

ATTORNEY GENERAL OF THE STATE OF NEW YORK

In the Matter of

Purdue Pharma L.P.

Assurance No.: 15-151

**ASSURANCE OF DISCONTINUANCE
UNDER EXECUTIVE LAW SECTION
63, SUBDIVISION 15**

Pursuant to the provisions of Section 63(12) of the Executive Law and Article 22-A of the General Business Law, Eric T. Schneiderman, Attorney General of the State of New York, caused an inquiry to be made into certain business practices of Purdue Pharma L.P. (“Purdue,” or the “Company”). Based upon that inquiry, the Office of the Attorney General (“the OAG”) has made the following findings, and Purdue has agreed to modify its business practices and comply with the following provisions of this Assurance of Discontinuance (“Assurance”).

I. BACKGROUND

1. Purdue is a Delaware limited partnership with its principal place of business at 201 Tresser Blvd., Stamford, Connecticut 06901. Purdue is engaged in the manufacture, marketing and sale of prescription and non-prescription pharmaceutical products, in particular the extended-release, long-acting opioid OxyContin® (oxycodone HCl extended-release tablets), which contain the active ingredient oxycodone.¹ The U.S. Food and Drug Administration (the “FDA”) approved OxyContin in 1995, and it is currently indicated for the

¹ Purdue markets and sells other prescription opioid products, including Butrans, Dilaudid, MS Contin and Hysingla.

management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

2. OxyContin, a narcotic painkiller, contains “black box” warnings of serious risks from taking the product, such as addiction and respiratory depression, which can lead to death.

3. According to IMS Health, in 2012 Purdue had U.S. sales of OxyContin totaling \$2.78 billion, and in 2013, had U.S. sales of \$2.56 billion.

4. To market OxyContin, among other things, Purdue employs an extensive network of sales representatives who establish and maintain relationships with health care providers (“HCPs”), which include medical doctors, doctors of osteopathy, nurse practitioners, pharmacists and physicians’ assistants. The Purdue sales reps “detail” HCPs’ offices, where they provide informational resources on OxyContin and other Purdue opioid products, with the objective of encouraging these providers to prescribe OxyContin and other Purdue opioid products to their patients under appropriate circumstances.

5. In addition to a yearly salary, Purdue’s sales representatives may receive a bonus that is based on the number of prescriptions written by HCPs in their territory, which can create an incentive to encourage more prescribing, including of opioids.

6. Between the 1990s and 2011, prescriptions of oxycodone, an active ingredient in opioid analgesics manufactured by many independent companies including Purdue, more than doubled in the U.S., and sales of the product increased more than tenfold.² Between 2008 and 2011, OxyContin accounted for approximately 10% of the total oxycodone prescriptions in New York State. During this time period, according to the New York City Department of Health and Mental Hygiene, the number of opioid painkiller prescriptions filled by New York

² See <http://www.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing>.

City residents increased by 31%, from approximately 1.6 million to approximately 2.2 million, with oxycodone accounting for 53% of those prescriptions.³

7. Between 1997 and 2011, there has also been a sharp increase in the prevalence of opioid addiction, which in turn has been associated with a rise in overdose deaths and heroin use.⁴ According to the federal Centers for Disease Control and Prevention, in New York State, from 2003 to 2012, deaths involving opioid analgesics increased five-fold, from 179 in 2003 to 883 in 2012.⁵

II. THE OAG'S INVESTIGATIONS AND FINDINGS

8. In 2014, the OAG commenced an investigation of Purdue, focusing on two areas: (i) Purdue's Abuse and Diversion Detection ("ADD") Program (also known as the "Region Zero" program); and (ii) Purdue's unbranded website www.inthefaceofpain.com, which provides information about how to advocate for patients in pain but does not explicitly reference any specific pharmaceutical product.

A. The ADD Program

9. In 2007, Purdue agreed with a number of states (not including New York) to take steps to reduce the abuse and diversion of OxyContin, in particular by implementing the ADD Program. Purdue's ADD Program requires all Purdue sales representatives and medical liaisons who contact HCPs for the purpose of promoting a Purdue opioid product to report to the Company facts that suggest that an HCP potentially may be involved in the abuse or diversion of such products. After an ADD report is filed, Purdue conducts an internal inquiry of the HCP and determines whether to place that provider on a list, such that the HCP may not be contacted for purposes of promoting Purdue opioid products (the "No-Call List"). If Purdue

³ See <http://www.nyc.gov/html/doh/html/pr2013/pr013-13.shtml>.

⁴ See <http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957>.

⁵ See <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a2.htm>.

places an HCP on the No-Call List, no bonus may be earned from prescriptions written by that HCP after such determination.

10. The ADD Program is based on Purdue sales representatives making observations during calls on HCPs. Under the ADD Program, if a Purdue sales representative learns of or observes any of the situations described below, which may suggest that an HCP (or his or her patients) may be involved in the abuse and diversion of opioids, the activities or observations must be reported promptly to the Company. These situations include:

- a. An apparent pattern of an excessive number of patients for the practice type. For example, on a consistent basis, a long line of patients waiting to get prescriptions, a waiting room filled to capacity or standing room only, or patient contact with a prescriber that is exceedingly brief or non-existent.
- b. An atypical pattern of prescribing techniques or locations. For example, repeated prescribing from an automobile or repeated prescribing at atypical times, such as after usual office hours when the health care professional is not on call.
- c. Information from a highly credible source or several sources that an HCP or his/her patients are diverting medication.
- d. An HCP who has a disproportionate number of patients who pay cash for office visits and dispensed medication.
- e. An HCP with a sudden unexplained change in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or the practice type.
- f. An allegation that individuals from a particular HCP's practice have overdosed.
- g. A credible allegation that an HCP or his/her staff or patients have abused or are actively abusing substances.
- h. An HCP's practice where unauthorized individuals are signing prescriptions or dispensing controlled substances.
- i. An HCP's practice with large numbers of patients who travel significant distances, for example across state lines, to obtain and/or fill their prescriptions without a rational explanation.
- j. An HCP's practice where there are reports that patients make frequent early requests for new prescriptions significantly in advance of the time the initial prescription would normally have been completed.

- k. A credible allegation that an HCP is under active investigation related to diversion or substance abuse by any law enforcement or regulatory authority.
- l. An HCP who moves his or her practice from one state to another on more than one occasion within a couple of years without rational explanation.
- m. An HCP with an atypical patient population from that customarily observed in such an office based on its location and other attendant circumstances. For example, a disproportionate number of younger patients for the nature of the practice.

11. Between January 1, 2008, and March 7, 2015, Purdue placed 103 New York HCPs on its No-Call List. Purdue's sales representatives had detailed approximately two-thirds of those HCPs, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period. Of the 71 HCPs on the No-Call List upon whom Purdue sales representatives called to promote OxyContin, 64 wrote OxyContin prescriptions. Of the 32 HCPs on the No-Call List never called on by a Purdue sales representative to promote OxyContin, 15 wrote more than 10 OxyContin prescriptions. Purdue spent approximately three thousand dollars in meal expenses for 38 of the 103 HCPs on the No-Call List upon whom its sales representatives called.

12. Some of the HCPs in New York State whom Purdue detailed, and subsequently placed on its No-Call List, were subsequently arrested and/or convicted for illegal prescribing of opioids, including:

- Matthew Bennett, a Buffalo-area physician whom Purdue detailed 46 times between 2009 and 2012, was arrested in August 2012, and pleaded guilty in April 2015 to illegal distribution of oxycodone. Bennett wrote 868 OxyContin prescriptions during the period in which he was detailed by Purdue.
- David Brizer, a Rockland psychiatrist whom Purdue detailed 8 times in 2010 and 2011, was arrested by the OAG in February 2013, and pleaded guilty in March 2013 to illegally selling opioid prescriptions. Brizer wrote 563 prescriptions for OxyContin during the period in which he was detailed by Purdue.
- Richard Cedeno, a Bronx physician's assistant whom Purdue detailed 54 times between 2009 and 2013, was arrested by the OAG in June 2013, and pleaded

guilty in June 2015 to participating in a Medicaid fraud scheme. Cedeno wrote 400 OxyContin prescriptions during the period in which he was detailed by Purdue.

- Rools Deslouches, a Long Island physician's assistant whom Purdue detailed 18 times in 2011, was arrested in June 2012, and pleaded guilty in November 2014 to illegally distributing oxycodone. Deslouches wrote 210 OxyContin prescriptions during the period in which he was detailed by Purdue.
- Eric Jacobson, a Queens physician whom Purdue detailed 18 times in 2010, was arrested in June 2012, and pleaded guilty in 2014 to conspiracy to distribute oxycodone. Jacobson wrote 1,014 OxyContin prescriptions during the period in which he was detailed by Purdue.
- Leonard Marchetta, a Staten Island physician's assistant whom Purdue detailed 27 times between 2008 and 2011, was arrested in September 2014, and pleaded guilty in January 2015 to conspiracy to distribute narcotics. Marchetta wrote 532 OxyContin prescriptions during the period in which he was detailed by Purdue.
- Anand Persaud, a Long Island physician whom Purdue detailed 98 times from 2009 through 2013, and was arrested by the OAG in July 2013 for illegally selling oxycodone prescriptions. Persaud wrote 1,575 prescriptions for OxyContin during the period in which he was detailed by Purdue.
- Frank Telang, a Long Island physician whom Purdue detailed 31 times between 2008 and 2011, was arrested in December 2011, and pleaded guilty in November 2013 to illegally prescribing oxycodone. Telang wrote 701 OxyContin prescriptions during the period in which he was detailed by Purdue.
- Rohan Wijetilaka, a Westchester cardiologist whom Purdue detailed 78 times between 2008 through 2012, was arrested in July 2012, and pleaded guilty in June 2014 to health care fraud. Wijetilaka wrote 3,056 OxyContin prescriptions during the period in which he was detailed by Purdue.

13. While the above charges did not involve OxyContin, and the OAG did not charge that promotion by Purdue played a role in the cases it prosecuted, in certain limited circumstances, Purdue sales representatives may have been aware of red flags regarding some of these prescribers before filing an ADD report as required by the policy, at which point the sales representative should have stopped detailing the HCP sooner. In addition, in three instances, Purdue sales representatives detailed HCPs after HCPs were placed on the No-Call

List. This is due, in part, to the fact that Purdue sales representatives are not currently required to check a No-Call List before contacting a particular HCP.

14. Purdue sales representatives filed ADD reports for 89 of the 103 HCPs on the No- Call List. Of the 14 HCPs for whom an ADD report was not filed and therefore came to Purdue's attention other than through a sales representative, only 5 had been called on within the 6 months prior to the HCP being placed on the No-Call List.

15. Although the ADD Program can be an effective tool in identifying potential abuse and illegal diversion of opioids, these findings demonstrate opportunities for improvement in Purdue's implementation of the program.

B. Purdue's Lack of Disclosure on www.inthefaceofpain.com

16. Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. A document linked to the site briefly mentions opioid abuse, but the site itself does not.

17. Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs, comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost \$4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at

many levels. Pressure from patients and the larger public is a key element in creating momentum for change.”

18. Although Purdue created the content on www.inthefaceofpain.com, as indicated by the Purdue copyright at the bottom of each page, the site creates the impression that it is neutral and unbiased. However, prior to this investigation, the website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost \$231,000, for speaker programs, advisory meetings and travel costs, to 11 of the Advocates whose testimonials appeared on the site. The videos on YouTube also fail to disclose Purdue’s payments to the Advocates.⁶

19. Purdue’s failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.

C. Limitations in HCPs’ Knowledge of Appropriate Prescribing Practices

20. Prescriber education has the potential to increase awareness of risks associated with opioids in general and OxyContin in particular. As part of the FDA’s mandated Risk Evaluation and Mitigation Strategy (“REMS”) in 2010, Purdue conducted a survey of HCPs selected randomly from those that prescribed OxyContin but not all of whom Purdue detailed. That survey indicated deficiencies in certain HCPs’ knowledge of appropriate opioid prescribing practices. For example, the survey showed that more than 40% of OxyContin prescribers did not know that individuals who are considered at increased risk of OxyContin abuse include individuals with a personal or family history of mental illness such as major depression, and that more than 30% of prescribers did not know that monitoring for misuse, abuse and addiction may include urine drug testing.⁷ Another survey showed that approximately 78% of HCPs who responded knew that individuals with a family history of

⁶ In April 2015, a year after the OAG launched its investigation, Purdue removed the profiles of Advocates with whom it has financial relationships from www.inthefaceofpain.com.

⁷ See <http://www.cpdd.org/pages/Meetings/CPDD11AbstractBook.pdf>.

mental illness are at increased risk of opioid abuse. Subsequent to that time, each of the prescribers surveyed was sent prescriber education materials pursuant to the OxyContin REMS and the Classwide Extended Release/Long Acting Industry REMS, which has been in place since 2012.

D. Opioid Patients' Need for Information Regarding Addiction Treatment

21. Patients undergoing opioid therapy benefit from information about the risks of addiction and some may need information about addiction treatment resources. One study indicated that opioid use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.⁸ A second study published in 2015, based on computer-assisted review of electronic health records, concluded that 13.5% of patients receiving chronic opioid therapy had either problem opioid use or a diagnosis for opioid abuse or dependence.⁹ Although there is presently no consensus regarding the incidence or prevalence of abuse or addiction to opioids among patients treated with chronic opioid therapy, efforts to reduce opioid abuse and overdose deaths should address not only those who abuse opioids such as OxyContin without a prescription, but also those who take the medication as prescribed, yet begin to abuse opioids or become addicted to them.

⁸ See Joseph A. Boscarino et al., *Risk Factors For Drug Dependence Among Out-Patients On Opioid Therapy In A Large US Health-Care System*, 105 *Addiction* 1776 (2010); Joseph A. Boscarino et al., *Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 versus DSM-4 diagnostic criteria*, 30 *J. Addictive Diseases* 185 (2011).

⁹ See Roy E. Palmer et al., *The Prevalence Of Problem Opioid Use In Patients Receiving Chronic Opioid Therapy: Computer Assisted Review Of Electronic Health Record Clinical Notes*, 156 *Pain* 1208 (2015).

III. RELEVANT LAW

22. The New York General Business Law prohibits “deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service” in New York State. N.Y. Gen. Bus. Law § 349.

23. The New York General Business Law also prohibits “false advertising in the conduct of any business,” or advertising that is misleading in a material respect. Whether an advertisement is materially misleading depends on “the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity to which the advertising relates under the conditions prescribed in said advertisement.” N.Y. Gen. Bus. Law § 350.

24. The New York Executive Law prohibits “illegal or fraudulent acts” in the conduct of any business, trade or commerce, and allows the OAG to institute a special proceeding for restitution, damages, and/or injunctive relief against any party which has committed such acts. N.Y. Exec. Law § 63(12).

25. The OAG concludes that Purdue’s website www.inthefaceofpain.com (and related content posted by Purdue on YouTube) violates the above-referenced provisions because it fails to disclose Purdue’s financial relationships with “advocates,” creating a false impression of neutrality.

26. The OAG concludes that Purdue’s detailing of certain problematic HCPs, even after Purdue had reason to know through its sales representatives that some of these HCPs may have been engaging in improper prescribing practices violates the above-referenced provisions.

NOW, WHEREAS, Purdue neither admits nor denies the Attorney General’s findings in paragraphs 9 through 21 above; and

WHEREAS, New York laws prohibiting deceptive business practices and false and misleading advertising confer important consumer and public health protections; and

WHEREAS, Purdue has cooperated with the OAG's investigation; and

WHEREAS, the Attorney General is willing to accept the terms of this Assurance under Executive Law Section 63(15) and to discontinue his investigation; and

WHEREAS, the parties each believe that the obligations imposed by this Assurance are prudent and appropriate; and

WHEREAS, the Attorney General has determined that this Assurance is in the public interest.

IT IS HEREBY UNDERSTOOD AND AGREED, by and between the parties that:

IV. PROSPECTIVE RELIEF

A. Maintenance of ADD Program

28. Purdue shall continue to maintain its ADD Program consisting of internal procedures designed to ensure that Purdue's interactions with HCPs that reveal observations or circumstances that suggest potential concerns about abuse, diversion, or inappropriate prescribing of opioid medications generate appropriate review and follow-up. Within ninety (90) business days after the Effective Date of this Assurance, Purdue shall implement the modifications set forth below. The ADD Program shall remain in place for as long as Purdue promotes OxyContin to HCPs through sales representatives.

29. The ADD Program applies to Purdue sales representatives and medical liaisons who contact HCPs for the purpose of promoting Purdue opioid products ("ADD Covered Persons"). The Program requires those persons to file a written report (an "ADD Report") with Purdue's Law Department when they observe or learn of the situations described in Paragraph 10 above, which may suggest that an HCP may be involved in the abuse or diversion of

opioids. In addition to those already outlined in the policy, the following situations shall also trigger a report under the ADD Program:

- a. That an HCP lacks understanding about the risks associated with prescribing opioids. For example, an HCP who states that he or she does not have basic information about the risks of addiction associated with opioid therapy.
- b. Facts that suggest that the HCP's patients are seeking opioids for misuse and abuse, including but not limited to facts that suggest that an HCP has failed to comply with New York's Internet System for Tracking Over-Prescribing/Prescription Monitoring Program (I-STOP/PMP).

30. Purdue shall continue to implement in New York the following elements of the ADD Program as long as it promotes OxyContin to HCPs through sales representatives:

- a. Upon identification of potential abuse, diversion, or inappropriate prescribing of opioids involving an HCP with whom ADD Covered Persons interact, Purdue shall conduct an internal inquiry which shall include but not be limited to a review of the HCP's prescribing history and relevant facts about the HCP's practice, and shall take such further steps as may be appropriate based on the facts and circumstances, which shall include ceasing to promote Purdue opioid products to the particular HCP or providing further education to the HCP about appropriate use of opioids.
- b. Purdue shall immediately cease promoting Purdue opioid products to an HCP when an ADD Report is filed about that HCP, and shall resume promoting Purdue opioid products to the HCP only after Purdue's Law Department reasonably concludes, based on available information, that it is appropriate to resume sales calls on that HCP.

- c. Purdue shall implement and maintain a training and education program with respect to the ADD Program. That training shall cover the details of the revised Program, and Purdue shall require all ADD Covered Persons to complete the training and education program no later than ninety (90) business days after the Effective Date of this Assurance, and to complete the training each year.
- d. No sales incentive (bonus) program for sales of Purdue opioid products shall allow incentive credit to be earned for prescriptions by an HCP once that HCP has been placed on the No-Call List.

31. Additionally, Purdue will adopt the following measures as part of the ADD

Program:

- a. Each week, all ADD Covered Persons shall check whether HCPs they plan to call upon that week are on Purdue's No-Call List. If an ADD Covered Person promotes a Purdue opioid product on a planned call to an HCP on the No-Call List, that individual shall be subject to review for potential disciplinary action, including but not limited to censure, probation and termination.
- b. Purdue may resume promoting Purdue opioid products to an HCP about whom an ADD Report has been filed only after its Law Department *in writing* reasonably concludes, based on available information, that it is appropriate to resume sales calls on that HCP.
- c. On a monthly basis, Purdue shall provide to the OAG the names of any HCPs in New York whom it has placed on the No-Call List, assuming a new HCP has been added.
- d. Purdue shall maintain other measures to identify the potential abuse, diversion, or inappropriate prescribing of opioids, including but not limited to: (i)

reviewing news media stories addressing the potential abuse, diversion, or inappropriate prescribing of opioids and/or the governmental investigation and/or arrest of HCPs to whom Purdue has promoted opioids; and (ii) examining data sources, such as HCPs' prescription history, to identify HCPs who should be reviewed for potential placement on the No-Call List.

- e. Purdue's performance evaluations of persons involved in marketing or promoting Purdue opioid products shall meaningfully take into account that sales persons inform HCPs to whom the sales persons promote opioids about its potential for abuse and diversion, and how to minimize those risks.
- f. If an ADD Covered Person fails to file an ADD Report regarding an HCP, and Purdue determines that person knew or should have known that HCP was engaged in conduct covered by the Policy, that person shall be subject to disciplinary action by Purdue, including but not limited to censure, probation and termination.

32. For a minimum of three years, ADD Covered Persons in New York shall enter detailed call notes regarding sales calls to HCPs in which compliance or potential abuse issues are raised, and the Purdue Corporate Compliance department shall, on a quarterly basis, audit and review a sample of such call notes to, *inter alia*, evaluate compliance with the ADD Program and determine whether ADD Reports need to be filed regarding particular HCPs.

33. Purdue shall not employ a compensation structure for persons involved in marketing or promoting Purdue opioid products, in which more than 30% of the individual's total compensation (including bonus) is based on the volume of OxyContin prescriptions.

B. Disclosures Regarding Unbranded Websites

34. If the name, image, audio or video recording of, or a quotation from, a person appears on any unbranded, publicly available web page or social media account controlled or maintained by Purdue, such as the “Voices of Hope” sub-page on www.inthefaceofpain.com, and such name, image, audio or video recording of, or quotation from, the person is accompanied on the web page or social media account by a discussion of the treatment of pain, Purdue shall disclose the existence of individual payments of \$10 or more by Purdue to such person, and aggregate payments by Purdue to such person exceeding \$100 in a calendar year, as follows:

- a. The disclosure shall be designated on the relevant web page with an asterisk accompanying the name of the person. The amount of the aggregate payment to the person for each of the prior three calendar years will be available via one click from the relevant web page. If a person has not been paid by Purdue in the prior three calendar years, the asterisk and aggregate payment amounts previously posted will be removed.
- b. If the person is an HCP, the aggregate payment amount will be based on payments in prior calendar years as published in the CMS Open Payments Enterprise Portal or the equivalent for non-physician HCPs. If the person is not an HCP, the aggregate payment amount will be based on payments by Purdue in prior calendar years.
- c. Aggregate payment amounts as set forth in this Paragraph will be updated on the relevant web page no later than July 15th of the relevant year.
- d. Should any person identified in Paragraph 34 receive a payment from Purdue, for the first time, after the period for reporting described in paragraphs 34 (b)

and (c), Purdue will, within 30 days, include an asterisk denoting that such individual has received a payment. The aggregate payment amount to that individual will be available via one click from the relevant web page no later than July 15th of the following calendar year.

- e. Within 90 days after the Effective Date, Purdue will update the relevant web pages with the disclosures set forth in this Paragraph. Prior to executing these updates, Purdue will provide to the OAG a sample of the relevant web pages for review and comment.
- f. This Paragraph will remain in effect for as long as the CMS Open Payments provision is in effect. If Purdue determines that its obligations under this Paragraph should no longer be in effect because the CMS Open Payments provision is no longer in effect, it will provide written notice to the OAG regarding its basis for such determination and will comply with this Paragraph for thirty (30) days after providing written notice.

35. On publicly available websites and social media accounts it controls and maintains in which medication to treat pain is referenced, Purdue shall provide, on the site itself, information regarding the risks of opioids, including the risk of addiction, including the information set forth in Paragraph 20 above.

C. Prescriber Training

36. Persons involved in marketing or promoting Purdue opioid products to HCPs shall, at the first visit each year to each New York HCP after the Effective Date, ask the HCP whether he or she completed a training program regarding the appropriate prescribing of opioids, the content of which is compliant with the FDA's REMS for Extended Release/Long-Acting Opioids. If such New York HCP indicates that he or she has not completed such

training, then the sales representative shall provide information about training, in the form of the document set forth as Exhibit A.

D. Treatment Resources

37. Purdue shall make available and provide, upon request, information regarding addiction treatment resources to HCPs to whom it markets or promotes Purdue opioid products. These materials shall be provided to Purdue by the OAG.

V. PENALTIES, FEES AND/OR COSTS

38. Within 30 days of the Effective Date, Purdue shall pay \$75,000 by check to the “State of New York Department of Law.”

VI. LIQUIDATED DAMAGES

39. If Purdue violates any material provision of this Assurance, the OAG may elect to demand that Purdue pay liquidated damages of \$1,000 per episode of non-compliance. Before liquidated damages may be imposed, the OAG shall give Purdue written notice that Purdue may be subject to liquidated damages under this Paragraph. In the event that Purdue does not cure the violation or provide the requested information within thirty (30) days of receipt of the OAG’s written notice, the OAG may impose liquidated damages pursuant to this Paragraph. The damages period shall commence on the date after the period to cure has lapsed.

VII. COMPLIANCE

40. Initial Compliance: Within ninety (90) days of the Effective Date, Purdue shall submit a letter, along with supporting documentation, certifying its compliance with Paragraphs 28 through 38 of this Assurance. Purdue shall then, on an annual basis for three years, certify its continuing compliance with the provisions of this Assurance.

41. Auditor: to evaluate the ADD Program, Purdue shall appoint an auditor (the “Auditor”), an independent individual or entity selected by Purdue and paid for and contracted by Purdue as follows:

- a. Within 30 days of the Effective Date, Purdue shall select the Auditor, subject to OAG approval.
- b. Each year, for three years, Purdue shall provide the Auditor with information about its implementation of the ADD Program along with ADD Reports filed during that year and the Company’s determination regarding each report. The Auditor shall evaluate Purdue’s compliance with Section IV.A. above and the reasonableness of Purdue’s decisions regarding whether to continue marketing or promoting opioid products to the HCP at issue in each ADD Report.
- c. The Auditor shall present its findings in a written report (the “Auditor’s Report”) to the OAG and Purdue. The first Auditor’s Report shall be due one (1) year after the Effective Date.

VIII. GENERAL PROVISIONS

42. Purdue’s Representations: The OAG has agreed to the terms of this Assurance based on, among other things, the representations made to the OAG by Purdue and its counsel and the OAG’s own factual investigation as set forth in the above Findings. To the extent that any material representations are later found to be inaccurate or misleading, this Assurance is voidable by the OAG in its sole discretion.

43. Communications: All communications, reports, correspondence, and payments that Purdue submits to the OAG concerning this Assurance or any related issues is to be sent to the attention of the person identified below:

Michael Reisman, Esq.
Assistant Attorney General Health Care Bureau
Office of the New York State Attorney General
120 Broadway
New York, New York 10271

44. Receipt by the OAG of materials referenced in this Assurance, with or without comment, shall not be deemed or construed as approval by the OAG of any of the materials, and Purdue shall not make any representations to the contrary.

45. All notices, correspondence, and requests to Purdue shall be directed as follows:

Robin E. Abrams
Vice President, Associate General Counsel
Purdue Pharma L.P.
201 Tresser Blvd.
Stamford, Connecticut 06901

46. Valid Grounds and Waiver: Purdue hereby accepts the terms and conditions of this Assurance and waives any rights to challenge it in a proceeding under Article 78 of the Civil Practice Law and Rules or in any other action or proceeding.

47. No Deprivation of the Public's Rights: Nothing herein shall be construed to deprive any member or other person or entity of any private right under law or equity.

48. No Blanket Approval by the Attorney General of Purdue's Practices: Acceptance of this Assurance by the OAG shall not be deemed or construed as approval by the OAG of any of Purdue's acts or practices, or those of its agents or assigns, and none of them shall make any representation to the contrary.

49. Monitoring by the OAG: To the extent not already provided under this Assurance, Purdue shall, upon request by the OAG, provide all documentation and information necessary for the OAG to verify compliance with this Assurance. Purdue may request an extension of particular deadlines under this Assurance, but OAG need not grant any such

request. This Assurance does not in any way limit the OAG's right to obtain, by subpoena or by any other means permitted by law, documents, testimony, or other information.

50. No Limitation on the Attorney General's Authority: Nothing in this Assurance in any way limits the OAG's ability to investigate or take other action with respect to any non-compliance at any time by Purdue with respect to this Assurance, or Purdue's noncompliance with any applicable law with respect to any matters.

51. No Undercutting of Assurance: Purdue shall not take any action or make any statement denying, directly or indirectly, the propriety of this Assurance or expressing the view that this Assurance is without factual basis. Nothing in this paragraph affects Purdue's testimonial obligations, or right to take legal or factual positions in defense of litigation or other legal proceedings to which the OAG is not a party. This Assurance is not intended for use by any third party in any other proceeding and is not intended, and should not be construed, as an admission by Purdue of any liability or finding set forth herein.

53. This Assurance shall apply only in and be governed by the laws of the State of New York without regard to any conflict of laws principles.

54. If a court of competent jurisdiction determines that Purdue has breached this Assurance, Purdue shall pay to the OAG the cost, if any, of such determination and of enforcing this Assurance, including, without limitation, legal fees, expenses, and court costs.

55. None of the parties shall be considered to be the drafter of this Assurance or any provision for the purpose of any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter hereof. This Assurance was drafted with substantial input by all parties and their counsel, and no reliance was placed on any representation other than those contained in this Assurance.

56. In the event that any one or more of the provisions contained in this Assurance shall for any reason be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Assurance.

57. No representation, inducement, promise, understanding, condition, or warranty not set forth in this Assurance has been made to or relied upon by Purdue in agreeing to this Assurance.

58. This Assurance contains an entire, complete, and integrated statement of each and every term and provision agreed to by and among the parties, and the Assurance is not subject to any condition not provided for herein. This Assurance supersedes any prior agreements or understandings, whether written or oral, between and among the OAG and Purdue regarding the subject matter of this Assurance.

59. This Assurance may not be amended or modified except in an instrument in writing signed on behalf of all the parties to this Assurance.

60. The division of this Assurance into sections and subsections and the use of captions and headings in connection herewith are solely for convenience and shall have no legal effect in construing the provisions of this Assurance.

61. Binding Effect: This Assurance is binding on and inures to the benefit of the parties to this Assurance and their respective successors and assigns, provided that no party, other than the OAG, may assign, delegate, or otherwise transfer any of its rights or obligations under this Assurance without prior written consent of the OAG.

62. Effective Date: This Assurance is effective on the date that it is signed by the Attorney General or his authorized representative (the "Effective Date"), and the document may be executed in counterparts, which shall all be deemed an original for all purposes.

AGREED TO BY THE PARTIES:

Dated: Stamford, CT

Aug. 17th, 2015

Purdue Pharma L.P.

By: Robin E. Abrams

Robin E. Abrams

Vice President, Associate General Counsel

Dated: New York, New York

August 19, 2015

ERIC T. SCHNEIDERMAN

Attorney General of the State of New York

LISA LANDAU

Health Care Bureau Chief

By: Michael D. Reisman

MICHAEL D. REISMAN

Assistant Attorney General

Health Care Bureau

EXHIBIT A

ER/LA Opioid Analgesics REMS

The Extended-Release and Long-Acting (ER/LA) Opioid Analgesics
Risk Evaluation and Mitigation Strategy (REMS)



REMS-Compliant Prescriber Training

In 2007, Congress granted the FDA the authority to require manufacturers of medicinal products to implement a Risk Evaluation and Mitigation Strategy (REMS) if the FDA determines a REMS is necessary to ensure that a drug's benefits outweigh its risks. A REMS is a safety strategy required by the FDA from manufacturers to manage a known or potential serious risk associated with a medication and to enable patients to have continued access to such medications by managing their safe use.

FDA has required a shared REMS for all extended-release (ER) and long-acting (LA) opioid medications called the "ER/LA Opioid Analgesics REMS".

If you prescribe ER/LA opioid analgesics, FDA strongly encourages you to complete a REMS-compliant continuing education (CE) program that provides updated training on the risks and safe use of ER/LA opioids. Numerous CE activities that meet REMS standards (also known as "REMS-compliant CE") are currently available in both live and online formats. These activities are offered by accredited providers of CE at nominal or no cost to you. A listing of the ER/LA Opioid Analgesics REMS-compliant CE activities supported by the REMS Program Companies (RPC), a consortium of ER/LA opioid companies, can be found at: <https://search.er-la-opioidrems.com/>.

Providers of REMS-compliant CE adhere strictly to the accreditation standards of the Accreditation Council for Continuing Medical Education® (ACCME) or other CE accrediting bodies.

The REMS also includes a one-page document that prescribers can use to counsel patients on the risks and safe use of ER/LA opioid analgesics. This patient counseling document can be accessed at:

<http://www.er-la-opioidrems.com/lwgUI/rems/pcd.action>

Additional information/resources may be found at <http://www.er-la-opioidrems.com>.