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)**

SEVENTEENTH 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 Seventeenth Monitor Report, and the undersigned's twelfth 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" 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 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 generally

[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), Purdue Products 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 employees.

INTRODUCTION – STEPS TAKEN SINCE SIXTEENTH REPORT

1. Since the filing of the Sixteenth Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue including the: Executive Vice President, General Counsel and Corporate Secretary; Vice President, Chief Compliance Officer; Vice President, Legal Strategy and Public Health Initiatives; Vice President, Sales & Marketing; Director, Ethics & Compliance; Associate Director, Ethics & Compliance; Analyst, Ethics and Compliance; and Purdue's outside counsel.

2. Since the filing of the Sixteenth 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.

SIXTEENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Sixteenth 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. Continuing to work with the Company regarding using rebate information for Suspicious Order Monitoring purposes. (Fifteenth Report, Paragraph 26.)

b. Using information from the Savings Card program for Suspicious Order Monitoring. (Fifteenth Report, Paragraph 45.)

c. Providing the Monitor with Reports of Concerns on a quarterly basis. (Fifteenth Report, Paragraph 59.)

d. Providing the Monitor with the Incident Report database on a quarterly basis. (Fifteenth Report, Paragraph 103.)

DISCUSSION AND ANALYSIS

I. BAN ON PROMOTION

A. Sales Team for Public Health Initiative Products

4. 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.)

5. In the Eleventh Report, the Monitor provided an overview of the outside sales force that Purdue had contracted to promote its Public Health Initiative ("PHI") products. (Eleventh Report, Paragraphs 13 to 31.) At the time, in August 2022, there were five employees with the contracted company involved in the promotion of Nalmefene: The National Business Director, who devoted 25% of his time to this project, three Key Account Managers ("KAMs"), and one Virtual Key Account Manager ("VKAM"). (Eleventh Report, Paragraph 15.)

6. The Company recently updated the undersigned regarding staffing of the contracted sales force working on behalf of the Company. There is currently a Project Director, spending 25% of their time, and a Regional Manager and 10 Key Account Managers spending 100% of their time, promoting and selling the Company's Nalmefene product. One of the Key Account Manager positions is currently vacant.

7. The Vice President, Chief Compliance Officer, reported to the undersigned that she has received the training records from all the contracted sales force staff, demonstrating that they have completed training on the Injunction and certifying that any Opioid-related questions are referred in writing to the Company's Medical Information Team. This certification occurs every six months.

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

9. The undersigned requested and received a copy of the certifications and training for the contracted sales force and finds them consistent with the Company's obligations under the Injunction.

10. The Monitor also requested all Opioid-related questions or requests sent from the contracted sales force to the Medical Information Team. The Company has reported that no questions or requests have been made.

11. In the Eleventh Report, the Monitor reviewed the training and promotional materials for Nalmefene, and reported those materials were consistent with the Injunction. (Eleventh Report, Paragraphs 28 and 29.)

12. Since then, the Company has updated the training and promotional materials. The Monitor requested and received the updated materials, reviewing well over 100 documents. This included specific trainings about the requirements of the Injunction, as well as reference to the Injunction in the general trainings about Nalmefene. It further included call scripts, Frequently Asked Questions, Requests for Proposals for investigator-initiated research, print advertising, digital ads, social media content, mail pieces, pricing and ordering materials, press releases, emails, websites, tablecloths and banners, and other material relating to promotion and training.

13. Having reviewed the training and promotional materials, and recognizing that the contracted sales personnel also have certified that they have received and understand training on the Injunction and will direct inquiries relating to Opioid Products to Purdue's Medical Information team, the Monitor is not aware of any inconsistencies with the Injunction relating to the Company's promotion and distribution of Nalmefene.

B. Attendance at Conferences

14. Section II.A of the Injunction sets forth the ban on promoting Opioids or Opioid Products. "Promoting" is expressly defined in the Injunction as "the dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, does, and/or strengths of Opioid Products." (Injunction, I.O.)

15. The prohibition Purdue agreed to covers activities relating to sales representatives, outside speakers, medical education programs, websites and social media, written publications, digital and printed advertisements, Internet search optimization techniques, and Internet marketing. (Injunction, II.A.1.a-h.)

16. The Injunction also sets forth permissible activities, and expressly permits the promotion of products related to the treatment of Opioid use disorders, abuse addiction or overdose, and rescue medications. (Injunction, II.A.3-4.)

17. As noted in the last Report, Medical Affairs intended to have a booth at the upcoming American Society of Health-System Pharmacists Mid-Year conference in early December 2023, to represent Purdue Medical Affairs, address questions, provide a high-level overview of the Public Health Initiatives, and share research priorities. The Company agreed to

follow up with representatives of Medical Affairs after the conference to ascertain if there were any inquiries or interactions relating to Opioid Products. (Sixteenth Report, Paragraphs 7-11.)

18. The Company reported that no inquiries or interactions occurred at the conference relating to Opioid Products.

C. Customer Service Department Responses to Patients Seeking Disposal Pouches for Opioids

19. During this reporting period, the Company sought review and approval from the Monitor for a proposed practice of having the Customer Service Department respond to Health Care Provider ("HCPs") requests, seeking prepaid mail-back envelopes for disposal of Opioid Products.

20. On April 3, 2023, the U.S. Food and Drug Administration ("FDA") published requirements that Opioid analgesic manufacturers provide prepaid mail-back envelopes to outpatient pharmacies and other dispensers as a safe disposal option and develop educational materials. (https://www.fda.gov/news-events/press-announcements/fda-moves-forward-mail-back-envelopes-opioid-analgesics-dispensed-outpatient-settings).

21. The FDA's requirement is part of the Agency's Risk Evaluation and Mitigation Strategy ("REMS"). REMS is "a drug safety program that the [FDA] can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." (https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems).

22. Purdue and Rhodes are part of the consortium of REMS Program Companies ("RPC"), consisting of manufacturers of long and short-acting opioid analgesics, which share a class-wide, single REMS. (https://www.opioidanalgesicrems.com/home.html).

23. The RPC intends to use a vendor to manage the distribution and destruction of the mail-back envelopes and will ensure that outpatient pharmacies and dispensers are able to order mail-back envelopes by phone and online through the Opioid Analgesic REMS website and Call Center.

24. The REMS modification was submitted to the FDA in January 2024, and, after FDA approval, the RPC will have six months to implement the program.

25. At issue is whether Purdue's Customer Service Department can direct HCPs to the Opioid Analgesic REMS website and Call Center or the third-party vendor, should the Company receive an inquiry regarding how to obtain the mail-back envelopes.

26. Both the Injunction and Company policy set the permissible interactions with HCPs, and instances when the Customer Service Department can field and respond to calls or emails from HCPs. (Seventh Report, Paragraphs 37 to 57; Injunction, II.2.f., g.)

27. The Injunction does not preclude the Company from all contact with HCPs. In the context of the Promotion ban, it expressly permits the Company to "[p]rovide scientific and/or medical information in response to an unsolicited request by a Health Care Provider concerning Opioid Products by providing truthful, balanced, non-misleading, non-promotional scientific or medical information that is responsive to the specific request." (Injunction, II.2.f.) However, "[s]uch responses should be handled by medical or scientific personnel at the Company who are independent from the sales or marketing departments." (Injunction, II.2.f.)

28. Moreover, subject to limited exceptions not relevant here, Company policy provides that "all medical and Patient and Health Care Professional Opioid Product Inquiries should be handled by the Medical Information Department." (Customer Service Department Call Handling Response and Logging Process Standard Operating Procedure (CS 7.20, page 1).)

29. While inquiries about the mail-back envelopes relate to Opioid Products, the Customer Service Department will only be referring the HCPs to the vendor that can provide the prepaid mail-back envelopes that are required by the FDA's REMS. In this scenario, the Monitor does not find it necessary for the Customer Service Department to refer such inquiries to Medical Information.

30. **To the extent any contact by a HCP goes beyond simply requesting the envelopes, the Monitor recommends that Customer Service transfer such inquiries to Medical Information. The Monitor further recommends that the Company train the Customer Service and Medical Information Departments on this issue, and maintain a record of any such inquiries that occur. The Company agrees to this recommendation.**

II. GOVERNMENT AFFAIRS AND LOBBYING RESTRICTIONS

A. Contracted Firms

31. Since the filing of the Sixteenth Report, the Monitor has reviewed 21 quarterly reports reflecting the actions of contracted firms at the state level and three at the federal level, covering the period from October 1 to December 31, 2023.

32. Contracted firms monitored legislation relating to various topics. No firms provided testimony or advocacy, and all firms certified compliance with the terms and conditions of the Injunction.

33. The undersigned Monitor finds that the activities of the contracted firms are consistent with Section II, Part D of the Injunction.

B. Public Policy Agenda

34. In the last Report, the undersigned noted that the Government Affairs & Public Policy Department was "currently working on developing an updated public policy agenda

relating to the Public Health Initiatives that will help steer government affairs activity going forward, and hopes to start actively undertaking that agenda next calendar year." (Sixteenth Report, Paragraph 40.)

35. The undersigned has requested the updated public policy agenda, and, to date, the Company has reported that it has not been finalized and approved. The undersigned will provide additional detail in the next Report.

III. BAN ON HIGH DOSE OPIOIDS

36. Under Section II.E of the Injunction, Purdue 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).

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

IV. SUSPICIOUS ORDER MONITORING AND REPORTING

A. Access to Blinded Downstream Customer 867 Data

38. In the Ninth Report, the Monitor detailed that the Company did 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.)

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

40. The Monitor noted in the Twelfth Report that the Company had reached an agreement with two of the four pharmacy chains, but negotiations with CVS and Rite Aid had reached an impasse. (Twelfth Report, Paragraphs 84 to 88.)

41. Last year, CVS entered into a settlement agreement that requires, among other things, that it:

> shall consent to the provision by their distributors of the Settling Pharmacy's unblinded "867 Data" (data sent from the distributor to the manufacturer concerning the sale of its products to Settling Pharmacy) to opioid manufacturers on any particular Designated Controlled Substances manufactured by them as soon as commercially reasonable and at no cost to the manufacturers, provided that, pursuant to a prior written agreement with Settling Pharmacy, the opioid manufacturers agree (a) to ensure the confidentiality of the 867 Data, except as required by law; (b) to implement safeguards and procedures to limit access to and use of the 867 Data, except as required by law; (c) that the 867 Data shall be used solely for compliance purposes as part of their Suspicious Order Monitoring programs; and (d) that the 867 Data shall be shared only with specified personnel and shall not be shared with business or sales personnel.

(https://nationalopioidsettlement.com/wp-content/uploads/2023/10/2023-12-09-CVS-Global-Opioid-Settlement-Agreement-with-2023-02-03-Technical-Corrections-and-2023-09-29-Updates.pdf, page 636.)

42. **The Monitor recommends that the Company seek to enter into a written agreement with CVS, consistent with the terms set forth above, to gain access to the unblinded 867 Data. The Company agrees to this recommendation.**

B. Site Visits

43. In the Sixth Report, the undersigned detailed the Company's plan to have site visits of each customer at least once every three years. At the time there were 56 wholesaler customers. (Sixth Report, Paragraph 157 to 161.)

44. The site visits focus on the professional experience of the direct customer's key employees and total employees, SOM processes, relationship and contact with law enforcement, and the physical layout of the customer's facility. Recommendations are often made regarding training in topics of drug diversion and supply chain networking and resources. In some instances, specific recommendations are made, such as the importance of conducting downstream customer site visits and the location of security cameras.

45. In calendar year 2023, the SOM Team conducted 18 physical site visits of distributor customers, and two virtual visits of customers to review a new warehouse and a new distribution center.

46. The SOM Team relayed to the undersigned that, in addition to fulfilling the requirements of the SOP and assessing the wholesaler's SOM program and physical layout, the site visits have been beneficial in forging and continuing relationships with the wholesaler and the Company's SOM Team.

47. The recommendation from the Sixth Report that each customer receive a physical site visit at least once every three years has been in effect for over two years, and by the end of calendar year 2024, all customers will have had a site visit in that three-year period. The Company also provided the undersigned a schedule reflecting the site visit schedule.

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

48. During calendar year 2023, there were 12,504 orders fulfilled by the Company to Distributors. Of those, 1,656 orders pended and were reported to the DEA, and 28 orders were rejected by the Company. In comparison, during calendar year 2021, there were 13,158 orders fulfilled by the Company to Distributors. Of those, 2,071 orders pended and were reported to the DEA, and 51 orders were rejected by the Company. (Eighth Report, Paragraph 74.)

49. The reasons for rejection vary. Some orders are rejected because the wholesaler placed duplicate orders for the same downstream customer, the wholesaler incorrectly keyed in information such as the date of the order, or an error in the wholesaler's system. An order was rejected because it was placed for a direct customer's previous address. Orders can be rejected that are placed to try to account for supply disruptions. An order was rejected for a new customer because the order was placed prior to the SOM Team onboarding the new customer. At times, the wholesaler asks the SOM team to reduce an order, and rather than doing so the entire order is rejected. Often orders are rejected because the wholesaler fails to timely provide sufficient information in response to the SOM Teams inquiries within seven days.

50. Reviewing the correspondence relating to rejected pended orders reflects that the SOM Team works diligently to get additional information about pended orders, often reaching out to the wholesaler multiple times, both to obtain additional information and following up on the additional information provided.

D. Atypical/Excessive Quantity Thresholds and Use of Rebate Information for Suspicious Order Monitoring

51. 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.)

52. 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.)

53. At issue throughout the past 21 months of review and reporting is whether using information for SOM purposes that the Company receives for validating rebates could violate the Health Insurance Portability and Accountability Act ("HIPAA") and/or the Company's contractual provisions with Pharmacy Benefit Managers ("PBMs"), which the Company believes largely derive from restrictions that the PBMs are subject to under HIPAA, and, conversely, whether failing to use this information could violate the Controlled Substances Act and/or the Injunction.

54. The Monitor noted in the last Report that, "[w]hile the undersigned is close to reaching conclusions and making recommendations, the Company has requested additional time to consider those conclusions and recommendations." (Sixteenth Report, Paragraph 55.)

55. On November 20, 2023, the same date that the Monitor filed the Sixteenth Report, the undersigned also provided the Company with its draft analysis and conclusions that failure to use the rebate information for SOM purposes was inconsistent with DEA's expectations that registrants use all information available to it to comply with its obligations under the Controlled Substances Act and its regulations to detect and prevent diversion. The Monitor further considered whether failing to consider rebate information that could shed light on potential diversion could be deemed a violation of the Controlled Substances Act and the Injunction.

56. While the Company was not prepared to substantively discuss these issues until immediately prior to the filing of this Report, the Company has recently addressed this issue at its highest levels. The undersigned has had productive discussions with the Company and the Company is prepared to take certain steps to attempt to address the Monitor's concerns regarding atypical prescriptions. As a result of the Company's delay in making this proposal, the Monitor has not formed an opinion as to whether it should make additional recommendations regarding use of the rebate validation process for SOM purposes.

57. The Monitor expects the Company to diligently and expeditiously respond to any further questions the Monitor has about the Company's proposal, and if sufficient progress is not made in the near future, the Monitor will consider filing an interim Report. Otherwise, the Monitor will report further in the next Report.

E. Restricting Supply of Company Opioid Products to Downstream Customers

58. As set out in substantial detail in the last Report, the Company has now implemented a process to restrict supply of controlled substances marketed and sold by Purdue of Purdue Opioid Products to downstream customers that pose a risk of diversion. (Sixteenth Report, Paragraphs 57 to 107.) The following paragraphs provide an update and assessment of the status of the implementation of this process, results to date, issues that have arisen, and recommendations going forward.

340B/FSS Designated Downstream Customers

59. In the last Report, the Monitor explained that Designated Downstream Customers that held contracts under Section 340B of the Public Health Service Act or the Federal Supply Schedule ("FSS") would be treated differently than other downstream Customers upon SOP implementation. Specifically, "[f]or 340B and FSS Downstream Customers deemed to be Designated Downstream Customers, Purdue will notify the Direct Customer and DEA, but will not: (a) request that Direct Customers stop shipping controlled substances marketed and sold by Purdue; (b) include FSS and 340B customers on the quarterly list of Designated Downstream Customers provided to all of Purdue's distributors; or (c) terminate the Designated Downstream Customer from the Purdue Chargeback Program." (Sixteenth Report, Paragraph 77.)

60. The Report also noted that this was intended to be a temporary measure and, absent objection from the Veterans Administration or the Health Resources & Service Administration, 340B/FSS Designated Downstream Customers would be treated the same as other Designated Downstream Customers. (Sixteenth Report, Paragraph 84.)

61. The Company notified the Federal agencies and did not receive any objection. Accordingly, the 340B/FSS Designated Downstream Customers are now treated the same as the others, and the SOP has been amended to reflect this treatment.

Results to Date

62. The Company implemented the SOP on October 2, 2023, and, to date, three Downstream Customers of Interest have been identified. Since the last Report, the process for review and evaluation of the three Downstream Customers of Interest has run its course. (Sixteenth Report, Paragraph 94.) The Company provided the undersigned with the materials reviewed through the process of evaluating the Downstream Customers of Interest, and the Monitor discussed the specifics of the matters with the Chief Compliance Officer, and the Director, Ethics & Compliance.

a. ***Downstream Customer of Interest One***

63. One of the Downstream Customers first came to the attention of the SOM Team because of a reported DEA sanction and settlement. After conducting further review as detailed in paragraph 61 of the Sixteenth Report, the Company reported the information to the customer's parent distributor and requested that the distributor conduct a due diligence review. This is consistent with the SOP. (Sixteenth Report, Paragraph 62.)

64. The Company also reported the Downstream Customer of Interest to the DEA. While not required by the SOP, doing so is consistent with Company practice when identifying chargeback outliers and downstream customers of interest.

65. The SOP provides that the parent distributor's "due diligence review should include an in-depth analysis of [Indicators of Possible Diversion] including, at a minimum:" cash to non-cash ratio; single-entity ratio; unusual formulation purchasing, prescriber to pharmacy

distance, pharmacy to patient distance; prescriber activity and licensure; irregular activity of the downstream customer (i.e., dispensing only controlled substances); and the customer's previous termination(s) history. (CC-SOP-000019, 6.I.4.)

66. Similarly, the letter from the Company to the parent distributor provides, "We ask that your due diligence review include an analysis of: [the same factors listed above, as well as a t] horough review of indicator(s) of potential diversion identified by Purdue and shared with you, and [o]ther data you deem relevant."

67. After exchanges with the parent distributor and considered review, Purdue concluded that the pharmacy should be maintained as a customer for controlled substances and should be removed from the Downstream Customer of Interest list.

b. Downstream Customer of Interest Two

68. As to the second Downstream Customer of Interest, this pharmacy also came to the attention of the SOM Team because of a DEA sanction and settlement. After conducting further review, the Company provided notice to the parent distributor and the DEA.

69. After reviewing and analyzing the information provided, Purdue concluded that the downstream customer should be maintained as a customer for controlled substances and removed from the Downstream Customer of Interest list.

c. Downstream Customer of Interest Three

70. The third Downstream Customer of Interest came to the attention of the SOM Team through review of chargebacks. Upon further reviewing the downstream customer as a chargeback outlier, the SOM Team discovered an outdated mailing address, multiple suppliers in ARCOS, and a history of disciplinary action.

71. After exchanges with the parent distributor, Purdue concluded that the Customer of Interest should be a Designated Downstream Customer and requested that the parent distributor cease shipping Purdue's controlled substances to that customer.

72. As required by the SOP (Sixteenth Report, Paragraphs 68 and 69), Purdue also notified the rest of the Company's direct customers, requesting that they cease shipping Purdue controlled substances to the Designated Downstream Customer and notifying them that they would not honor chargeback requests on sales to the Designated Downstream Customer.

73. The SOM Team relayed to the undersigned that to date they have not received any pushback or concerns from any of the direct customers receiving notice of the Designated Downstream Customer, and have received positive feedback from many of the direct customers receiving the notice.

Contract Negotiations

74. In the last Report, the Monitor provided updates on the status of the negotiations with the principal distributors and recommended that: (1) "the Company endeavor to mutually agree with the three main distributors that each distributor terminate supply to customers the Company identifies as posing a diversion risk following a review consistent with the SOP where the Company makes a determination that the customer is a Designated Downstream Customer;" and (2) "individuals at higher levels of Purdue not typically responsible for commercial and contracting functions become directly engaged in the outreach to and negotiations with the distributors and GPOs, and those Company individuals endeavor to elevate the negotiations to higher levels at the distributors and GPOs as well." (Sixteenth Report, Paragraphs 95-107.)

75. The Monitor is pleased that the Company has been working to timely fulfill these recommendations, and the Vice President, Chief Compliance Officer has been regularly and consistently involved in advancing and participating in these discussions.

76. While at the time of filing of the last Report, only one of the main distributors had agreed to honor Purdue's request not to ship Opioid Products to Designated Downstream Customers, there has now been meaningful engagement and exchanges with the three principal distributors.

77. All three of the principal distributors have now agreed to cease shipping Purdue controlled substances to Designated Downstream Customers, upon request made by Purdue.

Analysis

78. Through the process of working with direct and downstream customers on the first three reviews of Downstream Customers of Interest, the Company and the parent distributors have worked together and, in many respects, gained experience and learned lessons that will be instructive going forward.

79. First, in the last Report, the Monitor reported on the shortcomings of the SOP and processes to restrict supply of Opioid Products to Designated Downstream Customers, because (a) the Company's branded Opioid Products are largely not subject to chargebacks, and (b) the Company had earlier contended that implementing these processes were dependent upon contract amendments with the Company's distributors and GPOs. (Sixteenth Report, Paragraph 84, 106.)

80. The agreements reached with the three principal distributors to cease shipping Purdue controlled substances to Designated Downstream Customers, upon request made by

Purdue, largely resolves these shortcomings. The recommendation from the last Report is fulfilled. (Sixteenth Report, Paragraph 101.)

81. Moreover, the undersigned appreciates the direct involvement and diligence of the Vice President, Chief Compliance Officer in advancing those discussions. The Company has fulfilled the recommendation from the last Report to elevate these negotiations. (Sixteenth Report, Paragraph 104.)

82. Second, in working through the steps set out by the SOP, the Company has received constructive feedback from the distributors. These exchanges have led to minor modifications to the SOP, including how notice is provided to the direct and downstream customers, and giving Designated Downstream Customers that fail to meet the timelines an opportunity to be reinstated twice, assuming all conditions are met.

83. Third, continued application of the SOP will further inform what is necessary to fulfill both the letter and spirt of the SOP. For example, one distributor has suggested it won't necessarily perform due diligence on the downstream customer in a manner addressing all the indicators of possible diversion requested by the Company and set forth in the SOP. It is premature to draw conclusions or make recommendations on whether this impacts the efficacy of the program, and further review and application will inform this determination.

84. The Monitor appreciates the continuing efforts of the Company, in partnership with its customers, and believes the program established by the Company is one that should be replicated across the industry.

F. Suspicious Order Monitoring Review of Savings Card Information

85. As noted in the last Report, the Company successfully negotiated amendments to the contracts with the Savings Card program vendors to allow the information to be shared with the SOM Team. (Sixteenth Report, Paragraphs 108 to 110.)

86. The SOM Team reported to the undersigned that they have been receiving the savings card information since December 2023, and are reviewing and analyzing it by applying various filters. While they have not identified any trends or outliers to date, as additional information is received it will better inform the use of and applicability of this data for SOM purposes.

V. INITIAL COVERED SACKLER PERSONS

87. 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's compliance with the Injunction.

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

STEPHEN C. BULLOCK
Monitor