UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	
	Chapter 11
PURDUE PHARMA L.P., *et al*.,	**Case No. 19-23649 (RDD)**
Debtor.[1]	**(Jointly Administered)**

ELEVENTH MONITOR REPORT

Comes now, Stephen C. Bullock, as duly contracted Monitor for Purdue Pharma L.P. to report to the Court as follows:

EXECUTIVE SUMMARY

This Eleventh Monitor Report, and the undersigned's seventh since being appointed on February 18, 2021, will include an outline of actions taken over the last three months to determine compliance with the terms and conditions of the Voluntary Injunction ("Injunction"), discussion of the results of areas of further inquiry or recommendations from the last two Reports, additional recommendations provided to Purdue Pharma L.P. ("Purdue Pharma" or "the Company"), and the Company's response to those recommendations.

Based on what has been reviewed to date and subject to the recommendations contained herein, Purdue Pharma and the Initial Covered Sackler Persons appear to be making a good faith

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

effort to comply with the terms and conditions of the Injunction, and the Company has been responsive in fulfilling the Monitor's requests for information, documents, and interviews with Purdue Pharma employees.

INTRODUCTION – STEPS TAKEN SINCE NINTH REPORT

1. Since the filing of the Ninth Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue Pharma including the: Executive Vice President, General Counsel and Secretary; Vice President, Ethics and Compliance; Vice President, Legal Strategy and Public Health Initiatives; Vice President, Chief Security Officer; Head of Commercial Operations and Strategic Portfolio Management; Head of Market Access; Head of Pricing; Director, Ethics and Compliance; Associate Director, Ethics and Compliance; and Manager, Ethics and Compliance. The undersigned has also had interviews with the National Business Director and the General Counsel of a company providing contracted sales support for Nalmefene to the Company.

2. Since the filing of the Ninth Report the Monitor has continued to request, receive, and review a variety of documents, reports, and materials. The undersigned has received information relating to standing requests, new requests, and documents and reports generated by the Company to directly address inquiries made by the undersigned.

NINTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Ninth Report, multiple recommendations and areas of inquiry were identified. The Company agreed to all recommendations made and has been assisting in both addressing the recommendations and providing necessary information relating to areas of further inquiry.

4. The recommendations and areas of inquiry included:

a. That the Company provide the undersigned with a schedule detailing when each Group Purchasing Organization ("GPO") and Managed Care Organization ("MCO") agreement is scheduled for renewal or amendment, and whether the individual contract includes certain terms recommended in the Ninth Report. (Ninth Report, Paragraphs 124, 132, 141.)

b. That the Company, in the normal course of amendments to GPO and MCO agreements, make commercially reasonable, good faith efforts to include in these agreements the terms recommended in the Ninth Report. (Ninth Report, Paragraphs 123, 131, 140.)

c. That the Company inform the Monitor promptly after contract completion or renewal whether the terms were included. (Ninth Report, Paragraphs 124, 132, 141.)

d. That the Company prepare an analysis and presentation of: (i) the availability, accuracy, and reliability of days' supply data in managed care rebate submissions; (ii) the reasons why strength, days' supply, and/or MME cannot be implemented as a threshold validation in Company contracts; and (iii) possible approaches to implement a threshold based on MME and/or MME/day. (Ninth Report, Paragraph 138.)

e. That the Company seek to obtain unblinded 867 Data for Suspicious Order Monitoring purposes from pharmacy chains that blind the downstream data that Purdue Pharma receives. (Ninth Report, Paragraph 180.)

f. That the Company report to the Monitor the process undertaken and success of efforts to gain access to unblinded downstream customer 867 data within 30 days of the filing of the Ninth Report. In instances where these efforts do not succeed, that the Company confer with the Monitor to explore potential alternative strategies to obtaining the blinded data. (Ninth Report, Paragraph 181.)

TENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

5. Pursuant to the recommendation contained in Paragraph 181 of the Ninth Report, on June 29, 2022, the Monitor filed the Tenth Report, detailing efforts made by the Company since the filing of the Ninth Report to gain access to unblinded 867 Data from four pharmacy chains. (Tenth Report, Paragraphs 7-12.)

6. The Tenth Report made the following recommendations:

a. That the Company, including the Executive Vice President, General Counsel and Secretary, work promptly and in good faith to attempt to reach agreements with the pharmacy chains so that the Company has access to the blinded 867 data for purposes of Suspicious Order Monitoring of downstream customers; and

b. That the Company report to the Monitor the actions undertaken and outcome of these further efforts within 30 days of the filing of the Tenth Report.

(Tenth Report, Paragraphs 13-14.)

7. The recommendations and inquiries in the Ninth and Tenth Reports, as well as actions taken in response, will be further discussed in each of the sections below.

8. Additionally, where new or continuing areas of inquiry have been undertaken since the Ninth and Tenth Reports, these new areas will be identified and discussed.

DISCUSSION AND ANALYSIS

I. BAN ON PROMOTION AND FINANCIAL REWARDS BASED ON VOLUME OF OPIOID SALES

A. Sales Team for Public Health Initiative Products

9. Under the terms of the Injunction, the Company is prohibited from "[e]mploying or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers or Patients." (Injunction, II.A.1.a.)

10. In 2018, the Company terminated their sales team for Opioid Products. (First Report, Paragraph 34.)

11. During the period from March 2020 to October 2020, Adlon had two third-party contract sales teams consisting of approximately 90 people for the purpose of promoting its non-Opioid product, Adhansia XR®. An additional contract sales team for Adhansia XR was added in November 2020, with 60 additional customer service representatives. (Fifth Report, Paragraph 45.)

12. The Company reported to the Monitor that in December 2021, it discontinued the use of an outside sales force for Adhansia. Accordingly, the Company no longer has employees or entities promoting any of its Opioid or ADHD products directly to Health Care Providers or patients. (Eighth Report, Paragraph 21.)

13. With the Food and Drug Administration's approval of Purdue's abbreviated new drug application for the vial form of Nalmefene, an Opioid antagonist medication used in the management of Opioid overdose, the Company reported to the Monitor that it intended to use select members of the Commercial department and a limited contractor presence to promote approved Public Health Initiative products to Health Care Providers. (Eighth Report, Paragraph 22.)

14. The Monitor interviewed the Head of Market Access for the Company and the National Business Director for the contractor the Company hired to assist with the promotion of Nalmefene, as well as reviewed relevant documents guiding the promotional efforts.

15. In total, there are five employees with the contracted company involved in the promotion of Nalmefene: The National Business Director, who devotes 25% of his time to this project, three Key Account Managers ("KAMs"), and one Virtual Key Account Manager ("VKAM").

16. The National Business Director is responsible for employing and directly supervising the KAMs and VKAM, assisting in strategy for promotion of Nalmefene, and identifying additional resources and capabilities that the contract company could provide to assist in Purdue Pharma's efforts.

17. The KAMs and VKAM were hired in late March and April, spent the last three weeks of May in training, and began speaking to hospitals in June 2022.

18. The KAMs are individually assigned geographic regions consisting of states in the Northeast, mid-Atlantic and Central United States. The regions, as well as potential customers in those regions, have been provided to the KAMs by Purdue Pharma's analytics department. The Company identified the geographic regions and hospitals by assessing, among other things, the volume of Naloxone, another Opioid antagonist medication used in the management of overdose, used in that area.

19. The VKAM uses the lists generated by the Company and first calls the hospitals to endeavor to identify the best person or persons in the hospital for the KAM to contact. Each KAM has initially been provided with a nonprioritized list of approximately 150 hospitals.

20. Internal to the Company, there are two National Account Executives ("NAEs") working on promoting Nalmefene. The NAEs serve a similar function as the contracted KAMs, yet different geographic areas. The NAEs are long-time Company employees, working principally with managed care, insurance companies and the Medicaid program on access to the Company's Opioid Products, and the Nalmefene promotion is an additional responsibility assigned to them.

21. The Company's Head of Market Access explained that it is very different from a typical pharmaceutical product launch, in that during the initial effort the KAMs and NAEs are casting a wide net, determining if the hospitals are interested in learning more about the product and speaking to Company representatives.

22. The Head of Market Access has a weekly call with the KAMs, VKAM, and NAEs to seek feedback and give direction, with the National Sales Director providing coaching and assessment to the contracted personnel.

23. The KAMs, VKAM and NAEs identify themselves as representing Purdue Pharma. To date, the National Sales Director and Head of Market Access told the undersigned that the hospitals are not asking questions regarding Opioid Products or other issues about the Company unrelated to Nalmefene.

24. The KAMs and NAEs are not presenting Nalmefene as a replacement to Naloxone, nor trying to take Naloxone's market share, but rather as an additional option for the hospital when presented with an Opioid overdose.

25. The KAMs, VKAM and NAEs have received specific training concerning the Injunction, as well as reporting Adverse Effects, Product Complaints, and Medical Inquiries relating to other products distributed by the Company.

26. All promotional materials used in interacting with the hospitals are prepared by Purdue Pharma. Until recently, the KAMs and NAEs were only presenting the package insert materials containing the Full Prescribing Information. The Company submitted its core launch materials for Nalmefene to the Food and Drug Administration's Office of Prescription Drug Promotion and recently received OPDP's comments, which have been incorporated into all Nalmefene promotional materials. The KAMs and NAEs are now using these materials in their meetings.

27. The Injunction expressly carves out from its prohibitions "[p]romotional activity relating to any products that are indicated for the treatment of Opioid-induced side effects," including "dissemination of information or activities relating to . . . the prevention, education, and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction." (Injunction II.A.3.ii.)

28. The Monitor reviewed the promotional materials relating to Nalmefene and finds that these materials are consistent with the terms of the Injunction.

29. Moreover, the Monitor is satisfied that the training, procedures, and policies guiding those promoting Nalmefene adequately inform them of their requirements under the Injunction.

30. The contracted sales personnel also have certified that they have received and understand training on the Injunction and will direct inquiries relating to Opioid Products to Purdue Pharma's Medical Information team.

31. Accordingly, Purdue Pharma is performing its business relating to Nalmefene consistent with the Injunction.

B. Bonus, Salaries, and Incentives to Purdue Employees

32. The Injunction requires that Purdue Pharma "shall not offer or pay any remuneration . . . to or from any person in return for the prescribing, sale, use or distribution of Opioid Product." (II.B.1).

33. A discussion of the bonus, salaries, and incentives available to Purdue employees and officers between 2019 and 2021 was previously discussed in the Fifth and Sixth Reports. (Fifth Report, Paragraphs 86-93; Sixth Report, Paragraphs 48-69.)

1. Incentive and Retention Programs

34. The incentive and retention programs available to Purdue Pharma employees cover three unique categories of employees: key insider employees ("Key Employee Incentive Plan" or "KEIP"); a retention program for key employees ("Key Employee Retention Plan" or "KERP"); and an incentive compensation program for the Market Access and Trade & Distribution Teams.

35. In each instance, the incentive and/or retention programs for the KEIP and KERP employees are submitted to Bankruptcy Court for review and approval. The 2022 plans were submitted by the Company on April 27, 2022, and final orders approving the plans were entered on May 20 and June 27, 2022.

a. Key Insider Employees

36. Purdue Pharma's KEIP employees, as permitted by the Bankruptcy Code (11 U.S.C. § 101(31)(B)(i)–(vi)), last year were the Chief Executive Officer, the General Counsel, the Chief Financial Officer, the Chief Technical Operations Officer, and the President of Rhodes Pharmaceuticals. Given retirements and restructuring, the only two positions eligible to

participate in the 2022 KEIP are (a) the President and CEO, and (b) the Executive Vice President, General Counsel & Secretary.

37. For the KEIP employees, the incentive compensation includes both an annual award and a long-term award.

38. The 2022 annual award follows the same structure and content as the 2021 annual award. (*See* Sixth Report, Paragraph 59.) Payment is subject to the Company achieving its 2022 performance metrics, set out as the corporate scorecard. KEIP employees are eligible to receive between 75% and 100% of the annual award, depending upon whether the 2022 corporate objectives are fully achieved. The annual award will be paid in March 2023.

39. The long-term award also follows the structure of the 2021 award (*see* Sixth Report, Paragraph 60), except that in 2022 there is an agreed-upon reduction of the long-term award for the CEO. The long-term award will be paid in March 2023, and is subject to certain clawback provisions (i.e., voluntary resignation or termination for cause prior to March 15, 2025).

b. Key Employee Retention Plan Awards

40. For other employees at Purdue Pharma, the additional compensation of an annual award and long-term award are structured as part of a retention plan. The 2022 KERP annual award follows the same structure and payout timeframes as the 2021 awards. The 2022 KERP long-term award also follows the same structure as the 2021 KERP long-term award, however the payout timeframe is different. The 2022 KERP long-term award will be paid in March 2023 and is subject to certain clawback provisions (i.e., voluntary resignation or termination for cause prior to March 15, 2025) (Sixth Report, Paragraph 61.)

41. Consistent with the Plans for 2019 and 2020, in 2021, the annual bonus and long-term financial incentive payments for Purdue's Key Insider Employees (KEIP) were contingent upon the achievement of the 2021 Corporate Objectives within the Company's 2021 scorecard. The Company's scorecard identified three factors – or strategic pillars -- to be used to determine if a bonus should be paid out: Value Creation (40%), Innovation and Efficiency (50%), and People and Culture (10%). (Fifth Report, Paragraph 88.) In 2021, annual bonus and long-term financial incentive payments to the Company's key employees who participated in the Key Employee Retention Plan ("KERP") were not contingent upon the achievement of the 2021 Corporate Objectives within the Company's 2021 scorecard.

42. In 2022, the weighting of those strategic pillars has been slightly modified to reflect: Value Creation (50%), Innovation and Efficiency (40%), and People and Culture (10%).

43. Unlike in 2021, the 2022 strategic pillar of Value Creation in the Corporate Objectives contains no reference to any Opioid Products.

44. While Purdue Pharma's operating profit was a factor in the 2021 strategic pillar of Innovation and Efficiency, the 2021 Corporate Objectives provided that the "[a]ctual performance will be adjusted for the margin on branded opioid sales being higher or lower than Target," making express that the Company has decoupled the performance of the opioid products from corporate objectives and benchmarks. (Fifth Report, Paragraph 88.)

45. The 2022 Corporate Objectives did not expressly exclude branded Opioid Product performance in calculating incentive payments. However, when brought to the Company's attention by the Monitor, Company representatives pointed out that the exclusion was noted in pleadings filed with the Bankruptcy Court, and that the 2022 Corporate Objectives

scorecard would be revised to make the exclusion express. The undersigned finds that its omission was an oversight.

c. Field Market Access Employees

46. The employees in the field Market Access Team have a different compensation structure. (*See* Fifth Report, Paragraphs 62-69.) Moreover, the Injunction has a provision directly addressing sales and marketing employees, providing that "[t]he Company shall not provide financial incentives to its sales and marketing employees, or take disciplinary actions against its sales and marketing employees, that are directly based on, or tied to sales volume or sales quotas for Opioid Products, unless otherwise permitted by the Bankruptcy Court." (Injunction, II.B.1).

47. The undersigned has requested and received some information relating to the 2022 compensation structure for the Field Market Access employees, but additional analysis is necessary. **Accordingly, the Monitor will report on the compensation structure of the field Market Access employees in the next Report.**

48. Subject to this further review, the Monitor finds the bonus, salaries, and incentives available to the Company's employees consistent with the Injunction.

C. Adequacy of the Company's Training and Education Regarding the Injunction

49. In the Ninth Report, the Monitor detailed updates and changes to the Company's training and education regarding the Injunction. (Ninth Report, Paragraphs 22-26.) Since then, the Company has been working on an Injunction training program that would be provided as an on-demand course, rather than a live course facilitated by the Law Department.

50. The Company provided the undersigned the opportunity to review the proposed training and offer feedback and suggestions. The undersigned's suggestions were accepted by the Company.

51. Although not live, the training is easy to understand, provides several opportunities for interaction, and tests comprehension by presenting occasional that the viewer must answer.

52. While the Company agrees that there may need to be additional training to new employees depending on their specific duties and responsibilities, the Monitor finds the training to sufficiently inform Company employees of their general obligations under the Injunction.

II. BAN ON FUNDING/GRANTS TO THIRD PARTIES TO PROMOTE OPIOIDS

A. Grants and In-Kind Contributions

53. Grants and in-kind contributions are decided by virtue of a multi-disciplinary committee that includes personnel from the Law department and Ethics and Compliance department. Personnel from the Commercial department of Purdue Pharma are not involved in making decisions involving the awarding of any grants or in-kind contributions, and Purdue Pharma prohibits making any contribution requested by any customer.

54. In 2020 up through early May 2021, Purdue Pharma awarded grants and contributions totaling $3,848,429. Eighty-three percent of the total grants went to universities, nonprofits, health care providers, and other organizations addressing prevention, harm reduction, treatment and recovery of opioid misuse or abuse. Eleven percent of the grants were identified as relating to COVID-19, and the remaining six percent of the grants were for areas such as wellness, education, and economic development. (Fifth Report, Paragraph 97.)

55. Materials provided to the undersigned reflect that from June 2021 to July 15, 2022, Purdue Pharma awarded grants and contributions totaling $226,730. Sixty-eight percent of the total grants were identified as falling within the category of economic development, yet principally involved human services organizations including disaster relief, support for senior citizens, and back to school programs. Twenty-two percent of the contributions were organizations involved in treatment or recovery of Opioid Use Disorder treatment and recovery. Nine percent of the contributions related to youth education programs or services.

56. The Company also contributes to two state business organizations. Purdue Pharma continues to participate in the Republican State Legislative Committee, the Council of State Governments, and the State Legislative Leadership Foundation, with the first being a partisan organization, and the latter two educational-based nonpartisan organizations.

57. The Monitor finds that these contributions and donations are consistent with the terms of the Injunction.

B. Spend Reports, Research Payments and Studies

58. Payments made to HCPs and for research must be evaluated under the ban on promotion, the prohibitions against paying any remuneration in return for the prescribing, sale use or distribution of Opioid Products, and the ban on funding or grants to third parties to promote Opioids.

1. Federal Spend Reports, State Audit Reports and Research Payments

59. The undersigned reviewed the 2020 state audit reports from Connecticut, the District of Columbia, Minnesota, Nevada, Vermont, and Massachusetts, as well as the federal spend report covering last year. (Sixth Report, Paragraph 71.)

60. To date, the undersigned has received and reviewed state reports for 2021 from Massachusetts, Nevada, and Connecticut. While the states do not all request the same information, the reported expenditures did not relate to Opioid Products and could not be construed in violation of the Injunction.

61. The 2021 Federal Spend Report reflected expenditures of $2,588,163.44 to seven payees relating to Opioid Products. These expenditures principally concern an Opioid Reversal Advisory Board and activities around Nalmefene.

62. The Company is still in the process of compiling and providing any materials that might exist concerning research payments related to Opioid Products. **The Monitor will provide additional review and analysis in the next Report.**

2. Studies

63. Since the filing of the Ninth Report, three studies funded by Purdue Pharma were completed and prepared for submittal for publication. Each were presented to the undersigned Monitor for review prior to commencing the publication process.

64. The first publication, initially entitled *Long-term Association of Wearable Health Technology with Depression and Opioid Use in Chronic Pain Patients*, grew out of a joint project initiated in 2016 between Purdue and the Geisinger Clinic, and was reviewed and discussed by the undersigned in August 2021. (Sixth Report, Paragraphs 80-83.)

65. The Company informed the Monitor that this study has been conditionally accepted for publication by the Clinical Journal of Pain, which had requested that the Company confirm its consent to publication. In response to a comment received from a reviewer from the journal, the title of the publication was revised to "*Long-term use of Wearable Health Technology by Chronic Pain Patients.*"

66. The second publication, *OxyContin Utilization in Children in the United States*, described the findings of a post marketing study required by the FDA as part of the agency's 2015 approval of OxyContin for pediatric use in opioid-tolerant patients ages 11 and older.

67. The study examined OxyContin utilization in pediatric patients (ages 17 years and younger) before and after the 2015 FDA-approval for pediatric use in opioid-tolerant patients aged 11 years and older. The study found that the most common indication for OxyContin prescriptions in children between 6 and 17 years of age from 2011 to 2017 was pain management following surgery. It further found that OxyContin is predominantly prescribed within the FDA-approved age ranges in children of 11 years old and older.

68. However, in contrast to the FDA dosing information, the study found that many of the children in this study were not opioid-tolerant according to the product label definition. That finding has resulted in an additional PMR to evaluate the risk for adverse outcomes in opioid non-tolerant pediatric patients prescribed OxyContin.

69. Two Purdue employees will be listed as authors along with authors from the Duke Clinical Research Institute. The study is in the final stages of review and submission for publication is anticipated in September 2022.

70. The third publication, *Use of an expert panel to determine opioid prescription indications in a US administrative claims database,* is part of the pediatric OxyContin utilization study (mentioned above) and part of the FDA's post-marketing requirement, conducted in conjunction with Genesis Research.

71. Based on a U.S. claims database, the report used a panel of physicians experienced in pain management to adjudicate the indication and appropriateness of use for extended-release OxyContin prescriptions in pediatric patients between the ages of 11 and 17.

72. As currently described in an updated draft of the publication, the most frequent indication was postoperative pain, predominantly post-lower limb surgery, and pain due to trauma or injury, predominantly lower limb trauma/injury. Physician adjudicators assigned indications for OxyContin prescriptions based on claims data when the drug claim was not directly linked with the procedure or diagnosis codes. The study found that using physician adjudicators may be a novel methodology for assessing the indications associated with prescription drug claims.

73. Two Purdue employees will be listed as authors together with authors from Genesis Research.

74. As to uses of the studies if accepted for publication, Purdue Pharma reports that the Company might reference it in other potential and related post-marking requirements manuscripts, and reference or provide the study in response to unsolicited requests from HCPs on this topic.

75. The Monitor finds that publishing these studies does not violate the terms of the Injunction.

76. **In considering publication of post marketing requirements studies, the prior Monitor recommended that "if such data is published in a scientific journal on websites controlled by Purdue Pharma that a disclaimer be provided that includes reference to the risks association with opioids and opioid products and the appropriate warning information contained in package inserts, prescribing information and medication guides." (First Report, Paragraph 55). The Company agrees to this recommendation.**

77. **As agreed to in the Sixth Report, and especially as Purdue Pharma employees are included as authors of these studies, if there are activities planned around**

using these reports after publication, the undersigned has requested and recommends that the Company first advise the Monitor, to ensure conformity with II.A.1.b of the Injunction ("Using speakers, key opinion leaders, lecturers and/or speaking events for Promotion of Opioids or Opioid Products"). (*See* Sixth Report, Paragraph 87.) The Company agrees to this recommendation.

C. Review of Opioid Products Contracts and Agreements.

78. In the Ninth Report, the Monitor reviewed the Pricing Consultants' evaluation of the Company's contract terms with Group Purchasing Organizations ("GPO") and Managed Care Organizations ("MCO") for consistency with the promotion and remuneration provisions of the Injunction contained in II.A. and II.B., and made several recommendations for consideration.

79. Regarding GPO contracts, the undersigned recommended that "the Company continue to make commercially reasonable, good faith efforts to negotiate carve-outs for Opioid Products from sales-based payments in its distributor GPO contracts in the normal course of the contract renewal process for distributor GPO contracts." (Ninth Report, Paragraph 123.)

80. Regarding MCO contracts, the undersigned recommended that the Company:

a. "in the normal course of the contract renewal/amendment process for managed care rebate agreements, make commercially reasonable, good faith efforts to include . . . a validation exhibit or language [regarding what government utilization the Company may exclude as duplicate claims] in all managed care agreements" (Ninth Report, Paragraph 131); and

b. "in the normal course of amendments to managed care rebate agreements make commercially reasonable, good faith efforts to include language in all managed care agreements explicitly making [prescription level data] fields mandatory in

submission of claim data with all current rebate customers" (Ninth Report, Paragraph 131).

81. For both GPO and MCO contracts, the Monitor requested that the Company provide the Monitor a schedule for when the agreements are up for renewal and that the Company inform the Monitor promptly after agreement completion, amendment or renewal. (Ninth Report, Paragraphs 132, 141.)

82. Finally, the Monitor requested that the Company provide the undersigned an analysis and presentation of:

a. "the business conditions and cost/benefit analysis for collecting the Medicaid claim details from State Medicaid agencies willing to provide claims data" (Ninth Report, Paragraph 133);

b. "the availability, accuracy, and reliability of days' supply data in managed care rebate submissions; the reasons why strength, days' supply, and/or MME cannot be implemented as a threshold validation in Company contracts; and possible approaches to implement a threshold based on MME and/or MME/day" (Ninth Report, Paragraph 138).

83. The Company provided the Monitor with a schedule detailing when the MCO and GPO contracts are up for renewal, and whether those specific contracts include the recommended specific terms.

84. To date, negotiations of certain of the Purdue MCO contracts have begun, but none of the contracts has been executed. Since none of the Distributor GPO Agreements has come up for renewal, the recommendations have not yet been negotiated or included in an amendment.

85. The Company also provided the cost/benefit analysis for collecting the Medicaid claims details. It is in the process of completing the analysis of the analysis regarding days' supply data and threshold validations. **The Monitor will report the findings of both analyses in the next full Report.**

III. LOBBYING RESTRICTIONS

86. Since the filing of the Ninth Report, the Monitor has reviewed: 20 quarterly reports reflecting the actions of contracted firms at the state level and three at the federal level, covering the period from April 1 to June 30, 2022.

87. In all instances, the state and federal contracted firms only monitored legislation and legislative, executive, and administrative activities.

88. The Monitor also reviewed two reports filed by the Company with the Clerk of the U.S. House and Secretary of the Senate covering the period from January 1 to June 30, 2022, regarding political contributions. There were none.

89. The undersigned Monitor finds that the Company is complying with Section II, Part D of the Injunction.

IV. BAN ON HIGH DOSE OPIOIDS

90. Under Section II.E of the Injunction, Purdue Pharma agreed to abide by whatever decision is made by the Food and Drug Administration (FDA) on the pending Citizens Petition dated September 1, 2017, concerning a ban on high doses of prescription and transmucosal Opioids exceeding 90 morphine milligram equivalents (FDA-2017-P-5396).

91. A review of Regulations.gov finds that no action has been taken by the FDA on this Citizens Petition.

V. BAN ON PRESCRIPTION SAVINGS PROGRAM

92. Under Section II. F. of the Injunction, Purdue Pharma agreed it would not directly or through a third party promote savings cards, vouchers, coupons, or rebate programs to HCPs for any Opioid Product, or provide financial support to a third party to circumvent this restriction. However, Purdue Pharma is authorized to provide savings cards, vouchers, coupons, or rebate programs, including point-of-dispense programs, in response to requests from HCPs, patients or caregivers, or on its company and product-specific websites.

93. In the Fifth Report, the undersigned provided a detailed explanation of the existing savings card, point-of-dispense savings, and electronic voucher savings programs for the Company's Opioid Products. (*See* Fifth Report, Paragraphs 114-124.)

94. The Company has reported to the Monitor that there have been no changes to the terms or conditions of these plans and programs since the filing of the Fifth Report. An addition to the program has been implemented that now blocks physicians who are on the Company's "No Call list" from accessing savings cards.

95. Accordingly, the offering and execution of these plans and programs continue to be in compliance with the Injunction.

VI. SUSPICIOUS ORDER MONITORING AND REPORTING

A. Restricting Supply of Company Opioid Products to Downstream Customers

96. In the Eighth Report, the undersigned recommended that "the Company establish policies and procedures for placing restrictions on certain downstream customers and provide the Monitor the opportunity to review these policies and procedures prior to implementation." (Eighth Report, Paragraph 86; *see also* Ninth Report, Paragraphs 198-199.)

97. The Company has notified the undersigned that it has identified a vendor and is engaged in working to create an SOP regarding termination of chargebacks for outliers.

98. **The Monitor renews its recommendation from the Eighth Report, and requests review of the SOP prior to implementation. The Company has agreed to this recommendation and request.**

B. Corporate Security

99. Since the last report, the Undersigned has requested and received materials relating to the Company's Corporate Security functions, as well as interviewed the Company's Vice President, Chief Security Officer.

100. The Chief Security Officer has been with the Company for 14 years. Prior to joining the Company, he worked for 27 years with another pharmaceutical company and as a special agent with a state law enforcement agency prior.

101. The Chief Security Officer reports to the Vice President of Human Resources, but has independent interaction with the Law, Compliance, Manufacturing, and Information Technology departments, as well as with the Company's Chief Executive Officer.

102. The principal responsibilities of the Corporate Security department include investigations, physical security of the Company's offices, including the Wilson, NC manufacturing plant, supply chain security, and IT security.

103. The investigative program involves internal functions such as reviews of conflicts of interest, theft, fraud and misappropriation of funds; investigating reports of concern received from the Product Complaints and Pharmacovigilance departments for potential diversion, loss or theft; reviewing fraud-related complaints received by the Compliance department; addressing questions regarding product integrity such as potential for counterfeiting;

and conducting threat assessment and risk mitigation activities relating to the Company or its employees.

104. An employee in Corporate Security principally involved in investigations spends most of his time investigating reports of concern from the Product Complaints and Pharmacovigilance departments.

105. When a pharmacist or customer says that a bottle is missing some tablets, Corporate Security works with colleagues in North Carolina to review information, including camera coverage, to see if there has been any short-fill of product that might explain why tablets are missing.

106. To the extent the Company determines that any reports of concerns should be provided to the Drug Enforcement Administration, Corporate Security works with the Director, Ethics and Compliance to get the proper forms/and or information to the DEA.

107. Corporate Security is also responsible for oversight and monitoring of supply chain security, spanning from when the Opioid alkaloid is shipped from overseas sources to the United States to when the finished Opioid Product is shipped from the Company's manufacturing site in Wilson, NC to the customer/distributor's warehouse.

108. The Monitor also reviewed the Company's policies and procedures relating to supply chain security, storage and access of controlled substances, corporate security, processing of product complaints, and training materials relating to some of these matters.

109. The undersigned has requested yet not yet received copies of all reports of concern from 2021 to the present. **The Monitor will report the findings from this review in the next Report.**

110. Subject to that review, the Monitor's review and analysis of the Corporate Security department found nothing inconsistent with the terms of the Injunction.

111. Additionally, as explained in the Ninth Report, the SOM team is working on a Requirements Document establishing when a downstream customer should be reviewed by Corporate Security for potential diversion. (Ninth Report, Paragraphs 19-20.)

112. As of the date of the filing of this Report, the undersigned has not received nor reviewed the Requirements Document.

C. Access to Blinded Downstream Customer 867 Data

113. In the Ninth Report, the Monitor detailed that the Company does not have visibility into downstream customer distribution for a portion of the Company's branded Opioid Products. Specifically, "[d]epending on the product and the month, Pearl determined 35 to 45 percent of the 867 package sales of the Company's branded Opioid Products were 'blinded' between 2018 and June 30, 2021, meaning the Company had no visibility into the product movement beyond the distributor level. Recently, the Company placed that estimate as between 33 and 37 percent." (Ninth Report, Paragraph 175.)

114. The lack of visibility into the Company's downstream movement of Branded Opioid Products is because "[f]our large pharmacy chains 'blind' their data, meaning that the manufacturer does not receive any information about the identity or location of the downstream customer that dispensed the Opioid Product to an end user." (Ninth Report, Paragraph 171.)

115. In the Ninth Report, the Monitor requested "that the Company endeavor to gain visibility into these transactions, including seeking to obtain the pharmacy chains' permission to have their 867 Data unblinded for SOM purposes," and "that the Company report to the Monitor

the process undertaken and success of these efforts within 30 days of the filing of this Report." (Ninth Report, Paragraphs 180-181.)

116. On June 29, 2022, the undersigned filed the Tenth Report. At that time, no agreement had been reached with any of the four pharmacy chains to provide Purdue Pharma blinded 867 data.

117. The Company has kept the Monitor apprised of the communications and exchanges with representatives of the pharmacy chains and, in one instance, the undersigned spoke directly with counsel for one of the pharmacy chains.

118. As noted in the Tenth Report, not all the pharmacy chains have been providing the 867 data to the Distributors. (Tenth Report, Paragraph 10.) In discussions with the Company, the pharmacy chains have expressed concerns about the 867 data being used for commercial purposes or purposes other than just Suspicious Order Monitoring. The chains have also expressed concerns about the security of and access to their 867 downstream customer data.

119. As of the filing of this Report, the status of negotiations with the four pharmacy chains regarding agreements for access to 867 data for SOM purposes is:

a. The Company and one pharmacy chain have entered into an agreement;

b. The Company and a second pharmacy chain are poised to enter into an agreement; and

c. With respect to the other two pharmacy chains, the Company has exchanged draft agreements and are engaged in good faith negotiations.

120. While the undersigned hoped for a more expeditious resolution of this issue, based on reports from the Company, the Monitor believes that both Purdue Pharma and the

pharmacy chains that have not yet signed are working in good faith to reach an agreement so that the Company can have access to the blinded 867 data for SOM purposes.

121. **The Monitor encourages the Company and the pharmacy chains that have not yet signed to work promptly and in good faith to reach agreements, so that the SOM team has access to the blinded downstream customer 867 data.**

122. **The Monitor requests that the Company report to the Monitor the actions undertaken and outcome of these further efforts within 30 days of the filing of this Eleventh Report.**

VII. INITIAL COVERED SACKLER PERSONS

123. The undersigned has received signed certifications from the Initial Covered Sackler Persons or their representatives certifying that they have not actively engaged in the Opioid business in the United States and have taken no action to interfere with Purdue Pharma's compliance with the Injunction.

The Undersigned Monitor respectfully submits this Eleventh Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor