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)**

TWELFTH MONITOR REPORT

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

EXECUTIVE SUMMARY

This Twelfth Monitor Report, and the undersigned's eighth 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 Report, 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 ELEVENTH REPORT

1. Since the filing of the Eleventh Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue Pharma including the: Vice President, Ethics and Compliance; Vice President, Legal Strategy and Public Health Initiatives; Vice President, Chief of Technical Operations; Head of Market Access; Head of Pricing; Director, Sales and Operation Planning; Director, Ethics and Compliance; Associate Director, Ethics and Compliance; and Manager, Ethics and Compliance. The undersigned has also had interviews with outside counsel of the Company concerning a regulatory issue.

2. Since the filing of the Eleventh 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.

ELEVENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Eleventh 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 that warrant further consideration in this Report included:

a. Reporting on the compensation structure of the field Market Access employees. (Eleventh Report, Paragraph 47.)

b. Additional review and analysis of research payments. (Eleventh Report, Paragraph 62.)

c. Update on GPO and MCO negotiations and amendments. (Eleventh Report, Paragraph 84.)

d. Review of the cost/benefit analysis for collecting the Medicaid claims details. (Eleventh Report, Paragraph 85.)

e. Review of the analysis regarding days' supply data and threshold validations. (Eleventh Report, Paragraph 85.)

f. Review and analysis of process for terminating distribution to certain downstream customers. (Eleventh Report, Paragraph 98.)

g. Review and analysis of reports of concern from 2021 to the present. (Eleventh Report, Paragraph 109.)

h. Review and analysis of a Requirements Document establishing when a downstream customer should be reviewed by Corporate Security for potential diversion. (Eleventh Report, Paragraph 111-112.)

i. Review and analysis of the Company obtaining unblinded 867 Data for Suspicious Order Monitoring purposes from pharmacy chains that blind the downstream data that Purdue Pharma receives. (Eleventh Report, Paragraph 121-122.)

DISCUSSION AND ANALYSIS

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

A. Field Market Access Employees Compensation Structure

5. In the Eleventh Report, the undersigned detailed the structure of salaries, bonuses, and incentives for Purdue Pharma's employees, and noted that an explanation of the compensation arrangements for field Market Access employees would be offered in this Report. (Eleventh Report, Paragraphs 32-47.)

6. The employees in the field Market Access team have a different compensation structure than the rest of the Company employees. (*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.)

7. In addition to reviewing pertinent documents, the undersigned also interviewed the Head of Market Access.

8. There are two Market Access employees that fall under the compensation program described in the last report: the Head of Market Access, who oversees the entire program, and an employee who performs contracting and analytics for the Company's larger customers.

9. There are three Market Access employees under the different compensation system. One employee is responsible for Trade and Distribution, principally interacting with the three largest wholesalers, Amerisource Bergen, Cardinal, and McKesson. The other two

employees are national account executives, working with smaller plans, healthcare plans, and Medicaid programs, principally ensuring product availability and negotiating fees.

10. One of the three field-based employees would have been eligible to participate in the Company's pre-bankruptcy Long Term Results Program ("LTRP"). Therefore, consistent with the treatment for all non-insider LTRP eligible employees, in 2022 this employee is eligible for a 2022 KERP Long Term Award. (*See* Eleventh Report, Paragraph 40.)

11. Over the last two years, two employees left the Market Access team, a Director of National Accounts and a third national account executive. The Company decided not to immediately replace the departing employees, and now all employees in the Department report directly to the Head of Market Access.

12. Unlike 2021, the compensation for Market Access employees contains no express component tied to product performance, as the Company is no longer promoting Adhansia XR. Instead of the 2021 plan component weighting of 50% individual goals, 25% corporate performance and 25% product performance, for 2022, the plan component weighting is 50% individual goals and 50% corporate performance.

13. The participants' individual annual target bonus dollar amounts are unchanged. Just as before, the individual goals are set out by role-specific Management By Objectives ("MBOs").

14. Two of three Market Access employees have individual objectives relating to OxyContin contracts and formulary position, and all three employees have individual objectives relating to the Public Health Initiatives.

15. Regarding OxyContin, individual market access objectives are not specifically based on top-line Opioid Product sales. Rather, the objectives are based on maintaining market

and formulary access while preserving an overall ratio of net profits as a percentage of every dollar of product sold. The actual ratio can vary among individual contracts, and the target is set as an overall corporate objective by the Commercial Department. In some instances, part of the individual objectives is to develop new relationships.

16. Some references in the MBOs that, while listed as a possible area for the field Market Access team to be evaluated on, are not used in evaluating the field Market Access team. This includes subjects like sales contests and project sprints. The Head of Market Access explained these as artifacts from earlier MBOs, and that the Company has kept the language in the documents to preserve flexibility, for example if Company opted to conduct sales contests for non-Opioid Products. He could not even recall when the Company last had a sales contest involving Opioid Products.

17. **Prior to finalizing the 2023 field Market Access team Individual Compensation Plan and MBOs, the Monitor recommends that the Company closely review the IC Plan and MBOs and remove objectives that are unlikely to be used in that year. The Company has agreed to this recommendation.**

18. Although being listed in a preferred position on a formulary certainly influences the availability and price of that product relative to other products or treatments and thereby the sales, even in those instances where a Market Access team could lose part of their incentive compensation to a change in formulary status, that loss is not directly "based on, or tied to sales volume or sales quotas for Opioid Products," as prohibited by the Injunction.

19. The undersigned Monitor finds that the incentive compensation program for the field Market Access team does not violate the Injunction.

B. Sales Team for Public Health Initiative Products

20. In the prior Report, the undersigned provided information on the promotional and sales activities for Nalmefene, a Public Health Initiative ("PHI") Product, undertaken by both Company employees and an outside contractor working on Purdue Pharma's behalf. (Eleventh Report, Paragraphs 9-31.)

21. While PHI products are expressly carved out of the prohibitions against promotional activities, there is nothing in the Injunction expressly permitting or prohibiting the Company from providing financial incentives to its sales and marketing team based on sales volume or sales quotas for PHI products. (Injunction, I.A.3(ii) and (iii); I.B.1. and 2.)

22. However, if the Company emerges from bankruptcy, it will be operating under a new injunction ("Operating Injunction"). The Operating Injunction prohibits financial incentives based on sales volume. (Operating Injunction, III.A.2.k(i) (Company shall not "[e]mploy or contract with sales representatives to detail PHI Products (i.e., through direct interaction, whether in-person or virtual, with individual prescribing or dispensing health care professionals or their staffs) who are compensated based on sales or volume of PHI Products").)

23. The undersigned requested and received information explaining the compensation structure for both the Purdue Pharma employees engaged in promoting and selling Nalmefene, and the contracted sales force.

24. Regarding the contracted sales force, the Contractor pays its employees a salary, and has bonus structures in place that are updated each quarter.

25. During the second quarter of 2022, 100% of the quarterly bonus for the Key Account Managers ("KAMs") was based on demonstrating core competencies for the initial team deployments. This included actively participating in training classes, passing product knowledge

assessments, and demonstrating competence in educating about disease awareness, products, and services with a customer, including proper use within compliant guidelines. The core competencies also included an assessment of the KAMs engagement with potential customers the KAMs called upon. The compensation was not based, however, on sales of Nalmefene.

26. For the third quarter, the KAMs were assessed on identifying key opportunity hospitals and starting to develop a plan for those hospitals. They were also assessed on executing a minimum number of calls and contacts with the hospitals each day or week. Again, however, compensation was not based on sales.

27. For the fourth quarter, 35% of the KAM's bonus is dependent upon having five or more individual hospitals that either purchase Nalmefene vials or have Nalmefene on their formulary by the end of the year. Accordingly, the KAM's compensation is based on sales of Nalmefene.

28. The Virtual Key Account Manager ("VKAM") had second quarter training and certification requirements like the KAMs, and in the third quarter was assessed principally on interactions with the hospitals, key HCPs within the hospitals, and the VKAM's interactions with the KAMs. For the fourth quarter, a portion of the VKAM's bonus is impacted by the number of hospitals called upon by the VKAM that either purchase Nalmefene vials or have Nalmefene on their formulary by the end of the year. Accordingly, the VKAM's compensation is also based on sales of Nalmefene.

29. Regarding Purdue Pharma field Market Access employees, for PHI products the individual objectives include entering into agreements with the major distributors for distribution of Nalmefene; working with the contracted KAMs to onboard and train them; introducing

Nalmefene to key GPOs; securing Nalmefene on formularies; and introducing Nalmefene to hospitals and HCPs.

30. Moreover, there is nothing in the MBOs nor the written evaluations conducted by the Head of Market Access of the individual Market Access employees that indicate any bonus decisions were made on sales volume of Nalmefene.

31. Given that no compensation decisions for the Company's internal sales force were made based upon the sales or failure to make sales of Nalmefene, the Monitor finds the compensation structure for the Company's employees consistent with the Injunction and the Operating Injunction**.**

32. Even though compensation decisions for the contracted sales forces will be made based upon the sales or failure to make sales of Nalmefene, the Monitor finds the compensation structure consistent with the Injunction. Purdue Pharma agrees that before the Operating Injunction becomes effective the bonus structure for the contracted sales force will be modified to delete any component based on sales of Nalmefene.

C. Purdue Pharma's Manufacturing and Procurement Quotas

33. Pursuant to the Federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and implementing regulations, the Drug Enforcement Administration ("DEA") sets aggregate manufacturing and procurement quotas for certain controlled substances, including Opioids. Upon application, the DEA then allocates individual manufacturing and procurement quotas to manufacturers. The DEA can revise a company's quota at any time during the year because of increased or decreased sales or exports, new manufacturers entering the market, new product development, or product recalls. (Sixth Report, Paragraph 24.)

34. The manufacturing quota is the maximum amount of a basic class of controlled substance, or Active Product Ingredient ("API"), that can be manufactured in any given year, unique to each DEA registered manufacturer. 21 CFR 1303.21(a). The procurement quota sets the quantity that an authorized manufacturer may procure and use of each basic class of substance for the purpose of manufacturing into finished dosage forms or other substances. 21 CFR 1303.12(a).

35. The Fifth and Sixth Reports detailed the Company's manufacturing and procurement quotas from 2018 to 2021. (Fifth Report, Paragraphs 75-84; Sixth Report, Paragraphs 24-47.) Because Purdue Pharma sold its manufacturing facility in Coventry, Rhode Island, the Company no longer requests manufacturing quota allotments from the DEA. (Sixth Report, Paragraphs 31-37.) Accordingly, the Company's requests for quota are for procurement of API.

36. The undersigned requested and received responsive documents and interviewed the Vice President, Chief of Technical Operations, and Director, Sales and Operation Planning.

37. In making a quota request, the Company gathers anticipated requirements for the upcoming year, taking into consideration:

a. Forecasts from the market analytics and forecasting group;

b. A snapshot of current inventory, and projections as to anticipated inventory at the end of the year;

c. Historical sales information, including dispositions through the current and prior year;

d. Whether the Company anticipates it has inventory that will expire during the coming year and whether they will have to destroy that inventory;

e. Whether the Company is bidding on or recently received new awards that could increase their market share; and

f. Any supporting data that would determine the upcoming needs for the upcoming year.

(Sixth Report, Paragraph 30.)

38. In addition to manufacturing for Purdue and Rhodes, the Company also manufactures oxycodone Opioid Products for Mundipharma and a fixed amount of annual authorized generic product for other companies. The sales to other companies are in fulfilment of settlements in patent ligation; to Mundipharma, it is a much more typical, ongoing commercial manufacturing-type agreement. In both instances, it continues to be less than 10 percent of the Company's manufacturing of oxycodone Opioid Product.

39. The requests for quota allotment for hydromorphone, oxycodone, morphine, and hydrocodone between 2022 and 2023 have all declined. The reasons for these declines include both projected inventories remaining at the end of this year, fluctuation in market share, and continuing decreasing demand for the Company's branded and generic Opioid Products.

40. Conversely, however, the quota requests all increased between what was granted in 2021 and what was requested in 2022. This does not necessarily suggest an increase in manufacturing of Opioid Products, as other factors can certainly come into play, including the necessity to destroy stale or dated API and trying to build up an inventory of API in stock. DEA regulations allow the Company to request quota that covers the projected demand and an allowable amount of inventory of up to 50% of the prior year's dispositions, though with oxycodone the DEA typically allows inventory of only around 30%.

41. The undersigned Monitor finds that there is nothing in the requested and granted procurement quotas contrary to the ban on promotion of Opioids and Opioid Products in the Injunction.

D. Educational and Information Mailings to HCPs

42. The Injunction sets forth in what manner the Company can contact or provide information to Health Care Providers. Most broadly, the Company cannot disseminate any information "that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses, and/or strengths of Opioid Products." (Injunction I.O.) The Company is expressly permitted to "[p]rovide scientific and/or medical information in response to an unsolicited request by a Health Care Provider concerning Opioid Products by providing truthful, balanced non-promotional scientific or medical information that is responsive to the specific request." (Injunction II.A.2.f.) In doing so, however, "[s]uch responses should be handled by medical or scientific personnel at the Company who are independent from the sales or marketing departments." (Id.)

43. Purdue Pharma's recently revised Code of Ethics provides that the Company "keeps HCPs informed of the approved uses, safety, indications, contraindications, side effects and characteristics" of its products, "including through mailings to healthcare professionals and approved educational and/or promotional materials."

44. The Monitor requested and received copies of all mailings and educational and/or promotional materials provided to HCPs relating to Opioid Products since entry of the Injunction. The Company produced 156 files from both Purdue and Rhodes, though many were emails attaching documents, thereby making the aggregate number of communications significantly less.

45. The communications include letters and emails to specific HCPs concerning: availability and backorder issues; product inserts; specific questions such as whether an Opioid Product has any animal-derived ingredients or gluten; listing of product ingredients; use of a specific product when undergoing certain medical procedures; requests for credits for missing patches; requests for sales representatives; inquiries regarding product shelf life and expiration; requests for educational materials/product handouts for patients; inquiries as to whether special DEA licenses are required for prescribing; concomitant use of a Company Opioid Product with other Opioid Products; insurance plans in a specific state covering a Company Opioid Product; inquiries about local vendors in other countries; dose conversions; a literature search regarding recommendations for Opioid tapering; the availability of a generic equivalent for a branded Opioid Product; requests to perform clinical studies; direct requests for products; storage of products; publication of clinical trials and requests to speak to an author of a research paper; proposed research proposals; and the cost of medication for patients.

46. All the outgoing communications from the Company to HCPs were from the Medical Information Department, and the Company has informed the undersigned that all were in response to specific inquiries from individual HCPs.

47. In reviewing each communication, the Monitor find that they are not promotional, were addressed by the Medical Information Department, and are consistent with the express terms of II.A.2.f of the Injunction.

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E. Social Media Policies

48. The Injunction has several provisions proscribing the Company's use of social media and Internet marketing. (Injunction, II.A.1.d. ("[c]reating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network and/or social or other media account for the Promotion of Opioids or Opioid Products"); II.A.1.f ("[c]reating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements"); II.C.3. ("[f]or the purposes of Promoting Opioids or Opioid Products, the Company shall not provide links to any Third Party website or materials or otherwise distribute materials created by a Third Party relating to any Opioids or Opioid Products").)

49. Earlier Reports have reviewed the websites and social media accounts of the Company to assess for consistency with the Injunction. (Fifth Report, Paragraphs 25-27.) The undersigned requested and received the Company's social media policies to further assess compliance.

50. The social media policy applies to all employees and officers of the Company, even if those employees are using social media for personal reasons or purposes unrelated to their employment. The policy also includes social networking, micro-blogging, content sharing and blogging.

51. The policy is not limited to affirmative postings or usage, and also places an obligation upon the employee to report to the Company if, through use of the Internet and/or other digital platforms, the employee observes misinformation about the Company or a product of the Company. The policy limits the ability of Company employees to like or share Company

posts or pages related to branded products, including Opioid Products, and further provides that employees cannot post any material identifying the Company or its products. The employees also cannot use a Company email address to register on any social network, blog or other online tool utilized for personal reasons.

52. The policy also provides general guidelines for those employees authorized to speak or write on behalf of the Company or Company brands. All social medical activities on behalf of Purdue are subject to review and approval by the Medical Services, Regulatory Affairs and Law Departments.

53. For official usage and posting, the policy expressly states that creation of a social media account and/or profile page must comply with all relevant Purdue standard operating procedures and guidelines, including but not limited to Reporting of Adverse Events and Product Complaints; Material Review Process; Privacy Policy; and Confidential and Proprietary Information guidelines.

54. The seven-page social media policy does not include any reference to the restrictions on promotion or any other facet of the Injunction. However, given that employees not involved in content promotion are prohibited from posting information identifying the Company or its products, and there are levels of review for any authorized posting, the Monitor finds that including reference to the Injunction and its terms in the social media policy is unnecessary.

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F. Review of Standard Operating Procedures

55. In the Eighth Report, the Monitor undertook a more comprehensive review of Standard Operating Procedures that in any way involve Opioid Products, recommending that certain SOPs be revisited and that the Company review the entirety of the SOPs and corporate policies relating to Opioids and incorporate the requirements of the Injunction where appropriate. (Eighth Report, Paragraphs 53-63.)

56. The Company has recently provided the Monitor with the following revised SOPs: Process and Guidance for Providing Meals to Healthcare Professionals; Process for Fulfillment of Unsolicited Requests; and Customer Vetting Process.

57. The Monitor is still reviewing these SOPs and intends to seek interviews of certain Company employees, so will include review and analysis in the next Report.

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

A. 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) Opioid Reversal Advisory Board

59. As noted in the last Report, in 2021 there were 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. (Eleventh Report, Paragraph 61.)

60. The undersigned requested and received information regarding this advisory board. The materials provided suggest the Board was convened to gain insights and knowledge

on current overdose trends, protocols, and processes in the Board-member institutions for treating Opioid overdose, and management of patients following Opioid overdose reversal. The Opioid Reversal Advisory Board was also tasked with providing counsel on opportunities, processes, and potential hurdles in reintroducing a Nalmefene injection into healthcare settings

61. The undersigned Monitor finds these activities consistent with the terms of the Injunction. Generally, the Injunction permits the Company to engage HCPs "to assist the Company in responding to, preparing for, and participating in, any initiatives, advisory committees, working groups, action plans, boards, [and] meetings…." (Injunction, II.A.2.d.). Moreover, even if the Advisory Board was construed as promotional, the Injunction does not restrict the Company from promoting rescue medicines for Opioid overdose. (Injunction, II.A.4.(iii).)

2) Additional Payments Relating to Opioid Products

62. As noted in the last Report, the Company was still in the process of compiling and providing any materials that might exist concerning research payments related to Opioid Products. (Eleventh Report, Paragraph 62.)

63. The Company has now provided the undersigned information about additional expenditures in 2019 and 2021 relating to Opioid Products. The Company reported additional expenditures of $17,437.85 in 2019 and $38,847.43 in 2021, paid principally to university-based research hospitals or healthcare centers.

64. The expenditures relate to a number of post-marketing studies the FDA required of Opioid manufacturers in 2013 regarding extended-release/long-acting Opioids, specifically attempting to better understand: the risks of abuse, addiction, overdose, death and misuse among patients with chronic pain; predictors of those risks; validated proxies for Opioid abuse and

addiction, such as doctor or pharmacy shopping; and the risk of hyperalgesia (abnormally heightened sensitivity to pain) relative to efficacy following long-term use. Rather than each company individually conducting the studies, with the FDA's encouragement, 13 companies are collaborating through a consortium, the Opioid PMR Consortium ("OPC"). *See generally, Postmarketing studies program to assess the risks and benefits of long-term use of extend-release/long-acting opioids among chronic pain patients,* Postgraduate Medicine, Vol. 132, No. 1, pp. 44-51 (2020) (https://www.tandfonline.com/doi/pdf/10.1080/00325481.2019.1685793).

65. While the Injunction does not expressly carve out FDA post-marketing studies, the Monitor finds that these expenditures are consistent with its terms. The studies could not reasonably be construed as promotional and are required by the FDA.

B. Review of Opioid Products Contracts and Agreements.

66. 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.

67. Recommendations included making a good-faith effort to negotiate certain provisions in the Group Purchasing and Managed Care Organizations' contracts, and keeping the Monitor apprised of those efforts. (Ninth Report, Paragraphs 123, 131, 141.)

68. Over the last several months, the Company has successfully negotiated the inclusion of these provisions in three Managed Care Organizations' contracts. While the Company has also negotiated extensions of existing contracts with two Group Purchasing Organizations, there was no need to revise those specific agreements based upon the Ninth Report.

69. The Company also provided a cost/benefit analysis for collecting Medicaid claims details and an analysis regarding days' supply data and threshold validations, and presented that information to the Monitor and the Monitor's consultant. The undersigned has not yet reached any conclusions regarding this analysis, so will report further in the next Report.

III. LOBBYING RESTRICTIONS

70. Since the filing of the Ninth Report, the Monitor has reviewed 21 quarterly reports reflecting the actions of contracted firms at the state level and three at the federal level, covering the period from July 1 to August 31, 2022.

71. In all instances, the state and federal contracted firms only monitored legislation and legislative, executive, and administrative activities, even in instances where the legislation involved matters like access to Opioid agonists.

72. The Monitor also reviewed one report filed by the Company with the Clerk of the U.S. House and Secretary of the Senate lobbying activities for calendar year 2022, reporting that the Company had expenditures for lobbying through the Company's Executive Director for Government Affairs. The Company disclosed that the lobbying was for "[m]onitor[ing] Congressional activity relating to Medicare, Medicaid, PDUFA, public health, mental health and substance use disorder treatment."

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

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IV. BAN ON HIGH DOSE OPIOIDS

74. 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).

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

V. SUSPICIOUS ORDER MONITORING AND REPORTING

A. Access to Blinded Downstream Customer 867 Data

76. 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.)

77. The lack of visibility into the Company's downstream movement of branded Opioid Products was 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.)

78. In the Ninth Report, the Monitor recommended "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.)

79. 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.

80. In discussions with the Company, the Company has represented to the Monitor that pharmacy chains have expressed concerns about the 867 data being used for commercial purposes or other purposes than just suspicious order monitoring. The chains have also expressed concerns about the security of and access to their 867 downstream customer data.

81. As of the filing of this Report, the Company has entered into an agreement with two of the pharmacy chains for access to their 867 data for SOM purposes. The information from one of the chains is currently being provided to Purdue Pharma for SOM purposes. That data is analyzed through Purdue Pharma's Due Diligence Plus system, along with other data sources that have been consistently used for suspicious order monitoring.

82. The Company is still working with Walmart, the other pharmacy chain that has agreed to share unblinded 867 data, its principal distributor and IQVIA, to determine how to get the Company's SOM team access to the unblinded 867 data while ensuring that this data cannot also be accessed by Purdue Pharma's Commercial Department.

83. **If the Company cannot come up with a satisfactory technical solution in the next two months to obtain the data, the Monitor recommends that the Company request the unblinded 867 data in spreadsheet format, and perform a manual review until the time the data can be incorporated into the SOM system. The Company has agreed to this recommendation.**

84. Regarding the remaining two pharmacy chains, CVS and Rite Aid, almost seven months after first requesting the unblinded data, it is the Monitor's sense that the Company has reached an impasse in negotiations.

85. Regarding CVS, the Company has represented to the Monitor that the parties have been consistently communicating and working in good faith to reach an agreement. However, as a general matter, while CVS is amenable to providing the unblinded 867 data to Purdue Pharma, and allowing the undersigned access, CVS appears to be concerned about third parties potentially gaining access to its unblinded 867 data through Purdue Pharma.

86. Under the Injunction and the Operating Injunction, if an Attorney General or other law enforcement agency requested this data from Purdue Pharma, it is the undersigned's judgment that the Company would have to provide the CVS data to the requesting law enforcement agency.[2]

[2] *See* Voluntary Injunction, Section II.G.2 ("Upon request, the Company shall promptly provide reasonable assistance to law enforcement investigations of potential diversion and/or suspicious circumstances involving the Company's Opioid Products subject to, and without waiving, any applicable privilege objections."). *See also* Operating Injunction, Sections II.F.2.e ("Utilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product, including, but not limited to: a monthly review of Downstream Customer Data; review of Downstream Customer Data to identify downstream customers that consistently have a large volume of chargebacks meriting further investigation; the establishment of objective methods for identifying chargeback units that merit further review; and the review of chargeback reports to identify downstream customers that have higher chargebacks on a repeat basis. If chargeback data reveals suspicious indicia (e.g., the number or frequency of chargebacks), the Company shall investigate further. To the extent the inquiry does not resolve the concern, the Company shall report the identity of the downstream customer to DEA and to the relevant direct customers."); II.F.2.g ("Upon request (unless otherwise required by law), report to any requesting State Attorney General or State controlled substances regulatory agency or Department of Justice component any direct customer or downstream customer in such requesting State Attorney General's or agency's State identified as part of the monitoring required by Sections III.F.2(a)-(f), and any customer relationship in such State terminated by the Company relating to diversion or potential for diversion. DEA will be notified of all Suspicious Orders. Additionally, rejected order information will be shared with DEA in compliance with governing statutes and regulations. These reports shall include the

87. Purdue Pharma has represented to the Monitor that it has proposed several avenues to CVS to try to mitigate these concerns, but these avenues have not been successful.

88. Regarding Rite Aid, the Company has represented to the Monitor that the parties have not reached a point where there have been meaningful negotiations.

89. **As CVS and Rite Aid appear unwilling to provide Purdue Pharma unblinded 867 data given the proscriptions of the Voluntary Injunction and, likely, the Operating Injunction, the Monitor is at a loss of what additional requests or recommendations of the Company the undersigned can make.**

90. **The Monitor would underscore that, while this issue has been daylighted because Purdue Pharma is operating under an Injunction and with a Monitor, this is not a problem in any way limited to Purdue Pharma. Any manufacturer of Opioid Products that cannot gain access to unblinded 867 data from the pharmacy chains for SOM purposes is necessarily operating a suspicious order monitoring program that lacks visibility into the downstream movement of what can be a significant amount of that manufacturer's Opioid Products. And, even if Purdue Pharma was to gain access to unblinded 867 data, it would only be for the downstream movement of Purdue Pharma's products, not all Opioid Products. Hence, the problem is industry wide and in no way limited to Purdue Pharma.**

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following information, to the extent known to the Company."); II.F.6 ("Upon request, the Company shall provide full cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products, including criminal law enforcement agencies, drug control agencies, professional licensing boards, and Attorney General's offices. For the avoidance of doubt, the Company must provide full cooperation to DEA and any component of the Department of Justice."); and III.F.2.h ("Purdue is obligated to "retain record copies of documentation associated with Sections III.F.2(a)-(g), and make such documentation available to any federal, state, or local law enforcement agency upon request.").

91. **The Monitor commends Walmart and the other pharmacy chain that worked with Purdue Pharma to provide access to unblinded 867 data for SOM purposes, and encourages CVS and Rite Aid to redouble their efforts to find a satisfactory solution.**

B. Restricting Supply of Company Opioid Products to Downstream Customers

92. 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; Eleventh Report, Paragraphs 96-98.)

93. The Director of Ethics and Compliance informed the undersigned that they anticipate that the Company's vendor will report provide the Company a draft of the SOP in the upcoming weeks and that the Company should have a product that they can use soon.

94. **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.**

C. Distributor Site Visits

95. In total this year, eleven site visits have occurred, with one more scheduled for 2022. These visits are consistent with the recommendations of the Sixth Report, committing to visit each distributor at least once every three years. (Sixth Report, Paragraphs 167-171.)

96. Additionally, the Associate Director of Ethics and Compliance reported that, for all new customers, the SOM team will have an onsite site visit of the new distributor within six months of the new customer relationship. This further enhances the Company's commitment to have a virtual site visit of all new distributor-customers prior to filling any orders for the

Company's Opioid Products. (*See* Fifth Report, Paragraph 164.). As a result, new customers will not have a three-year delay prior to the first onsite visit.

97. The first four site visits of the year, in March and April of 2022, were all virtual. (Ninth Report, Paragraph 197.)

98. The SOM conducted seven site visits in June through October of 2022. Five were in person visits, while two were virtual.

99. In three of the visits in June through October, the SOM team made recommendations to the distributor on how to improve their processes, including: additional monitoring cameras; additional training; resources for conducting additional due diligence of downstream customers; and establishing a two-person rule for being in the vault where the Opioid Products are stored.

100. Separate from the site visits, it was brought to the Monitor's attention that a member of the sales team of one of the Company's distributors was contacting pharmacies, stating that "[t]here was a lawsuit with the 3 big wholesalers, which will create a setback for ordering control medication. [The Distributor] is a secondary wholesaler, with no contracts! we can help you with getting medications!" The distributor sales team member also provided links to the three distributors' websites, which referenced their national settlement and injunction.

101. During a previously scheduled site visit to that the distributor, the Director and Associate Director of Ethics and Compliance brought this sales communication to the attention of the distributor's CEO, who stated that he was embarrassed, understood how the email could be perceived, and was unaware of and did not condone the use of that sales language.

102. As a result, Purdue Pharma's site visit report details that the distributor committed to retraining all its sales personnel and implementing email templates and key word monitoring of sales-related email accounts.

103. The Undersigned is satisfied that Purdue Pharma took the concerns raised by the Monitor seriously, and because of the Company's actions, the distributor is taking corrective actions.

104. **The Monitor recommends that, over this next quarter, the Company confirm that the distributor has implemented the corrective actions. The Company agrees to this recommendation.**

D. Reporting of Orders of Interest or Customers of Interest to the Distributor and Drug Enforcement Administration

1) Distributor Orders of Interest

105. In the Sixth Report, the Company agreed to reporting all orders of interest to the distributor and the DEA. (Sixth Report, Paragraphs 147.) The undersigned has since been reporting the number of orders reported to the DEA and the Distributor. (Seventh Report, Paragraph 149; Eighth Report, Paragraphs 74-75.)

106. During calendar year 2021, there were 13,158 orders fulfilled by the Company to Distributors. Of those, 2,071 orders pended and were reported to the DEA, and 51 orders were rejected by the Company. (Eighth Report, Paragraph 74.)

107. From January through September 2022, there have been 9,315 orders fulfilled by the Company to Distributors. Of those, 1,507 orders pended and were reported to the DEA and Distributor, and 19 orders have been rejected by the Company.

108. The percentage of pended orders has slightly increased this calendar year with 15.7% of all orders pended and reported in 2021, and 16.2% of orders through September of this year.

109. The Director of Ethics and Compliance conveyed that he has not received any pushback from the DEA as to the increased quantity of pended orders being reported and has fielded occasional calls from DEA diversion investigators in individual field offices inquiring about some of the outlier reports concerning downstream customers of interest or concern. `

2) Downstream Customers of Interest

110. To date, the undersigned Monitor has received and reviewed Outlier reports through August 2022. There have been 58 outliers this year reported to the DEA and the downstream customer's distributor. Downstream customers are reported more frequently based upon 867 data than chargebacks, and typically include additional areas of concern including prior disciplinary history, concerning customer reviews, and/or receiving Opioid Products from multiple suppliers.

111. As explained in the Fifth Report, the SOM team analyzes 15 different factors in determining whether a downstream customer should be identified as an outlier. (Fifth Report, 199-202.) Since that Report, the SOM team has added additional data sources and factors for evaluation: (i) nearby addiction treatment facilities and behavioral health centers; (ii) nearby schools and colleges for stimulant products; (iii) CDC Opioid dispensing statistics; (iv) city and country drug crime rates; (v) the Department of Health and Human Services Office of Inspector General Exclusion Database; and (vi) the DEA's Automated Reports and Consolidated Ordering System ("ARCOS") All Buyers Statistics database.

112. The ARCOS database is a comprehensive drug reporting system which monitors the flow of controlled substances from their point of manufacture through commercial distribution channels to point of sale at the retail dispensing level. While initially created to give state and federal investigators information to assess for diversion, in 2018 Congress passed a measure permitting manufacturers and distributors the ability to view and download the number of distributors and amount each distributor sold to a downstream customer in the last available six months of data. As explained by the DEA in announcing the enhancement, "This new tool will provide valuable information for the distributors to consider as part of their assessment." (**https://www.dea.gov/press-releases/2019/02/26/dea-announces-enhanced-tool-registered-drug-manufacturers-and**).

113. While the database is rather unwieldy, the Company worked with its Information Technology Department to create a searchable program by individual pharmacy. Now, the Company can review a rolling six-month history of the pharmacy's distribution of Opioid Products by drug family, providing insight beyond just the distribution of the Company's Opioid Products. It provides another tool the Company can employ when reviewing downstream customers of concern.

114. The Monitor commends the Company for continuing to find new sources of data to analyze and use in reviewing downstream customers of concern.

E. Review of Product Complaints by Corporate Security

115. In the Eleventh Report, the undersigned provided an overview of the Corporate Security functions, and in the Ninth Report noted that the Company was working on a Requirements Document detailing when a product complaint would trigger further review by Corporate Security. (Eleventh Report, Paragraphs 99-112; Ninth Report, Paragraphs 19-21.)

116. The Monitor has received and reviewed the Requirements Document. It identifies complaint categories of: (a) short count, meaning less than the stated amount of product listed on the label; (b) foreign product, which includes incorrect product, more than one product in a package, and instances when the reported product color is different than expected; (c) indicia, meaning missing or illegible imprinting or embossing on the prescription or the product; and (d) Other, which encompasses counterfeit or non-Purdue product.

117. The Document details that Corporate Security will review a complaint about a product short count whenever there are five or more missing tablets or capsules in a rolling three-month period from the same reporter; three or more buprenorphine patches missing in a rolling three-month period or two or more missing in a single complaint; and for blister packages, five or more empty cavities or one or more blister cards in a rolling three-month period from the same reporter or facility.

118. For foreign product and indicia complaints, Corporate Security will review whenever there is more than one complaint from the same reporter or facility during a rolling three-month period.

119. And, if a complaint involves counterfeit or non-Purdue products, those complaints will be referred to the DEA.

120. The undersigned commends the Company, both for setting forth clear guidelines when a product complaint warrants greater scrutiny, and for ensuring that the complaints are reviewed on a rolling basis, to ensure that a complete picture can be formed from what could otherwise be construed as isolated complaints.

VI. INITIAL COVERED SACKLER PERSONS

121. The undersigned has requested but not yet received all 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. Upon receipt, the Monitor will supplement this Report if any issues arise.

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

STEPHEN C. BULLOCK
Monitor