it is not safe or effective;
- b. Employing a speakers program that paid doctors kickbacks to increase their prescribing of Subsys;
- c. Employing the IRC to fraudulently and deceptively induce third-party payors to approve prescriptions of Subsys in patients where the use of Subsys was not indicated, safe, or effective;
- d. Providing free product trials and free interim products to patients whose Subsys prescriptions had not been approved, thereby inducing the patient to use Subsys for inappropriate conditions and to potentially become dependent on Subsys.

111. For each of Insys' willful violations of KRS 367.170, the Commonwealth is entitled to recover a civil penalty of not more than two thousand dollars (\$2,000) per violation and ten thousand dollars (\$10,000) for each violation targeted at consumers over the age of 60.

COUNT II

Restoration of Property due to Violations of Kentucky Consumer Protection Act

(KRS 367.110 et seq.)

112. Insys' conduct was deceptive to both patients and prescribers. Patients are laypersons and lack the medical expertise to independently assess pharmaceutical claims. By engaging in the conduct described above, Insys induced physicians to prescribe Subsys for off-label, and inappropriate use. Furthermore, Insys' misleading, fraudulent, and deceptive marketing practices increased the demand for opioids, exacerbating the diversion and abuse of opioids in Kentucky.

113. Insys' conduct has caused substantial, indeed grievous, injury to Kentucky persons. The staggering rates of opioid use, abuse, and addiction resulting from Insys' marketing schemes have caused substantial injury to the Commonwealth, its residents, and to businesses including, but not limited to:

- a. A substantial number of Kentucky residents prescribed opioids, such as Subsys, for chronic pain have experienced the life-upending effects of addiction, abuse, misuse, overdose and death. For those who can stop taking narcotic opioids, there are years of struggling with the pull of the drugs and the fear of relapse (and often relapse itself), counseling sessions, or lining up each morning for daily maintenance drugs. And those who cannot overcome the need for opioids must deal with the compulsive use of and need for opioids, the haziness when they are on the drugs, and the nearly constant struggle to maintain their supplies of the drugs, whatever the cost. Both groups face a dramatically heightened risk of serious injury or death and sometimes an unrecoverable toll on their health, work, and family.
- b. Elderly Kentuckians are particularly vulnerable to serious adverse outcomes, including overdose, injury, and death;
- c. Kentuckians, including thousands of infants and children, who have never taken opioids also have also been and continue to be injured. Infants have suffered NAS and painful withdrawal, children have lost parents [and even grandparents] and/or have been displaced from homes, and adults have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

- d. Kentuckians have incurred health care costs due to the prescription of opioids for chronic pain and the treatment of opioids' adverse effects, including addiction and overdose.
- e. This increased demand also has created additional illicit markets in other opiates, particularly heroin. Patients addicted to opioids frequently migrate to lower-cost heroin, with the serious personal costs that accompany their use of unlawful drugs.
- f. All of this has caused substantial injuries to the Commonwealth and its residents—in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

114. These profound injuries are not outweighed by any countervailing benefits to consumers or competition since there is no benefit from the fraudulent and misleading promotion of Subsys. Further, no public policy justifies Insys' conduct. In light of Insys' fraudulent and deceptive promotional campaigns (and especially given the addictive nature of these drugs) the injuries caused by Insys' misconduct could not reasonably have been avoided by those Insys harmed.

115. Insys' acts and practices as alleged herein substantially impacted the community of patients, health care providers, law enforcement, and other Kentucky government functions, and caused significant actual harm.

116. The Commonwealth is included among the persons in interest to whom the Court may order restoration of money or property under KRS 367.200.

117. The Commonwealth is entitled, pursuant to KRS 367.200, to restoration of moneys paid out when the Commonwealth paid for prescription opioids as a direct result of Insys' violations of the KCPA and the ongoing expenditures for additional medical care and provision of other services that the Commonwealth has been required to make as a direct result of the violations alleged herein.

COUNT III

Violations of Kentucky Medicaid Fraud Statute (KRS 205.8463; KRS 446.070; KRS 205.8469(1))

118. The Commonwealth 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.

119. Medicaid was created in 1965 and operates under Title XIX of the Social Security Act. Medicaid is a cooperative venture between the Federal and State governments to assist States in the provision of medical care to their poorest and most vulnerable citizens, including the poor, the disabled, the elderly, the blind, pregnant women, infants and dependent children. Medicaid is the largest program providing medical and health-related services to America's poorest people.

120. Within broad federal statutory and regulatory guidelines a State: (a) establishes its own eligibility standards; (b) determines the type, amount, duration, and scope of services; (c) sets the rate of payment for services; and (d) administers its own program. These statutes and regulations are set forth generally in the Grants to States for Medical Assistance Programs sections of the United States Code (42 U.S.C. § 1396 *et seq.*) and the Code of Federal Regulations (42 C.F.R. § 430 *et seq.*). The Medicaid program is administered at the federal level by the United States Department for Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

121. The Medicaid program in Kentucky ("Kentucky Medicaid") is administered at the State level by the Kentucky Cabinet for Health and Family Services (CHFS), Department for Medicaid Services ("DMS"). DMS is a body politic created by the Kentucky Constitution and laws of the Commonwealth of Kentucky and, as such, is not a citizen of any State. DMS is a governmental agency in the Executive Branch of the Commonwealth of Kentucky. Finally, DMS

is the single state agency charged with administration of the Kentucky Medicaid program pursuant to Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396a(a)(5), 42 C.F.R. § 431.10, 42 C.F.R. § 100, KRS 12.020(II)(8)(k), KRS 194A.030(2), KRS Chapter 205, KAR Title 907, and other applicable law.

122. Spending on Kentucky Medicaid has grown exponentially. During FY 2016, Kentucky's state share of Medicaid was \$1,611,591,800, which is roughly 30.9% of the Kentucky State budget. Spending on Kentucky's Medicaid increased by about 69.5 percent between fiscal years 2012 and 2016 and continues to increase. For FY 2019, the Kentucky General Assembly appropriated \$1,881,992,500 for the operation of Kentucky Medicaid and \$2,043,016,800 for FY 2020. From January 2010 until September 2018, Kentucky's Medicaid program spent \$1,729,185 on a total of 6,063 opioid prescriptions.

123. Enrollment in Kentucky Medicaid continues to expand as well. As of April 2018, Kentucky Medicaid covered over 1,278,799 men, women and children, or approximately 28.6% of Kentucky's total population of 4,472,265.

124. KRS 205.8463 is violated when any person "intentionally, knowingly, or wantonly make[s], present[s], or cause[s] to be made or presented to an employee or officer of the CHFS any false, fictitious, or fraudulent statement, representation, or entry in any application, claim, report, or document used in determining rights to any benefit or payment." KRS 205.8463(2).

125. It is likewise a violation of KRS 205.8463 for any person to "in any matter within the jurisdiction of the CHFS under this chapter, knowingly falsify, conceal, or cover up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry." KRS 205.8463(4).

126. Under KRS 205.8469(1), “[t]he Attorney General, on behalf of the Commonwealth, may commence proceedings to enforce KRS 205.8451 to 205.8483.”

127. Additionally, KRS 446.070 provides that “[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

128. Insys’ practices, as described in the Complaint, violated KRS 205.8463(2) & (4). Insys engaged in a deceptive and fraudulent marketing scheme that was designed to, and successfully did, cause the prescribing and sales of Subsys to skyrocket in Kentucky. Insys employed fraudulent and deceptive marketing and promotional schemes that induced prescribers to prescribe, and payors to pay for, Subsys prescriptions for conditions that were not approved by the FDA, nor safe or effective, and that were not the result of independent medical judgment that Subsys was medically necessary or appropriate for the condition.

129. Insys deceptively and misleadingly marketed Subsys for non-cancer chronic pain conditions that were not approved by the FDA or shown to be safe and effective. Furthermore, Insys utilized the IRC to increase Subsys prescriptions by fraudulently obtaining approvals of Subsys for off-label use. Additionally, Insys used its speaker program to induce doctors into prescribing Subsys in exchange for bribes and kickbacks, and not because of the prescriber’s judgment that the medicine was medically necessary or appropriate.

130. Insys intentionally deployed these schemes for the purpose of getting the Kentucky Medicaid program to pay for Subsys prescriptions.

131. Insys’ fraudulent schemes induced Kentucky health-care providers into prescribing Subsys that they would not otherwise have prescribed. Insys’ scheme caused doctors to write

prescriptions for Subsys for non-FDA approved conditions that were presented to the Commonwealth's Medicaid program for payment.

132. The Commonwealth's Medicaid program only covers the costs of care that "meets professionally recognized standards," are not obtained through fraud, material misrepresentation, or material omission, or do not constitute "provider abuse." *See* 907 KAR 1:671(40) (defining "unacceptable practice[s]" prohibited by Kentucky's Medicaid regulations). Kentucky's Medicaid regulations expressly provide that it is an "unacceptable practice" to "[k]nowingly submit[], or caus[e] the submission of false claims." 907 KAR 1:671(40)(a). "[I]nducing, or seeking to induce, a person to submit false claims" is also an "unacceptable practice," as are "[k]nowingly making, or causing to be made, or inducing, or seeking to induce, a false, fictitious or fraudulent statement or misrepresentation of material fact in claiming a Medicaid payment, or for use in determining the right to payment" and "[h]aving knowledge of an event that affects the right of a provider to receive payment and concealing or failing to disclose the event or other material omission with the intention that a payment be made or the payment is made in a greater amount than otherwise owed." 907 KAR 1:671(40)(a)-(c).

133. Due to Insys' actions, doctors, pharmacists, other health care providers, and/or other agents of the Medicaid program expressly or impliedly certified to the Commonwealth that Subsys prescriptions were medically necessary and reasonably required because they were influenced and/or deceived by Insys' speaker programs, IRC programs, and deceptive marketing of Subsys for non-cancer conditions. As a result of Insys' actions, doctors, pharmacists, other health care providers, and/or other agents of the Medicaid program expressly or impliedly certified to the Commonwealth that it was not paying for "unacceptable practices."

134. As a direct and proximate result of Insys' deception, fraud, and misrepresentations and/or omissions, Kentucky health-care providers and Kentucky patients were deceived or misled about the use of Subsys for off-label, non-FDA approved conditions or were induced to prescribe or consume Subsys for uses that were not medically necessary or appropriate.

135. Insys knew that, as a natural consequence of its actions, governments such as the Commonwealth, through programs like Medicaid, would necessarily be paying for prescriptions of Subsys to treat non-cancer chronic pain conditions.

136. Insys' misrepresentations were material because if the Commonwealth had known that doctors, pharmacists, and other health care providers, based upon untrue or misleading information and fraudulent schemes, were certifying and/or determining that opioids were medically necessary, the Commonwealth would have refused to authorize payment for, or otherwise severely restricted, the use of Subsys.

137. Alternatively, the misrepresentations were material because they would have a natural tendency to influence or be capable of influencing whether the costs of Subsys were paid by the Commonwealth.

138. By virtue of the above-described acts, Insys knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Commonwealth to approve and pay such false and fraudulent claims.

139. To the extent that such prescribing is considered customary or consistent with generally accepted medical standards, it is only because standards of practice have been tainted by Insys' deception.

140. The Commonwealth, unaware of the fraudulent nature and falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Insys,

paid the claims that would not have been paid but for Insys' misrepresentations, omissions, and fraudulent and illegal business practices.

141. By reason of Insys' unlawful acts, the Commonwealth has been damaged, in a substantial amount to be determined at trial. Medicaid spending accounts for nearly 30% of all funds appropriated under the 2016-2018 biennium budget. Historically, costs of prescription drugs have represented the largest component of Kentucky's Medicaid budget. These costs have increased over time. Costs of prescriptions written due to Insys' deceptive marketing scheme, and costs of addressing the public health crisis caused or substantially contributed to by that scheme, are direct and proximate results of Insys' violations as alleged herein and a significant financial burden on the Commonwealth. In 2016, Kentucky's Medicaid spending for medications to treat opioid addiction was \$117 million, double the amount from only two years prior, which totaled \$56 million in 2014.

142. As a direct and proximate result of Insys' fraud, misrepresentations and/or omissions, the rising number of persons addicted to prescription opioids have led to a dramatic increase in social problems, including drug abuse and criminal acts to obtain opioid drugs, including prescription opioids, heroin, and fentanyl. These social problems significantly and negatively impact the public health and the resources provided for Medicaid, emergency, and other services.

143. Insys' practices, as described in the Complaint, violated KRS 205.8463(2) & (4). Through these acts Insys either presented or caused to be presented to an employee or officer of the CHFS, false or fraudulent claims and knowingly used or caused to be used a false statement, or statement which concealed or covered up a material fact, to get a false or fraudulent claim paid or approved by a program within the jurisdiction of the CHFS.

144. Because of the above violations of KRS 205.8463(2) & (4), the Commonwealth is entitled to recover damages from Insys in an amount to be proved at trial.

145. Because of the above violations of KRS 205.8463(2) & (4), the Commonwealth is entitled to recover from Insys additional civil damages in accordance with the provisions of KRS 446.070.

COUNT IV

Violations of Kentucky Assistance Program Fraud Statute

(KRS § 194A.505(6); KRS § 194A.990)

146. The Commonwealth 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.

147. KRS 194A.505(6) provides: “No person shall, with intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice.”

148. Insys, by reason of the acts and/or omissions set forth herein, with the intent to defraud or deceive, devised a scheme or artifice to obtain benefits from the Kentucky Medicaid program that it was not entitled to receive, in violation of KRS 194A.505(6).

149. KRS 194A.505(8) provides: “The Attorney General on behalf of the Commonwealth of Kentucky may commence proceedings to enforce this section, and the Attorney General shall in undertaking these proceedings exercise all powers and perform all duties that a prosecuting attorney would otherwise perform or exercise.”

150. Additionally, KRS 446.070 provides that “[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

151. KRS 194A.990(5) provides: “Any person who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, forfeit and pay a civil penalty of payment to the cabinet in the amount of all benefits and payments to which the person was not entitled.”

152. By engaging in the conduct set forth above, Insys violated KRS 194A.505(6), and the Kentucky Medicaid program, as a direct and proximate result, paid for Subsys prescriptions that were not medically necessary and will be required to make payments for ongoing medical treatment and care on behalf of Kentucky Medicaid patients in the future.

153. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover damages from Insys in an amount to be proved at trial.

154. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Insys additional civil damages in accordance with the provisions of KRS 446.070.

155. Because of the above violations of KRS 194A.505(6), the Commonwealth is entitled to recover from Insys, in addition to any other penalties provided by law, forfeit and pay a civil penalty in the amount of all benefits and payments to which Insys was not entitled in accordance with the provisions of KRS 194A.990(5).

COUNT V

Continuing Public Nuisance

156. The Commonwealth 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.

157. A public nuisance is an unreasonable interference with a right common to the general public.

158. Circumstances that may sustain a holding that an interference with a public right is unreasonable include conduct that involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience.

159. A common or public nuisance has also been described as a condition of things which is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large, which may result either from an act not warranted by law, or from neglect of a duty imposed by law.

160. Through its deceptive and fraudulent marketing and promotion of Subsys, Insys has assisted in the creation of a condition that significantly interferes with the public health, the public safety, the public peace, the public comfort or the public convenience and is prejudicial to the health, comfort, safety, property, sense of decency, or morals of the citizens at large.

161. The public nuisance was foreseeable to Insys, which knew or should have known of the harm it would cause.

162. The public nuisance is substantial and unreasonable. Insys' actions were not only unreasonable, but unlawful and grievously harmful to the health and safety of Kentucky residents, and the harm from Insys' intentional misconduct outweighs any offsetting benefit.

163. This injury to the public includes, but is not limited to (a) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive inappropriate prescribing of Subsys and other opioids and the failure to provide more appropriate pain treatment; (b) high rates of opioid abuse and addiction, overdoses, and outbreaks of other serious diseases (like Hepatitis C), and fatalities; (c) children removed from their homes and newborns born addicted to opioids;

(d) lost employee productivity due to opioid-related addiction and disability; (e) the creation and maintenance of a secondary, criminal market for opioids; (f) greater demand for emergency services, law enforcement, addiction treatment, and social services; and (g) increased health care costs for individuals, families, and the Commonwealth.

164. Insys' actions were, at the very least, a substantial factor in opioids continuing to be widely available and widely used and in the public health crisis. Without Insys' actions, opioid use would not be so widespread, and the opioid epidemic that now exists in Kentucky would be less severe.

165. The public nuisance—i.e., the opioid epidemic—contributed to and expanded by Insys' fraudulent and deceptive promotional activities can be abated.

166. The health and safety of Kentucky's citizens is a matter of great public importance and of legitimate concern to the Commonwealth and its residents.

167. The Commonwealth has been, and continues to be, injured by Insys' actions in contributing to and expanding the public nuisance. As a direct result of Insys' acts, the Commonwealth has suffered economic harm, including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT VI

Fraud

168. The Commonwealth 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.

169. Insys, fraudulently, intentionally, willfully, or recklessly made misrepresentations and omissions of facts material to the Commonwealth and its residents, and employed deceptive

and fraudulent schemes in order to induce them to prescribe, purchase, administer, and consume opioids as set forth in detail above.

170. These representations, omissions, and actions include, but are not limited to:
- a. Promoting Subsys for non-cancer chronic pain conditions for which it was not FDA approved and for which it is not safe or effective;
 - b. Employing a speakers program that paid doctors kickbacks to increase their prescribing of Subsys;
 - c. Employing the IRC to fraudulently and deceptively induce third-party payors to approve prescriptions of Subsys in patients where the use of Subsys was not indicated, safe, or effective; and
 - d. Providing free product trials and free interim products to patients whose Subsys prescriptions had not been approved, thereby inducing the patient to use Subsys for inappropriate conditions and to potentially become dependent on Subsys.

171. Insys' fraudulent and deceptive actions, misrepresentations, and omissions were reasonably calculated to deceive and, in fact, did deceive the Commonwealth and its residents.

172. Insys intended that the Commonwealth and its residents would rely on its misrepresentations and omissions.

173. The Commonwealth and its residents reasonably relied upon Insys' misrepresentations and omissions.

174. As a direct and proximate result of Insys' misrepresentations and omissions of material fact, the Commonwealth suffered actual pecuniary damage.

COUNT VII

Unjust Enrichment

175. The Commonwealth 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.

176. Many Kentucky citizens who could not otherwise afford medical care rely on the Commonwealth to provide medical care through programs such as Medicaid, and the Commonwealth also pays for opioids through, for instance, its workers compensation program.

177. By illegally and deceptively promoting Subsys, Insys has unjustly enriched itself at the Commonwealth's expense. The Commonwealth has made payments for Subsys prescriptions, and Insys benefited from those payments. Insys received, or will receive, income, profits, and other benefits, which it would not have received if it had not engaged in the deceptive and illegal conduct described in this Complaint. This enrichment was without justification.

178. Insys has unjustly retained a benefit to the Commonwealth's detriment, and its retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

179. While the Commonwealth and its institutions are struggling to pay for the services needed to combat the opioid crisis, and have expended funds in paying for prescription opioids that could otherwise have been used to serve Kentucky's residents, Insys has reaped millions of dollars in profits from its deceptive and fraudulent promotion of Subsys.

180. In equity and fairness, it is Insys, not the Commonwealth and its taxpayers, who should bear the costs occasioned by Insys' deceptive campaign.

181. Accordingly, under principles of equity, Insys should be disgorged of money retained by reason of its deceptive and illegal acts that in equity and good conscience belong to the Commonwealth and its citizens.

COUNT VIII

Negligence

182. The Commonwealth 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.

183. Insys owed the Commonwealth a duty to not expose the citizens of the Commonwealth to an unreasonable risk of harm.

184. Insys had a legal duty under Kentucky common law to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in marketing and selling opioids.

185. Insys has a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, Insys, having engaged in conduct that created an unreasonable risk of harm to others, had, and still has, a duty to exercise reasonable care to prevent the threatened harm.

186. Insys breached its duty to exercise the degree of care commensurate with the dangers involved in selling dangerous controlled substances.

187. Insys breached its duty to the Commonwealth by aggressively promoting Subsys for use in non-cancer chronic pain conditions, and by employing a fraudulent speaker program and fraudulent IRC program to increase the amount of Subsys that was prescribed and approved for payment by third-party payors, thereby increasing the number of patients using and becoming addicted to the powerful opioid.

188. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

189. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the Commonwealth's communities.

190. Reasonably prudent manufacturers of prescription opioids would have anticipated that the scourge of opioid addiction would result from its actions and would wreak havoc on

communities and the significant costs that would be imposed upon the governmental entities associated with those communities.

191. Reasonably prudent manufacturers of opioids would know that fraudulently and deceptively marketing a highly addictive opioid for non-cancer chronic pain conditions for which it was neither approved nor safe and effective, and employing fraudulent schemes to increase the number of patients using the opioid would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to Insys.

192. Insys had control over its conduct in the Commonwealth. Insys controlled its deceptive and fraudulent marketing efforts to mislead the public, including its acts and omissions in detailing by its sales representatives, and other schemes described in this Complaint.

193. Upon information and belief, Insys' actions were a substantial factor in opioid use continuing to be so widespread, and the consequential enormous public health crisis of prescription opioid and heroin overuse, abuse, and addiction that now exists.

194. Upon information and belief, Insys acted with actual malice and a wanton and reckless disregard for the lives and safety of others, and said actions have a great probability of causing substantial harm.

195. The Commonwealth seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of Insys. It does not seek damages that may have been suffered by individual residents of the Commonwealth for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Insys.

196. Insys' misconduct alleged in this case is ongoing and persistent.

197. As a direct and proximate result of Insys' negligence, the Commonwealth has suffered actual pecuniary damage including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT IX

Negligence per se

198. The Commonwealth 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.

199. Violation of a statute gives rise to a private right of action where the injured is within the class of persons the statute intended to be protected. This is true even where the statute is penal in nature and provides no civil remedy.

200. Insys' conduct was negligence *per se* in that it violated the Kentucky laws discussed herein, including, but not limited to, KRS 194A.505 and KRS 205.8463.

201. The Commonwealth was a party intended to be protected by such laws and whose injuries said laws were designed to prevent. Insys' violations of said laws proximately caused injury to the Commonwealth.

202. Insys violated these laws, by, *inter alia*:

- a. Disseminating unfair, false, deceptive, and misleading statements and statements that were false and misleading by virtue of material omissions in its promotion of Subsys;
- b. Presenting or causing to be presented false or fraudulent claims to the Commonwealth through its fraudulent and deceptive promotion of Subsys.

203. As a direct and proximate result of Insys' negligence *per se*, the Commonwealth has suffered actual pecuniary damage including substantial and ongoing expenditures to prevent further harm and to provide services to Kentuckians impacted by the opioid epidemic.

COUNT X

Punitive Damages

(KRS 411.186)

204. The Commonwealth 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.

205. By engaging in the conduct set forth above, Insys acted toward the Commonwealth with oppression, fraud, malice, gross negligence, and/or reckless disregard for the lives and safety of others to a degree sufficient to warrant the imposition of punitive damages pursuant to KRS 411.186 to deter such further conduct on behalf of Insys and, similarly situated parties.

VI. PRAYER FOR RELIEF

206. WHEREFORE, Plaintiff, the Commonwealth of Kentucky, *ex rel.* Attorney General Andy Beshear, respectfully requests the following:

- a. Entry of judgment against Insys, finding that it committed repeated violations of KRS 367.170;
- b. For an injunction, pursuant to KRS 367.190, prohibiting Insys from further marketing, sales, or distribution practices violating KRS 367.170;
- c. An award of civil penalties in the amount of two thousand dollars (\$2,000) for each violation of KRS 367.170, and ten thousand dollars (\$10,000) for each violation targeted to consumers over the age of 60, pursuant to KRS 367.990;
- d. Restoration to the Commonwealth of all moneys or property which it has paid out as a result of Insys' violations of the KCPA alleged in this Complaint, pursuant to KRS 367.200;
- e. An order directing Insys to abate and pay damages for the public nuisance;
- f. An order declaring pursuant to KRS 446.070 that Insys committed repeated violations of KRS 205.8463 and KRS 194A.505;

- g. Civil penalties in the amount of all benefits and payments to which Insys was not entitled in accordance with the provisions of KRS 194A.990(5);
- h. Civil damages not addressed by KRS 194A.990(5) in accordance with the provisions of KRS 446.070;
- i. Pecuniary damages for past and future losses and expenditures;
- j. Punitive damages against Insys pursuant to KRS 411.186;
- k. Restitution or disgorgement of Insys' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;
- l. An award of reasonable attorney's fees, interest, and costs to Plaintiff for pre-judgment and post-judgment conduct;
- m. A trial by jury;

And any and all such other relief as this Honorable Court deems just and proper.

Respectfully submitted,

ANDY BESHEAR
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