

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Hon. Madeline Cox Arleo
 :
 : Criminal No. 20-
 v. : 18 U.S.C. § 371
 :
 :
 PURDUE PHARMA L.P. :

I N F O R M A T I O N

The defendant having waived in open court prosecution by indictment, the Attorney for the United States charges:

COUNT ONE
(Conspiracy to Defraud the United States of America and to Violate the Federal Food, Drug, and Cosmetic Act)

1. At all times relevant to this Information:
 - a. The defendant, PURDUE PHARMA L.P. (“PURDUE PHARMA,” the “Defendant,” or “the Company”), a privately-held Delaware limited partnership headquartered in Stamford, Connecticut, manufactured, sold, and distributed opioids, including its branded opioid medications OxyContin (oxycodone HCl), Butrans (buprenorphine), and Hysingla ER (hydrocodone bitartrate).
 - b. Beginning in or around February 2002 through in or around July 2017, PURDUE PHARMA occupied a research and development (“R&D”) facility in Cranbury, New Jersey, at which it conducted non-clinical discovery science research. Beginning in or around at least 2002 and continuing through

the first half of 2015, PURDUE PHARMA sold and distributed OxyContin extended-release tablets within the United States that were manufactured by The P.F. Laboratories Inc. at a facility in Totowa, New Jersey. Between in or around 2005 and in or around 2010, PURDUE PHARMA leased office space in West Paterson, New Jersey from a third party, which was used as overflow office space for personnel associated with the Totowa manufacturing operations. From in or around March 2017 through in or around September 2019, PURDUE PHARMA began leasing a smaller R&D facility in Princeton, New Jersey.

c. Purdue Pharma Inc. (“PPI”) was the general partner of PURDUE PHARMA, and the Board of Directors of PPI managed PURDUE PHARMA and its wholly owned subsidiaries (collectively, the “Purdue Entities”). PURDUE PHARMA was the main operating entity of the various Purdue Entities.

d. The United States Drug Enforcement Administration (“DEA”) was a United States federal law enforcement agency that enforced the controlled substances laws and regulations within the United States.

Overview of PURDUE PHARMA's Unlawful Conduct

2. PURDUE PHARMA was a leading manufacturer of opioid pain management medications, including OxyContin, and made billions of dollars per year through the sale of these drugs. Given the highly addictive nature of PURDUE PHARMA's products and the significant risk of their being used in an illegal manner, PURDUE PHARMA was subject to extensive regulatory oversight by the DEA. For instance, in order to lawfully manufacture and sell its opioid products in the United States, PURDUE PHARMA was required to, among other things, maintain effective controls to prevent the misuse and illegal distribution ("diversion") of its products and to make truthful and accurate reports to the DEA, including reports relating to its sales figures for opioid products. These important regulatory measures were designed to ensure an adequate and uninterrupted supply of controlled substances such as OxyContin for legitimate medical and scientific purposes, while at the same time preventing the diversion of these products by health care professionals or others dispensing drugs without valid prescriptions.

3. Beginning in or around May 2007 and continuing through in or around February 2018, PURDUE PHARMA conspired to defraud the DEA by evading and undermining the DEA's regulatory authority in order to maximize profits from the sale of its opioid products. During this time, PURDUE PHARMA marketed OxyContin and other drugs directly to health care professionals, including medical doctors, doctors of osteopathy, nurse practitioners, physicians' assistants, and pharmacists (collectively, "Health Care Providers" or

“Prescribers”) PURDUE PHARMA knew or had good reason to believe were engaged in diversion—including through sales representatives visiting their practices and providing them with prescription savings cards that defrayed the costs of opioid prescriptions for patients—while, at the same time, representing to the DEA that it had effective controls in place to prevent such abuse. To the contrary, after PURDUE PHARMA’s anti-diversion programs identified certain Health Care Providers engaging in conduct indicative of diversion, the Company knowingly continued to reap billions of dollars in revenue from those Health Care Providers.

4. During that same period, PURDUE PHARMA also defrauded the DEA by interfering with and impairing the DEA’s ability to establish accurate annual quotas for oxycodone and other Schedule II narcotics that reflected the legitimate medical needs of the United States. Specifically, PURDUE PHARMA provided the DEA with figures that it claimed constituted the total current sales and prescription trends for its opioid products, but failed to inform the DEA that those sales figures included prescriptions written by prescribers that PURDUE PHARMA either knew were engaging in diversion or was willfully blind to their unlawful conduct.

5. From in or around May 2007 through in or around February 2018, PURDUE PHARMA also participated in the unlawful diversion of its opioid products by promoting its products to Health Care Providers who wrote medically unnecessary and unlawful prescriptions for its drugs that were subsequently dispensed through pharmacies.

6. Beginning in or around 2007 and continuing through in or around 2018, PURDUE PHARMA also entered into illegal kickback arrangements by: (1) making unlawful payments to certain doctors purportedly as “fees” for speaking engagements when, in reality, those payments were intended to induce the doctors to prescribe more of PURDUE PHARMA’s opioid products; and (2) paying kickbacks to Practice Fusion, Inc. (“Practice Fusion”), an electronic health records (“EHR”) provider, in exchange for Practice Fusion utilizing its software to influence physician prescribing of extended-release opioid pain medications, including OxyContin, Butrans, and Hysingla.

Background

PURDUE PHARMA’s Branded Opioid Products and its Marketing Efforts

7. In or around 1996, PURDUE PHARMA began selling OxyContin as a treatment for chronic pain. PURDUE PHARMA released its opioid product Butrans in or around 2011, and Hysingla in or around 2015.

8. OxyContin and other prescription opioids possess properties similar to heroin: they can create a euphoric high, which makes them addictive and, at higher doses, can cause respiratory depression and death. Because OxyContin and other prescription opioid products contain narcotic ingredients, such as oxycodone and hydrocodone, there is demand for the products in illicit markets. Those who abuse opioid products face significant health risks, as they can grow tolerant to the drug’s analgesic effects, requiring progressively higher doses to obtain the same levels of pain relief, which leads to an increased risk of physical dependency, withdrawal, addiction, and overdose.

9. To encourage the prescribing of OxyContin and its other opioid products, PURDUE PHARMA engaged in a nationwide marketing campaign directed at patients and Prescribers. One of PURDUE PHARMA's marketing mechanisms was its network of sales representatives.

10. PURDUE PHARMA employed hundreds of sales representatives, who established and maintained in-person relationships with Prescribers and their staff, calling on or "detailing" their offices with the goal of influencing prescribing decisions and encouraging a greater number of prescriptions for PURDUE PHARMA products.

11. PURDUE PHARMA directed its sales representatives to repeatedly visit the most prolific Prescribers of its opioid products and encourage those Prescribers to prescribe increased numbers of PURDUE PHARMA opioid products. PURDUE PHARMA adopted this marketing strategy, in part, because it knew that the top 2 percent of opioid Prescribers wrote close to 80 percent of OxyContin prescriptions nationwide. PURDUE PHARMA identified these highest-prescribing Prescribers as "Super Core" and "Core" prescribers on "call lists" that it provided to its sales representatives. PURDUE PHARMA compiled these call lists even after its own analytics showed that the highest Prescribers of opioids were those most likely to be engaged in diversion.

12. PURDUE PHARMA also instructed its sales representatives to provide Prescribers with prescription savings cards to defray the cost to patients when filling prescriptions for PURDUE PHARMA opioid products at a pharmacy. This practice facilitated the Prescribers' prescribing of PURDUE PHARMA's

opioid products by reducing patients' out-of-pocket costs for opioid prescriptions.

13. PURDUE PHARMA's own marketing analyses showed that when a PURDUE PHARMA sales representative detailed a Prescriber and/or PURDUE PHARMA provided the Prescriber with prescription savings cards, that Prescriber would prescribe more PURDUE PHARMA products. PURDUE PHARMA was also aware of a corresponding decrease in prescription rates for Prescribers that PURDUE PHARMA stopped detailing.

Purdue Pharma's Knowledge of the Diversion of its Opioid Products

i. The Abuse and Diversion Detection Program, Reports of Concern, and the "Region Zero" List

14. By the early 2000s, PURDUE PHARMA was aware that patients were abusing its prescription opioid products and these products were being diverted from lawful uses to illicit ones. In response to the threat of diversion, PURDUE PHARMA implemented several anti-diversion measures, including Standard Operating Procedure 1.7.1—later named the "Abuse and Diversion Detection Program" (the "ADD Program")—in or around November 2002. The ADD Program remained in effect until in or around April 2018, shortly after PURDUE PHARMA ceased promoting opioids to Prescribers.

15. Although the specific practices of the ADD Program changed throughout the years, one consistent policy was that every member of PURDUE PHARMA's field organization (including sales representatives, medical liaisons, state government liaisons, and other field representatives) was required to generate a written report to PURDUE PHARMA's headquarters upon learning of

circumstances or making observations that suggested the abuse or diversion of opioids. PURDUE PHARMA called these “Reports of Concern” or “ROCs.”

16. Among the circumstances or indicators of diversion that PURDUE PHARMA identified as warranting an ROC were:

- a Prescriber seeing an excessive number of patients for the practice type;
- a Prescriber engaging in an atypical pattern of prescribing techniques;
- information from a credible source that a Prescriber, or patients of that Prescriber, were engaging in diversion;
- information that a Prescriber was writing a large number of prescriptions for patients paying with cash;
- an unlicensed individual signing or dispensing prescriptions;
- credible allegations that a Prescriber was under investigation by any law enforcement or regulatory authority;
- long lines of patients waiting for prescriptions from a Prescriber; or
- a brief or non-existent contact between a patient and a Prescriber.

The ADD Program relied on ROCs submitted by PURDUE PHARMA’s sales force in order to make determinations about individual Prescribers. The Company, however, supplemented its review of Prescribers by using data analytics that reviewed the prescribing habits of the country’s most prolific opioid prescribers.

17. Senior-level PURDUE PHARMA employees reviewed each ROC submitted to the ADD Program; they assessed the circumstances of the ROC, including the nature of the concern or allegation, the source of the information, and whether there was corroborating evidence to support the underlying

concern. Those employees then determined whether PURDUE PHARMA should stop promoting its opioid products to that individual or practice due to a “concern about potential abuse or diversion.” These determinations resulted in decisions to “continue calling” or “cease calling” on a Prescriber. PURDUE PHARMA referred to the list of Prescribers that it determined it should cease detailing as the “Region Zero” list.

18. The ADD Program further required PURDUE PHARMA to take such further steps as appropriate, including “providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities.”

ii. Purdue’s Conduct Regarding ADD/Region Zero Prescribers

19. Between 2007 and 2018, PURDUE PHARMA received ROCs and/or reviewed data analytics regarding approximately 6,500 separate Prescribers and pharmacies. In over a hundred instances, despite receiving information indicating that a Prescriber was engaging in diversion, PURDUE PHARMA continued to market and promote its opioid products to the suspicious Prescriber.

20. In hundreds of other instances, although the Company decided to cease in-person detailing of a suspicious Prescriber placed on the Region Zero list, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to that Prescriber, increasing the likelihood that Prescriber’s diversionary prescriptions would be filled at pharmacies.

21. In thousands of other instances, after receiving information that a Prescriber was engaging in diversion and therefore ceasing its direct marketing

activities to that Prescriber, PURDUE PHARMA nevertheless knowingly continued to profit from ongoing, unlawful prescriptions written by that Prescriber. Despite knowing that the Prescriber was continuing to write unlawful prescriptions for PURDUE PHARMA's products, the Company still failed to report that Prescriber to any medical, regulatory, or law enforcement official, and thus continued to profit from the illegal diversion of its products, often right up to the point when the Prescriber was charged with a drug diversion crime or otherwise lost his or her ability to prescribe.

22. PURDUE PHARMA was also aware that it was generating over one hundred million dollars a year from prescriptions written by Prescribers who had been flagged for the Region Zero list ("Region Zero Prescribers"). At various times, PURDUE PHARMA executives also provided the Company's Board of Directors with data regarding prescriptions by Region Zero Prescribers, including the exact prescriptions, units, and dollars generated by each such Prescriber.

23. To further grow profits, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to hundreds of Region Zero Prescribers, despite knowing that those Region Zero Prescribers were engaging in behavior indicative of diversion. Even while acknowledging in emails that providing prescription savings cards to Region Zero prescribers was "inconsistent with our reason for not calling on the prescriber," in certain instances, senior-level PURDUE PHARMA employees—including members of its ADD Program—approved delivering prescription savings cards to such providers.

24. PURDUE PHARMA received additional, direct evidence that many of its Region Zero Prescribers were in fact actively engaged in diversion when it introduced an abuse-deterrent reformulation of OxyContin (“ADF OxyContin”) in 2010. ADF OxyContin was designed to be more difficult to crush, and therefore more difficult to abuse. Shortly after ADF OxyContin’s release, PURDUE PHARMA’s internal analyses showed a two-thirds decrease in prescriptions written by Region Zero Prescribers, thus directly linking the abuse of its products to the activities of those Prescribers. Nevertheless, PURDUE PHARMA repeatedly analyzed and profited from the remaining prescriptions written by Region Zero Prescribers, without taking any significant steps to stop the flow of profits by reporting these suspicious Prescribers to the authorities.

25. Notwithstanding all of the above evidence showing that PURDUE PHARMA was failing to prevent its opioid products from being abused and diverted by problematic Prescribers, PURDUE PHARMA touted the effectiveness of its anti-diversion programs to the DEA. For example, on or about April 12, 2011, a senior member of PURDUE PHARMA’s legal department and a senior member of its compliance team met with DEA personnel to discuss PURDUE PHARMA’s anti-diversion efforts, including its ADD Program. During the meeting, these two senior-level PURDUE PHARMA employees explained that the ADD Program was designed to prevent the marketing and promotion of PURDUE PHARMA’s opioid products to Prescribers who were engaging in abuse or diversion. PURDUE PHARMA representatives communicated with DEA staff again in or around October 2011 and December 2011 to discuss, among other

things, the effectiveness of its ADD Program. Once again, during these conversations, PURDUE PHARMA represented that its ADD Program was effective in combatting illegal diversion.

26. This conduct included the following actions regarding Prescribers 1 through 10.

Prescriber-1

27. Prescriber-1 was a “Super Core” prescriber located in Nevada. Between in or around January 2007 and in or around February 2018, PURDUE PHARMA sales representatives detailed Prescriber-1 at least 422 times. During that time, Prescriber-1 generated over \$6.7 million in gross proceeds for PURDUE PHARMA through prescriptions Prescriber-1 wrote for OxyContin.

28. On or about October 21, 2009, while PURDUE PHARMA was actively marketing to Prescriber-1, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, informing PURDUE PHARMA that a local pharmacist had complained that Prescriber-1 was not prescribing OxyContin responsibly. The pharmacist complained that Prescriber-1’s patients were selling their prescriptions written by Prescriber-1, but that Prescriber-1 refused to change prescribing habits after the pharmacist told Prescriber-1 of his concerns. After receiving this information, PURDUE PHARMA continued its sales and marketing efforts towards Prescriber-1.

29. On or about June 23, 2010, a PURDUE PHARMA sales representative submitted a second written ROC to the ADD Program about Prescriber-1’s behavior, explaining that:

[T]he pharmacy manager, says [Prescriber-1] is known as the “Candyman” . . . because [Prescriber-1] will immediately put every patient on the highest dose of narcotics [Prescriber-1] can, whether it’s OxyContin or another product. He says when he goes to local pharmacist meetings, when [Prescriber-1’s] name comes up everyone in the room cringes and moans because of [Prescriber-1’s] practices. He says [Prescriber-1] is doing all kinds of wacky dosing and tablet strengths. He says he feels like [Prescriber-1] is not doing what [Prescriber-1] should be doing with medications. On occasion he has refused to fill prescriptions from [Prescriber-1’s] office He said he’s been seeing some crazy dosing of OxyContin coming in, especially from [Prescriber-1].

30. On or about July 1, 2010, a PURDUE PHARMA sales representative submitted a third written ROC to the Company’s ADD program about Prescriber-1’s behavior. The sales representative reported speaking with a Prescriber that had inherited a patient from Prescriber-1 who was taking 80mg of OxyContin five times per day (totaling 400mg), which was outside of the normal course of medical practice.

31. During a review following the ROC, senior-level PURDUE PHARMA employees within the ADD Program learned that a sales representative had visited Prescriber-1’s office multiple times and witnessed a registered nurse who was not authorized to prescribe opioids writing such prescriptions on Prescriber-1’s behalf in Prescriber-1’s absence.

32. On or about August 2, 2010, PURDUE PHARMA placed Prescriber-1 in Region Zero and instructed its sales representatives to cease calling on Prescriber-1.

33. Five days later, on or about August 7, 2010, a marketing executive emailed a senior-level PURDUE PHARMA employee in the ADD Program the following message:

Can we mail savings cards to [Prescriber-1], or do we want to avoid providing them at all due to region zero status?

34. The senior-level PURDUE PHARMA employee within the ADD Program emailed a response to the marketing executive the same day, writing: “We have mailed savings coupons to region zero doctors, depending on the circumstances.”

35. Prescriber-1’s patients redeemed at least 80 prescription savings cards linked to Prescriber-1 while Prescriber-1 was listed in Region Zero.

36. On or about August 23, 2011, a marketing representative emailed a senior-level PURDUE PHARMA employee within the ADD Program regarding resuming detailing Prescriber-1:

I was wondering if there is any updated information on [Prescriber-1]. [Prescriber-1] has been listed as “do not see” since before I was in the field with [PURDUE PHARMA]. I just know that some competitors are making calls on [Prescriber-1] and I was wondering if there was new information that would allow me to do the same.

37. On or about October 10, 2011, the senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to members of the ADD Program recommending PURDUE PHARMA sales representatives resume calling on Prescriber-1. The memorandum acknowledged that the Company was aware that Prescriber-1 allowed “[Prescriber-1’s] nurse unsupervised to treat patients and write prescriptions for controlled substances in [Prescriber-1’s] absence.” In a draft of the memorandum, the senior-level PURDUE PHARMA employee wrote that a justification for directing sales representatives to resume calling on Prescriber-1 was the “substantial decline in [Prescriber-1’s] writing of opioid prescriptions.”

38. On or about October 10, 2011, PURDUE PHARMA directed its sales representatives to “resume calling on [Prescriber-1].”

39. Thereafter, PURDUE PHARMA sales representatives detailed Prescriber-1 until PURDUE PHARMA disbanded its opioid sales force in February 2018.

40. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-1, all of which were used to reduce the price of prescriptions for the Company’s opioid products.

41. In total, from the time it first knew or had good reason to believe that Prescriber-1 was diverting opioids in October 2009 until the date it disbanded its opioid sales force in February 2018, PURDUE PHARMA detailed Prescriber-1 approximately 371 times, redeemed roughly 256 prescription savings cards linked to Prescriber-1, and earned over \$4.9 million in gross proceeds from OxyContin prescriptions written by Prescriber-1.

42. Between in or around October 2009 and in or around February 2018, PURDUE PHARMA never took any action to refer Prescriber-1 to the DEA or any other regulatory or law enforcement agency.

Prescriber-2

43. Prescriber-2 was a “Super Core” prescriber located in New York. Between in or around January 2007 and in or around June 2017, PURDUE PHARMA sales representatives detailed Prescriber-2 at least 113 times. During that time, OxyContin prescriptions written by Prescriber-2 generated over \$4.2 million in gross proceeds for PURDUE PHARMA.

44. On or about November 10, 2014, while PURDUE PHARMA was actively marketing to Prescriber-2, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program about Prescriber-2's behavior, stating:

[Prescriber-2] left [Prescriber-2's] long time established practice with [Prescriber-2's] partners, [DOCTOR-1] and [DOCTOR-2]. It was reported to me that there were disagreements about the type of patient [Prescriber-2] was treating and the medications and quantities [Prescriber-2] is prescribing for them to be all OxycodoneIR 30mg scripts. [Prescriber-2] is now in a new practice location with a chiropractor doing "pain management". I spoke to a [COMPANY-1] pharmacist/manager down the road who questions the legitimacy of [Prescriber-2's] prescriptions and who will no longer fill for [Prescriber-2] because [Prescriber-2] won't speak over the phone with pharmacist and [Prescriber-2] sent a husband/wife/ and son from the same family and all were trying to fill OxycodoneIR 30 mg high tablet count scripts all being treated by [Prescriber-2]. A former employee of [Prescriber-2's] former practice told me that "all of the drug addicts followed [Prescriber-2]" and no longer come to the [STREET-1] location to be treated for internal medicine.

45. On or about November 24, 2014, in a follow-up interview with a senior-level PURDUE PHARMA employee within the ADD Program, the sales representative recounted that Prescriber-2's former medical assistant told the representative that "many of [Prescriber-2's] patients were drug seekers." The sales representative also told the senior-level PURDUE PHARMA employee that the sales representative no longer wanted to detail Prescriber-2.

46. On or about November 24, 2014, the senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to members of the ADD Program recommending that PURDUE PHARMA sales representatives cease calling on Prescriber-2 and that PURDUE PHARMA refer Prescriber-2 to the DEA for investigation.

47. In response to the memorandum, another senior-level PURDUE PHARMA employee within the ADD Program sent an email to the other members of the ADD Program asking, “Can we discuss this? My question is about a referral where we only really have information told to us from others.” A few hours later, the ADD Program reversed course based on a group “consultation,” recommending PURDUE PHARMA continue calling on Prescriber-2.

48. On or about November 25, 2014, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-2 and directed the sales representative who reported Prescriber-2 to return to the prescriber’s office, evaluate the practice, and report back to the ADD Program. There is no indication that this follow-up report occurred.

49. Thereafter, PURDUE PHARMA sales representatives resumed detailing Prescriber-2.

50. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-2, all of which were used to reduce the price of prescriptions for the Company’s opioid products filled by patients in New Jersey. For example, on or about March 16, 2016, a patient of Prescriber-2 used a savings card to defray the cost of filling a prescription for PURDUE PHARMA’s opioid products at a pharmacy located in New Jersey.

51. On or about June 23, 2017, PURDUE PHARMA learned that Prescriber-2 was indicted for unlawfully distributing controlled substances.

52. On or about June 24, 2017, PURDUE PHARMA placed Prescriber-2 in Region Zero and instructed its sales representatives to cease calling on Prescriber-2.

53. In or around December 2018, Prescriber-2 was convicted of unlawful distribution of controlled substances.

54. In total, from the time it first knew or had good reason to believe that Prescriber-2 was diverting opioids in November 2014 to when it ceased calling on Prescriber-2 following Prescriber-2's indictment in June 2017, PURDUE PHARMA detailed Prescriber-2 approximately 34 times, redeemed roughly 6 prescription savings cards linked to Prescriber-2, and earned approximately \$834,402 in gross proceeds from OxyContin prescriptions that Prescriber-2 wrote.

55. Between in or around November 2014 and in or around June 2017, PURDUE PHARMA never took any action to refer Prescriber-2 to the DEA or any other regulatory or law enforcement agency.

Prescriber-3

56. Prescriber-3 was a "Super Core" prescriber located in Alabama. Between in or around 2010 and in or around 2013, Prescriber-3 wrote the most prescriptions for OxyContin in the United States. Between in or around January 2007 and in or around March 2013, PURDUE PHARMA sales representatives detailed Prescriber-3 at least 214 times. During that time, OxyContin prescriptions written by Prescriber-3 generated over \$24 million in gross proceeds for PURDUE PHARMA.

57. On or about December 9, 2011, while PURDUE PHARMA was actively marketing to Prescriber-3, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program informing PURDUE PHARMA that Prescriber-3 was under investigation by law enforcement.

58. In a follow-up interview with a senior-level PURDUE PHARMA employee within the ADD Program, the sales representative also stated that “the only unusual aspect of [Prescriber-3’s] practice is the volume of patients that [Prescriber-3] treats per day. [The sales representative] estimates that [Prescriber-3] treats 100 patients per day and may see 4 or 5 patients” at a time.

59. On or about February 9, 2012, the senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to members of the ADD Program recommending that PURDUE PHARMA sales representatives continue calling on Prescriber-3.

60. On or around February 13, 2012, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-3.

61. Thereafter, PURDUE PHARMA sales representatives continued to detail Prescriber-3.

62. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-3, all of which were used to reduce the price of prescriptions for the Company’s opioid products.

63. On or about February 1, 2013, two PURDUE PHARMA sales representatives separately submitted a second and third written ROC to the ADD Program containing additional information suggesting that Prescriber-3 was

diverting opioids. One ROC reported that Prescriber-3 was undergoing a license review by the state medical review board due to Prescriber-3's opioid prescribing patterns. The second ROC reported that Prescriber-3 was prescribing opioids for patients out of a primary care physician's office in Tennessee, despite the fact that Prescriber-3 was not licensed to practice in that state; and that one of Prescriber-3's patients was fearful to take prescriptions Prescriber-3 wrote for multiple controlled substances in significant quantities.

64. On or around February 15, 2013, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to the members of the ADD Program recommending that PURDUE PHARMA continue calling on Prescriber-3. In addition to restating the information reported by the two 2013 ROCs, the memorandum stated, among other things, that Prescriber-3 "ran his clinic like a machine," writing between "5,000 and 6,000 opioid prescriptions" every month. PURDUE PHARMA considered this volume of opioid prescriptions to be "extreme" even among the most prolific Region Zero prescribers based on a May 2012 analysis performed for the ADD program.

65. On or about February 19, 2013, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-3.

66. Thereafter, PURDUE PHARMA sales representatives detailed Prescriber-3 and PURDUE PHARMA continued to honor the redemption of prescriptions savings cards linked to Prescriber-3, until Prescriber-3 surrendered his state medical license in or around March 2013, ending Prescriber-3's ability to prescribe PURDUE PHARMA's opioid products.

67. On or about September 22, 2016, Prescriber-3 was indicted for unlawful distribution of controlled substances and health care fraud. Prescriber-3 pleaded guilty to those charges in or around October 2016.

68. In total, from the time it first knew or had good reason to believe that Prescriber-3 was diverting opioids in December 2011 to when PURDUE PHARMA ceased calling on Prescriber-3 after Prescriber-3 surrendered his/her medical license in March 2013, PURDUE PHARMA detailed Prescriber-3 approximately 40 times, redeemed roughly 332 prescription savings cards linked to Prescriber-3, and earned over \$7 million in gross proceeds from OxyContin prescriptions that Prescriber-3 wrote.

69. Between in or around December 2011 and in or around March 2013, PURDUE PHARMA never took any action to refer Prescriber-3 to the DEA or any other regulatory or law enforcement agency.

Prescriber-4

70. Prescriber-4 was a “Super Core” prescriber located in Michigan. Prescriber-4 also served as a paid member of PURDUE PHARMA’s Speaker Program and spoke on behalf of the Company approximately 21 times between 2012 and 2013. Between in or around January 2007 and in or around May 2014, PURDUE PHARMA sales representatives detailed Prescriber-4 at least 325 times. During that time, OxyContin prescriptions written by Prescriber-4 generated approximately \$16,952,962 in gross proceeds for PURDUE PHARMA.

71. On or about February 7, 2012, while PURDUE PHARMA was actively marketing to Prescriber-4, a PURDUE PHARMA sales representative submitted

a written ROC to the ADD Program informing PURDUE PHARMA that Prescriber-4's office had been raided by law enforcement.

72. In response to the ROC, the ADD Program reviewed call notes taken by sales representatives during visits to Prescriber-4's office. A call note dated August 6, 2008, provided the following:

This is a report of concer[n]. Dr. had a patient on OxyContin 400mg q12h The Dr. got a fax from [HOSPITAL-1] saying that the patient had cut up and chewed 3 duragesic patches and was treated in the emergency room. Dr. wrote a letter of discharge to the patient.

73. After receiving this information through its ADD Program, on or about March 26, 2012, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-4.

74. Thereafter, PURDUE PHARMA sales representatives continued to detail Prescriber-4.

75. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-4, all of which were used to reduce the price of prescriptions for the Company's opioid products.

76. On or about May 2, 2014, PURDUE PHARMA learned that Prescriber-4 was indicted for unlawfully distributing controlled substances and health care fraud.

77. On or about May 8, 2014, PURDUE PHARMA placed Prescriber-4 in Region Zero and instructed its sales representatives to cease calling on Prescriber-4.

78. In or around November 2016, Prescriber-4 pleaded guilty to unlawful distribution of controlled substances and health care fraud.

79. In total, from the time it first knew or had good reason to believe that Prescriber-4 was diverting opioids in February 2012 to when PURDUE PHARMA ceased calling on Prescriber-4 after his/her indictment for unlawfully distributing controlled substances and health care fraud in May 2014, PURDUE PHARMA detailed Prescriber-4 approximately 134 times, redeemed roughly 688 prescription savings cards linked to Prescriber-4, and earned over \$4.6 million in gross proceeds from OxyContin prescriptions that Prescriber-4 wrote.

80. Between in or around February 2012 and in or around May 2014, PURDUE PHARMA never took any action to refer Prescriber-4 to the DEA or any other regulatory or law enforcement agency.

Prescriber-5

81. Prescriber-5 was a “Super Core” prescriber located in Virginia. Between in or around January 2007 and in or around November 2017, PURDUE PHARMA sales representatives detailed Prescriber-5 at least 260 times. During that time, OxyContin prescriptions written by Prescriber-5 generated approximately \$6,306,322 in gross proceeds for PURDUE PHARMA.

82. In or around December 2010, while PURDUE PHARMA was actively marketing to Prescriber-5, the ADD Program reviewed Prescriber-5 after a PURDUE PHARMA data analysis identified Prescriber-5 (i) as a Prescriber “whose prescribing appeared to be outside of the usual prescribing pattern for extended release oxycodone,” or (ii) among those Prescribers with a dramatic decline in OxyContin prescriptions following the release of ADF OxyContin.

83. After receiving this information, on or about August 1, 2011, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-5.

84. On or about September 25, 2012, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program detailing Prescriber-5's behavior:

[Prescriber-5] has not been in the last two calls I have made on this office, office staff stated that [Prescriber-5] is typically in the office three full days a week. [Prescriber-5's] [single entity opioid] volume is large for a family medicine doctor who does not appear to be working full time.

85. During a follow-up interview undertaken in response to the ROC, the sales representative informed a senior-level PURDUE PHARMA employee within the ADD Program that the representative was "concerned with the doctor's pattern of prescribing oxycodone immediate release" because a nurse practitioner who had left Prescriber-5's office "complained to [the representative] that [Prescriber-5] prescribed the same combination of drugs to all of [Prescriber-5's] patients—360 mg of oxycodone immediate release," which was outside of the normal course of medical practice.

86. During the same interview, the sales representative also informed the senior-level PURDUE PHARMA employee within the ADD Program that the representative observed several patients waiting in line outside a locked door at the rear of the office on a day when the representative believed Prescriber-5 was not in the office. The sales representative noted that the patients at the rear door appeared "disheveled," and did not fit the demographics of the affluent

neighborhood in which Prescriber-5's office was located. The sales representative also reported that although Prescriber-5 was not in the office, once the rear door was unlocked, the waiting patients were able to enter and receive what appeared to be prescriptions. The sales representative further stated that based upon all of these observations, the representative no longer felt comfortable detailing Prescriber-5.

87. After receiving the ROC, the ADD Program also conducted additional research on Prescriber-5 and learned that a state medical board had reprimanded Prescriber-5 because Prescriber-5 had continued to prescribe controlled substances to patients after the patients tested positive for controlled substances that were not prescribed by Prescriber-5. PURDUE PHARMA's ADD Program also learned that two other prior disciplinary actions were taken against Prescriber-5 in 2004 and 2006, and another state's medical board suspended Prescriber-5's license in 2006.

88. After receiving this information, on or about November 2, 2012, PURDUE PHARMA placed Prescriber-5 in Region Zero and instructed its sales representatives to cease calling on Prescriber-5.

89. During the time that Prescriber-5 was in Region Zero, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-5. During that period, Prescriber-5's patients redeemed at least 32 prescription savings cards linked to Prescriber-5.

90. Despite knowing of Prescriber-5's history of diversion, PURDUE PHARMA directed its sales representatives to resume calling on Prescriber-5 in

or around 2013. Specifically, approximately four months later, on or about March 15, 2013, a PURDUE PHARMA district manager sent an email to the ADD Program asking that PURDUE PHARMA reevaluate the instruction to cease calling on Prescriber-5.

91. On or about April 15, 2013, PURDUE PHARMA directed its sales representatives to resume calling on Prescriber-5.

92. Thereafter, PURDUE PHARMA sales representatives resumed detailing Prescriber-5.

93. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-5, all of which were used to reduce the price of prescriptions for the Company's opioid products.

94. On or about November 2, 2017, a PURDUE PHARMA sales representative submitted a second written ROC to the ADD Program informing PURDUE PHARMA of additional suspicious activity at Prescriber-5's office:

Report of concern- today I overheard patients in the waiting room talking about how far they drove, many hours to come to [Prescriber-5's] office. I noticed that a[n] office staff member, that was previously trained physician in another country was seeing patients, and never noticed the doctor actually seeing the patient before the end of the visit.

95. It was not until in or around March 2018, one month after PURDUE PHARMA disbanded its opioid sales representative program, that PURDUE PHARMA placed Prescriber-5 in Region Zero a second time and instructed its non-opioid sales representatives to cease calling on Prescriber-5.

96. In total, from the time it first knew or had good reason to believe that Prescriber-5 was diverting opioids in September 2012 until the date it

disbanded its opioid sales force in February 2018, PURDUE PHARMA detailed Prescriber-5 approximately 155 times, redeemed roughly 135 prescription savings cards linked to Prescriber-5, and earned over \$2 million in gross proceeds from OxyContin prescriptions that Prescriber-5 wrote.

97. Between in or around September 2012 and in or around February 2018, PURDUE PHARMA never took any action to refer Prescriber-5 to the DEA or any other regulatory or law enforcement agency.

Prescriber-6

98. Prescriber-6 was a “Super Core” prescriber located in Ohio. PURDUE PHARMA began detailing Prescriber-6 no later than 1998. Between in or around January 2007 and in or around February 2018, PURDUE PHARMA sales representatives detailed Prescriber-6 at least 226 times. During that time, OxyContin prescriptions written by Prescriber-6 generated approximately \$47,145,003 in gross proceeds for PURDUE PHARMA.

99. In or around February 2004, while PURDUE PHARMA was actively marketing to Prescriber-6, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, informing PURDUE PHARMA of a complaint from a pharmacist about Prescriber-6’s habits with respect to prescribing OxyContin.

100. During a follow-up internal review of Prescriber-6, a district manager informed a senior-level PURDUE PHARMA employee within the ADD Program that Prescriber-6 was engaged in “some inappropriate dosing.”

101. Despite receiving this information, on or about March 1, 2004, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-6.

102. On or about June 11, 2008, a PURDUE PHARMA sales representative submitted a second written ROC to the ADD Program, informing PURDUE PHARMA of another pharmacist complaint about Prescriber-6's OxyContin prescribing habits. The representative reported that the pharmacist was "concern[ed] with the dosing on some of [Prescriber-6's] rx's [and] has refused to fill" them.

103. After receiving this information, PURDUE PHARMA took no action and continued its sales and marketing efforts towards Prescriber-6.

104. On or about January 26, 2009, PURDUE PHARMA received a report from a separate pharmacist that Prescriber-6 was writing excessively high doses of OxyContin.

105. After receiving this information, PURDUE PHARMA took no action and continued its sales and marketing efforts towards Prescriber-6.

106. On or about February 26, 2009, a PURDUE PHARMA Drug Safety Associate forwarded a February 24, 2009 ROC from a PURDUE PHARMA sales representative to the ADD Program, informing PURDUE PHARMA that a third-party Health Care Provider had told the representative that Prescriber-6 was "listed in the State Medical Board of Ohio Formal Action Report" and that Prescriber-6 "sees a lot of pain patients and prescribes a lot of pain medication."

107. On or about March 11, 2009, a member of PURDUE PHARMA's ADD Program uploaded a copy of a January 2009 State Medical Board Complaint regarding Prescriber-6. The Complaint was based on Prescriber-6's excessive and inappropriate prescriptions of OxyContin, including at least eight patients for whom Prescriber-6 prescribed between 1,040mg and 1,920mg of OxyContin per day (i.e., 14 to 24 tablets of OxyContin's highest 80mg dose per day).

108. After receiving this information, on or about September 25, 2009, PURDUE PHARMA placed Prescriber-6 in Region Zero and instructed its sales representatives to cease calling on Prescriber-6.

109. In or around April 2010, Prescriber-6's medical license was suspended.

110. During the time that Prescriber-6 was in Region Zero, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-6. During that period, Prescriber-6's patients redeemed at least 436 prescription savings cards linked to Prescriber-6.

111. Although Prescriber-6 was on the Region Zero list, sales representatives continued to submit ROCs to the ADD Program informing PURDUE PHARMA of Prescriber-6's continued diversion of opioids. Specifically, on or about June 30, 2010, a sales representative submitted a written ROC to the ADD Program informing PURDUE PHARMA that a pharmacist was notified by the pharmacy board not to fill OxyContin prescriptions issued by Prescriber-6. Similarly, on or about February 23, 2011 and on or about September 21, 2011, two separate PURDUE PHARMA sales representatives submitted written

ROCs to the ADD Program informing PURDUE PHARMA that pharmacists had told those representatives that Prescriber-6 prescribed OxyContin outside of the usual course of medical practice.

112. On or about January 1, 2015, the state medical board terminated Prescriber-6's probation.

113. On or about March 10, 2015, a PURDUE PHARMA district manager sent an email to the ADD Program asking that PURDUE PHARMA reevaluate the instruction to cease calling Prescriber-6. Despite knowing of Prescriber-6's history of diversion, on or about March 25, 2015, PURDUE PHARMA directed its sales representatives to resume calling on Prescriber-6.

114. Thereafter, PURDUE PHARMA sales representatives detailed Prescriber-6 until PURDUE PHARMA disbanded its opioid sales force in February 2018.

115. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-6, all of which were used to reduce the price of prescriptions for the Company's opioid products.

116. On or about September 11, 2019, Prescriber-6 was indicted for unlawfully distributing controlled substances.

117. In total, from the time it first knew or had good reason to believe that Prescriber-6 was diverting opioids in February 2004 until the date it disbanded its opioid sales force in February 2018, PURDUE PHARMA detailed Prescriber-6 approximately 226 times, redeemed roughly 420 prescription

savings cards linked to Prescriber-6, and earned over \$47.1 million in gross proceeds from OxyContin prescriptions that Prescriber-6 wrote.

118. Between in or around January 2007 and in or around February 2018, PURDUE PHARMA never took any action to refer Prescriber-6 to the DEA or any other regulatory or law enforcement agency.

Prescriber-7

119. Prescriber-7 was a “Core”/”Super Core” prescriber located in Nevada. Between in or around January 2007 and in or around February 2018, PURDUE PHARMA sales representatives detailed Prescriber-7 at least 262 times. During that time, OxyContin prescriptions written by Prescriber-7 generated approximately \$10,681,172 in gross proceeds for PURDUE PHARMA.

120. On or about September 23, 2003, while PURDUE PHARMA was actively marketing to Prescriber-7, a senior-level PURDUE PHARMA employee emailed the ADD Program, writing “[h]ave you looked at [Prescriber-7]” and warned that Prescriber-7, a primary care physician, had “about twice the volume” of opioid prescriptions of any other primary care Prescriber in the nation.

121. During a follow-up review of Prescriber-7 by the ADD Program, the sales representative who detailed Prescriber-7 informed the ADD Program that the representative had heard that Prescriber-7 was under investigation by the state medical board.

122. After receiving this information, on or about July 6, 2004, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-7.

123. In or around 2008 and 2009, PURDUE PHARMA conducted an investigation of a Las Vegas pharmacy (“Pharmacy-1”) based on numerous indicators of diversion, including cars with out of state license plates parked outside of the pharmacy, clients loitering outside of the pharmacy, and clients exchanging prescription drugs in the open. As part of the investigation, a senior-level PURDUE PHARMA employee within the ADD Program and a PURDUE PHARMA compliance executive identified Prescriber-7 as one of the top three prescribers for Schedule II opioids dispensed by the pharmacy. PURDUE PHARMA did not conduct any further investigation of Prescriber-7 after receiving this information.

124. In or around December 2010, Prescriber-7 was flagged for review by the ADD Program after a PURDUE PHARMA data analysis identified Prescriber-7 (i) as a Prescriber “whose prescribing appeared to be outside of the usual prescribing pattern for extended release oxycodone,” or (ii) among those Prescribers with a dramatic decline in OxyContin prescriptions following the release of ADF OxyContin. In addition to these trends, the ADD Program review also uncovered that Prescriber-7 had “a patient overdose[] on OxyContin.”

125. After receiving this information, on or about August 1, 2011, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-7.

126. On or about February 27, 2013, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, informing PURDUE PHARMA that the state medical board had filed a complaint against Prescriber-

7 with respect to Prescriber-7's prescribing OxyContin and other opioids outside of the usual course of medical practice. Although Prescriber-7 was under review by the ADD Program, sales representatives continued to detail Prescriber-7.

127. On or about April 5, 2013, PURDUE PHARMA placed Prescriber-7 in Region Zero and instructed its sales representatives to cease calling on Prescriber-7.

128. Although Prescriber-7 was on the Region Zero list, sales representatives continued to submit ROCs to the ADD Program informing PURDUE PHARMA of Prescriber-7's continued diversion of opioids. Specifically, on or about October 27, 2014, a sales representative submitted a written ROC to the Company's ADD program, informing PURDUE PHARMA that the representative had heard that Prescriber-7 was under investigation by law enforcement.

129. During the time that Prescriber-7 was in Region Zero, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-7. During that period, at least 31 prescription savings cards linked to Prescriber-7 were redeemed by Prescriber-7's patients.

130. After Prescriber-7 was assigned to the Region Zero list, the sales representative and district manager assigned to Prescriber-7's territory made annual requests to the Company to resume calling on Prescriber-7.

131. Despite knowing of Prescriber-7's history of diversion, PURDUE PHARMA directed its sales representatives to resume calling on Prescriber-7 in or around 2015. Specifically, on or about December 17, 2014, a sales

representative requested to resume detailing Prescriber-7. After an “expedited” ADD Program review, on or about March 27, 2015, PURDUE PHARMA directed its sales representatives to resume calling on Prescriber-7.

132. Thereafter, PURDUE PHARMA sales representatives detailed Prescriber-7 until PURDUE PHARMA disbanded its opioid sales force in February 2018.

133. PURDUE PHARMA also continued to honor the redemption of prescription savings cards linked to Prescriber-7, all of which were used to reduce the price of prescriptions for the Company’s opioid products.

134. In total, from the time it first knew or had good reason to believe that Prescriber-7 was diverting opioids in September 2003 until the date it disbanded its opioid sales force in February 2018, PURDUE PHARMA detailed Prescriber-7 approximately 262 times, redeemed roughly 259 prescription savings cards linked to Prescriber-7, and earned over \$10.6 million in gross proceeds from OxyContin prescriptions that Prescriber-7 wrote.

135. Between in or around January 2007 and in or around February 2018, PURDUE PHARMA’s ADD Program never took any action to refer Prescriber-7 to the DEA or any other regulatory or law enforcement agency.

Prescriber-8

136. Prescriber-8 was a “Super Core” prescriber located in Virginia. Between in or around January 2007 and in or around December 2013, PURDUE PHARMA sales representatives detailed Prescriber-8 at least 227 times. During

that time, OxyContin prescriptions written by Prescriber-8 generated approximately \$714,611 in gross proceeds for PURDUE PHARMA.

137. On or about June 4, 2008, while PURDUE PHARMA was actively marketing to Prescriber-8, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, informing PURDUE PHARMA that Prescriber-8 was prescribing controlled substances with an expired DEA license. After receiving this information, PURDUE PHARMA's ADD Program accessed Prescriber-8's prescription history which showed that 90% of his OxyContin prescriptions were for the product's highest 80mg dose.

138. After receiving this information, on or about June 5, 2008, PURDUE PHARMA placed Prescriber-8 in Region Zero and instructed its sales representatives to cease calling on Prescriber-8. However, on or about August 28, 2008, PURDUE PHARMA directed sales representatives to resume calling on Prescriber-8 after learning that Prescriber-8's DEA license was renewed.

139. In or about April 2010, a PURDUE PHARMA sales representative submitted a second written ROC to the ADD Program about Prescriber-8's behavior. Among other things, the sales representative reported that Prescriber-8 (i) had "some patients [who] got addicted who bought the 80mg OxyContin on the street," (ii) had consistently high prescription numbers, (iii) was frequented by patients with out-of-state license plates, and (iv) spent very little time with each patient – approximately 45 seconds.

140. After receiving this information, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-8.

141. In or about April 2011, a PURDUE PHARMA sales representative submitted a third written ROC to the ADD Program regarding Prescriber-8. Among other things, the representative reported that Prescriber-8 prescribed a PURDUE PHARMA opioid product to an inappropriate patient. The ADD Program took no action after receiving the ROC and PURDUE PHARMA continued its sales and marketing efforts towards Prescriber-8.

142. On or about November 12, 2013, a PURDUE PHARMA sales representative submitted a fourth written ROC to the ADD Program informing PURDUE PHARMA that Prescriber-8 was under investigation and had passed prescribing responsibilities to another physician. The ROC was submitted after the sales representative learned that Prescriber-8 had lost the ability to prescribe, but had hired a nurse practitioner to continue issuing prescriptions at his direction.

143. Thereafter, PURDUE PHARMA sales representatives called on Prescriber-8 and his clinic one additional time.

144. On or about December 23, 2013, the ADD Program learned that Prescriber-8's state medical license was suspended. PURDUE PHARMA placed Prescriber-8 in Region Zero and instructed its sales representatives to cease calling on Prescriber-8.

145. In or about November 2018, Prescriber-8 pleaded guilty to conspiracy to distribute controlled substances. As part of the plea, Prescriber-8 admitted that Prescriber-8 helped prescribe opioids—including hundreds of thousands of oxycodone pills—without a legitimate medical purpose.

146. In total, from the time it first knew or had good reason to believe that Prescriber-8 was diverting opioids in June 2008 and when PURDUE PHARMA ceased calling on Prescriber-8 (a second time) after learning that Prescriber-8 could no longer write prescriptions in December 2013, PURDUE PHARMA detailed Prescriber-8 approximately 209 times, redeemed roughly 250 prescription savings cards linked to Prescriber-8, and earned over \$445,000 in gross proceeds from OxyContin prescriptions that Prescriber-8 wrote.

147. Between in or around June 2008 and in or around December 2013, PURDUE PHARMA never took any action to refer Prescriber-8 to the DEA or any other regulatory or law enforcement agency.

Prescriber-9

148. Prescriber-9 was a “Super Core” prescriber located in Nevada. Between in or around January 1998 and in or around March 2017, PURDUE PHARMA sales representatives detailed Prescriber-9 at least 595 times. During that time, OxyContin prescriptions written by Prescriber-9 generated approximately \$15.3 million in gross proceeds for PURDUE PHARMA.

149. On or about December 1, 2002, while PURDUE PHARMA was actively marketing to Prescriber-9, a PURDUE PHARMA sales representative submitted a telephonic ROC to the ADD program, informing PURDUE PHARMA that the Nevada “State Board of Medical Examiner[s] is conducting an investigation relating to [Prescriber-9]” and that the “Board had pulled and reviewed four of [Prescriber-9]’s charts,” including some that the sales representative believed “included prescriptions for OxyContin Tablets.”

150. After receiving the ROC, a senior-level PURDUE PHARMA employee within the ADD Program reviewed call notes taken during visits to Prescriber-9's office from January 1998 through November 2002 which contained several red flags, including that: Prescriber-9 saw "big abuse potential with Oxy[contin]" and his patients regularly requested higher doses; that Prescriber-9 "got [a patient] addicted" to opioids; and that Prescriber-9 admittedly did not properly conduct drug screens to evaluate whether patients were abusing opioids.

151. A senior-level PURDUE PHARMA employee within the ADD Program also reviewed Prescriber-9's prescription history from late 2000 through late 2002 and concluded in an internal memo that Prescriber-9 "is a high prescriber of OxyContin" and a high prescriber of controlled substances.

152. On or about March 13, 2003, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to members of the ADD Program recommending that PURDUE PHARMA sales representatives continue calling on Prescriber-9.

153. Thereafter, PURDUE PHARMA sales representatives continued to detail Prescriber-9.

154. On or about December 7, 2004, a PURDUE PHARMA employee within the ADD Program accessed call notes taken during visits to Prescriber-9's office from January 1998 through November 2002 and additional notes from December 2002 through November 2004. Those call notes indicated, among other things, that Prescriber-9 placed a patient on a treatment plan that called for the patient to take 9 OxyContin 80mg tablets per day.

155. Thereafter, PURDUE PHARMA took no action and continued to market its opioid products to Prescriber-9.

156. On or about September 16, 2006, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, informing PURDUE PHARMA that Prescriber-9 was “being investigated by board of medical examiners for over prescribing opioids” and that a local television channel had run a story the day before regarding one of Prescriber-9’s patients who had overdosed.

157. On or about October 10, 2006, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to members of the ADD Program recommending that PURDUE PHARMA sales representatives continue calling on Prescriber-9 “pending the outcome of the alleged investigation of [Prescriber-9].”

158. On or about October 11, 2006, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-9.

159. Thereafter, PURDUE PHARMA sales representatives continued to detail Prescriber-9.

160. In or around 2008 and 2009, PURDUE PHARMA conducted an investigation of Pharmacy-1 based on numerous indicators of diversion. As part of the investigation, a senior-level PURDUE PHARMA employee within the ADD Program and a PURDUE PHARMA compliance executive identified Prescriber-9 as one of the top three prescribers for Schedule II opioids dispensed by the pharmacy. A further review of Prescriber-9’s prescription data by the ADD

Program showed thousands of OxyContin prescriptions written by Prescriber-9 between January 2007 and December 2008, with over 55% at the highest 80mg dose. The same data also showed that over 23% of Prescriber-9's patients paid for opioid prescriptions with cash.

161. After receiving this information, PURDUE PHARMA continued its sales and marketing efforts towards Prescriber-9.

162. On or about August 17, 2010, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program informing PURDUE PHARMA that the sales representative learned that a pharmacy was "filling a stack of [Schedule II] prescriptions (not just OxyContin)" for a single patient and that some of the prescriptions were written by Prescriber-9.

163. After receiving this information, PURDUE PHARMA continued its sales and marketing efforts towards Prescriber-9.

164. On or about October 27, 2014, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, informing PURDUE PHARMA that the sales representative had learned from two separate reliable sources that Prescriber-9 was under investigation and that Prescriber-9's practice would soon be shut down.

165. After receiving the ROC, the ADD Program reviewed Prescriber-9's medical licensing information, finding that on "June 13, 2013, [Prescriber-9] entered into a Settlement Agreement with the [Nevada State] Board in settlement of a formal complaint issued by the Board against [Prescriber-9] for two counts of malpractice."

166. On or around October 29, 2014, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to members of the ADD Program recommending that PURDUE PHARMA sales representatives “should not call” on Prescriber-9.

167. On or about October 30, 2014, PURDUE PHARMA placed Prescriber-9 in Region Zero and instructed its sales representatives to cease calling on Prescriber-9.

168. Thereafter, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-9, all of which were used to reduce the price of prescriptions for the Company’s opioid products.

169. On or around November 11, 2016, a senior-level PURDUE PHARMA employee within the ADD Program received an email from another PURDUE PHARMA employee including a “list of top NV problematic ADD files/decisions” that attached copies of the prior memoranda regarding Prescriber-9, among others.

170. Thereafter, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-9 until March 2017, all of which were used to reduce the price of prescriptions for the company’s opioid products.

171. On or about February 13, 2018, PURDUE PHARMA learned that Prescriber-9 was arrested and charged with unlawful distribution of controlled substances and health care fraud.

172. On or about December 10, 2018, Prescriber-9 plead guilty to unlawful distribution of controlled substances. As part of the plea, Prescriber-9 admitted “prescrib[ing] and distribut[ing] dosages and amounts of Fentanyl, Oxycodone and hydrocodone” to patients outside the course of [] professional practice and without a legitimate medical purpose.”

173. In total, from the time it first knew or had good reason to believe that Prescriber-9 was diverting opioids in December 2002 to the time PURDUE PHARMA ceased redeeming prescription savings cards linked to Prescriber-9 in March 2017, PURDUE PHARMA detailed Prescriber-9 over 438 times, redeemed roughly 884 prescription savings cards linked to Prescriber-8, and earned over \$15.3 million in gross proceeds from OxyContin prescriptions that Prescriber-9 wrote.

Prescriber-10

174. Prescriber-10 was a “Super Core” Prescriber and owner of a multi-prescriber pain clinic located in New York. Prescriber-10 was among the top prescribers of OxyContin in the nation between 2007 through 2014, writing as many as 12,961 OxyContin prescriptions in a year. Between in or around January 2007 and in or around September 2014, PURDUE PHARMA sales representatives detailed Prescriber-10 at least 227 times. During that time, OxyContin prescriptions written by Prescriber-10 generated approximately \$25,856,922 in gross proceeds for PURDUE PHARMA.

175. On or about November 2003, while PURDUE PHARMA was actively marketing to Prescriber-10, a PURDUE PHARMA sales representative submitted

a telephonic ROC to the ADD Program, informing PURDUE PHARMA that Prescriber-10 had told the sales representative that “he was recently investigated—and cleared of wrongdoing—by the NY Department of Health and the DEA.” Prescriber-10 also informed the sales representatives that the investigators stated he prescribed “too much” fentanyl and OxyContin. Prescriber-10 further stated that he “doubt[ed] that he will radically change his practice because he believes he treats pain appropriately.”

176. After receiving the ROC, the ADD Program conducted additional research on Prescriber-10 and learned that Prescriber-10 had written an average of 1,450 opioid prescriptions per month, including 350 prescriptions for OxyContin, over the previous two years.

177. On or about December 3, 2003, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to the members of the ADD Program recommending that PURDUE PHARMA continue calling on Prescriber-10.

178. On or about December 8, 2003, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-10.

179. On or about June 18, 2010, Prescriber-10 was identified for review by the ADD Program after Prescriber-10 was revealed by a PURDUE PHARMA data analysis as one of eight Prescribers who had been found by multiple audits to meet certain criteria, including “outliers of [OxyContin] Total and/or 80mg growth” and “percentage cash pay[.]” The analysis attached Prescriber-10’s prescribing history for February 19 through May 19, 2010 showing thousands

of oxycodone prescriptions along with certain call notes taken during visits to Prescriber-10's practice, including an April 29, 2010 note stating that Prescriber-10 told the PURDUE PHARMA sales representative that Prescriber-10 "won't prescribe meds with abuse prevention as a priority" and prescribes opioid products "assuming the p[atient] is legit until proven otherwise." No ADD memo was drafted or circulated after the ADD Program received this referral and PURDUE PHARMA continued its sales and marketing efforts towards Prescriber-10.

180. On or about March 2, 2012, Prescriber-10 was flagged by a PURDUE PHARMA data audit of "prescriber outliers" whose prescribing patterns "either increased dramatically or decreased dramatically during the quarter reviewed."

181. On or about March 5, 2012, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-10, despite an ongoing review by the ADD Program.

182. More than three weeks later, on March 28, 2012, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to the members of the ADD Program. The memorandum noted that Prescriber-10's overall opioid prescriptions decreased from 3,000 to 4,000 opioid prescriptions per month between February 2010 and June 2011, to approximately 1,000 opioid prescriptions per month between August 2011 and January 2012. The memorandum also stated that Prescriber-10's opioid products from PURDUE PHARMA decreased from 400 to 700 products per month to approximately 200 products per month over the same period. The audit found

that although Prescriber-10's prescriptions decreased, the number of prescriptions for his assistants increased by a similar amount.

183. After receiving this information, PURDUE PHARMA continued its sales and marketing efforts towards Prescriber-10.

184. On or about September 16, 2014, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program, writing "[Prescriber-10] was visited by the F.B.I. as well as the D.E.A. on Friday morning, September 12, 2014. They removed files from his office." An email from a senior-level ADD employee to the sales representative indicated that the "Law Department has initiated an internal inquiry regarding [Prescriber-10]," but no ADD memo was drafted or circulated.

185. On or about November 4, 2014, PURDUE PHARMA placed Prescriber-10 in Region Zero and instructed its sales representatives to cease calling on Prescriber-10. However, PURDUE PHARMA continued to direct its sales representatives to detail the other Prescribers working in Prescriber-10's pain clinic following Prescriber-10's addition to Region Zero.

186. During the time that Prescriber-10 was in Region Zero, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-10. During that period, at least 55 prescription savings cards linked to Prescriber-10 were redeemed by Prescriber-10's patients, some as late as February 2016.

187. On or about April 29, 2016, a senior-level executive in PURDUE PHARMA's Compliance Department sent an email to a senior-level PURDUE

PHARMA employee within the ADD Program attaching a Department of Justice press release regarding Prescriber-10's 114-count indictment for "Illegally Issuing Hundreds of Thousands of Prescriptions For Controlled Substances."

188. On or about May 26, 2016, a PURDUE PHARMA district manager submitted a written ROC to the ADD Program, writing:

"I have a growing concern over a legal action that has been underway for some time in the [New York] area. There is a very large pain practice – [Prescriber-10] and associates – the owner of which – [Prescriber-10] has recently been indicted for multiple controlled substances actions. We have reported [Prescriber-10] under SOP 1.7.1 – when we first learned of the possible action many months ago, and [Prescriber-10] has been a "no call" physician for some time. My concern revolves around our appropriate continued promotion within the office to the remaining prescribers who may or may not be part of the actions.

The district manager also attached the text of the ROC to a separate email sent to his regional manager, senior-level executives in PURDUE PHARMA's Compliance Department, and a senior-level employee within the ADD Program that same day.

189. On or about June 1, 2016, the same PURDUE PHARMA district manager sent a follow-up email to his regional manager and senior-level PURDUE PHARMA employees within the ADD Program regarding his concern about Prescriber-10 controlling the prescriptions of his mid-level employees, stating:

All new patients previous to the shut down are seen by [Prescriber-10] who sets the treatment plan and then transfers them to one of the other providers. [Prescriber-10] oversaw the practice and dictated the prescribing for all his employee providers. Each provider takes weekly turns prescribing continued prescriptions for the entire patient population. I do not know the specific charges brought against [Prescriber-10], but am concerned that his providers may

become involved in charges. . . . [T]his is an unusual situation where each provider has an enormous history of prescriptions due to the way the office is run. . . . I can put these concerns into 10 separate ADD reports if you think that is prudent. Please advise.

190. After receiving this information, PURDUE PHARMA continued its sales and marketing efforts towards the 10 mid-level prescribers employed by Prescriber-10. Specifically, PURDUE PHARMA sales representatives detailed the mid-level Prescribers in Prescriber-10's practice on 101 different days between June 22, 2016 and November 28, 2017. Contemporaneous internal PURDUE PHARMA documents showed that the detailing of these mid-level prescribers would continue to influence Prescriber-10's prescribing behavior despite the lack of direct marketing to Prescriber-10.

191. On or about January 7, 2020, Prescriber-10 pleaded guilty to conspiring to unlawfully distribute controlled substances and health care fraud. As part of the guilty plea, Prescriber-10 admitted that, between June 2006 and April 2016, Prescriber-10 conspired to distribute and dispense controlled substances, including oxycodone, without a legitimate medical purpose and not in the usual course of professional practice.

192. In total, from the time it first knew or had good reason to believe that Prescriber-10 was diverting opioids in November 2003 to when PURDUE PHARMA last redeemed prescription savings cards linked to Prescriber-10 in February 2016, PURDUE PHARMA detailed Prescriber-10 approximately 227 times, redeemed roughly 232 prescription savings cards linked to Prescriber-10, and earned over \$25.8 million in gross proceeds from OxyContin prescriptions that Prescriber-10 wrote.

193. Between in or around January 2007 and in or around February 2016, PURDUE PHARMA never took any action to refer Prescriber-10 to the DEA or any other regulatory or law enforcement agency.

The DEA's Enforcement and Implementation of the Controlled Substances Act

194. Title II of the Comprehensive Drug Abuse Prevention Control Act of 1970, more commonly known as the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.*, sets forth those regulations that the DEA enforces related to prescription drugs and other substances that pose a risk of abuse and dependence (*i.e.*, "controlled substances"). By establishing rules for the lawful handling of controlled substances and imposing penalties for their diversion, the CSA protects against the "substantial and detrimental effect[s] of controlled substances] on the health and general welfare of the American people." *Id.*

195. The CSA classifies controlled substances into one of five "schedules" based on their accepted medical uses, potential for abuse, and psychological and physical effects on the body. 21 U.S.C. §§ 811, 812. OxyContin and Hysingla are Schedule II controlled substances because they have a high potential for abuse and may lead to severe psychological or physical dependence. 21 U.S.C. § 812(b)(2). The CSA also establishes the regulatory framework governing the legal obligations of entities engaged in the lawful manufacture, distribution, and dispensing of controlled substances. 21 U.S.C. § 801, *et seq.* This framework includes a registration system and a quota system.

i. The Registration System

196. The CSA requires all entities that seek to manufacture, distribute, prescribe, or dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. §§ 822, 823; 21 C.F.R. §§ 1301.23, 1301.24. Successful applicants are called “registrants.” 21 C.F.R. § 1300.02(b). The CSA authorizes transactions by registrants within the legitimate distribution chain and makes all other transactions illegal. See 21 U.S.C. §§ 841–843.

197. The CSA directs the DEA to register a manufacturer or distributor of Schedule II controlled substances only if the DEA determines that, among other things, registration would be “consistent with the public interest.” 21 U.S.C. §§ 823(a), (b), (d), (e). The DEA considers several factors when making that determination, including whether the applicant maintains effective controls against diversion. See 21 U.S.C. §§ 823(a)(1), (b)(1), (d)(1), (e)(1). This assessment includes consideration of information provided by the applicant.

198. At all times relevant to this Information, PURDUE PHARMA and certain Purdue Entities annually applied for and received DEA registrations as manufacturers and/or distributors of controlled substances. Accordingly, PURDUE PHARMA was required to comply with the CSA, including the duty to maintain effective controls against diversion.

199. During the time period of the conspiracy, however, PURDUE PHARMA failed to maintain effective controls against diversion by, among other things, ignoring information suggesting that certain Prescribers were engaged in diversion and continuing to detail those Prescribers; providing and/or redeeming

prescription savings cards linked to Prescribers it knew or had good reason to believe were engaged in diversion; and failing to report those Prescribers to law enforcement or regulatory authorities when required by its own internal policies.

ii. The Quota System

200. In addition to restricting the total number of registered manufacturers and distributors, the DEA also regulates the total quantity of controlled substances manufactured in a given year through a quota system. See 21 U.S.C. § 826. The quota system supplements the registration system by ensuring the closed system of distribution receives sufficient supplies of medicines to meet the United States' legitimate "medical, scientific, research, and industrial needs" while minimizing the manufacture of excess controlled substances available for diversion into illicit markets. See 21 U.S.C. § 826(a).

201. To determine the annual legitimate need for each class of controlled substance and set appropriate quotas, the DEA relies upon several sources of data, including data from manufacturers concerning the quantity of legitimate prescriptions written for controlled substances on an annual basis. 21 C.F.R. Part 1303.

202. At all times relevant to this Information, PURDUE PHARMA and certain Purdue Entities annually applied for and received authorization from the DEA to manufacture specific quantities of its Schedule II controlled substances in accordance with the DEA's annual quotas. To support its requested quota allocation, PURDUE PHARMA provided the DEA with data concerning the quantity and sales volume of prescriptions for PURDUE PHARMA Schedule II

controlled substances. To maximize its available supply of opioid products and resulting profits, PURDUE PHARMA presented these data as constituting the annual legitimate sales of its opioid products, but knowingly and intentionally failed to inform the DEA that a significant portion of the prescriptions reported (valued at over \$1.17 billion between May 2007 and February 2018) were written by Region Zero Prescribers that PURDUE PHARMA either knew or believed to be engaged in diversion.

The Federal Food, Drug, and Cosmetic Act

203. In order to legally market a drug in interstate commerce, a drug's manufacturer is required to comply with all applicable provisions of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq.* and its implementing regulations. The FDCA defines the term "drug" to include articles that: (1) are intended for use in the diagnosis, cure, treatment, or prevention of disease in an individual; or (2) are intended to affect the structure or any function of the body of man. 21 U.S.C. § 321(g)(1)(B) and (C).

204. Because of their toxicity and other potential harmful effects, certain drugs are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A). These drugs are known as "prescription drugs." 21 U.S.C. § 353(b)(1)(A).

205. Dispensing prescription drugs, such as OxyContin, without a valid prescription from a licensed practitioner results in the "misbranding" of the drug. 21 U.S.C. § 353(b)(1)(B). A valid prescription means a prescription issued in the usual course of professional practice for a legitimate medical purpose. The FDCA

prohibits misbranding any drug that is held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k).

The Conspiracy

206. From on or about May 11, 2007 through on or about February 9, 2018, in the District of New Jersey and elsewhere, the defendant,

PURDUE PHARMA L.P.,

did knowingly and intentionally conspire and agree with others to:

a. defraud the United States and an agency thereof, namely, the DEA, by impeding, impairing, obstructing, and defeating the ability of the DEA to prevent the diversion of controlled substances; and

b. aid and abet the misbranding of prescription drugs, held for sale after shipment in interstate commerce, without valid prescriptions, contrary to Title 21, United States Code, Sections 331(k), 333(a)(1), 353(b)(1), and Title 18, United States Code, Section 2.

Goals of the Conspiracy

207. One goal of the conspiracy was for PURDUE PHARMA to evade the DEA's regulatory functions in order to maximize profits from the sale of its opioid products, including to Prescribers PURDUE PHARMA knew or had good reason to believe were engaged in diversion. PURDUE PHARMA defrauded the DEA of, among other things, its ability to:

a. regulate PURDUE PHARMA and the Purdue Entities pursuant to the controlled substances laws and regulations, including the ability to assess

whether PURDUE PHARMA's and the Purdue Entities' DEA registrations were in the public interest;

b. detect, investigate, and prevent the diversion of controlled substances from legitimate channels of distribution; and

c. establish production, manufacturing, and procurement quotas for Schedule II controlled substances (*i.e.*, oxycodone, hydrocodone) that accurately reflected the legitimate medical needs of the United States and that minimized the surplus of Schedule II substances that could be diverted into illicit markets.

208. It was a further goal of the conspiracy for PURDUE PHARMA to profit by aiding and abetting Prescribers that it knew dispensed its opioid products without valid prescriptions.

Manner and Means of the Conspiracy

209. It was part of the conspiracy that:

a. PURDUE PHARMA and others reported to the DEA that it operated an effective anti-diversion program when, in reality, PURDUE PHARMA facilitated the prescribing of controlled substances by over a hundred Prescribers that PURDUE PHARMA either knew or had good reason to believe were engaging in diversion.

b. PURDUE PHARMA employed sales and marketing practices that encouraged the increased prescription and dispensing of PURDUE PHARMA opioid products by Prescribers that PURDUE PHARMA either knew were

engaging in diversion or was willfully blind to the fact they were engaging in diversion. Specifically:

i. PURDUE PHARMA employed a network of sales representatives who encouraged Prescribers that the Company either knew were engaging in diversion or was willfully blind to the fact they were engaging in diversion to write and dispense more prescriptions of the Company's Schedule II opioid products;

ii. PURDUE PHARMA provided Prescribers the Company either knew were engaging in diversion or was willfully blind to the fact they were engaging in diversion with prescription savings cards to encourage: (1) Prescribers to write prescriptions for the Company's Schedule II opioid products, (2) patients to submit prescriptions for the Company's Schedule II opioid products to a pharmacy; and (3) pharmacies to fill prescriptions for the Company's Schedule II opioid products; and

iii. PURDUE PHARMA knowingly failed to report diversion by certain Prescribers to the DEA and other law enforcement authorities even though its own anti-diversion program required it to do so.

b. PURDUE PHARMA provided the DEA with figures that it claimed constituted the total quantity of legitimate prescriptions for its Schedule II controlled substances, but knowingly and intentionally failed to inform the DEA that a significant percentage of the prescriptions were written by Prescribers that PURDUE PHARMA knew or had good reason to believe were engaged in diversion.

- c. It was further part of the conspiracy that:
- i. PURDUE PHARMA and others distributed prescription drugs through interstate commerce to intermediary distributors and pharmacies;
 - ii. PURDUE PHARMA's prescription drugs were held for sale at retail pharmacies across the country, including in the District of New Jersey;
 - iii. PURDUE PHARMA knew that certain Prescribers that its sales representatives detailed and supplied with prescription savings cards wrote invalid OxyContin and other opioid prescriptions;
 - iv. PURDUE PHARMA continued detailing and supplying these Prescribers with prescription savings cards after learning that these providers were writing invalid prescriptions; and
 - v. PURDUE PHARMA intended for its opioid products to be dispensed pursuant to these invalid prescriptions to maximize its revenue. Approximately 96 percent of its opioid products dispensed pursuant to these invalid prescriptions were paid for by health care benefit programs, as defined at 18 U.S.C. § 24(b).

Overt Acts

210. In furtherance of the conspiracy, and in order to effect the goals thereof, PURDUE PHARMA and others committed or caused the commission of the following overt acts in the District of New Jersey and elsewhere:

a. On or about August 23, 2011, a marketing representative emailed a senior-level PURDUE PHARMA employee within the ADD Program regarding resuming detailing Prescriber-1, who had been placed in Region Zero.

b. On or about November 10, 2014, while PURDUE PHARMA was actively marketing to Prescriber-2, a PURDUE PHARMA sales representative submitted a written ROC to the ADD Program about Prescriber-2.

c. On or around February 15, 2013, a senior-level PURDUE PHARMA employee within the ADD Program circulated a memorandum to the members of the ADD Program recommending that PURDUE PHARMA continue calling on Prescriber-3, despite the fact that Prescriber-3 was writing between 5,000 and 6,000 opioid prescriptions per month and that the ADD Program had received two prior ROCs regarding Prescriber-3.

d. On or about March 26, 2012, after receiving an ROC and other information through its ADD Program concerning Prescriber 4, including that Prescriber-4's office had been raided by law enforcement, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-4.

e. On or about August 1, 2011, following a review of Prescriber-5 by the ADD Program based on prescribing patterns that fell outside the usual course for extended release oxycodone, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-5.

f. On or about September 25, 2009, PURDUE PHARMA placed Prescriber-6 in Region Zero and instructed its sales representatives to cease calling on Prescriber-6. However, during the time that Prescriber-6 was in Region

Zero, PURDUE PHARMA continued to honor the redemption of prescription savings cards linked to Prescriber-6.

g. On or about March 27, 2015, after an “expedited” ADD Program review, PURDUE PHARMA directed its sales representatives to resume calling on Prescriber-7. Prior to this determination, Prescriber-7 had been in Region Zero and the ADD Program had received multiple ROCs concerning Prescriber-7.

h. On or about November 12, 2013, a PURDUE PHARMA sales representative submitted a fourth written ROC to the ADD Program informing PURDUE PHARMA that Prescriber-8 was under investigation and had passed prescribing responsibilities to another physician. Thereafter, PURDUE PHARMA sales representatives continued to call on Prescriber-8 and his/her clinic at least one more time.

i. On or about October 30, 2014, PURDUE PHARMA placed Prescriber-9 in Region Zero and instructed its sales representatives to cease calling on Prescriber-9, but continued to honor the redemption of prescription savings cards linked to Prescriber-9, all of which were used to reduce the price of prescriptions for the Company’s opioid products.

j. On or about March 5, 2012, PURDUE PHARMA directed its sales representatives to continue calling on Prescriber-10, despite an ongoing review by the ADD Program.

k. On the following dates, PURDUE PHARMA provided inaccurate and misleading information to the DEA, knowing that the DEA would

use that information to establish annual quotas for OxyContin and other Schedule II narcotics that reflected the legitimate medical needs of the United States. Specifically, PURDUE PHARMA provided the DEA with figures that it claimed constituted the total current sales and prescription trends for its opioid products, but failed to inform the DEA that those sales figures included prescriptions written by Region Zero Prescribers that PURDUE PHARMA either knew were engaging in diversion or was willfully blind to the fact they were engaging in diversion:

Date	Name of Registrant	Molecule
Feb. 27, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
Mar. 17, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
May 9, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
June 9, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
June 26, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
July 22, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
Aug. 8, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
Sept. 11, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
Oct. 23, 2008	Purdue Pharmaceuticals L.P.	Oxycodone
Apr. 7, 2009	Purdue Pharmaceuticals L.P.	Oxycodone
June 25, 2009	Purdue Pharmaceuticals L.P.	Oxycodone
Aug. 17, 2009	Purdue Pharmaceuticals L.P.	Oxycodone
Oct. 19, 2009	Purdue Pharmaceuticals L.P.	Oxycodone
Nov. 13, 2009	Purdue Pharmaceuticals L.P.	Oxycodone
Apr. 22, 2010	Purdue Pharmaceuticals L.P.	Oxycodone
Apr. 22, 2010	Purdue Pharmaceuticals L.P.	Oxycodone
Apr. 23, 2015	Purdue Pharmaceuticals L.P.	Oxycodone
May 26, 2015	Purdue Pharmaceuticals L.P.	Oxycodone

Aug. 28, 2015	Purdue Pharmaceuticals L.P.	Oxycodone
Oct 2, 2015	Purdue Pharmaceuticals L.P.	Oxycodone
May 7, 2018	Purdue Pharmaceuticals L.P.	Oxycodone
Jul. 10, 2018	Purdue Pharma Manufacturing L.P.	Oxycodone

All in violation of Title 18, United States Code, Section 371.

COUNT TWO
(Conspiracy to Violate the Federal Anti-Kickback Statute)

1. Paragraphs 1 through 205 and Paragraphs 209 and 210 of Count One of this Information are re-alleged and incorporated herein.

Background

2. Beginning as early as in or around June 2009, PURDUE PHARMA instituted a promotional program in which PURDUE PHARMA recruited and paid Prescribers for speaking engagements purportedly designed to educate other Prescribers about PURDUE PHARMA opioid products (“the Speaker Program”).

3. In certain instances, PURDUE PHARMA knowingly and willfully retained Prescribers as paid corporate speakers and advisors with the purpose of inducing them to write prescriptions for PURDUE PHARMA opioid products, most of which were ultimately billed to insurance programs, including Medicare.

4. This conduct included the following actions regarding Prescribers 11 and 12:

Prescriber-11

a. PURDUE PHARMA paid Prescriber-11 to serve as a speaker for the Speaker Program despite the fact that it knew Prescriber-11 was an ineffective speaker.

b. For instance, in November 2009, PURDUE PHARMA personnel discussed that Prescriber-11 was “not a strong speaker or presenter” and observed that Prescriber-11 spoke as though “he had marbles in his mouth.”

c. In September 2010, PURDUE PHARMA’s Head of Marketing and other senior-level PURDUE PHARMA employees discussed cancelling a 400-

attendee presentation by Prescriber-11, to avoid “embarrassing” Prescriber-11 and “attendees evangelizing any negative occurrences to others not in the presentation” because Prescriber-11 was so inept.

d. In 2011, PURDUE PHARMA received evaluations from attendees of Prescriber-11’s speeches reporting that they “couldn’t follow [Prescriber-11]” and “[Prescriber-11] couldn’t be understood.”

e. PURDUE PHARMA also found that, in Prescriber-11’s speeches, Prescriber-11 made unsubstantiated promotional claims, including that it was safer to operate machinery under the influence of opioid pain medications than while suffering from pain.

f. PURDUE PHARMA also knew that, in December 2010, Prescriber-11 was “flagged” to the ADD Program by an internal PURDUE PHARMA Sales Operations audit due to Prescriber-11’s “outlier” prescribing of high doses of OxyContin. However, senior-level PURDUE PHARMA executives stopped the review, with one writing “I don’t think Sales Ops knows who [Prescriber-11] is,” and another noting “I had dinner with [Prescriber-11] just last night.”

g. Nevertheless, to induce Prescriber-11 to continue writing prescriptions for OxyContin, the Company provided Prescriber-11 with approximately 85 paid speaking engagements. From in or around 2010 through in or around 2018, Prescriber-11 wrote the most Medicare-reimbursed prescriptions for OxyContin in the United States.

Prescriber-12

h. On December 13, 2010, Prescriber-12 told a PURDUE PHARMA sales representative that Prescriber-12 would stop prescribing PURDUE PHARMA's drugs unless the Company retained Prescriber-12 as a paid corporate speaker, stating that Prescriber-12 would "re-evaluate the use of [Purdue] products if not chosen," and, "right now we are in a lose-lose situation, and it can very simply be a win-win situation."

i. Between December 21, 2010, and March 11, 2011, the sales representative's supervisor provided feedback to PURDUE PHARMA senior executives indicating that the Company should retain Prescriber-12 as a paid corporate speaker.

j. As an inducement to keep Prescriber-12 writing prescriptions, PURDUE PHARMA retained Prescriber-12 as a paid speaker on March 11, 2011, compensating Prescriber-12 \$1,500-\$2,000 per speaking engagement.

k. From 2011 through 2018, PURDUE PHARMA paid Prescriber-12 at least \$120,000 in speaking fees, items, and reimbursements. During that period, Prescriber-12's prescriptions for OxyContin paid by Medicare totaled at least \$131,000.

The Conspiracy

5. From at least as early as in or around June 2009 through in or around February 2018, in the District of New Jersey, and elsewhere, the defendant,

PURDUE PHARMA L.P.,

did knowingly and willfully conspire and agree with others to offer and pay remunerations, directly and indirectly, overtly and covertly, in cash and in kind, to any person to induce such person to purchase, order, and arrange for, and recommend purchasing and ordering, any good and item, namely, its opioid products, such as OxyContin, for which payment was made in whole or in part under a Federal healthcare program, as defined in Title 18, United States Code, Section 24(b), contrary to Title 42, United States Code, Section 1320a-7b(b)(2)(B).

Goal of the Conspiracy

6. The goal of the conspiracy was for PURDUE PHARMA and others to profit by paying Prescribers kickbacks disguised as “speaker” fees in exchange for the Prescribers’ writing prescriptions for PURDUE PHARMA’s opioid products, which were then billed to Medicare and other Federal health care programs for reimbursement.

Manner and Means of the Conspiracy

7. It was part of the conspiracy that defendant PURDUE PHARMA entered into agreements with Prescribers to pay fees through the Speaker Program to induce Prescribers to write prescriptions for PURDUE PHARMA’s opioid products that were paid for by Medicare.

Overt Acts

8. In furtherance of the conspiracy, and in order to effect the goal thereof, PURDUE PHARMA and others committed or caused the commission of the following overt acts in the District of New Jersey and elsewhere.

a. From in or around June 2009 through in or around 2016, PURDUE PHARMA paid Prescriber-11 at least \$476,000 in fees, items, and reimbursements as kickbacks to induce Prescriber-11 to write prescriptions for PURDUE PHARMA's opioid products. During that period, Medicare paid over \$7 million for Prescriber-11's prescriptions for OxyContin.

b. From in or around March 2011 through in or around 2018, PURDUE PHARMA paid Prescriber-12 at least \$120,000 in fees, items, and reimbursements as kickbacks to induce Prescriber-12 to write prescriptions for PURDUE PHARMA's opioid products.

All in violation of Title 18, United States Code, Section 371.

COUNT THREE
(Conspiracy to Violate the Federal Anti-Kickback Statute)

1. Paragraphs 1 through 205 and Paragraphs 209 and 210 of Count One, and Paragraphs 1 through 4 and Paragraphs 7 and 8 of Count Two, of this Information are re-alleged and incorporated herein.

Overview of the Conspiracy

2. Practice Fusion was a Delaware corporation with headquarters in San Francisco, California. Practice Fusion was a cloud-based EHR vendor that generally provided its cloud-based EHR product to healthcare providers without charge. Practice Fusion provided EHR services to tens of thousands of active healthcare provider users in the United States, including in New Jersey and Vermont, and its software was used during millions of patient encounters each month. One revenue source for Practice Fusion was selling “sponsorships” of clinical decision support (“CDS”) alerts in its EHR to pharmaceutical companies.

3. Practice Fusion’s CDS alerts typically worked as follows for a healthcare provider using its EHR: a message would appear on the Practice Fusion EHR alerting the healthcare provider examining a patient that, given the particular personal health information and circumstances of the patient, the provider should consider certain clinical information, perform certain tests or assessments, complete certain documentation, and, in some circumstances, prescribe certain types of drugs. Practice Fusion understood that pharmaceutical companies would pay for its CDS because the CDS could boost sales of the pharmaceutical companies’ products.

4. From as early as in or around March 2016, PURDUE PHARMA paid Practice Fusion to design and implement a CDS that would cause Prescribers to write an increased number of prescriptions for its extended release opioids (“EROs”)—including OxyContin, Butrans, and Hysingla—some of which were ultimately billed to Medicare and other Federal health care programs for reimbursement.

Background

5. PURDUE PHARMA began discussing the prospect of using Practice Fusion’s CDS alerts in furtherance of PURDUE PHARMA’s marketing goals as early as fall 2013, when Practice Fusion pitched to PURDUE PHARMA the possibility of using its EHR to screen patients for whether they were suitable for long-term opioid therapy, including assessing whether the patient had a history of substance abuse.

6. PURDUE PHARMA did not pursue a CDS alert to assist doctors in screening patients for risk of opioid addiction and abuse; instead, PURDUE PHARMA wanted to develop a CDS to increase sales of its ERO products.

7. In or around May 2014, Practice Fusion forwarded to PURDUE PHARMA news stories concerning Practice Fusion’s implementation of a CDS alert paid for by a vaccine manufacturer. The article was forwarded within PURDUE PHARMA to an executive-level corporate officer with the message: “I know you know of Practice Fusion, we too are working to get our pain management tools into their platform.” The executive responded, “Thanks. The key is understanding how it grows or protects scripts.”

8. In a March 23, 2015 email, a Practice Fusion employee explained that PURDUE PHARMA “has communicated that the average dosage of OxyContin is declining” and that “[p]roviders are hesitant about using high dosages to combat pain for a variety of reasons, mostly, political pressure. . . . As a result, Purdue is toying with the idea of using Pain Assessment tools with the provider at every visit and before every [prescription].”

9. On or about March 31, 2015, Practice Fusion presented a “pitch deck” to PURDUE PHARMA that indicated that a new pain CDS could be “based on” the “brand objectives” of PURDUE PHARMA’s ERO products, including targeting “opioid naïve patients”—*i.e.*, patients who were not previously prescribed opioids—and targeting patients who were using immediate release opioids (“IROs”).

10. PURDUE PHARMA subsequently confirmed that it wished to utilize a Practice Fusion CDS to “target” opioid naïve and IRO users, as those patients represented potential new users of PURDUE PHARMA’s EROs. Further, PURDUE PHARMA would make more money if the CDS helped “keep[] an appropriate patient on a consistent dose” of PURDUE PHARMA EROs. Practice Fusion subsequently recommended creating a CDS alert to address PURDUE PHARMA’s commercial goals.

11. While Practice Fusion and PURDUE employees used euphemisms like “appropriate patients,” “identify care gaps,” and “better manage patients,” both parties understood a goal of the program was to increase ERO use. As

described below, the parties did not ensure only “appropriate” patients received the CDS alerts.

12. Following the March 31, 2015 presentation, Practice Fusion built “[a] model to show potential commercial impact of increased patients being screened for pain and risk of opioid abuse.” The model estimated that PURDUE PHARMA would achieve a “patient gain” of 2,777 PURDUE PHARMA ERO users and between \$8,458,232 and \$11,277,645 in additional opioid revenue by funding a Pain CDS. Given these gains, Practice Fusion calculated a return on investment (“ROI”) of between 5.8 and 7.8 times of PURDUE PHARMA’s cost of funding the proposed Pain CDS.

13. An April 1, 2015 internal Practice Fusion email (excerpted below), containing an early version of the model, focused on how Practice Fusion would align the Pain CDS with PURDUE PHARMA’s commercial objectives driving the increased use of its ERO products:

We could use these values to present an economic benefit of the proposed program in three ways or any additional suggestions.

1. Value of keeping an appropriate patient on a consistent dose of one of the products throughout the 2 year term of the program
2. Value of conversion from IR to ER and consistent dosing over the term of the program
3. Value of a % market share in the branded ERO space; [REDACTED] mentioned they enjoy an 83% share in the branded ERO space. We can track and measure two things during the program. Share of the current branded EROs on our platform and potential new market entrants to ERO therapy as a result of the clinical intervention

During our planning call, we can work with [REDACTED] to help develop outcomes measures that can map back to these metrics.

14. An April 22, 2015 internal Practice Fusion email confirmed this focus, stating: “Since this is being sent to a marketing audience the idea of ROI has to be part of the plan to justify the costs of the program.” The email further inquired “[d]o you think we can develop some sort of ROI model that can make assumptions of increased patient volumes or increased persistency on these products to calculate an estimated ROI?”

15. On April 24, 2015, Practice Fusion circulated internally three documents: “(1) Full proposal, (2) ROI Model, and (3) PPT proposal for meeting.” The “Meeting Objectives” in the PowerPoint presentation included “Discuss ROI Model” and a slide from the presentation stated “Practice Fusion anticipates an ROI of 5.8:1 for the proposed project,” and “Review Full ROI Model for discussion and agreement.”

16. Practice Fusion did not include its calculations regarding increased opioid patient volume, increased opioid sales, or increased persistency on opioid products in the final pitch materials. Rather, on or about April 23, 2015, Practice Fusion’s Director of National Accounts directed: “Don’t include the ROI in the proposal. We’ll walk the client through the ROI.” Thus, the final deck, which was used during an April 30, 2015 meeting with PURDUE PHARMA, removed all references to “ROI” and, according to another Practice Fusion employee, allowed Practice Fusion to “voice over . . . how the program works and its commercial impact” during the meeting with PURDUE PHARMA’s marketers.

17. Following the meeting, Practice Fusion emailed personnel in PURDUE PHARMA’s marketing department on July 16, 2015, “to re-engage

around” the Practice Fusion CDS, stating “[w]e feel that the proposed program can help meet the strategic commercial needs of the pain franchise at Purdue.”

18. On or about July 30, 2015, a senior PURDUE PHARMA executive sent an email to a second PURDUE PHARMA marketing executive advising that the Brand Managers in charge of two of PURDUE PHARMA’s three ERO brands “can benefit” by attending the upcoming meeting with Practice Fusion at which the Pain CDS proposal would be presented.

19. On or about September 1, 2015, two Practice Fusion employees travelled to PURDUE PHARMA’s headquarters to propose that PURDUE PHARMA pay Practice Fusion approximately \$1,000,000 to develop and implement the Pain CDS to influence health care providers to prescribe more EROs.

20. PURDUE PHARMA marketing personnel representing each of its three ERO brands attended the September 1, 2015 presentation. The presentation included a pitch deck in which Practice Fusion proposed that PURDUE PHARMA “[l]everage [the] Practice Fusion Platform to deliver Clinical Decision Support and measure the impact and real world outcomes on patient care”; deliver “clinical patient-centric provider messages” targeted at healthcare providers with “opioid naïve patients”, and patients receiving immediate release oxycodone and hydrocodone (the active ingredients in OxyContin and Hysingla).

21. The pitch also touted Practice Fusion’s abilities to provide “educational messages” targeted to healthcare providers with patients with diagnoses of “chronic pain and with history of non-Opioids in their chart,”

prompt providers to assess patients' pain, and "evaluate conversion rates from IR opioid or chronic pain non opioid treatment to ERO."

22. PURDUE PHARMA employees understood based on the presentation that the Pain CDS would keep pain top of mind and influence physicians to switch more patients from non-opioids and IROs to PURDUE PHARMA's EROs. PURDUE PHARMA marketing personnel also liked that the proposed CDS allowed it to, in essence, be present in the exam room while physicians interacted with patients.

23. Practice Fusion included a "study" in its proposal to PURDUE PHARMA, but PURDUE PHARMA's brand leads that attended the September 1, 2015 meeting were uninterested in a study and to them the Pain CDS "was all about marketing." Practice Fusion employees made clear during the September 1, 2015 meeting that the parties would "measure success" through "metrics [like] switches from IR to ER, etc."

24. On September 4, 2015, PURDUE PHARMA was emailed a "revised deck" that was "based on our meeting this week." The revised deck included a new slide devoted to "Project Goals" (excerpted below) including: "Educate providers around appropriate patients for ERO therapy"; "Identify care gaps through clinical decision support alert tools at the point of care"; "Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy"; and to provide PURDUE PHARMA a "[d]etailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics)."

Project Goals

- + Educate providers around appropriate patients for ERO therapy
- + Identify care gaps through clinical decision support alert tools at the point of care
- + Aid providers in identifying patients who are experiencing pain and prompt corrective action or change in therapy
- + Create or enhance pain score capture and functional assessment data
- + Provide to Purdue detailed data and analytics
 - Detailed process metrics (quarterly metrics)
 - Detailed analysis of current market landscape and treatment patterns (one time deliverable)
 - Detailed analysis of effectiveness of clinical decision support alerts on treatment patterns (focus on IR/non opioid to ERO conversion) and outcomes (quarterly metrics)
- + Produce a published peer reviewed manuscript


25. In September and October 2015, PURDUE PHARMA marketing personnel integrated the Practice Fusion Pain CDS proposal into their internal 2016 Marketing Tactic presentations. According to internal PURDUE PHARMA documents, the objective of the program was to “Grow ERO prescriptions within the Practice Fusion ehr [electronic health record],” by using the Practice Fusion platform to cause providers to “reassess chronic pain patients for the need for Extended Release Opioids.” PURDUE PHARMA identified the “strategic pillar” of the Pain CDS as “Portfolio Tactic – Grow the ERO market” and described the program as “[a]lerts for patients with chronic pain will occur at the point of prescription.”

26. In a document titled Marketing Portfolio Budget Review, PURDUE PHARMA noted that “[p]romotion within an EMR may help to grow ERO market and Purdue products” and that PURDUE PHARMA would “achieve” an

“[i]ncrease[d] awareness and usage of ER Opioids by educating providers around appropriate patients for ERO therapy” (emphasis in original).

27. Moreover, the document stated that PURDUE PHARMA’s partnership with Practice Fusion would **“drive ERO demand thru EMR Patient Messages”** (emphasis in original). A portion of that slide is depicted below:

Promotion within an EMR may help to grow ERO market and Purdue products

What Is It? 

- Develop a **partnership with Practice Fusion eHR to help manage chronic pain** patients by targeting Pain Specialists and PCPs and **drive ERO Demand thru EMR Patient messages**

What We Will Do?

- Leverage existing Chronic Pain Quality Measures to **reassess chronic pain patients for the need for Extended Release Opioids**

28. Likewise, an internal September 10, 2015 PURDUE PHARMA email from a PURDUE PHARMA marketing executive addressed to marketing personnel working on each of PURDUE PHARMA’s ERO brands noted, “Practice Fusion estimates a high ROI of 5 to 1 but I think we should be more conservative going into this program for the first time in order to under promise and over deliver.”

29. Attached to that email was a PURDUE PHARMA summary of the Practice Fusion proposal that listed the “KPI” [key performance indicator] of the Pain CDS as: “Increase in ERO prescribing.” The summary also estimated that the Pain CDS would cause 22,500 patients to switch to EROs, translating to a favorable 2 to 1 return on an approximately one-million-dollar investment in the

Pain CDS. A later, more conservative calculation estimated the program would return 1.31 to 1.

30. The Pain CDS project received internal PURDUE PHARMA approval in or around late 2015. Each of PURDUE PHARMA's three ERO brands contributed equal amounts from their marketing budgets to fund the marketing project. PURDUE PHARMA marketing personnel agreed to provide remuneration for the Pain CDS because it understood that the Pain CDS would increase sales of its EROs.

31. Shortly after authorizing the Pain CDS arrangement, beginning in late 2015 and continuing into early 2016, a PURDUE PHARMA marketing executive worked with Practice Fusion personnel to design a Pain CDS alert to proliferate ERO prescriptions. Specifically, the PURDUE PHARMA marketing executive reviewed Practice Fusion's draft Pain CDS and proposed edits that would enhance the likelihood that it would increase prescriptions.

32. For example, a January 29, 2016 email from the PURDUE PHARMA marketing executive—a non-physician with no expertise in treating pain or prescribing opioid medications—proposed editing the Pain CDS to allow Prescribers to “check off ‘Extended Release Opioid initiated’ – by adding this we think this will trigger the prescriber to assess again if a change in therapy is needed as a follow up.”

33. Before signing off on the project, a PURDUE PHARMA senior executive required a mockup of the CDS alert. A PURDUE PHARMA marketing executive wrote to Practice Fusion: “see the request below from my boss. I think

if we show him the workflow documents with ERO message added that should do it for him.” Practice Fusion revised the proposed workflow “to reflect extended release opioid as a treatment option for a finding of pain during the initial assessment.”

The Pain CDS Contract

34. Practice Fusion and PURDUE PHARMA entered into a written statement of work contracting for the Pain CDS effective March 1, 2016 (the “Pain CDS Contract”). Despite the parties’ understanding that the purpose of the Pain CDS was to increase ERO prescriptions, the contract stated that the “Parties agree and acknowledge that the collaboration project will follow national evidenced-based guidelines, and will not encourage the prescribing or utilization of a Purdue-specific product or services.”

35. Notwithstanding the Pain CDS Contract, a written internal Practice Fusion recap of the initial conference call between Practice Fusion and PURDUE PHARMA to design the project stated that the “success” of the Pain CDS program would be “increased prescriptions for Purdue meds APPROPRIATELY (EROs in general and specifically Purdue’s).” Another summary, circulated within both companies stated that the “[p]rimary goal of the project is to increase Rx for Purdue’s medications.”

36. Contemporaneous to the development of the commercially-focused Pain CDS, on or about March 15, 2016, the United States Centers for Disease Control and Prevention (“CDC”) published the “CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016” (“CDC Guidelines”). Shortly

after the CDC Guidelines were released, they were circulated within both PURDUE PHARMA and Practice Fusion, including among those involved in developing the Pain CDS.

37. Both Practice Fusion and PURDUE PHARMA employees involved in creating the Pain CDS reviewed the CDC Guidelines during development of the Pain CDS. However, in creating the CDS alerts the parties ignored the CDC Guideline's recommendations addressing prescribing of EROs.

38. In or about April 2016, PURDUE PHARMA personnel requested that the Pain CDS include opioids as a treatment option in addition to treatments identified within a 2016 New England Journal of Medicine ("NEJM") article entitled "Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies." That article admonished, among other things, that it was not intended to provide clinical instruction in the treatment of chronic pain, and that the benefits of opioids for treatment of chronic pain were "much more questionable" than for treatment of acute pain.

39. Similar to the CDC Guidelines, the NEJM article identified concerns about overdosing and abuse by patients and "Factors associated with the risk of opioid overdose or addiction." The NEJM article further provided a table of "Mitigation Strategies against Opioid Diversion and Misuse."

40. Despite reviewing and purportedly relying on the NEJM article in developing the Pain CDS, PURDUE PHARMA did not design the Pain CDS to address any of the factors identified as risks of opioid overdose and addiction; nor did the parties incorporate any of the "Mitigation Strategies against Opioid

Diversion and Misuse.” PURDUE PHARMA and Practice Fusion physicians working on the project possessed and reviewed both the NEJM article and CDC Guidelines; nonetheless, both signed off on the Pain CDS despite knowing that the program had been commercially conceived, funded by opiate brand managers, and did not incorporate the above-referenced guidelines designed to curb opioid abuse.

41. PURDUE PHARMA marketing personnel, who lacked expertise in administering or prescribing opioids, were involved in decisions relating to key functionalities of the Pain CDS, including use of the Pain Score, use of the brief pain inventory (“BPI”), the contents of the Care Plan options, the guidelines and clinical quality measure (“CQM”) on which the Pain CDS was purportedly based, and the CDS logic. As evidenced below, personnel from PURDUE PHARMA’s marketing teams remained involved in numerous aspects of designing the CDS:

a. An April 8, 2016 internal PURDUE PHARMA email confirming that the eMarketing Director—not a physician—had “decided with the marketing team to use the BPI.”

b. An April 8, 2016 internal PURDUE PHARMA email noting that “There are no guidelines that support teasing out chronic vs acute pain.”

c. An April 11, 2016 email confirming that the Director of eMarketing was involved in defining chronic pain for purposes of the Pain CDS.

d. An April 14, 2016 email between two PURDUE PHARMA physicians and the Director of eMarketing suggesting the Pain CDS care plan include options supported by the NEJM article “plus opioids?” Less than an hour

later PURDUE PHARMA wrote Practice Fusion that it was “noodling on” the “care plan.” The email was sent by a PURDUE PHARMA doctor to Practice Fusion and PURDUE PHARMA’s Director of eMarketing.

e. An April 26, 2016 internal PURDUE email noting that the Director of eMarketing “needs to sign off” on the CDS Clinical Logic.

42. Shortly after the execution of the Pain CDS Contract, in a document dated April 5, 2016 (excerpted below), a PURDUE PHARMA in-house physician listed “Concerns” relating to the arrangement, warning the Pain CDS “can increase ERO use” and PURDUE PHARMA “[c]an’t look as if we are directing information or therapy” or “causing a change in Rx [prescriptions].”

Concerns:

- Is this a STUDY or is a MARKETING project? Different issues depending on the answer.
- No mention of consent
- No mention of IRB
- Data collected just to see if BPI influences actions around Rx or Tx
- BPI can increase ERO use
- If data collected, can it be used for promotional work by MSLs or Reps down the road?
- No discussion of long term outcomes, no discussion of patient follow up for additional study
- Can’t look as if we are directing information or therapy
- Program must be retrospective in nature - it can not look as if we are causing a change in Rx.
- What is the sample size possible with this study? Can we do a pre-look for possible responders and users of PHR
- Will there be sufficient responders? What is the in-silico possible response rate?
- Ask EHR co about use rates of their Portal by Pts - and other programs with response rates
- If this is done by Marketing, it CAN’T look like a study - if it’s a STUDY it MUST be run by Medical
- Need more thought about outcomes and what we’d want to see from this.

43. On or about May 11, 2016, a Practice Fusion employee reported (as shown below) on a call with PURDUE PHARMA personnel about the development of the CDS and observed that he kept “hearing the client [PURDUE PHARMA] revert back to ‘Rx lift’ as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking

about the objectives of the prospective and retrospective analyses.” (“Rx lift” refers to increased prescriptions.)

Hi [REDACTED]

I wanted to make sure that the two of you are aligned with your respective stakeholders in terms of what the goals of the Purdue pain program are. I keep hearing the client revert back to “Rx lift” as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking about the objectives of the prospective and retrospective analyses. [REDACTED] seems to be championing this vision as the new commercial + analytics stakeholder.

During the last meeting [REDACTED] mentioned that the goals of the analytic project were to “meet all marketing science objectives, and whatever other HEOR objectives we can get to” which does not at all align with the analytic plan the client already “approved”. Please let me know if I should setup some time for us to strategize internally here.

44. Despite knowledge that the Pain CDS was conceived with the intent of increasing PURDUE PHARMA’s drug sales, that PURDUE PHARMA marketing personnel participated in the design of the Pain CDS, that marketing personnel had been involved in selecting the BPI to be used, and that the BPI could increase ERO usage during a time of great national concern around opioid abuse, PURDUE PHARMA nonetheless proceeded with implementing the CDS to broaden use of EROs.

45. Moreover, the Pain CDS program was not “run by medical” as the document, referenced in Paragraph 43 above, conceded that it “MUST” be if the program were a study. As detailed below, PURDUE PHARMA’s marketers remained involved throughout the design and implementation even after the Pain CDS went live and continued to inquire and assess whether it achieved their stated goal of influencing ERO prescribing.

46. On or around June 2016, the PURDUE PHARMA in-house physician reiterated his/her concerns that the parties were using the Pain CDS for commercial objectives. Specifically, on June 8, 2016, PURDUE PHARMA’s in-

house physician emailed Practice Fusion’s physician “I need to talk w/ either you or [Director of National Accounts] about the project. I’d like to brief you on some issues before I brief your team. The project is not being canceled – but we do need to adjust course.”

47. After emailing Practice Fusion, the PURDUE PHARMA in-house physician emailed his superior, also a physician, that he “organized a convo w/ [PURDUE PHARMA colleagues, including a PURDUE PHARMA marketing executive] yesterday evening. We collectively agreed to take the project in a direction far more aligned to what you and I discussed. I’m feeling far more comfortable w/ this result.” PURDUE PHARMA’s in-house physician did not write in either the email to Practice Fusion or the email to his boss at PURDUE PHARMA what the changes to the analytics plan were.

48. On June 15, 2016, a PURDUE PHARMA analyst emailed a colleague regarding the analytics plan for the Practice Fusion project. PURDUE PHARMA’s physician, who was concerned about the commercial focus of the program and who did not put in writing the changes to the analytics plan, was not included in the communication. The PURDUE PHARMA analyst noted the “biggest difference between the old plan and the new plan is measuring by compounds, ***instead of focusing on ERO and IRO to ERO switches and TRx lift to Purdue products.***” (emphasis added).

49. The “changes to the analytics approach,” imposed by PURDUE PHARMA included affirmatively not measuring whether the CDS would satisfy PURDUE PHARMA’s marketing objectives (increased ERO prescriptions

generally and PURDUE PHARMA prescription “lift” specifically). Despite raising concerns about the CDS program in June 2016, PURDUE PHARMA’s physician did not implement any changes to the CDS workflows or alerts before they went live in doctors’ offices nationwide in July 2016. PURDUE PHARMA’s physician knew and understood that PURDUE PHARMA’s Director of eMarketing’s objective was to use the CDS (paid for by PURDUE PHARMA’s marketing budgets) to increase PURDUE PHARMA prescriptions, yet after identifying “issues” with the program he merely changed the “analytics”—not the CDS triggers or alerts that had been designed with a goal of arranging for and recommending increased ERO prescribing.

50. Notwithstanding the concerns raised by its own in-house physician, PURDUE PHARMA proceeded with implementing the Pain CDS to increase use of EROs. Moreover, PURDUE PHARMA’s marketing department remained involved throughout the design and implementation of the Pain CDS, even after it went live and continued to inquire and assess whether it influenced ERO prescribing.

The Pain CDS in Operation In Doctors’ Offices Across the Country

51. The Pain CDS went live on Practice Fusion’s platform in or around early July 2016. As finalized, the Pain CDS contained three separate alerts. The first encouraged healthcare providers to record a pain score. The second suggested that doctors take a BPI of patients who had recorded two or more pain scores of four or more (on a zero to ten-point scale) within the previous three months, or who had a chronic pain diagnosis. The third indicated that a follow

up plan should be created for treating the patient's pain, appearing only if the patient reported pain on the pain scale of four or higher twice within four months, or if a patient with chronic pain has had a BPI completed. PURDUE PHARMA anticipated that these alerts would increase ERO prescriptions.

52. The CDS also utilized a drop-down menu of options for pain treatments to populate the treatment plan, including the use of EROs. This menu deviated from medical guidelines in several respects, including, but not limited to:

a. Deviating from the CDC Guidelines by recommending EROs as a treatment option for patients besides those with "severe, continuous pain;" those who had not been prescribed immediate-release opioids first; those who had not "received immediate-release opioids daily for at least 1 week;" and those for whom "[n]onpharmacologic therapy and nonopioid pharmacologic therapy are preferred."

b. Recommending the use of EROs despite the CDC's "clinical evidence review finding "insufficient evidence to determine long-term benefits of opioid therapy for chronic pain" and "an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent".

c. Placing the use of EROs on equal footing with a list of alternative treatment options sourced, in part, from a NEJM article that was not intended to address how to treat patients with chronic pain and which did not support the use of EROs for (i) patients with "less than severe pain," (ii) patients

without around-the-clock pain, or (iii) patients for whom alternative non-opioid treatments were effective.

d. Listing EROs as a treatment option on equal footing with IROs and non-opioid therapy—contrary to accepted medical practice.

e. Listing EROs as an option for patients who had not previously received opioid therapy (i.e., the opioid naïve).

f. Listing EROs as a treatment option without regard to whether the provider had the adequate expertise to prescribe EROs.

Purdue Pharma Continued to View the Pain CDS as a Commercial Program After Its Implementation

53. After the Pain CDS went live in EHRs across the country, PURDUE PHARMA continued to view the program as a commercial venture. In or about October 2016, internal PURDUE PHARMA marketing emails inquired when PURDUE PHARMA would see an analysis of the commercial impact of the Pain CDS. A PURDUE PHARMA marketing executive responded that he was not sure whether PURDUE PHARMA could perform such an analysis “in this environment.”

54. On October 12, 2016, an internal PURDUE PHARMA document titled “Urgent Tactics” with a list of “HIT Ideas” was sent in response to an internal PURDUE PHARMA request for “immediate action tactics to appropriately grow [new total prescriptions].” It stated, “Have the Analytics Group look at the Practice Fusion Pain Guideline Pilot data available to date to get an early read on the effectiveness of the Clinical Decision Support alerts on improving the pain management of members of the test group of HCPs [health care providers] vs.

the control group.” In this context, “improving pain management” was equated with growing new total prescriptions.

55. Practice Fusion and PURDUE PHARMA also planned an in-person meeting at PURDUE PHARMA’s headquarters to report on a retrospective study and the results of the Pain CDS. PURDUE PHARMA instructed Practice Fusion to answer whether “the CDS alerts change prescribing behavior” and “show ERO prescribing as it tracks with CDS.” PURDUE PHARMA remained interested in understanding whether, and by what measure, the Pain CDS achieved its intended goal of arranging for ERO prescribing.

56. On or about December 14, 2016, Practice Fusion personnel conducted the presentation at PURDUE PHARMA’s headquarters. During this meeting, Practice Fusion reported that through November 30, 2016, the Pain CDS had alerted during 21 million patient visits, involving 7.5 million patients, and 97,000 healthcare providers. During this presentation Practice Fusion explained that since Pain CDS alerts went into effect “there is a general shift toward EROs from IROs”; and the “biggest shift [was] within Emergency Medicine, Orthopedics, and Pain Medicine.”

57. Practice Fusion also analyzed the effectiveness of various alternative (non-opioid) pain treatment options, finding that overall EROs were the least effective option in lowering pain, as only 39.17% of patients treated with EROs had lower pain. Similarly, Practice Fusion’s data found that EROs were the second least effective treatment option in lowering pain among patients with chronic pain, finding that EROs lowered pain in only 40.41% of patients.

58. Practice Fusion additionally provided data and information to PURDUE PHARMA identifying the “Top Diagnosis Groups” that received EROs. PURDUE PHARMA did not take any steps in connection with the Pain CDS to ensure that EROs were being prescribed to “appropriate” patients, let alone consistent with the CDC Guidelines or NEJM article.

59. A PURDUE PHARMA attorney present at the December 14, 2016 meeting expressed reservations about the Pain CDS, noting that it had not received appropriate legal review, and considered “pausing” the program.

60. The Pain CDS was not “paused” or modified to be consistent with medical guidelines. Instead, the parties allowed the Pain CDS to remain active on Practice Fusion’s platform. On July 25, 2017, a PURDUE PHARMA medical affairs researcher emailed a PURDUE PHARMA compliance professional suggesting that the compliance professional “could ask [a PURDUE PHARMA marketing executive] for the [Practice Fusion] proposal, specifically requesting information specific to practice fusion and the objective of increasing opioid sales.”

61. As had been initially contemplated during the proposal process, Practice Fusion and PURDUE PHARMA prepared a poster detailing the “results” of the Pain CDS that was presented at a public symposium. The parties’ presentation concluded, among other things, that a CDS can “help physicians follow chronic pain management clinical guidelines and improve documentation of care-related data and activity.” While the poster observed that “[d]ocumentation of opioid therapy in care plans shifted from 33.1% at start to

20.2% at conclusion,” the parties did not include an analysis of actual opioid prescribing trends—as opposed to care plan documentation—and did not assess ERO prescribing. The presentation demonstrated that it caused a large increase in the number of patients having care plans recorded; approximately 4,800 to 6,300 more care plans per month were completed in association with the Pain CDS than by providers who did not receive the alerts. Moreover, the parties did not reveal in this presentation that a goal of the Pain CDS was to increase ERO prescribing, that PURDUE PHARMA’s marketers were involved in designing the program, that the Pain CDS was financed by marketing budgets, or whether the Pain CDS influenced prescribing of EROs.

The Pain CDS Increased Prescriptions of Extended Release Opioids, Including Purdue Pharma’s EROs

62. The Pain CDS alert was live on the Practice Fusion platform from early July 2016 to the Spring of 2019. The Pain CDS alerted more than 230,000,000 times during this period. Physicians wrote hundreds of thousands of ERO prescriptions after one of the Pain CDS alerts triggered.

63. Healthcare providers who received the Pain CDS alerts prescribed EROs at a higher rate than those who did not.

64. Based on the higher rate of opioid prescriptions among providers who received the Pain CDS, the alerts resulted in tens of thousands of additional prescriptions for EROs, a substantial portion of which were paid for by federal healthcare programs such as Medicare and Medicaid.

The Conspiracy

65. Beginning at an unknown time, but not later than in or about March 2016, through at least November 2016, in the District of New Jersey, the District of Vermont, and elsewhere, the defendant,

PURDUE PHARMA L.P.,

did knowingly and willfully conspire and agree with Practice Fusion and others to offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to Practice Fusion in return for arranging or recommending purchasing and ordering, any good and item, namely, its opioid products, such as OxyContin, for which payment was made in whole or in part under a Federal healthcare program, as defined in Title 18, United States Code, Section 24(b), contrary to Title 42, United States Code, Section 1320a-7b(b)(1)(B).

Goal of the Conspiracy

66. The goal of the conspiracy was for PURDUE PHARMA and others to profit by paying Practice Fusion remuneration in exchange for the addition of a Pain CDS to its EHR because PURDUE PHARMA believed the Pain CDS would “arrange for and recommend” prescriptions for EROs which would then be billed to Medicare and other Federal healthcare programs for reimbursement.

Manner and Means of the Conspiracy

67. It was part of the conspiracy that defendant PURDUE PHARMA entered into an agreement with Practice Fusion to pay Practice Fusion almost \$1 million in exchange for Practice Fusion adding a Pain CDS to its EHR in order to induce healthcare providers to prescribe ERO medications.

68. It was further a part of the conspiracy that Defendant PURDUE PHARMA and Practice Fusion personnel collaborated on the design, approval, and execution of a Pain CDS designed to present EROs to healthcare professionals as a treatment option on equal footing with other treatments for pain without regard to whether EROs were medically appropriate.

Overt Acts

69. In furtherance of the conspiracy, and in order to achieve the goal thereof, PURDUE PHARMA and others committed or caused the commission of the following overt acts in the District of New Jersey, the District of Vermont, and elsewhere.

a. On or about March 31, 2015, Practice Fusion employees travelled to PURDUE PHARMA's headquarters to persuade PURDUE PHARMA to pay Practice Fusion to implement a Pain CDS on the Practice Fusion platform.

b. Practice Fusion personnel developed a model to estimate the return on investment that PURDUE PHARMA's ERO brands could be expected to receive in exchange for PURDUE PHARMA's sponsorship of the proposed Pain CDS.

c. Practice Fusion personnel communicated the result of their model to PURDUE PHARMA to persuade PURDUE PHARMA to agree to the Pain CDS.

d. On or about September 1, 2015, Practice Fusion employees travelled to PURDUE PHARMA's headquarters to persuade PURDUE PHARMA to pay Practice Fusion to implement the Pain CDS.

e. In or around September 2015, PURDUE PHARMA estimated the return on investment PURDUE PHARMA could expect to receive based on PURDUE PHARMA's sponsorship of the Pain CDS as proposed by Practice Fusion.

f. In or around September and October 2015, PURDUE PHARMA marketing personnel integrated the Pain CDS into their list of 2016 marketing tactics for internal PURDUE PHARMA consideration.

g. In or around March 2016, agents from PURDUE PHARMA and Practice Fusion executed a written contract pertaining to the Pain CDS.

h. From in or about December 2015 through June 2016, Practice Fusion and PURDUE PHARMA personnel designed the Pain CDS.

i. In or around March 2016, personnel from PURDUE PHARMA and Practice Fusion had telephonic meetings to refine the Pain CDS design, during which the financial objective of the Pain CDS was re-stated.

j. In or around early July 2016, Practice Fusion implemented the PURDUE PHARMA-sponsored Pain CDS on the Practice Fusion EHR platform.

k. From in or about March 2016 through in or about November 2016, PURDUE PHARMA paid Practice Fusion approximately \$959,700 in exchange for Practice Fusion's development and implementation of the Pain CDS.

l. On or about December 14, 2016, employees from Practice Fusion travelled to PURDUE PHARMA headquarters to present information

about, among other things, the effect the Pain CDS was having on healthcare provider prescribing behavior.

m. From in or about July 2016 until it was taken down in or about April 2019, Practice Fusion maintained the Pain CDS alert on its EHR platform, resulting in the alert triggering during more than 230,000,000 patient visits.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE ALLEGATION AS TO COUNT ONE

1. As a result of committing the offenses in violation of 18 U.S.C. § 371, contrary to 21 U.S.C. §§ 331, 333(a)(1), and 353(b)(1)(B) alleged in Count One of this Information, defendant Purdue Pharma L.P. shall forfeit to the United States:

- a. pursuant to 18 U.S.C. § 982(a)(7), all property it obtained that constituted and was derived, directly and indirectly, from gross proceeds traceable to its conspiracy to defraud the United States, in violation of 18 U.S.C. § 371, contrary to 21 U.S.C. §§ 331, 333(a)(1), and 353(b)(1)(B); and
- b. pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), the value of any and all misbranded drugs and unapproved drugs that were introduced and delivered for introduction into interstate commerce contrary to 21 U.S.C. § 331(k),

the value of which totaled \$2,000,000,000.

FORFEITURE ALLEGATION AS TO COUNTS TWO AND THREE

2. Upon conviction of one or both of the Federal health care offenses, as defined in 18 U.S.C. § 24, charged in Counts Two and Three of this Information, the Defendant shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real or personal, the Defendant obtained that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the offense charged in each such count, and all property traceable to such property.

SUBSTITUTE ASSETS PROVISION
(Applicable to All Forfeiture Allegations)

3. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

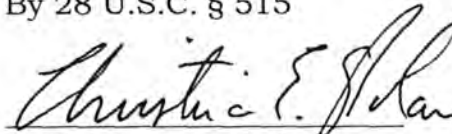
- a. cannot be located upon the exercise of due diligence;

- b. has been transferred or sold to, or deposited with a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

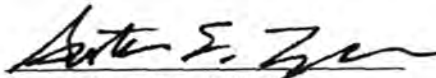
the United States shall be entitled, pursuant to 21 U.S.C. § 853(p) (as incorporated by 28 U.S.C. § 2461(c), and 18 U.S.C. § 982(b)), to forfeiture of any other property of the defendant up to the value of the above-described forfeitable property.



RACHAEL A. HONIG
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515



CHRISTINA E. NOLAN
United States Attorney
District of Vermont



GUSTAV W. EYLER
Director
Consumer Protection Branch, Civil Division
United States Department of Justice

CASE NUMBER: _____

**United States District Court
District of New Jersey**

UNITED STATES OF AMERICA

v.

PURDUE PHARMA L.P.

INFORMATION FOR

18 U.S.C. § 371

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