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)**

EIGHTH MONITOR REPORT

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

EXECUTIVE SUMMARY

This Eighth Monitor Report, and the undersigned's fourth 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 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.

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

INTRODUCTION – STEPS TAKEN SINCE SEVENTH REPORT

1. Since the filing of the Seventh Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue Pharma including the: Executive Vice President, General Counsel and Secretary; Vice President, Ethics & Compliance; Vice President, Sales/Marketing and General Manager, Adlon Therapeutics; Vice President, Legal Strategy & Public Health Initiatives; Associate General Counsel; Head of Pricing; Head of Analytics, Market Access & Pricing; Director, Ethics and Compliance; Associate Director, Ethics and Compliance; Manager, Ethics and Compliance; and Director of Customer Service.

2. Since the filing of the Seventh 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.

SEVENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

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

4. The recommendations and areas of inquiry included:

   a. Revising the Customer Service Standard Operating Procedures and Exhibits to:

      1. further clarify when and how the Company will assist in replacing a Buprenorphine patch (Seventh Report, Paragraph 73);

2. clarify under what circumstances a refund for the Company's other Opioid Products is given (Seventh Report, Paragraph 74); and
3. revise the definition of "Health Care Professional" to capture all positions and functions covered by the definition of "Health Care Provider" in the Injunction (Seventh Report, Paragraph 75).

b. Updated training, including:
    1. a more frequent and robust training schedule for all Company employees performing duties that could touch upon the prohibitions of the Injunction (Seventh Report, Paragraph 83); and
    2. assuming emergence from bankruptcy and the Company then conducting business under the Operating Injunction, a more interactive program to ensure that the Company's employees understand and incorporate the Operating Injunction's terms into their regular work at least every six months (Seventh Report, Paragraph 84).
c. Monthly review by the Director of Customer Service of the call/email logs to ensure conformity with the Injunction and the Standard Operating Procedure ("SOP") (Seventh Report, Paragraph 88).
d. Quarterly review of the call and email logs of the Customer Service and Medical Information Departments by a representative designated by the Company's Law Department to identify any issues or trends that might touch on matters prohibited by the Injunction (Seventh Report, Paragraph 89).
e. Training by the Ethics and Compliance/Suspicious Order Monitoring team to the Customer Service and Medical Information Departments defining the types of

information, communications or allegations that should be brought to the attention of the SOM team, as well as what details Customer Service should collect from the reporting Health Care Provider or patient to assist the SOM team in its review (Seventh Report, Paragraph 99).

f. A quarterly review of the call/email logs of the Customer Service and Medical Information Departments by the Director of Ethics & Compliance to assess whether there are issues that should be reported to the SOM team (Seventh Report, Paragraph 100).

g. Updating the Pricing Committee Charters to incorporate reference to the Injunction. (Seventh Report, Paragraph 115.)

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

6. Additionally, where new areas of inquiry have been undertaken since the Seventh Report, these new areas will be identified and discussed.

DISCUSSION AND ANALYSIS

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

A. Websites

7. Under Section II.A.2.b of the Injunction, the Company is permitted to maintain branded Opioid websites containing certain information. Specifically, the Company may:

> Maintain a website for any Opioid Product that contains principally the following content: the FDA-approved package insert, dosage strengths, dosage forms, packaging configurations, and medication guides; a statement directing patients or caregivers to speak with a licensed Health Care Provider; Risk Evaluation and Mitigation Strategy (REMS) materials; contact information to report an adverse event or product complaint; and/or information regarding savings programs, savings cards, vouchers, coupons, or rebate programs for the Company's Opioid Products.

8. In the prior Monitor's Initial Report, the Monitor noted he had reviewed the Company's website and social media sites and concluded that "[t]here are no promotional materials for opioid or opioid products on Purdue Pharma's current websites." (Initial Report, Paragraphs 24-25, 56-61, 66.)

9. The undersigned Monitor also reviewed the websites and found them to be compliant with the terms of the Injunction. (Fifth Report, Paragraph 25.)

10. Notwithstanding these findings, the Company reviewed the websites and proposed certain edits. After bringing those edits to the attention of the Monitor, the Company implemented the changes.

11. For example, the prior landing page for the Butrans Health Care Provider website provided the following statement:

HELP PATIENTS FOR THE WEEK AHEAD
Consider Butrans, a Schedule III, 7-day, transdermal patch medication

12. The current version (https://butrans.com/) now states:

BUTRANS, A SCHEDULE III, 7-DAY, TRANSDERMAL PATCH MEDICATION

13. As another example the prior landing page for the OxyContin website for patients and caregivers had provided:

Staying on the Path
Learn more about OxyContin

14. The landing page (https://oxycontin.com/) now provides:

Learn more about OxyContin

15. The Company made changes to the sites for OxyContin and Butrans, both for the websites targeted to Health Care Providers and to patients and caregivers. Moreover, there were some changes beyond the landing page titles for the websites.

16. While the prior language wasn't necessarily promotional, the Monitor commends the Company's initiative in removing language from the Company websites that go beyond reflecting factual and medical information.

B. Sales Team

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

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

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

20. All three sales teams had received enhanced Adhansia XR training regarding how to address questions unrelated to the product and had certified that any inquiries about Opioids or Opioid Products were to be referred to the Medical Information department. (Fifth Report, Paragraphs 45-47.) The Injunction does not otherwise restrict the Company from having sales representatives for non-Opioid products.

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

22. With the Food and Drug Administration's recent approval of Purdue's abbreviated new drug application for the vial form of Nalmefene, an Opioid antagonist medication used in the management of Opioid overdose, the Company reports to the Monitor that it intends to use select members of the Commercial department and a limited contractor presence, to be called key account managers, to promote approved Public Health Initiative products to Health Care Providers.

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

24. Accordingly, Purdue Pharma is performing its business consistent with this term of the Injunction.

C. Customer Service Department

1. **The Standard Operating Procedure**

25. In the Seventh Report, the Monitor recommended, and the Company agreed to update the SOP to better reflect the prohibitions of the Injunctions and the business practices in place.

26. The Monitor has reviewed the changes and updates to the SOP and exhibits.

27. The updated SOP clarifies -- and represents a change in business practices -- that (a) there are no longer any refunds for prescription products, and (b) requests for replacements are made and granted only through the pharmacy, not the patient or caregiver.

28. The pharmacy has discretion whether to provide replacement products. The SOP does not place any limits on either they type of Opioid product or the number of doses that can be replaced by the pharmacy.

29. However, a credit from the Company to the pharmacy for a replaced product is not guaranteed. For example, if Corporate Security or the Suspicious Order Monitoring team detects a trend in a pharmacy requesting a credit, either through review of Product Complaints or as part of the audit of call logs and emails, a credit could be denied.

30. **During the next reporting period, the Monitor will review the circumstances in which Opioid Products are being replaced, as well as the quantities of Opioid Products being replaced, and will include an assessment of these practices in the next Report.**

2. Customer Service Contacts with Pharmacies and Review of Call Logs to Ensure that the Injunction is being Followed

31. In the Seventh Report, the Monitor recommended that reviews of the Customer Service call logs be conducted at least monthly by the Director of Customer Service and at least quarterly by Suspicious Order Monitoring team and the Law department.

32. The Director of Customer Service has been reviewing these logs at the start of each month. The logs are reviewed in spreadsheet form. In addition to reviewing for potential noncompliance with the Injunction, the Director also includes a new column in the log spreadsheets with comments and recommendations for additional training.

33. The Director of Customer Service then forwards the logs to the Suspicious Order Monitoring team, with her comments. The SOM team is also reviewing the call logs monthly. Additionally, the SOM team now has daily access to the Customer Service email inbox. The Director of SOM reported to the undersigned that the review has not been overly burdensome,

has highlighted issues where processes could be tightened, and was beneficial for the training provided.

34. The Law Department reviews the call logs quarterly, along with the comments from the Director of Customer Service and the SOM team. It is the Monitor's understanding that the Law Department's review has also been completed. **To the extent any issues arise from that review, the undersigned will include in the next Report.**

35. The Monitor finds these reviews consistent with the recommendations from the Seventh Report.

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

36. As discussed in the Seventh Report, both the content and materials used to train Company employees regarding the Injunction has remained largely the same since it took effect. (Seventh Report, Paragraphs 79-80.)

37. The Monitor recommended updating the training, both as to content and frequency. Moreover, under the premise that the Company might soon be operating under the Operating Injunction, the undersigned recommended that the Company create a more interactive training program to occur at least every six months. (*Id.*, Paragraphs 83-84.)

38. The Company has revised the materials used for training on the Voluntary Injunction and intends to provide this training to individual groups or departments.

39. The undersigned Monitor was afforded the opportunity to review updated training materials and provide input. In addition to the terms of the Injunction, the training also include includes explanation of legalistic terms and examples of how the Injunction applies to selected business practices.

40. **As the updated training is implemented, the Monitor has requested that the Company include the Monitor in at least one of the training sessions to gain a better understanding as to how the materials are received. The Company has agreed to this recommendation.**

4. Review of Customer Service and Medical Information Inquires for Suspicious Ordering and Orders of Interest and Adequacy of Training regarding Suspicious Order Monitoring and interactions of Concern

41. Based on the Customer Service call logs, the Seventh Report identified: (a) interactions with patients and Health Care Providers that give rise to a risk of or potential for diversion of Opioid Products; (b) the lack of any formal process by which employees of Customer Service notify the SOM team of information that could indicate an unreasonable risk of diversion; and (c) the need for training by the SOM team to those employees who interact with Health Care Providers and patients and caregivers. (Seventh Report, Paragraphs 90-99.)

42. The Monitor further requested that the SOM team undertake a review of call and email logs, at least on a quarterly basis, to assess whether there are issues that should be reported to the SOM team. (Seventh Report, Paragraph 100.)

43. Since the last report, the SOM team has provided trainings to employees involved with Product Monitoring, Adverse Effects, Medical Information and Customer Service. The training sessions are approximately an hour in length, and to date there have five sessions, covering in total approximately 80 employees.

44. The SOM team used examples in the trainings collected from reviewing the call and email logs to highlight when employees should either seek more information from the caller or provide the SOM team or Corporate Security notice of the interaction. Among other things,

the training identified "red flags" the employees should be looking for, including certain verbiage used, product shortage complaints, and trends.

45. The reviews and training have also revealed areas where the Company's procedures and processes should be updated, including identifying whether concerns are raised about a particular pharmacy multiple times, ways to capture trends that might arise in calls, and whether there should be any limits on the number of buprenorphine patches that the Company will reimburse a pharmacy for replacing.

46. In the next Report, the Monitor will highlight any changes to processes and policies arising from the SOM review of procedures and processes.

II. CONTRACT AND PRICING REVIEW

47. In the Seventh Report, the Monitor provided a summary of the progress of the pricing and contract review, made one recommendation arising from that review, and concluded that "[t]the undersigned Monitor is not prepared to draw any further conclusions nor make any further recommendations until Pearl's review is complete, which will be in advance of the next Report." (Seventh Report, Paragraphs 107-122.)

48. The Seventh Report recommended incorporating language into the Company's Pricing Committee Charters recognizing the obligations of the Injunctions in making contracting decisions. (Seventh Report, Paragraph 115.) The Company has reported that the Pricing Committee Charters have been revised and that the agreed-upon language has been adopted and incorporated.

49. Pearl delivered its review and analysis to the Monitor in early February. Since then, Pearl and the Monitor have been in discussions and exchanging additional information with the Company. These exchanges and discussions are ongoing.

50. The purposes of these exchanges and discussions are to: (a) ensure that any information detailed in the Monitor Report does not violate the Protective Order; (b) afford the Company an opportunity to ask questions and/or seek further clarity around the observations and recommendations; and (c) endeavor to reach a shared understanding of the data forming the bases for observations and recommendations, and whether those observations and recommendations are properly drawn based on that data and the terms of the Injunction.

51. While the Company and the Monitor have achieved the purposes set out above for some sections of the Pearl review and analysis, rather than reporting out a partial assessment of the review and recommendations as the dialogue with the Company continues, the Monitor has concluded that it would be prudent to wait until these exchanges and discussions with the Company are concluded.

52. Accordingly, the Monitor anticipates including the narrative, observations and recommendations of the contract and pricing review in the next Report.

III. REVIEW OF STANDARD OPERATING PROCEDURES

53. In addition to the revisions to the Customer Service SOP, on occasion the Monitor has recommended changes to other SOPs. (*See, e.g.*, Sixth Report, Paragraph 161).

54. The purposes of the SOPs are to guide the day-to-day business practices and to assist the departments and employees in carrying out the Company's operations. The potential for an SOP to either not address or be inconsistent with the terms of the Injunction extend beyond Promotion.

55. The undersigned requested a listing of all SOPs and policies related to or in any way involving the Opioid Products. Excluding the operation and calibration of manufacturing

equipment and similarly technical topics, the Company provided an index listing 274 SOPs and policies, detailing practices in different business units across the Company.

56. Based upon the subjects, business areas and document titles, the Monitor requested approximately 50 of the SOPs for further review and analysis. Even of those identified for further review, only a subset involved matters that relate to or should take consideration of the requirements of the Injunction.

57. Absent an issue arising relating to the actions and recommendations of the Monitor, it is not evident that the SOPs have been thoroughly reviewed to ensure consideration or incorporation of the provisions of the Injunction. For the most part, the corporate compliance SOPs were created and last revised prior to the Injunction. Moreover, the business practices and SOPs impacted by the Injunction extend beyond the area of corporate compliance.

58. Illustrative examples of SOPs and policies that involve matters that are impacted by the Injunction include: Corporate Compliance Monitoring; Corporate Compliance Investigations; Corporate Compliance Hotline Operations; Ethics & Compliance Committees and Enterprise Risk Management Council; Ethics & Compliance Training; Fair Market Justification Statement; Ethics & Compliance Risk Management; Customer Vetting Process; Association Governance Committee; Guidance for providing meals to HCPs; Process for fulfillment of unsolicited requests for clinical product presentation; and Rhodes Code of Business Ethics.

59. The Monitor recommended that the Company review and revise these SOPs, and the Company has reported to the undersigned that it is in the process of doing so. **The undersigned will review those SOPs for consistency with the Injunction once the Company's work is complete.**

60. The Monitor does not hold concerns that the failure to reflect the Injunction's requirements within every relevant SOP indicates noncompliance with the terms of the Injunction. Rather, it is a sensible and preventative practice to ensure these SOPs and policies align with the Injunction's terms.

61. In raising this issue to the Company and independent of the Monitor's involvement and recommendations, the Ethics & Compliance Department informed the Monitor that it is creating a policy portal that allows Ethics & Compliance to maintain policies in a centralized place and disseminate them to employees where appropriate. Additionally, the Ethics and Compliance Department is working with a vendor to develop modules for training the employees on some of these policies.

62. **The undersigned Monitor recommends that the Company review the entirety of the SOPs and corporate policies relating to Opioids and incorporate the requirements of the Injunction where appropriate. The Company has agreed to this recommendation.**

63. The Company has explained to the Monitor that reviewing and revising the SOPs and creating of training modules is a priority of the Company, though will naturally take time. **The Monitor will include a summary of work completed by the Company in the next Report**.

IV. LOBBYING RESTRICTIONS

64. Since the filing of the Seventh Report, the Monitor has reviewed: 20 quarterly reports reflecting the actions of contracted firms at the state level and three at the federal level, covering the period from October 1 through December 31, 2021, and one additional state report covering the third quarter of 2021.

65. In one instance, a state-level firm reached out to representatives in the offices of the Governor, Attorney General and Legislative staff, to inform that the firm has taken over as the point for governmental affairs matters relating to Purdue Pharma.

66. Since the filing of the last Report, the Company's Executive Vice President, General Counsel and Corporate Secretary notified the Monitor that representatives of the Company may be speaking to members of Congress and their staff regarding the SACKLER Act (H.R. 2096/S. 2472 and H.R. 4777/S. 2497). The Act would prohibit a bankruptcy court from releasing claims against non-debtors brought by states, tribes, municipalities, or the federal government.

67. The undersigned Monitor reviewed the Act and informed the Company that interactions by the Company relating to the SACKLER Act would not be in contravention of the Injunction.

68. As of the filing of this Report, no Company employee or Officer interactions with members of Congress or their staff relating to the SACKLER Act have occurred. Federal consultants under contract with the Company have reached out to Congressional staff to gather information about possible hearings on the Act.

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

70. Since the filing of the last Report, the Head of Government Affairs and Public Policy has left the Company. That position has been filled by internally promoting a member of the state affairs team. The Company does not currently intend to fill the position vacated by the promotion. There are now five employees working in Government Affairs and Public Policy Department, down from six as of August 2021. (See Sixth Report, Paragraph 89.)

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

V. BAN ON HIGH DOSE OPIOIDS

72. 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).

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

VI. SUSPICIOUS ORDER MONITORING AND REPORTING

A. Pended Orders, Downstream Orders of Interest and Reporting to the Distributor and Drug Enforcement Administration

74. 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.

75. Moreover, as noted in the Seventh Report, between August 1, and October 31, 2021, based on the review of downstream customers, 35 downstream orders of interest were reported to the DEA and the customer's distributor. (Seventh Report, Paragraph 149.) Between November 1, 2021, and the filing of this Report, 61 downstream orders of interest were reported to the DEA and the customer's distributor, with the majority of those reports coming from the 867 data, rather than chargebacks.

76. In the Seventh report, the undersigned Monitor noted that the Company had begun receiving weekly detailed sales reporting information, or reports containing 867 data, from Amerisource Bergen regarding the Company's generic products, and that by reviewing this

information, the Company identified five unique downstream customer orders of interest for further review and reporting. (Seventh Report, Paragraph 146.)

77. Since the last Report, the Company is now procuring 867 sales data for Rhodes' generic and branded products from Amerisource Bergen, Cardinal and McKesson. Purdue Pharma receives the sales data weekly, and it typically reflects sales occurring between one and three weeks prior.

78. The sales data, and product inventory data, or 852 data, is reviewed in addition to, not in replacement of, the chargeback data.

79. Since the last report, the SOM team has also worked with Contracts and Government Programs at the Company to receive better information relating to the chargebacks, including the ability to review chargebacks by zip code, geographic area, and pharmacy size. The IT system that allows greater analysis of this information has also added the capability to review by zip code and hotspots. (Sixth Report, Paragraphs 176-180.)

B. Restricting Supply of Company Opioid Products to Downstream Customers

80. While practices have certainly improved relating to reporting rejected and pended orders and downstream orders of interest, the Company has never instituted any policies to preclude or discourage those downstream customers of interest or concern from continuing to dispense the Company's products.

81. Based on discussions with the Vice President of Ethics and Compliance, it is the Monitor's understanding that the Company has been considering what measures could be taken to limit the supply of Opioid Products to certain downstream customers.

82. At least one Opioid manufacturing Company, Mallinckrodt, PLC, has taken several steps to restrict certain downstream customers. When Mallinckrodt imposes a

chargeback restriction on a pharmacy, all direct customers and the DEA receive a letter notifying them that Mallinckrodt will no longer process chargebacks for that pharmacy. A chargeback restriction remains in place until Mallinckrodt approves the pharmacy's request for reinstatement, and a pharmacy is only reinstated after a third-party consultant or the pharmacy's distributor provides Mallinckrodt with a due diligence report that meets its standards. This process is outlined in Paragraph 11.10 of the Second Monitor Report in Mallinckrodt, PLC, et al. v. State of Connecticut, et al. (https://restructuring.primeclerk.com/mallinckrodt/Home-DocketInfo, Docket # 3409).

83. In that matter, the Monitor recommended that Mallinckrodt use best efforts to ensure that its chargeback restrictions restrict not only chargeback payments, but also the supply of Opioid products to a restricted pharmacy. Mallinckrodt is implementing this recommendation by 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. (Mallinckrodt Fourth Monitor Report, https://restructuring.primeclerk.com/mallinckrodt/Home-DocketInfo, Docket # 6185, Paragraphs 11.13-11.15.)

84. Moreover, as part of the settlement with the three largest distributors, Amerisource Bergen, Cardinal and McKesson, those distributors are establishing procedures for rejecting orders of controlled substances and terminating the eligibility of certain customers to receive controlled substances. (https://www.attorneygeneral.gov/wp-content/uploads/2021/07/2021-07-21-Final-Distributor-Settlement-Agreement.pdf, Sections XIII and XIV.)

85. Based on the Monitor's identification of the steps Mallinckrodt had taken, Purdue Pharma's SOM Director has been in conversations with his counterpart at Mallinckrodt.

86. **The Monitor recommends 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. The Company has agreed to this recommendation.**

87. It is evident that there is not meaningful sharing of best industry practices relating to Suspicious Order Monitoring and compliance. **As the Company continues its review and investigation as to what might be the best practice to place restrictions on downstream customers, the undersigned will also endeavor to further ascertain what additional information may be available and include in the next report the Company's progress.**

C. Other Measures Implemented by Suspicious Order Monitoring

88. Since the last report, the SOM team worked with Corporate Security so that SOM will now receive all reports of counterfeiting, loss, or theft. This has already proven to have value in identifying and reporting downstream customers of concern.

89. The SOM team also commenced reviewing the information gathered from the Opioid Product Savings Card program, to assess whether patients are receiving medications prior to when they should, whether there are patterns that might suggest doctor shopping, and anything else that could present a risk of or potential for diversion.

VII. INITIAL COVERED SACKLER PERSONS

90. 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 Eighth Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor