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)**

THIRTEENTH 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 Thirteenth Monitor Report, and the undersigned's ninth 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 prior 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 effort to comply with the terms and conditions of the Injunction, and the Company has been

[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.

generally responsive in fulfilling the Monitor's requests for information, documents, and interviews with Purdue Pharma employees.

INTRODUCTION – STEPS TAKEN SINCE TWELFTH REPORT

1. Since the filing of the Twelfth Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue Pharma including the: Vice President, Ethics & Compliance; Vice President, Legal Strategy and Public Health Initiatives; Associate General Counsel; Vice President, Medical Affairs; Director, Ethics & Compliance; and Associate Director, Ethics & Compliance. The undersigned has also had discussion with outside counsel for the Company concerning use of Protected Health Information.

2. Since the filing of the Twelfth 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.

TWELFTH AND ELEVENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Twelfth Report, multiple recommendations and areas of inquiry were identified. The Company agreed to all recommendations made. The recommendations and areas of inquiry that warrant further consideration in this Report included:

a. Review and analysis of recently revised SOPs, including Process and Guidance for Providing Meals to Healthcare Professionals; Process for Fulfillment of Unsolicited Requests; and Customer Vetting Process. (Twelfth Report, Paragraph 56-57.)

b. Obtaining access for the Company's Suspicious Order Monitoring ("SOM") team to the unblinded 867 data of an identified pharmacy chain, while ensuring that this

data cannot also be accessed by Purdue Pharma's Commercial Department. Or, alternatively, if the Company cannot come up with a satisfactory technical solution in the next two months to obtain the data, 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. (Twelfth Report, Paragraph 82-83.)

c. The continuing recommendation 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; Twelfth Report, Paragraph 92-94.)

d. Following up with one of the Company's customers to ensure that the customer's sales team is not improperly promoting controlled substances. (Twelfth Report, Paragraphs 100-104.)

4. Moreover, outstanding recommendations from the Eleventh Report include:

a. Update on Group Purchasing Organizations ("GPO") and Managed Care Organizations ("MCO") contract negotiations and amendments. (Eleventh Report, Paragraph 84.)

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

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

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

DISCUSSION AND ANALYSIS

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

A. Review of Standard Operating Procedures

5. In the Eighth Report, the Monitor undertook a more comprehensive review of Standard Operating Procedures ("SOPs") 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.)

6. The Company had provided the Monitor with the following revised SOPs prior to the filing of the last Report: Process for Fulfillment of Unsolicited Requests for Clinical Product Presentations; Customer Vetting Process; and Process and Guidance for Providing Meals to Healthcare Professionals ("HCPs"). A review of two of those SOPs follow; the undersigned has not yet undertaken analysis of the SOP relating to providing meals to HCPs.

Process for Fulfillment of Unsolicited Requests for Clinical Product Presentations (MA-MS-SOP-0000070)

7. This SOP sets forth the process for receiving and documenting unsolicited requests for Clinical Product Presentations ("CPP"), as well as the process for allowing such presentations. The SOP was updated in response to the Monitor's request that Company review relevant SOPs to ensure recognition of and conformity with the Injunction.

8. The undersigned reviewed the SOP, materials prepared by the Company in response to questions asked by the undersigned about the SOP, and interviewed the Company's Vice President, Medical Affairs.

9. A CPP is a clinical presentation, including oral testimony, on one of the Company's products presented upon unsolicited request. Typically, requests are made by Healthcare Professionals, MCOs, integrated delivery networks, state government agencies, or other formulary or Pharmacy and Therapeutics Committees, for the purposes of making decisions about safe and/or appropriate utilization, or placing the Company's products on formularies.

10. The SOP prescribes the departments in the Company involved in assessing the request, the determination whether a custom or standard presentation will meet the requestor's needs, who is permitted to provide the presentation, retention of the presentations, and documentation of interaction during the presentation, including questions received and answered.

11. Since the Injunction went into effect, the Company has only received one unsolicited request for a CPP regarding Opioids. The request came from a hospital pharmacy administrator, seeking a general presentation on pain management guidelines and alternatives to treatment with Opioids. The request was denied, and the requestor was counseled that if a pharmacist or nurse has a specific question about Purdue Pharma's products, they could call the Company's Medical Information Department.

12. Accordingly, no presentations have been provided, no consultants have been retained to deliver presentations, and there are no standard nor custom Clinical Product Presentations relating to Opioid Products since entry of the Injunction.

13. The Monitor finds that the SOP and the practices employed under the terms of SOP are consistent with the terms of the Injunction.

Customer Vetting Process (CC-SOP-000022)

14. The purpose of the Customer Vetting Process SOP is "to ensure that prior to proactively engaging a healthcare professional ('HCP') or pharmacy (collectively 'Customer') in any capacity (e.g., under contract, as the result of a proactive interaction), Purdue and its subsidiary companies (the 'Company') will perform certain due diligence to ensure that interacting with the customer is appropriate." It applies to all Company employees, as well as vendors that are interacting with Customers on the Company's behalf ("Vendor").

15. The SOP provides for two levels of vetting. The level most often used is an automated process. This process screens an HCP's license status or if the HCP has otherwise been flagged as a "No Contact Customer" by the Company.

16. Prior to engaging with an HCP or pharmacy, the SOP requires that the Company employee or Vendor check to see if the potential customer has been flagged on the No Contact Customer list. For those employees lacking direct access to the automated system, the SOP requires that the employee first contact Ethics & Compliance. Outside Vendors are advised on a weekly basis of potential customers who have been flagged and are instructed to cease any attempt to interact with the potential customer.

17. There are instances when an employee or Vendor might not have prior knowledge of all HCPs attending a meeting or event. When the name of the HCP or pharmacy is entered for review thereafter, if the individual has previously been flagged, the automated system immediately sends a notification to certain employee or Vendors, with a copy to their managers and to the Ethics & Compliance Department.

18. The email notification provides that a response detailing the circumstances of the contact must be completed within 48 hours of receiving the notice. The Law and Ethics & Compliance Departments will review the circumstances surrounding the inadvertent contact, and address remedial actions to eliminate future interactions.

19. When the Company was selling Adhansia, a non-Opioid, controlled substance product, the Company would also undertake a manual vetting of each HCP with whom it intended to interact for a commercial purpose. The manual process is also undertaken if the Company intends to enter into any sort of contractual relationship with an HCP. The manual process includes a public records and more extensive sanctions review, covering at least three years.

20. Upon flagging a potential Customer, that Customer is also reported to the Drug Enforcement Administration. The report to the DEA informs the agency that Purdue Pharma will have no further contact with the Customer, and includes the Customer's name, address, and DEA number. The notification does not include the reason for flagging the Customer, although the Company provides that information in instances where the DEA contacts the Company.

21. A decision to flag a Customer is permanent and cannot be changed.

22. Separately, the American Medical Association ("AMA") also has an "AMA No Contact List." This list is analogous to the Federal Trade Commission's "Do Not Call Registry," and prohibits nonpersonal promotion: marketing to the physician via mail, telephone, or facsimile. It does not prohibit in person interaction, however.

23. Only recently, the Company has returned to doing nonpersonal promotion; now, for Public Health Initiative products.

24. The SOP was recently updated to reflect changes in Company business practices. The decision to no longer market and sell Adhansia eliminated the need to do manual vetting of HCPs on a regular basis. Other changes included shifting responsibility for the automated and manual processes from the Commercial to the Information Technology Departments, and shifting the public records review responsibilities from Law to Ethics & Compliance.

25. The Monitor finds the Customer Vetting Process and SOP to be well thought out and consistent with the terms of the Injunction.

26. In providing a summary of this SOP, the undersigned omitted more granular details about the licensing statuses that create a flag, the factors considered in manual vetting and flagging a Customer, and internal processes for flagging as a No Contact Customer. These omissions are at the Company's request, due to the sensitivity of the matters involved; while the Monitor could file portions of this Report under seal, the Monitor believes that the above description provides adequate detail to inform about the undersigned's conclusion that the SOP is consistent with the Injunction.

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

A. Review of Opioid Products Contracts and Agreements

27. 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.

28. Recommendations included making a good-faith effort to negotiate certain provisions relating to carve-outs for Opioid Products from sales-based payments in its distributor

GPO contracts and inclusion of prescription-level data in its MCO contracts, and keeping the Monitor apprised of those efforts. (Ninth Report, Paragraphs 123, 131, 141.)

29. As of the date of the filing of this Report, the Company has successfully negotiated the recommended changes in all but three of the managed care rebate agreements. One of the three remaining agreements has been negotiated to reflect the recommendations but has not yet been executed. The remaining two contracts have not yet come up for renewal.

30. Regarding the recommendation to remove failure-to-supply penalties in the distributor GPO agreements, there are only three contracts remaining that include this provision. One of the distributors has indicated it will agree to the change, but the new contract has not yet been signed. One of the distributors has so far rejected the Company's request to remove the failure to supply clause; however, the negotiations over this provision have been escalated to the legal departments of the Company and the distributor. As to the third, the Company has only recently begun negotiations for a new agreement.

31. The Monitor commends the Company for its diligence in fulfilling these recommendations.

B. Exclusion of Duplicate Claims in Managed Care Contracts

32. In the Ninth Report, the undersigned noted that the Company's "managed care contracts are in line with standard industry practices." (Ninth Report, Paragraph 127.) The Report noted, however, that not all contracts have express language regarding what government utilization could be excluded from payment as duplicate claims, and further recommended that "the Company prepare a presentation of 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 128, 133.)

33. The Company prepared the recommended analysis, detailing the percentage of Medicaid claims level detail validated, the amounts recovered through identifying and disputing claims brought to the Company's attention through the validation, and the costs incurred by the Company in undertaking the validation. Representatives of the Company also met with the Monitor and the undersigned's Pricing consultant to further explain the analysis.

34. The Monitor is satisfied that, even if it might be a sound business practice to make the review and dispute of Medicaid claims more robust, the decision not to do so does not violate the terms of the Injunction.

III. LOBBYING RESTRICTIONS

35. Since the filing of the Twelfth Report, the Monitor has reviewed 20 quarterly reports reflecting the actions of contracted firms at the state level and two at the federal level, covering the period from September 1 to December 31, 2022.

36. 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.

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

IV. BAN ON HIGH DOSE OPIOIDS

38. 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).

39. 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

40. In the Ninth Report, filed nine months ago, 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.)

41. The Twelfth Report detailed the Company's efforts to gain visibility into the Opioid Product movement beyond the distributor level, by working with four large pharmacy chains that blind their data. At the time of the filing of that Report, two of the pharmacy chains had entered into agreements with the Company to share their 867 product movement data for SOM purposes, and negotiations with the other two pharmacy chains had reached an impasse. (Twelfth Report, Paragraphs 76-91.)

42. Since the filing of the Twelfth Report, and notwithstanding the Company reaching out to the two pharmacy chains that did not enter into an agreement, no further progress has been made with respect to those two pharmacy chains.

43. The prior Report also detailed that "[t]he 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," and recommended that "if the Company cannot come up with a satisfactory technical solution in the next two months to obtain the data, . . . 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." (Twelfth Report, Paragraphs 82-83.)

44. Approximately one month into this reporting period, the Company informed the undersigned that the pharmacy chain's distributor could not provide unblinded 867 data for SOM purposes in spreadsheet format because no such spreadsheets exist, and the distributor would have to code new programs to generate and report this data. At the time, however, the Company was anticipating it would have access to the unblinded 867 data by early January 2023.

45. In mid-January, in response the undersigned's inquiry, the Company informed the Monitor that, while the data had not yet been transferred from the distributor, the Company's vendor expected to soon receive a test file of the 867 data and, unless problems arose, the vendor would be able to incorporate the unblinded data into the Company's SOM system in a day. At the time, the Monitor requested that, if no further progress was made during the following couple of weeks, the Law Department elevate the issue to Walmart.

46. Last week, the Monitor again inquired about the status of access to the unblinded 867 data for SOM purposes. The Director of Ethics & Compliance reported that, despite several calls to the distributor even over that past week, the distributor was not committing to a date when the test file would be transmitted.

47. The Monitor renewed the request last week to the Law Department to escalate the issue. The Vice President, Legal Strategy and Public Health Initiatives, emailed Walmart's counsel in response to the request.

48. **The Monitor recommends that the Company place greater urgency on resolving this issue so that the Company has visibility for SOM purposes into the product movement of more of its branded Opioid Products.**

B. Atypical/Excessive Quantity Thresholds

49. In the Ninth Report, the undersigned explained that, while the Company's contracts in the context of rebate validations set thresholds for identifying keystroke errors, these "thresholds used in contract operations to exclude claims for prescriptions of excessively large quantities of Opioids from rebate payment do not take into account product strength (OxyContin, Hysingla and Butrans) or days' supply (OxyContin, Hysingla)." (Ninth Report, Paragraphs 134-137.) The Company agreed to conduct additional analysis on the issue, as well as explore possible approaches to implement a threshold based on MME and/or MME/day. (Ninth Report, Paragraph 138.)

50. Since then, the Company has been working in good faith with the Monitor, the Monitor's pricing and SOM consultants, as well as the Company's outside counsel to determine if a reasonable threshold could be set and/or seemingly excessive or high dose prescriptions could undertake further review for Suspicious Order Monitoring purposes.

51. There are a limited number of prescriptions filled about which the Company is aware through the rebate process that facially appear incredibly high and that would likely be a red flag of diversion in the SOM context. As an illustration, prescriptions are filled where a patient is receiving a 30-day supply of 10 to 15 80 mg oxycodone tablets for each day. The

prescription may well be entirely appropriate. However, just as the SOM team further examines downstream customer orders exceeding typical ordering thresholds, as of now there are no mechanisms for the SOM team to learn about or further assess the downstream customers dispensing these high-dose prescriptions.

52. Understandably, and notwithstanding the fact many States and plans set thresholds, the Company is reluctant to step into the shoes of a State or HCP in attempting to set threshold prescription limits. Moreover, even where the Company is aware of seemingly high-dose prescriptions through the rebate process, that information cannot be used for Suspicious Order Monitoring purposes due to contractual limitations on the use of that data stemming from the Health Insurance Portability and Accountability Act ("HIPAA").

53. Specifically, Pharmacy Benefit Managers ("PBMs") receive Protected Health Information ("PHI") subject to a HIPAA Business Associate Agreement with health plans, for the specific purpose of providing formulary management services for the health plans. (45 CFR 164.502(e), 164.504(e), 164.532(d)-(e).) The HIPAA payment purposes exception permits the disclosure of PHI to manufacturers for purposes of validating drug rebate contracts. (45 CFR 164.502(a)(1)(ii).) The Company reports that the PBMs have thus contractually restricted Purdue to this limited purpose since Purdue is not otherwise subject to HIPAA; PBMs are not in a position to grant Purdue data use permissions that are broader than what the PBMs are permitted to do with the PHI, and therefore would not be in a position to grant permission for SOMs purposes.

54. **The Monitor is satisfied that the Company is working in good faith to try to develop an acceptable process for further examination of downstream customers**

dispensing high-dose prescriptions, and will report additional actions taken in the next Report.

C. Restricting Supply of Company Opioid Products to Downstream Customers

55. In the Eighth Report, filed with the Court in February 2022, 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; Twelfth Report, Paragraphs 92-94.)

56. The undersigned also noted that "it is the Monitor's understanding that the Company has [already] been considering what measures could be taken to limit the supply of Opioid Products to certain downstream customers." (Eighth Report, Paragraph 81.)

57. In that Report, the Monitor provided a brief explanation of what another manufacturer is doing to restrict supplying its Opioid products to pharmacies that are considered by that manufacturer to represent a continuing or heightened risk of concern. (Eighth Report, Paragraphs 84-85.) The Report noted that, in addition to no longer processing chargebacks relating to the higher risk downstream customer of concern, the other manufacturer was "proposing a letter agreement to its direct customers, beginning with the largest three distributors, requiring them to agree to, among other things, suspend or terminate the distribution of controlled substances to any recipient that the company informs the distributor it is restricting." (Eighth Report, Paragraphs 84-85.)

58. The Monitor has now received and reviewed the proposed SOP and related materials for fulfilling this recommendation. In addition to reviewing the SOP, the undersigned has had interviews with the Vice President, Legal Strategy and Public Health Initiatives; Vice

President, Ethics & Compliance; Associate General Counsel responsible for Contracting; Director, Ethics & Compliance; Associate Director, Ethics & Compliance; and outside counsel.

59. One year after the recommendation was first made by the undersigned, the Monitor concludes that SOP is not ready for review in this Report and not near ready to be implemented. The Monitor is not satisfied that the approach the Company reports was recommended to it by a third-party vendor has adequately or realistically assessed how to limit distribution of Company products to High Risk Downstream Customers. Nor has the Company adequately worked with business units outside of the Suspicious Order Monitoring team to identify and resolve any contractual issues or obstacles that may arise. And, even if the draft SOP could be implemented, at best, it would do little to limit distribution of Company products to High Risk Downstream Customers.

60. First, the Company has not taken steps to ascertain whether it could get access to prescription-level data necessary to make a determine whether a downstream customer poses an elevated risk of diversion of controlled substances. While the Company's vendor has reportedly told the Company that the distributors possess this information, the Company appears not to have validated this assertion. Specifically, in responses to questions it became clear that the Company does not know how and whether the distributors obtain access to this information (through a HIPAA exception or otherwise) and whether the distributors are legally able or willing to share it.

61. Second, it appears that the Company has not been provided with exemplars of how the prescription level data the SOPs demand would look, what the volume of data would be, or examples of what sorts of analysis would need to be done with the information provided. Without access to such information in the development phase of the SOP, it has not been

possible for the undersigned to meaningfully analyze how the Company would use the prescription level data called for in the proposed SOP, if received.

62. Third, the scope of what would be immediately reviewed and implemented under the SOP is of extremely limited immediate value. The Company has explained that it could only immediately implement chargeback limitations on its branded Opioid products. The Company might only be able to request information from distributors of generic products by renegotiating their contracts with the distributors, though this has not been sufficiently explored.

63. As set forth in the Ninth Report, filed May 2022:

> 156. Through the Pricing review, the Monitor became aware that the vast majority of sales and distribution of Purdue Pharma's branded Opioid Products – OxyContin, Hysingla, and Butrans – are not included in the chargeback process.
>
> 157. Specifically, the Chargeback review process only includes between 2% to 24% of Purdue's Branded Opioid Products packages or 2% to 22% of Company branded Opioid Product MME, with the disparity from month to month and product to product:
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> . . .
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> 158. Given that 85% of the Company's revenues and 27% of the total MME sold over the reviewing period were branded Opioid Products, there is no insight into a substantial amount of Purdue's downstream sales and distribution through the chargeback review process.
>
> . . .

> 161. For branded products, however, the only distribution that would be captured by a review of chargebacks are those contracted indirect sales to institutional/inpatient facilities or alternate care sites, and not to retail pharmacies.

(Ninth Report.)

64. Accordingly, the Company has been designing a process to prevent High Risk Down Stream Pharmacy Customers from getting chargebacks for branded Opioid Products, even though there are almost no pharmacies that receive chargebacks for these branded Opioid Products. For example, of the over 218 thousand chargebacks processed by the Company in December 2022, only two percent were for branded Opioid Products; almost all of which were for institutional/inpatient facilities or alternate care sites, not retail pharmacies. And the Company has not adequately explored and addressed how it can request information or limit chargebacks for downstream customers dispensing generic Opioid Products.

65. Similar to accessing unblinded 867 data for SOM purposes, for the Company to successfully design and implement the agreed upon recommendation to identify and limit distribution of Company Opioid Products to High Risk Downstream Customers, it will take an effort beyond the two fulltime employees engaged in Suspicious Order Monitoring. There are legal and business issues that the SOM team cannot reasonably be expected to identify or resolve, and will take active engagement from the Law and Commercial Departments not just in the review, but in the design of the program. A year after the recommendation was made, it is evident to the undersigned that that engagement has been insufficient.

66. **The Monitor will continue working with the Company, and report on the progress next Report.**

D. Distributor Site Visits

67. In the Prior Report, the undersigned raised the issue that a member of the sales team of one of the Company's distributors was contacting pharmacies and encouraging them to purchase from that distributor because of the litigation and injunction relating to McKesson, Cardinal and Amerisource Bergen. That distributor committed to Purdue Pharma to remedy the issue, and the prior Report recommended that the Company revisit the issue with the distributor to ensure corrective actions had been taken. (Twelfth Report, Paragraphs 101-104.)

68. The Company followed up with distributor and received confirmation that they implemented the following:

a. Sales representatives now have templates for emails to downstream customers, and have been trained on the use of them;

b. Sales Managers have daily and weekly training with the sales representatives that includes customer communication "Do's and Don'ts;" and

c. Outgoing emails from sales representatives are monitored for key words, and management is notified when certain key words are used in an email.

69. The Monitor is satisfied that the corrective actions adequately address the matter, and no additional actions are necessary with this particular distributor.

E. Review of Suspicious Order Monitoring Staffing

70. In the Second Monitor Report, the prior Monitor made "[a] strong recommendation . . . to add sufficient staff so that the monitoring can be more robust…." (Second Report, Paragraph 77.) At the time, in August of 2020, there was only one Company employee dedicated to Suspicious Order Monitoring full time, with limited assistance from two other individuals. (Second Report, Paragraph 50.)

71. Since then, the Company now dedicates three fulltime positions to the SOM processes: a Director, Ethics & Compliance; an Associate Director, Ethics & Compliance; and a Manager, Ethics & Compliance. The Manager recently left employment, and the Company is in the process of seeking to fill that position.

72. While the staffing of the SOM processes has increased since the entry of the Injunction, the obligations placed upon the Company and those employees have also substantially increased – both because of continuous improvement efforts within the Company and because of observations and recommendations made by this and the prior Monitor.

73. The Monitor has been consistently impressed with the competence, commitment, and efficiency of those responsible for overseeing and executing the Company's SOM obligations. However, the Monitor believes it would be constructive to assess whether sufficient personnel are dedicated to this effort.

74. **Accordingly, the Monitor recommends the Company undertake a survey or assessment of other Opioid Manufacturers to better understand the personnel dedicated to Suspicious Order Monitoring by those other manufacturers. The Company has agreed to this recommendation.**

VI. REPORTING, ANALYSIS, AND RESOLVING: 1) REPORTS OF CONCERN; SHORT COUNTS; AND 3) SUSPECTED VIOLATIONS OF LAW OR POLICY

75. Employees are under an affirmative obligation to report any known or suspected ethical concerns to the Ethics & Compliance for investigation and/or remediation, where appropriate. As stated in the Company's Code of Ethics, "All Purdue employees are required to bring to the Company's attention information about suspected violations of law or policy,

regardless of the identity or position of the person who is suspected of engaging in improper conduct."

76. The Code of Ethics also provides that the employees can report known or suspected violations to their manager; another manager; a member of the Ethics & Compliance, Corporate Security, Human Resources, or Law Departments; the Integrity Helpline 877-PURDUE1 (1-877-787-3831); or through www.integrityhelpline.net, an intranet site internal to the Company. The Code of Ethics also makes clear that:

> To the extent possible and when appropriate under the circumstances, efforts will be made not to disclose the identity of an individual who reports a known or suspected violation of law, regulation or policy. Similarly protected will be the identity of individuals who participate in any investigation. Retaliation against employees who report issues in good faith is strictly prohibited.

77. In addition to internal reporting, the principal institutionalized channels by which a vendor, customer or member of the public can report known or suspected ethical concerns about the business operations or potential violations of the Injunction is by calling the Ethics & Compliance Helpline (877-787-3831), or by sending a message to the email address compliance@pharma.com.

78. Among other places, the email address is referenced on the websites for Opioid Products (https://oxycontin.com/patient/contact-us.html), guidance for suppliers (https://www.purduepharma.com/wp-content/pdfs/Purdue-Supplier-Code-of-Conduct-November-2017.pdf), and the employee training concerning the Injunction. It is also referenced in the Company's Code of Ethics, as the contact point if an employee would like additional content offering on a particular topic relating to Ethics & Compliance.

79. The undersigned requested and received all email communications to the compliance@pharma.com email address from August 1, 2021, through August 8, 2022. The

Company provided 1,870 individual files, though the files contained many duplicates and email chains were separated into individual files for each email received.

80. External to the Company and non-Opioid contracted sales forces, the communications sent to the compliance@pharma.com email address included, among other things, bulk and individual solicitations to sell products or services to the Company, requests of the Company to finance projects like a film or to contribute to causes, emails containing malware, requests for educational materials, and requests to purchase Company products. There are occasional emails from patients utilizing Company Opioid products. The vast majority of the emails received could be categorized as bulk or "spam" emails. There were no emails from senders outside the Company reporting known or suspected violations of law or policy.

81. Internal to the Company, the email address is used for many additional purposes. If one of the contracted sales forces for non-Opioid customers contacted an HCP on the No Contact Customer list, an automated message is sent to the email, and then the correspondence and steps to address that contact are also included. The emails received also include requests to purchase lunch for a sales event involving non-Opioid Company products; submission of a distributor's annual due diligence paperwork; and correspondence regarding challenges accessing online training modules. The emails received are triaged to appropriate personnel for handling.

82. The most frequent category of internal emails and correspondence, however, is broadly categorized as "Reports of Concern." These are most often, but not always, submitted by the Medical Information Department, Product Complaints, and Drug Safety. The reports can include information about possible counterfeited Opioid products, claims about the efficacy of an

individual dose of a product, or news articles about specific HCPs that allegedly diverted Opioid products.

83. Most often, however, the reports involved "short counts" of medication or missing blister packs. In addition to the initial report, at times there are the follow-up emails relating to the resolution or disposition of the report; this is not always the case, however. Like the other emails, they most often originate from calls or correspondence to the Medical Information Department, Product Complaints, and Drug Safety, but can include reports received by Corporate Security, or reports forwarded to Medical Information or Corporate Security by non-US companies like Purdue Pharma Canada and Mundipharma. The origin of the Report of Concern is typically an HCP, but also occasionally includes patients or federal agencies such as an Investigator from the Food and Drug Administration.

84. The Vice President, Ethics & Compliance, explained to the undersigned that the term "Report of Concern" is often misused, or overused. According to the Company's view, a "Report of Concern" should be construed as a known or suspected diversion of a Company-marketed controlled substance. Accordingly, a short count is not a known diversion, and may not even be a suspected diversion, absent a determination it is not the result of a packaging error and there is evidence of problematic patterns or behaviors suggesting potential diversion, such as prior reports of missing tablets from the same pharmacy. As another example, at times there are reports of a patient not showing any controlled substance in a urine screen; it could suggest diversion, although it could also suggest other problems, such as with the screening process or with the efficacy or quality of the Company's product.

85. Whether categorized as a short count or, more specifically, as a known or suspected abuse or diversion of a Company-marketed controlled substance, from the Monitor's

perspective the challenge is that the Company cannot provide the Monitor with any sort of listing or database of the Reports of Concern, the steps taken to review those Reports of Concern, and the ultimate resolution. The same holds true for product short counts that are subsequently investigated to determine if they might be a Report of Concern. Absent such established processes, there is no way to opine that these concerns are being adequately addressed and/or conform with the terms of the Injunction.

86. **The Monitor recommends that the Company develop processes to identify, track, and capture: (1) short counts and missing product; (2) known or suspected abuse or diversion of a Company-marketed controlled substance; and (3) known or suspected violations of law or policy. While these may be separate databases or processes, there will be some overlap.**

87. Moreover, it is unclear whether the Ethics & Compliance Helpline (877-PURDUE1) and the Integrity Helpline Portal are appropriately effective. Although the undersigned has not recently requested information as to the volume and content of contacts, and will do so for the next Report, from November 2019 through October 2021 there were 36 recorded entries in a database capturing all phone and portal activity. Two of those entries concerned issues relating to or brought forward by the contracted sales teams for non-Opioid products, and two related to the Company's employees in customer service and sales. All entries were appropriately resolved.

88. Additionally, there were no emails from Company employees received by compliance@pharma.com in the materials reviewed raising any topics relating to the Company's activities.

89. Finally, when an employee departs from the Company, two written questions are asked in the exit interview: (1) "Are you aware of any violations of Purdue policies or procedures by any employees or others affiliated with Purdue that have not been reported or addressed;" and (2) "Are you aware of any violations of law, or regulations, or any illegal or unethical activity by any employees or others affiliated with Purdue that have not been reported or addressed." The questions can be answered "yes" or "no," and there are three lines after each question to explain if checked "yes."

90. **The Monitor recommends that the Company analyze the avenues and processes other Opioid manufacturers and/or other businesses use to receive and capture reports of concerns and reports of known or suspected violations of law or policy, from both internal and external sources. Subject to that review, additional recommendations may be made.**

VII. INITIAL COVERED SACKLER PERSONS

91. 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 Thirteenth Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor