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)**

FOURTEENTH 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 Fourteenth Monitor Report, and the undersigned's tenth 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

[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 THIRTEENTH REPORT

1. Since the filing of the Thirteenth Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue Pharma including the: Vice President, Chief Compliance Officer; Vice President, Legal Strategy and Public Health Initiatives; Vice President of Quality; Associate General Counsel, Head of Corporate Law; Director, Ethics & Compliance; Director, Research and Development Quality; and Associate Director, Ethics & Compliance.

2. Since the filing of the Thirteenth 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.

THIRTEENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Thirteenth 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. Placing greater urgency on resolving access to a pharmacy chain's unblinded 867 data for Suspicious Order Monitoring ("SOM") purposes. (Thirteenth Report, Paragraph 48.)

b. Reporting additional actions taken concerning developing a process for further examination of downstream customers dispensing high-dose prescriptions. (Thirteenth Report, Paragraph 54.)

c. Reporting further progress on creating and implementing a program to restrict distribution of Purdue Pharma products to high-risk downstream customers. (Thirteenth Report, Paragraph 66.)

d. Undertaking a survey or assessment of other Opioid Manufacturers to better understand the personnel dedicated to Suspicious Order Monitoring by those other manufacturers. (Thirteenth Report, Paragraph 74.)

e. Developing 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. (Thirteenth Report, Paragraph 86.)

f. Analyzing 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. (Thirteenth Report, Paragraph 90.)

4. Moreover, there was an outstanding request from the Eleventh Report: "The undersigned has requested yet not yet received copies of all 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. Field Market Access Employees Compensation Structure

5. In the Twelfth Report, the undersigned reviewed compensation for the field Market Access employees and recommended that "[p]rior 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." (Twelfth Report, Paragraphs 16-17.)

6. The Monitor recently received and reviewed the Management by Objectives ("MBOs") for 2023. References to programs like sales contests and project sprints are no longer included. Accordingly, the Monitor finds that the 2023 MBOs are consistent with the terms of the Injunction.

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

A. Review of Opioid Products Contracts and Agreements

7. 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.

8. 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.)

9. As of the date of the filing of this Report, the Company has successfully negotiated the recommended changes in all but two of the managed care rebate agreements. The remaining two contracts have not yet come up for renewal.

10. Regarding the recommendation to remove failure-to-supply penalties in the distributor GPO agreements, in the last Report the undersigned explained that there were only three contracts remaining that include this provision. Since the filing of the last Report, the Company reported to the undersigned that two of those entities have refused to remove the failure-to-supply penalties, notwithstanding the issue being elevated to the legal departments of the Company and the distributor GPOs. The GPOs have asserted that they require this provision from all their suppliers and are unwilling to consider an exception.

11. Combined, the two distributor GPOs refusing to negotiate removal of the failure-to-supply penalty provisions distribute the majority of the Company's generic products. While it is disappointing the distributor GPOs are unwilling to agree to these contractual changes, the Monitor finds that the Company has fulfilled the recommendation to make commercially reasonable, good faith efforts to negotiate these provisions. (See Ninth Report, Paragraph 23.)

III. LOBBYING RESTRICTIONS

12. Since the filing of the Thirteenth Report, the Monitor has reviewed 23 quarterly reports reflecting the actions of contracted firms at the state level and one at the federal level, covering the period from January 1 to March 31, 2023.

13. In all instances, the state and federal contracted firms only monitored legislation and legislative, executive, and administrative activities relating to Opioids and Opioid Products.

14. Three contracted state firms reported contacts with representatives of state and tribal agencies and a state sheriff's association relating to PHI Initiatives, including suboxone donation programs.

15. The Injunction excludes from its lobbying restrictions "[c]ommunications by the Company, including to elected or appointed officials, federal or state legislative or administrative bodies, committees or subcommittees regarding the prevention, education, and treatment of opioid use disorders or opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction." (Injunction II.D.4.e.(ii).)

16. 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 the first quarter of 2023, 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."

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

IV. BAN ON HIGH DOSE OPIOIDS

18. 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).

19. 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

20. Prior reports have detailed the lack of visibility into downstream customer distribution of all the Company's branded Opioid Products, as well as measures taken by the Company to gain access to this information from four large pharmacy chains that blind their data. (Ninth Report, Paragraph 175; Twelfth Report, Paragraphs 76-91.)

21. In the Thirteenth Report, the undersigned explained that the Company was still working with one of the pharmacy chains and its principal distributor to gain access to this data. (Thirteenth Report, Paragraphs 43-47.)

22. As of April 15, 2023, the Company reported that the SOM team is now receiving and analyzing all unblinded 867 data from that specific pharmacy chain. The Monitor appreciates the Company's efforts to get this resolved.

B. Atypical/Excessive Quantity Thresholds

23. 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 to explore possible approaches to implement a threshold based on MME and/or MME/day. (Ninth Report, Paragraph 138.)

24. Moreover, as explained in the Thirteenth Report, in addition to those prescriptions exceeding the threshold for keystroke errors, "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." (Thirteenth Report, Paragraph 51.)

25. The Company has raised contractual and legal obstacles to providing the SOM Team with notice of downstream customers that are dispensing high-dose prescriptions.

26. Concerning the contractual obstacle, the Company has concluded that, when it comes to incredibly high dose prescriptions, and even those that exceed the keystroke error thresholds, the Company is precluded from providing any indication to Ethics & Compliance that it should review or analyze the dispensing downstream customer, even if that notification is simply the name and address of the pharmacy. The Company reports that this conclusion is based upon the fact that, according to its contracts with the Pharmacy Benefit Managers (PBMs"), the prescribing information is confidential and can only be used by the Commercial Department for rebate validation purposes, and use of that data for any other purpose is contractually prohibited.

27. Concerning the legal issue, the Company contends that Payors, via their PBMs that are providing formulary management services on their behalf, are permitted to disclose patient-level prescribing data (considered Protected Health Information) pursuant to a "payment"-related exception to the Health Insurance Portability and Accountability Act of 1996

("HIPAA") that allows drug manufacturers to receive Protected Health Information for purposes of validating claims under drug rebate contracts.

28. The Monitor understands the Company's concern to be that a PBM can only use or disclose Protected Health Information for the specific purposes permitted by the Payors under their HIPAA Business Associate Agreements, and that a PBM's ability to disclose patient-level prescribing data to a drug manufacturer like Purdue Pharma stems from the HIPAA payments exception for validating claims under drug rebate contracts. While Payors may use Protected Health Information for "healthcare operations" purposes, which include fraud and abuse detection and compliance programs, that exception applies only to compliance programs of the Payor, not of a manufacturer like Purdue Pharma. (*See* 45 CFR § § 164.501, 164.502.)

29. Under the express terms of the Injunction, Purdue Pharma:

> shall operate an effective monitoring and reporting system that shall include processes and procedures that:
>
> . . .
>
> b. Reasonably utilize available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of a Company Opioid Product; [and]
>
> c. Analyze all information that the Company receives that indicates an unreasonable risk of diversion activity of a Company Opioid Product or an unreasonable potential for diversion activity of a Company Opioid Product, by a direct customer or a downstream customer, including reports by employees and customers of the Company, Health Care Providers, law enforcement, state, tribal, or federal agencies[.]

(Injunction, II.G.1.)

30. The Injunction requires that the Company analyze *all* information it receives, providing no exception for information that the Company may have contractually agreed to use for limited purposes. The Company disagrees as discussed below.

31. Additionally, even Purdue Pharma's website explains that "The DEA's guidance states that pharmaceutical manufacturers need to go beyond 'know your customer' requirements and use available data within the Company to 'know your customer's customer.'" (https://www.purduepharma.com/about/ethics-and-compliance/suspicious-order-monitoring/ .) It would lead to an absurd result if a manufacturer could disregard the DEA's guidance that it must use available data, by asserting the data in the manufacturer's possession is unavailable due to a contractual limitation that was agreed to by that manufacturer. The Company contends that data is not "available" for uses other than rebate validation due to contractual provisions insisted upon by PBMs in order to pass through data use limitations set forth under federal privacy laws.

32. Moreover, it should be noted that, while contracts are subject to annual or biannual review and negotiation and some have been entered into for the first time or agreed and restated since 2019, many of the agreements between the Company and the Pharmacy Benefit Managers restricting use of this data are over a decade old, or even older. Suffice it to state that much has changed in the last decade when it comes to Purdue Pharma's business operations, not the least of which is the Voluntary Injunction.

33. Regarding the legal issue, the Monitor is not an expert on the intricacies of HIPAA. During the next reporting period, the Monitor will seek leave of the Court to contract with counsel or a consultant to further explore whether notice can be provided to the SOM Team without violating HIPAA. (Injunction, II.H.4.b.)

C. Restricting Supply of Company Opioid Products to Downstream Customers

34. 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.)

35. The undersigned reviewed the status of this recommendation in the last Report. (See Thirteenth Report, Paragraphs 58-65.)

36. The undersigned has had multiple meetings with the Company since the last Report that have included the substance of a proposed SOP. The Company is cooperatively working with the undersigned. As of the filing of this Report, the Monitor has not received the revised SOP detailing how the Company intends to restrict receipt of Company Opioid Product to High-Risk Downstream Customers.

37. Additionally, the Company recently reported to the undersigned that it has concluded that, absent amendments to its agreements with the distributors and GPOs, the Company could not restrict the supply of Opioid Products to downstream High-Risk Customers of Concern. Specifically:

a. All the contracts between Rhodes Pharmaceuticals and distributors covering generic products do not permit the Company to unilaterally change the terms relating to chargebacks, so denying a chargeback would violate these agreements.

b. About half of Rhodes' Group Purchasing Organization ("GPO") contracts and all of Purdue Pharma's GPO contracts relating to branded products provide that the

same price must be provided to all the GPO members, so denying a chargeback would violate these agreements.

c. Federal law requires the Company to sell product to distributors for 340B Programs and Federal Supply Schedule customers at no more than a "ceiling price." Accordingly, Purdue Pharma concluded it may not restrict chargebacks to these customers without violating that pricing obligation.

38. In the 15-plus months the Company has represented it has been working on the best method to limit the distribution of Opioid Products to High-Risk Downstream Customers of Concern, the Company has not spoken with its distributors or GPOs about the issue. The Associate General Counsel, Head of Corporate Law explained to the undersigned that they have not had any communications because the Company has not yet settled on the details of the program to deny chargebacks or otherwise attempt to limit distribution to these High-Risk customers.

39. The Associate General Counsel, Head of Corporate Law further informed the undersigned that, once a SOP is finalized, amendments will be required to various, but not all, distributor and GPO agreements, and the Company will attempt to amend the contracts that require amendment during the regular course of contract negotiations. Accordingly, assuming the Company can reach a successful negotiated resolution, full implementation may take up to a year.

40. The three largest distributors account for more than 90% of chargebacks for the Company's branded and generic Opioid Products. Three GPOs account for more than 90% of chargebacks for the Company's branded Opioid Products and seven GPOs account for more than 90% of chargebacks for the Company's generic Opioid Products.

41. **The Monitor recommends that, upon finalizing an SOP acceptable to the undersigned, the Company immediately request that the distributors and GPOs identified in the paragraph above open contract negotiations regarding these provisions, with the objective of having the contracts amended before the end of the next reporting period. The Company agrees as soon as practicable, but no later than June 22, 2023, to approach each of the distributors and GPOs to open contract negotiations, where necessary, regarding these provisions and make reasonable attempts to implement the recommended changes on commercially reasonable terms. The Company further agrees to provide regular updates whether these changes have been agreed to and implemented.**

D. Review of Suspicious Order Monitoring Staffing

42. In the Thirteenth Report, the undersigned recommended that "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." (Thirteenth Report, Paragraphs 70-74.)

43. Since filing that Report, the Company has taken several steps to try to gain a better sense of both the Company's needs, and how those needs might compare to other manufacturers distributing Opioid Products.

44. First, the Company is an active member of the Pharmaceutical Compliance Forum, a nonprofit membership organization of 111 different pharmaceutical companies and their compliance officers. In March 2023 during a plenary session of the Forum's annual meeting, Purdue Pharma's Vice President, Chief Compliance Officer requested information about other company's SOM programs, also providing her email and telephone if representatives

were wary about responding in a public forum. She only received one response, from a smaller company that is in the process of exiting the Opioid marketplace.

45. Second, Purdue Pharma identified a Human Resources consultant to determine the capabilities and prospects for obtaining meaningful comparators. The consulting company could not provide any assurances as to how valuable those responses would be, noting that they would need at least five other companies to provide information to reach any sort of meaningful conclusions. Moreover, there is concern that, absent a more robust understanding of the drug families manufactured and sophistication of the other companies' algorithms and automated processes, knowing how many employees are involved in SOM doesn't provide useful information. Given these potential limitations, the Company is not convinced the costs of undertaking the review would be worth the benefits.

46. The Vice President, Chief Compliance Officer in conjunction with the SOM Team undertook a review of SOM program staffing. This was prompted by the recent departure of an Ethics & Compliance Analyst, one of the SOM Team members. In recruiting for the open role, it was determined that it was most appropriate to split the responsibilities between two individuals – one with expertise in data analytics and a second with investigative experience.

47. To that end, the Company recently recruited for and filled a position titled "Suspicious Order Monitoring, Data Analytics." The Analyst will be responsible for retrieving, aggregating, and interpreting data to aid the SOM Team.

48. Additionally, the Company is in the process of recruiting for a position titled, "Senior Manager, Ethics & Compliance." This position requires prior experience working for the Drug Enforcement Administration, and will have a significant investigative component,

including investigating downstream customers using open source and publicly available databases and sites, as well as managing the setting of direct customer thresholds.

49. The Vice President, Chief Compliance Officer believes adding this additional staff will also permit the head of the SOM Team to be relieved from some of the daily operational responsibilities of suspicious order monitoring so that he can dedicate more of his efforts to overall management and looking more strategically at the SOM program.

50. The Company is also in the process of reviewing whether any technological changes or improvements should be made, though the review and determination will not be made until near the end of this calendar year.

51. The Monitor agrees that, given the limitations of an outside HR review, it should not be conducted at this time.

52. Regarding the Pharmaceutical Compliance Forum, one of the benefits the Forum offers is "[q]uarterly Member Company Benchmarking Surveys conducted; questions submitted by members; blinded/detailed analysis report provided." **While raising the issue in a plenary session proved ineffective, the Monitor has recommended that the Company request information through this Benchmarking Survey regarding SOM Team size and technology for companies manufacturing and distributing Opioids. The Company has agreed to this recommendation, and provided the undersigned a draft of the survey request for input.**

53. **The Monitor also requests that the Company keep the Monitor apprised on their review of whether technological changes or improvements should be made, and to provide the undersigned input prior to any final determination. 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

A. Reporting of Concerns to the Company

54. In the Thirteenth Report, the undersigned provided information on the various vehicles through which the Company receives and captures short counts, reports of concerns and reports of known or suspected violations of law or policy, and recommended 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." (Thirteenth Report, Paragraph 90.)

55. A more robust discussion of the current vehicles to receive and capture reports of concerns and reports of known or suspected violations of law or policy follows, as well as some contemplated enhancements.

1. Promotion of Integrity Helpline

56. In addition to what was detailed in the Thirteenth Report, the Company promotes the Integrity Helpline and obligation to report ethics concerns through several different avenues:

a. Every single email sent from a company computer from the Vice President, Chief Compliance Officer and members of the Ethics & Compliance Department has the Helpline number on it.

b. The Helpline number is regularly scrolling on the bottom of television monitors in the elevator lobbies of the Company's corporate office.

c. The Integrity Helpline is included in various places on the Company's intranet site, in the Healthcare Law Compliance Policies, and various online workplace

learning modules that address both the obligation to report concerns and the existence of the Integrity Helpline.

d. In 2022, the Company conducted a speak up anti-retaliatory campaign, and intends to do so this year as well. The Ethics & Compliance Department sends out materials reminding Purdue Pharma employees that the Company has a nonretaliation policy and encourages employees to raise issues that might be of concern and participate in any investigations that might occur. The effort is to make employees understand they can report without concern of retaliation and can choose to report ethical concerns confidentially.

e. One week every year, the Company has a dedicated "Ethics Week" designed to raise visibility concerning the ethics and compliance issues that could arise in the business, as well as further familiarizing all employees with the Ethics & Compliance Department. The CEO encourages participation from the Company's employees.

f. Currently, it is a hybrid program, both online and in person for those regularly working from the office. The schedule varies from year to year but typically includes some or all the following: Meet Your Compliance Officers, content on Ethics & Compliance Program initiatives (including Suspicious Order Monitoring), a keynote presentation followed by a social activity where employees can interact with one another and Ethics & Compliance Department staff, multiple written communications on ethics and compliance and employee activities (e.g., games, puzzles, videos).

g. Every Ethics Week includes references to the various reporting mechanisms available to employees, including the Helpline.

h. Finally, the Ethics & Compliance Department also provides content for managers to use in having ethics and compliance-related conversations with their team members.

3. Exit Interviews

57. As explained in the last Report, the Company currently requests that each departing employee respond to two written questions as part of that employee's 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." (Thirteenth Report, Paragraph 89.)

58. Since the last Report, the Company has added three additional questions: (1) "Are you aware of any violations of the Voluntary Injunction, entered by the bankruptcy court in *In re Purdue Pharma*, by any employees or others affiliated with Purdue other than matters you know have been reported or addressed?"; (2) "Are you aware of any potential conflicts of interest involving any employees or others affiliated with Purdue other than matters you know have been reported or addressed?"; and (3) "Do you have any suggestions or anything else to share regarding ethics and compliance?".

59. The Exit Interview Questionnaire also includes the reminder that if the employee "*wish[es] to <u>anonymously</u> report ethics and compliance concerns including but not limited to*

violations of law, regulations or policies, you may contact our Integrity Helpline. . ." (emphasis in original). The questionnaire then provides telephone, text and internet sites for making this contact.

60. It should be noted that, in addition to the exit interview questions expressly targeting potential violations of law, regulations or policies, there are also more general questions relating to, among other things, company culture and whether daily decisions in the Company demonstrate that quality and improvement are top priorities. The undersigned will further explore these areas in subsequent reports.

61. In 2022, 51% of employees that had voluntarily separated from the Company returned the exit interview forms, with only a slight drop off in answering the additional questions relating to ethics and compliance.

4. Climate Survey

62. Additionally, the undersigned raised the idea of conducting a climate survey or 360-degree review of employees regarding the corporate culture surrounding compliance and the reporting of concerns. The Vice President, Ethics & Compliance reported that conducting a survey is already included in the 2023 objectives for the Ethics & Compliance Department, and they are in the process of considering both the best vehicle for conducting the survey, as well as the content.

63. **The Monitor recommends that the Company provide a copy of the proposed climate survey to the undersigned prior to disseminating, as well as share the results of that survey with the Monitor. The Company has agreed to this recommendation.**

64. **In sum, although the Company has not undertaken a formal effort to survey or assess what other companies might do to solicit input concerning potential violations of**

law or policy, the Monitor is left with the impression that the Company takes seriously its obligations to encourage such input. The undersigned will continue to explore avenues to assess the Company's efforts relative to other companies, as well as internal improvements.

B. Tracking, Analyzing and Reporting Concerns

65. In the last Report, the Monitor also recommended that 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." (Thirteenth Report, Paragraph 86.)

66. This is in addition to an outstanding request from the Eleventh Report: "The undersigned has requested yet not yet received copies of all reports of concern from 2021 to the present. The Monitor will report the findings from this review in the next Report. (Eleventh Report, Paragraph 109.)

67. Regarding reports of concern, the Company provided a spreadsheet recently created by the Vice President, Ethics & Compliance listing 21 reports of concern between October 2021 and March 2023. All reports were received from either Product Complaints, Medical Services, Medical Information or Customer Services; none came from the Integrity Helpline. The spreadsheet entries related to short counts or missing products, missing seals on bottles, allegations of adulterated or counterfeited products, and product quality. Nine of the reports were reported to the Drug Enforcement Administration and, in one instance, a state pharmacy board; the remaining were either closed with no action taken or are still pending.

68. The Company timely provided this spreadsheet well in advance of this Report. The undersigned will further detail the process for tracking reports of concern in the next Report.

69. Regarding short counts, the undersigned interviewed the Vice President of Quality, who is responsible for the quality assurance/quality control functions relating to the manufactured products, and is in Wilson, NC, and the Director, Research and Development Quality, located in Stamford. The undersigned also reviewed relevant SOPs and policies.

70. The undersigned has not yet received sufficient information to report on the processes involved and the adequacy of those processes and consistency with the Injunction. The Monitor will provide additional detail in the next Report.

VII. INITIAL COVERED SACKLER PERSONS

71. 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 Fourteenth Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor