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)**

SIXTH 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 Sixth Monitor Report, and the undersigned's second since being appointed on February 18, 2021, will include an outline of actions taken to date to determine compliance with the terms and conditions of the Voluntary Injunction ("Injunction"), a 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 has been responsive in

[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.

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

INTRODUCTION – STEPS TAKEN SINCE FIFTH REPORT

1. Since the filing of the Fifth Report the undersigned Monitor has continued with a series of interviews with employees at Purdue Pharma, including discussions with Marc Kesselman, Executive Vice President and General Counsel and Secretary; Jon Lowne, Chief Financial Officer; Jim Doyle, Vice President & General Counsel at Rhodes Pharmaceuticals; Margaret Feltz, Vice President, Ethics & Compliance; Vice President & General Counsel at Rhodes Pharmaceuticals; Richard Silbert, Vice President, Legal Strategy & Public Health Initiatives; Donogh McGuire, Vice President, Technical Operations; Matthew O'Donnell, Executive Director, Head of Government Affairs & Public Policy; Kathy Konka, Director, Federal Government Affairs and Policy; Beth Evans, Director, Sales & Operations Planning; Penny Muir, Senior Manager, Ethics & Compliance; John Gilbride, Director, Ethics & Compliance; Adrienne Baker, Associate Director, Ethics & Compliance; Natalie Silva, Manager, Ethics & Compliance; William Shank, Head of Market Access; Christine DeStefano, Head of Total Rewards; and Roxana Aleali, Vice President, Deputy General Counsel and Assistant Corporate Secretary.

2. Since the filing of the Fifth Report the undersigned 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.

3. Since the filing of the Fifth Report the undersigned Monitor has retained the services of a consultant to assist in reviewing the rebate, pricing, and fee structures. As will be discussed below, that review is just getting underway.

FIFTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

4. In the Fifth Report filed by the undersigned Monitor, 15 different recommendations and areas of inquiry for this Sixth Report 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.

5. The recommendations and areas of inquiry included: the Company's pricing practices (Paragraph 74); quotas (Paragraph 85); bonus and incentive structure (Paragraphs 91 and 93); state audit reports and information concerning research (Paragraph 103); Purdue Pharma employees' organization and board memberships (Paragraph 110); drug discount cards (Paragraph 128); various topic pertaining to Suspicious Order Monitoring, including staffing (Paragraphs 141 and 181); further review of due diligence and annual reports (Paragraph 160); customer site visits (Paragraphs 162 and 164); automating threshold calculations (Paragraph 182); corroboration of pended order justifications (Paragraph 193); and further evaluation and assessment of the chargeback system (Paragraph 207).

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

7. Additionally, where new areas of inquiry have been undertaken since the Fifth Report, these new areas will be discussed.

DISCUSSION AND ANALYSIS

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

A. Medical Information Team

8. The undersigned has reviewed inquiries made of the Medical Information Team for the period from early April to mid-July 2021, and finds the responses and activities of Purdue Pharma's Medical Information team continue to comply with the Injunction.

B. Customer Service Department

9. Three days prior to filing this Sixth Report, the undersigned Monitor received a letter from Marc Kesselman, Executive Vice President and General Counsel and Secretary ("Customer Service Letter").

10. The Customer Service Letter is included with this Report as Appendix A.

11. The Customer Service Letter raises several matters necessitating further review and examination, including: (a) whether the actions of the Customer Service personnel are consistent with the Injunction; (b) the sufficiency of the remediation efforts the Company implemented on July 14, 2021; (c) the adequacy of the Company's training and education of its employees regarding the Injunction; and (d) whether the Company's actions in identifying, investigating, and remediating the issues raised in the Customer Service Letter prior to informing the undersigned are consistent with the letter and spirt of the Injunction's obligations that Purdue Pharma "fully, completely and promptly cooperate with the Monitor."

12. The Company has promised the undersigned its cooperation in providing documents, interviews and answering follow-up questions.

13. The undersigned will report findings in the next Report and/or take other actions as set forth in Section II.H.4 of the Injunction.

C. Commercial Team and Pricing Arrangements

14. Purdue Pharma continues to have third-party contract sales forces for the purposes of promoting its non-opioid product, Adhansia XR®. Those sales forces have received continuing training on the Injunction, and certified in July 2021 that any inquiries from a health care professional about a Purdue Pharma medication other than Adhansia XR would be referred in writing to the Company's Medical Information Team.

15. Since the entry of the Injunction, no inquiries have been referred.

16. In the prior Report, the undersigned detailed the pricing arrangements with Purdue Pharma's customers, Pharmacy Benefit Managers ("PBMs"), and Managed Care Organizations ("MCOs"), and recommended further review of those pricing practices. (Fifth Report, Paragraphs 45-74).

17. Omitted from the first five Monitor Reports was any explanation of the arrangements the Company makes with Group Purchasing Organizations ("GPOs"). A GPO is an entity that helps healthcare providers — such as hospitals, nursing homes and home health agencies — realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors.

18. GPOs do not receive product directly, but they do arrange discounts for their members. The member institutions buy at a discounted price from a wholesaler, and the manufacturer, in this case Purdue Pharma, reimburses the wholesaler the difference between the contract price and the list price, often referred to as Wholesale Acquisition Cost ("WAC").

19. Purdue Pharma has contracts with 11 different GPOs that include branded Opioid Products. The discounted price for Opioid Products can vary, depending upon the product

and the contract. Additionally, Purdue Pharma pays GPOs administrative fees under the agreements, either monthly or quarterly depending on the contract.

20. For generic Opioid Products, Rhodes Pharmaceuticals contracts with 14 different GPOs. Rhodes Pharmaceuticals typically pays the GPOs an administrative of fee, which varies depending upon the contract.

21. To gain a better understanding of the rebate, fee and discount arrangements, and the consistency of those prices with the terms of the Injunction, the undersigned Monitor recommended retaining consultants that could assist in undertaking a review, comparing among other things any differences in practices between scheduled and nonscheduled products, and the pricing practices of scheduled drugs across the industry. (Fifth Report, Paragraph 74).

22. The undersigned recently enlisted Pearl Management Consulting ("Pearl") to assist in undertaking this review. The principals at Pearl, John Glover and Beril Pekin, have significant experience relating to the pharmaceutical industry and pricing practices. Prior to founding Pearl, Mr. Glover served as Practice Leader for the contract operations outsourcing organization at IQVIA (formerly IMS Health) and Ms. Pekin was a Principal at IMS Health.

23. The undersigned has requested Court approval of this consultant to assist in undertaking the review, and expects to have full or partial results from the review prior to the issuance of the next quarterly report.

D. Purdue Pharma's Manufacturing and Procurement Quotas

24. As explained in the Fifth Report, pursuant to the Federal Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and implementing regulations, the Drug Enforcement Administration ("DEA") sets aggregate manufacturing and production quotas for certain controlled substances, including opioids. Upon application, the DEA then allocates individual

manufacturing and procurement quotas to manufacturers. The DEA can revise a company's quota at any time during the year because of increased or decreased sales or exports, new manufacturers entering the market, new product development, or product recalls. (Fifth Report, Paragraph 75).

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

26. From 2018 to 2020, the manufacturing and procurement quotas granted to Rhodes Technologies and Purdue Pharma remained relatively steady or declined. (Third Report, Paragraph 22). In 2021, however, the grants for API used in the manufacture of finished doses of oxycodone and hydrocodone for sale increased over 2020. As was explained in the prior Report, however, this increase is largely attributable to Project Catalyst, the divestiture of the Rhodes Technologies' manufacturing facility in Coventry, RI, and the need to manufacture test batches of finished products using other sources of API after that divestiture as well as changes in the quantities of Rhodes Pharma generic products. (Fifth Report, Paragraphs 78-83).

27. In the Fifth Report, the undersigned observed that "even if one disregards or subtracts the quota requested and received relating to Project Catalyst and only considers the commercial request, the requests granted for quota for API used in the manufacture of finished doses of oxycodone and hydrocodone for sale in 2021 substantially exceed that which was granted in 2020." (Fifth Report, Paragraph 84).

28. To better understand the change in quota, the undersigned Monitor requested additional information from the Company and interviewed Donogh McGuire, Vice President, Technical Operations, and Beth Evans, Director, Sales & Operations Planning.

29. DEA regulations require that by April 1 of each year, manufacturers of controlled substances must apply for quota for the upcoming year. 21 CFR 1303.12(b). Those requests are then considered by the DEA, with a determination made in the first week of December of the initial grant for the upcoming year.

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

a. Forecasts from the market analytics and forecasting group;

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

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

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

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

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

31. The quota requests are submitted by DEA registration number. Accordingly, up until 2020, Rhodes Technologies would request a manufacturing quota for the Coventry, Rhode Island manufacturing site. Upon the sale of the Rhodes Technologies facility to Noramco,

however, the Company submits only quota requests for the procurement of AIP used in the manufacture of finished doses. (Fifth Report, Paragraphs 80-83).

32. Purdue Pharma had also been submitting procurement quota requests tor two different facilities in North Carolina that manufacture finished doses: one in Wilson and one in Durham, known as the Treyburn manufacturing plant ("Treyburn").

33. Although the Treyburn manufacturing plant had a unique DEA registration number, under advisement by DEA, the Company submitted one application for quota under the Wilson, NC registration, and requested that the DEA split the approved quota between the two manufacturing sites.

34. Accordingly, in 2019 the Company had submitted one application for manufacturing of oxycodone, but approximately 60% of the product was manufactured at Wilson and 40% manufactured at Treyburn.

35. In 2019, Purdue Pharma sold Treyburn to Novo Nordisk. The Company ceased manufacturing operations in Treyburn in November 2019 and completely vacated the plant in December.

36. In October 2019, the Company informed the DEA that they were going to cease operations in Treyburn and requested to transfer back some of the quota that had been allocated to that site back to Wilson.

37. During the first week of December 2019, the Company received the quota approvals from the DEA for the upcoming year. The DEA had already split the 2020 quota between the two manufacturing sites, so the initial grant for finished doses of oxycodone for Wilson in 2020 appeared substantially less than what was granted in 2021. However, the DEA

made an additional grant early in 2020 to reflect the finished doses that had been previously manufactured at Treyburn.

38. When comparing the 2020 total grant to that granted in 2021 for oxycodone, there is only about a five percent increase in the quota for finished doses of oxycodone. The Company explained that the increase was primarily driven by increased demand in 2021 for the Rhodes Pharmaceuticals generic oxycodone immediate release product, and that the manufacture and use of OxyContin has continued to decrease in 2021 compared to prior years.

39. Regarding the increase in quota for hydrocodone in 2021, this was due to the fact that there was no grant in 2020, because Purdue Pharma still had API available from its 2019 grant and did need not additional quota in 2020.

40. Accordingly, the undersigned Monitor finds that any increases in granted procurement quota from 2020 to 2021 do not suggest any meaningful increase in production of Opioid Products over the prior year, and supports the conclusion that Purdue Pharma remains in compliance with the ban on promotion of Opioids and Opioid Products.

1. Production for Mundipharma

41. Included in the approved quotas and in addition to manufacturing Opioid Products for Purdue Pharma and Rhodes Pharmaceuticals, roughly five percent of the OxyContin produced in Wilson, NC is sent to approximately 25 locations outside the United States, pursuant to the Company's agreements with Mundipharma.

42. "Mundipharma" refers to the network of independently associated companies ("IACs") outside of the United States that are owned directly or indirectly by the Sackler Parties.

43. Moreover, as has been fully disclosed in filings with the Bankruptcy Court, in addition to the manufacturing of OxyContin for Mundipharma, Purdue Pharma has licensing and

royalty arrangements with Mundipharma, whereby Mundipharma can sell OxyContin outside the United States. (*See, e.g., Disclosure Statement for Fifth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and Its Affiliated Debtors*, Docket 2983 (06/03/21), p. 154.)

44. The Disclosure Statement further noted that the Sackler Parties will be required to use their best efforts to sell the IACs within seven years, with the proceeds going to the Master Distribution Trust, subject to deductions for previously funded Required Settlement Payments to the Master Disbursement Trust and certain other deductions as permitted by the Shareholder Agreement. (*Id.* at 155.)

45. Other than filings with the Bankruptcy Court, the undersigned Monitor has not reviewed the practices of the Mundipharma IACs, as doing so is beyond the scope of the Injunction.

46. The Injunction is unambiguous in only applying to activities and health care providers in the United States and its territories. For example, the definition of "promote" is "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, doses or strengths of Opioid Products," (Injunction, I.O). And "Health Care Provider" is defined as "any **U.S.-based** physician . . . or other person engaged in the business of providing health care services and/or prescribing an Opioid Product and any medical facility, practice, hospital, clinic, or pharmacy engaged in providing health care services and/or prescribing an Opioid Product **in the United States**." (Injunction, I.H., emphasis added).

47. Accordingly, in order for an exploration of the relationships with and practices of the IACs purchasing OxyContin from Purdue Pharma and selling and distributing OxyContin in

countries outside the United States to occur, it would require direction by the newly organized entity if Purdue Pharma emerges from bankruptcy, and/or amendments to the terms of the Injunction.

E. Bonus, Salaries, and Incentives to Purdue Employees

48. The Fifth Monitor's Report provided an overview of the bonus and incentive programs available to certain Purdue Pharma employees, and left outstanding and in need of further review two issues: (a) the inclusion of Project Catalyst in the 2021 corporate scorecard; and (b) the 2021 bonus and incentive structure for the Market Access Team. (Fifth Report, Paragraphs 86-92).

49. In further reviewing the compensation systems, the undersigned reviewed documents and participated a video meeting with William Shank, Head of Market Access; Christine DeStefano, Head of Total Rewards; Roxana Aleali, Vice President, Deputy General Counsel and Assistant Corporate Secretary; Richard Silbert, Vice President, Legal Strategy & Public Health Initiatives; Jon Lowne, Chief Financial Officer; Marc Kesselman, Executive Vice President and General Counsel and Secretary; and the Company's outside counsel.

1. Project Catalyst

50. As referenced in the Fifth Report, the 2021 Scorecard provides that 1.8% of the overall bonus and incentive target relates to "Delivery of Project Catalyst Implementation Plan to include regulatory submission of the following API transfers: Oxycodone APAP Tabs [oxycodone/acetaminophen] and Oxycodone Tabs." (Fifth Report, Paragraph 89).

51. A discussion of Project Catalyst is contained in the prior report in the section regarding manufacturing and production quotas, at Paragraphs 78 to 84. This understanding has since been further confirmed by conversations with the Company. As Purdue Pharma's Chief

Financial Officer explained, by divesting of the Coventry, Rhode Island API manufacturing site and entering into a long-term supply agreement with the purchaser, Purdue Pharma reduced significant underutilized overhead, thereby saving the Company money.

52. The undersigned Monitor finds that including Project Catalyst in the 2021 corporate scorecard, and using that scorecard as a basis for setting additional compensation for Key Insiders and the Market Access Team, does not violate the Injunction.

a. The scorecard expressly provides that the corporate performance objectives "will be adjusted for the margin on branded opioid net sales being higher or lower than Target." (Fifth Report, Paragraph 88).

b. Moreover, and more critically, Project Catalyst did not relate to, or involve, any effort to increase the sales of Purdue Pharma branded or generic Opioid Products, and the additional compensation tied to Project Catalyst available to certain employees for meeting the 2021 performance objectives cannot reasonably be construed as rewarding or disciplining Purdue Pharma employees or other third parties based on or tied to the sales volume for Opioid Products. (Injunction, II.B.1).

2. Incentive and Retention Programs

53. The incentive and retention programs available to Purdue Pharma employees cover three unique categories of employees: key insider employees ("Key Employee Incentive Program" or "KEIP"); a retention program for key employees ("Key Employee Retention Program" or "KERP"); and an incentive compensation program for the Market Access and Trade & Distribution Teams.

54. In each instance, the incentive and/or retention programs for the KEIP and KERP employees are submitted to Bankruptcy Court for review and approval. The 2021 plans were submitted by the Company on June 28, 2021. The hearing on the KERP was held on July 29, 2021, with the Bankruptcy Court entering an order approving the KERP on August 16, 2021. The hearing on the KEIP plan has been adjourned until August 27, 2021.

55. For 2021, representatives of the Company explained that the programs are similar to those approved by the Bankruptcy Court in 2020. Prior to the bankruptcy, the programs were all based, at least in part, upon corporate performance and attaining corporate objectives set out for that year. (Fifth Report, Paragraph 86).

56. Given the lack of detail regarding these programs as set out in the prior Monitor's and the undersigned's last report, a brief discussion of each of the programs follows.

a. Key Insider Employees

57. Purdue Pharma's KEIP employees, as permitted by the Bankruptcy Code (11 U.S.C. § 101(31)(B)(i)–(vi)), are the Chief Executive Officer, the General Counsel, the Chief Financial Officer, the Chief Technical Operations Officer, and the President of Rhodes Pharmaceuticals.

58. For the KEIP employees, the incentive compensation includes both an annual award and a long-term award.

59. The annual award is designed to mimic the economic structure of the Annual Incentive Plan that the KEIP employees would have been eligible to receive, had the Company not filed for bankruptcy. Payment is subject to the Company achieving its 2021 performance metrics, set out as the corporate scorecard. (Fifth Report, paragraphs 88-89). KEIP employees are eligible to receive between 75 and 100% of the annual award, depending upon whether the

2021 corporate objectives are fully achieved. Subject to certain clawback provisions (i.e. voluntary resignation or termination for cause prior to March 15, 2022), the annual award is paid in part in October 2021 and in total by March 2022.

60. The long-term award also follows the structure of what the KEIP employee would have been eligible to receive as a Long-Term Results Plan grant, had the Company not entered bankruptcy, except that it is reduced by 52.5% of that pre-petition formula. As is the case with the annual award, performance is measured by achievement of the objectives set out in the corporate scorecard.

b. Key Employee Retention Plan Awards

61. For other employees at Purdue Pharma, the additional compensation of an annual award and long-term award are structured as part of a retention plan. This annual award is a percentage of the employee's base salary based on the employee's level within the Company, and is not subject to individual or corporate performance goals. The long-term award is available to those at the Director level or higher, and is an amount equal to 60% of the target Long-Term Results Plan grant the employee would have received in 2021, had the Company not entered bankruptcy. Subject to certain clawback provisions (i.e. voluntary resignation or termination for cause prior to March 15, 2022), the annual award is to be paid in part in October 2021 and in total by March 2022, and the long-term award around July 2022.

c. Market Access Employees

62. For the six field-based employees of the Market Access Team who handle contracting negotiations with PBMs, MCOs and GPOs, three factors are considered in awarding incentive compensation for 2021: corporate performance (25%); product performance (25%); and individual goals or management by objective (50%).

63. The corporate performance is, as is the case with the Key Insiders, tied to overall performance by the Company in meeting its 2021 performance objectives.

64. The product performance component only relates to the performance of the Adhansia XR field sales team. It is tied to whether the Adhansia field sales team meets the targets set out in its sales plan. Adhansia XR is not an Opioid Product.

65. The individual goals are set for each member of Market Access and the Trade & Distribution teams. Depending on the team member, it can include factors such as formulary access for Adhansia XR, interactions with the field force, and professional and personal development.

66. Each of the Market Access Team members also have individual objectives relating to OxyContin contracts and formulary position. In most instances, the objectives are to maintain the current contracts and formulary position with PBMs or GPOs that are specifically identified for the individual Market Access Team member. In some instances, part of the individual objectives is to develop new relationships. The Company explained that it needs expanding relationships to learn how current portfolio products/disease states are being handled by customers, plus to be ready with additional relationships to support future/pipeline products.

67. The undersigned Monitor finds that the incentive compensation program for the Market Access Team does not violate the Injunction.

68. The Injunction provides, "The Company shall not provide financial incentives to its sales and marketing employees, or take disciplinary actions against its sales and marketing employees, that are directly based on, or tied to sales volume or sales quotas for Opioid Products, unless otherwise permitted by the Bankruptcy Court." (Injunction, II.B.1).

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

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

A. Spend Reports and Research Payments

70. Payments made for research must be evaluated under the ban on promotion, the prohibitions against paying any remuneration in return for the prescribing, sale use or distribution of Opioid Products, and the ban on funding or grants to third parties to promote Opioids. In the Fifth Report, the undersigned discussed research, and noted further review is necessary. (Fifth Report, Paragraphs 98 to 103).

71. The undersigned reviewed the 2020 state audit reports from Connecticut, the District of Columbia, Minnesota, Nevada, Vermont, and Massachusetts, as well as the federal spend report covering last year. While the states do not all request and the same information, the reported expenditures did not relate to opioid products or otherwise could be construed in violation of the Injunction.

72. The undersigned also interviewed Jim Doyle, Vice President & General Counsel of Rhodes Pharmaceuticals; Margaret Feltz, Vice President, Ethics & Compliance; Penny Muir, Senior Manager, Ethics & Compliance; Richard Silbert, Vice President, Legal Strategy & Public Health Initiatives; and outside counsel.

73. In 2020, Purdue Pharma spent $16,451,000 on Medical Affairs related to the branded Opioid Products. Medical Affairs spending included annual fees paid to the FDA, adverse event and product complaint reporting to the FDA, post-marketing research projects required by the FDA, and payments to the Opioid PMR Consortium and Risk Evaluation and Mitigation Strategies. Rhodes spent $2,826,000 in 2020 on Medical Affairs related to the Rhodes Opioid Products. Additionally, Rhodes spent $681,000 in 2020 on research and development activities related to the Rhodes Opioid Products (technical transfer, product development, cost of API, formulation and analytical chemistry).

74. The Company has reported to the undersigned that there was no spending in 2020 by the Company on clinical studies involving opioids.

75. The undersigned is still assessing the detail of this spending and its consistency with the Injunction, so the review will continue and reported in the next Monitor Report.

B. Research Submitted for Publication

76. Since the filing of the Fifth Report, two studies funded by Purdue Pharma were completed and prepared for submittal for publication. Both were presented to the undersigned Monitor for review prior to commencing the publication process.

77. The first, *An evaluation of the effect of the OxyContin® reformulation on unintentional fatal and non-fatal overdose,* is a post marketing study required by the FDA as part of the agency's ongoing review of the safety and efficacy of pharmaceutical products. The study was presented to the FDA in public meetings in September 2020.

78. The study assesses changes in the rates of fatal and non-fatal overdoses among people dispensed OxyContin or comparator opioids. The study was initially expected to be

submitted for publication last year, and is further discussed in the prior Monitor's First Report, at paragraphs 49-54.

79. As to uses of the study if accepted for publication, Purdue Pharma reports that the Company might reference it in other potential and related post-marking requirements manuscripts, and reference or provide the study in response to unsolicited requests from HCPs on this topic.

80. The second report, *Long-term Association of Wearable Health Technology with Depression and Opioid Use in Chronic Pain Patients*, grew out of a joint project initiated in 2016 between Purdue and the Geisinger Clinic, and is not a post-marketing study.

81. The study assessed patients over a 12-month period. It concluded that patients using wearable health technology such as smart phones and watches, along with a multidisciplinary pain program, had a statistically significant decrease in depression and opioid prescribing, compared to those only in a multidisciplinary pain program and those only receiving medical pain management.

82. In addition to authors from Geisinger Health, an employee of Purdue Pharma was a corresponding author.

83. Given that the study concludes that using the wearable health technology with a multidisciplinary pain program may decrease usage of opiates, its release does not raise any concerns that the study could lead to promotion of Opioid Products, as those terms are defined in the Injunction.

84. The Monitor finds that publishing these studies does not violate the terms of the Injunction.

85. In considering publication of post marketing requirements studies, the prior Monitor recommended that "if such data is published in a scientific journal on websites controlled by Purdue Pharma that a disclaimer be provided that includes reference to the risks association with opioids and opioid products and the appropriate warning information contained in package inserts, prescribing information and medication guides." (First Report, Paragraph 55).

86. **For purposes of consistency with the prior Monitor's findings and looking forward to other studies that might be submitted for publication, the undersigned recommends that paragraph 55 of the Monitor's First Report is followed for these and any other subsequent studies. The Company agrees to this recommendation.**

87. **Additionally, and especially as a Purdue Pharma employee is the corresponding author of the wearable health technology study, if there are activities planned around using this report after publication, the undersigned has requested and recommends that the Company first advise the Monitor, so as to ensure conformity with II.A.1.b of the Injunction ("Using speakers, key opinion leaders, lecturers and/or speaking events for Promotion of Opioids or Opioid Products"). The Company agrees to this recommendation.**

III. LOBBYING RESTRICTIONS

88. Since the filing of the Fifth Report, the undersigned Monitor has reviewed: 23 quarterly reports reflecting the actions of contracted firms at the state and federal level covering the period from April 1 through June 30, 2021, and two additional reports covering the first quarter of 2021; materials relating to the Association of Affordable Medicines; materials relating to Purdue Pharma's membership and/or payments to outside organizations; and certifications from Purdue Pharma employees regarding their participation in outside organizations. The

undersigned has also interviewed Matthew O'Donnell, Executive Director, Head of Government Affairs & Public Policy, and Kathy Konka, Director, Federal Government Affairs and Policy.

A. Government Affairs and Public Policy

89. The Head of Government Affairs & Public Policy reports to the Company's Senior Vice President and General Counsel, and the Department consists of six people. In addition to the Executive Director, Director, and an administrative assistant, three Regional Directors work in state government affairs, dividing the states into regions.

90. Prior to the bankruptcy filing, there were 10 employees involved in Government Affairs and Public Policy.

91. The Head of Government Affairs has been with the Company for six years, and the Regional Directors have been working for Purdue Pharma between 13 and 19 years. Additionally, 21 contract firms are retained at the state level, and two firms at the federal level.

92. The Government Affairs Department is one of the most outward facing departments of Purdue Pharma. In some respects, it is a traditional government affairs department, focusing on legislative priorities and actions occurring at the legislative or administrative levels. In other respects, and consistent with the terms of the Injunction, it is not. The Government Affairs Department's role has substantially changed since 2019; rather than actively working to influence legislative or administrative outcomes, it focuses on monitoring legislative and administrative activity, and getting information to those in the Company who might need the information.

93. As explained by the Head of Government Affairs, potential implications for business operations and compliance are evolving, based upon what is occurring at the state or

federal level. The ability to bring information to the Company in a timely manner assists the business in planning to adjust to any actual or potential legislative and administrative changes.

94. Leading into the time immediately prior to the entry of the Injunction, Purdue Pharma's interactions were largely around trying to determine how they might be able to assist states and policy makers in addressing the opioid crisis.

95. The Head of Government Affairs explained that since entry of the Injunction, Purdue employees and state contract lobbyists have only monitored legislation and have not taken affirmative steps to influence policy as relates to Opioids or more general issues relating to pharmaceutical manufacturers or the pharmaceutical industry. While the contract lobbyists could potentially be actively lobbying on behalf of other pharmaceutical manufacturers, they have not been engaging on behalf of Purdue for opioid-specific issues in any direct or affirmative manner.

96. This explanation is consistent with a review of the records. In no instance did the contract lobbyist reports reflect advocating in support or against legislation at the state or federal level during this period, notwithstanding the fact that measures being monitored included matters such as legislation relating to opioid manufacturer assessments, an opioid abatement fund, and budgetary language concerning how any settlement money from opioid litigation would be used.

97. Using information gathered from contract lobbyists and other industry sources, the Government Affairs department produces an aggregate summary report to upper-level employees regarding issues facing the industry, covering matters from pricing to reporting, formulary design and regulation of PBMs. They also capture information regarding substance use disorder treatment, buprenorphine, and opioid rescue medicines. The report frequency varies, depending upon the activities of state legislative sessions.

98. At the federal level, the Government Affairs Department interacts with other Purdue Pharma departments including Law, Ethics & Compliance, Communications and Corporate Social Responsibility, Medical Affairs, Pricing and Contract Administration, Market Access, and Data & Analytics.

99. The interactions with each department vary depending on the issue at hand, though much of the work involves discussions regarding prospective issues that may be impacted by pending legislation or regulation. On occasion, the Government Affairs Department provides insights from the ground on the evolving political and policy landscape as a part of discussions regarding implementation or compliance with a recently enacted law or strategy discussion.

100. At the end of 2019 early 2020, the Company's Government Affairs employees were visiting state legislatures, but ceased doing so as COVID began to increase. In early 2020, they worked in Missouri to pass a Prescription Drug Monitoring Program, meeting with the sponsor and other lawmakers. Missouri was the only state at the time that had not implemented such a program. Assisting in that effort is consistent with the terms of the Injunction.

101. At the federal level, since the entry of the Injunction, the Company has provided informational testimony at a congressional hearing held by the House Committee on Oversight Reform. This was at the request of the Committee, and Dr. Craig Landau, Purdue Pharma's Chief Executive Officer, presented testimony in December 2020.

102. The Government Affairs Department was also involved early in the pandemic in researching avenues of potential use of Betadine in the response to the outbreak, including whether an oral gargle of povidone-iodine, the active ingredient in Betadine, had an application specific to SARS-CoV-2. Betadine is an antiseptic product produced by Avrio Health, L.P, a subsidiary of the Company; it is not an Opioid Product.

103. Additionally, in the Spring of 2020, the Government Affairs Department worked with its contract lobbyists and Purdue Pharma's Corporate Social Responsibility Department to assist in providing donations of Betadine to New York and Connecticut.

104. As a department, the Government Affairs and Public Policy Department monitors output of data from government entities like the Centers for Disease Control and Prevention and Health and Human Services and have noted data demonstrating the negative impact the pandemic response has had on those suffering from substance use disorders, including opioid use disorders. The Government Affairs Department has not taken any formal steps, other than through input provided to Corporate Social Responsibility and grants, to help drive solutions or policies addressing increase in public health matters related to substance use disorders.

105. The department is currently working on developing an updated public policy agenda that will help steer government affairs activity going forward.

106. From a policy perspective, the work since the Injunction has been internal, principally exploring how to assist in addressing the opioid crisis. They have reviewed National Academy of Science reports and other information, aggregating the latest evidence-based research, and working with other departments within the Company, including medical affairs, regulatory, legal, and commercial.

107. The objective is to determine what matters the Company could support and actively advocate on behalf of in addressing the opioid crisis, consistent with the terms of the Injunction. This effort is in preparation for the Company's emergence from bankruptcy, with the hope that it will be aligned with the entity post-emergence.

108. The undersigned Monitor finds that the Government Affairs and Public Policy Department is performing in a manner that is consistent with the terms of the Injunction.

B. Membership and Participation in Outside Organizations

109. Purdue Pharma is no longer a member of the trade and advocacy groups Pharmaceutical Research and Manufacturers of America, (PhRMA) and Biology Innovation Organization (BIO), having terminated their membership in PhRMA after the end of the second quarter of 2019, and in BIO at the expiration of an annual membership at the end of 2019.

110. Purdue Pharma is an associate member of Healthcare Distribution Alliance ("HDA"), but not involved with policy development, decision making or positioning as an organization. The Government Affairs Department reports that that is the case with all manufacturers, and the Company's membership in HDA is more to maintain relationships with the distributors.

111. One of the organizations to which Purdue Pharma pays dues is the Association for Accessible Medicine ("AAM"), which advocates to advance policies and regulations that make accessibility to generic drugs easier for the consuming public. (Second Report, Paragraph 81).

112. The President of Rhodes Pharmaceuticals serves on AAM's Board of Directors, and the Advocacy & Policy and Science and Regulatory board-level committees.

113. The President, as well as seven other Rhodes employees, serve on various working groups of AAM, which typically meet weekly or biweekly.

114. At the prior Monitor's suggestion, the Company agreed that any employee serving on the board of any organization, including AAM, that engages in lobbying or educating state officials and federal officials on polices and regulations, the impact of which would be to

more easily enable or promote use of Opioids or Opioid Products, recuse from any board discussion or decisions, and refrain from participation in any working group that focuses on promotion of opioids or issues otherwise not permitted under the Injunction. (Second Report, Paragraph 90).

115. While the undersigned has received but not yet reviewed all the materials provided to the Company from AAM, the Monitor is aware of two instances in 2021 where Rhodes employees expressly refrained from participating in requests from AAM: one related to providing information concerning in-home opioid disposal, and the other related to whether to comment on a proposed DEA rule concerning suspicious orders of controlled substances. Regarding the latter, the Rhodes employee declined an invitation to comment and abstained from voting on whether comments should even be submitted.

116. In both instances, even though involvement likely would not have been inconsistent with the term of the Injunction, the Rhodes employees took a bright-line rule that they would not be involved in opioid-related issues or matters. Accordingly, of the information reviewed to date, the undersigned Monitor finds that the Company's participation in the AAM is consistent with the terms of the Injunction.

117. Purdue Pharma also asked all of its employees whether they were serving "as a director, board member, employee, agent, or officer of any entity that engages in promotion relating to opioids, opioid products, the opioid related treatment of pain, or products indicated to treat opioid-related side effects." No employees reported that they were serving in such a capacity.

118. The undersigned also reviewed the list of associations and organizations to which the Company pays dues, which includes some organizations that engage in political activity and are related to state government affairs.

119. Purdue Pharma participates in the Republican State Legislative Committee, the Democratic Legislative Campaign Committee, the Council of State Governments, and the State Legislative Leadership Foundation, with the first two being partisan organizations, and the latter two are educational-based nonpartisan organizations.

120. While occasionally attending meetings, the Company has not provided any materials to these organizations since entry of the Injunction. The Head of Government Affairs & Public Policy explained that, with a small government affairs organization, membership affords the opportunity meet with leaders and representatives from multiple states in one place, or collectively hear what the agenda or trends might be.

121. The undersigned Monitor finds that those dues and contributions are consistent with the terms of the Injunction and with the agreement reached between all interested parties and the Court relating to political contributions.

IV. BAN ON HIGH DOSE OPIOIDS

122. 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).

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

V. BAN ON PRESCRIPTION SAVINGS PROGRAM

A. Savings Programs Not Directed by the Company - Drug Discount Savings Cards

124. In the Fifth Report, the undersigned Monitor noted that "[a] basic internet search that includes the names of Purdue Pharma's branded opioid products brings up any number of websites purportedly offering coupons and comparing prices for these products," and that "the undersigned will take measures to better understand these websites and their connection, if any, to the Company." (Fifth Report, paragraphs 127 and 128).

125. The undersigned conducted internet research, spoke with representatives of Purdue Pharma, as well as interviewed a CEO of one of the drug discount card companies.

126. The drug discount or savings card companies include companies such as Inside Rx (www.insiderx.com); GoodRx (www.goodrx.com); WebMDRx (www.webmd.com/rx); Single Care (www.singlecare.com); NeedyMeds (www.needymeds.org); Script Save WellRx (www.wellrx.com); BuzzRx (www.buzzrx.com); RxSaver (www.rxsaver.com); Drugs.com (www.drugs.com, www.drugdiscount.info.com); Iodine (www.iodine.com); Optum Perks (www.perks.optum.com); and USA Rx (www.usarx.com).

127. The companies include nonprofits, for profits, and subsidiaries of PBMs. By the estimate of the CEO of one of these companies, the number of discount savings card companies likely runs in the hundreds.

128. The drug discount card companies, through their websites, permit a customer to enter the name of the sought-after prescription drug and the location in which

they are seeking the product. While the sites vary, the website returns information concerning and comparing the price for the requested product among several pharmacies in the geographic area.

129. In some instances, the information returned is for the branded product, and in some instances, it also includes the generic equivalent, if any.

130. The websites then typically allow the consumer to download and print a savings card from the discount card company, that includes information such as the drug's name and dosage, the estimated cost, and the Rx BIN, Rx Group and Rx PCN numbers, identifying for the pharmacy the PBM affiliated with discount card and other information.

131. The discount cards cannot be used with insurance, as the Purdue savings programs require, or any government-funded program.

132. The discount card companies negotiate and work with PBMs to establish the discounts, and at least one of them is wholly owned by a significant PBM.

133. In at least one instance, a drug savings card company has a direct link on its website to the Purdue Pharma savings programs for OxyContin. In another instance, a drug savings card company's website included inaccurate information about assistance programs and coupons offered by Purdue Pharma; that information, however, has been removed from the drug savings card company's website since June 2021.

134. It is the undersigned Monitor's understanding that the drug discount card companies make their money from transaction fees paid by the pharmacy for each prescription filled using the company's card or coupon, and at least some of the companies sell personal information gathered if requiring the customer to sign up for the card.

135. The undersigned Monitor is not aware of any direct connection to manufacturers, and the CEO of one of the discount card companies with whom the undersigned spoke was not aware of any connection between the sites and with Purdue Pharma or any other manufacturers. Representatives of Purdue Pharma reported to the undersigned that they have no connection to, or communications with, the third-party drug savings card programs and that Purdue Pharma does not engage in any activities regarding pricing comparisons.

136. As noted above, the drug savings cards offered by the discount card companies cannot be used with insurance, and both the Purdue Pharma savings card and the electronic voucher point-of-dispense programs can only be used by commercially-insured patients.

137. Accordingly, the undersigned Monitor finds that the third-party prescription drug discount card companies do not violate the terms of the Injunction.

138. The undersigned Monitor has discussed with the Company what measures could be taken to remove references to Purdue Pharma and/or misleading information about programs the Company offers. While certainly the website links and information may lead to additional calls or contacts with the Medical Information team, there is no practical way to both police and enforce the activities of these unrelated entities.

VI. SUSPICIOUS ORDER MONITORING AND REPORTING

139. In the Fifth Report, the undersigned Monitor made the following recommendations and observations relating to the Suspicious Order Monitoring and Reporting Program ("SOM"), all of which were agreed to by the Company:

a. Working with the Company, assess the efficiencies, necessary and needed redundancies, and impact of additional staffing on the SOM program to better

ascertain whether additional staffing might be recommended. (Fifth Report, Paragraph 141).

b. A review by an additional staff member of each of the threshold calculations. (Fifth Report, Paragraph 181).

c. To the extent that the factors in calculating the thresholds are changed by automating or embedding some of the calculations into the spreadsheets, the Company provide advance notice to allow the Monitor to review and comment on the proposed changes prior to its implementation. (Fifth Report, Paragraph 182).

d. That the Company establish guidelines for assessing under what circumstances and how often it conducts site visits to current customers and consider whether in person site visits should be conducted after a certain amount of time has elapsed from the last in person inspection. (Fifth Report, Paragraph 163).

e. That no orders can be taken from new customers until the site visit is complete and determined to be acceptable under the Company's criteria. (Fifth Report, Paragraph 164).

f. Working with the Company to explore whether there is a better way to capture or ensure some degree of corroboration of the customer's representations, if the representation is an observable fact. (Fifth Report, Paragraph 193).

g. An evaluation and assessments of updates to the Chargeback system and recommendations to the Company, if warranted. (Fifth Report, Paragraph 207).

h. Review of due diligence questionnaire response and annual reviews received by the Company in 2021. (Fifth Report, Paragraph 160).

140. In assessing the SOM system, the undersigned and consulting expert Jodi Avergun have had additional discussions with the Vice President of Ethics and Compliance, the Director and Associate Director of Ethics and Compliance, and the Manager of Ethics and Compliance, as well as reviewed additional documents and materials provided by the Company.

141. Each will be considered in turn.

A. Staffing redundancies

142. The Ethics and Compliance Department has been working to cross-train those working in SOM, as well as identifying areas benefitting from review by multiple individuals:

a. The Director and Associate Director both review and resolve pended orders, often working together on the same or related orders;

b. While the Associate Director has been responsible for creating thresholds, the Director is learning the process and going forward will be both creating and reviewing the thresholds;

c. The Director has trained the Associate Director and Manager how to report information to the DEA, in the Director's absence;

d. The Associate Director has been working with the IT vendor in creating the program used in reviewing downstream orders of interest. The Manager is currently using the system and providing information to the Director and Associate Director, as well as preparing the outlier reports for further review by the Director and Associate Director. All three employees will gain further training on the use of this product in the upcoming months, as well as work with the vendor to explore additional capabilities; and

e. Either the Director or Associate Director will participate in every site review.

143. As the Associate Director noted, suspicious order monitoring is most effective when knowledge is accumulated and shared over time, so each of the members of the SOM team are frequently exchanging information and knowledge.

144. The undersigned Monitor has no further recommendations at this time regarding staffing and redundancies for the SOM process.

B. Threshold Calculation and Review

145. Thresholds are the "maximum quantity in dosage units for each DEA controlled substance base code and/or strength unique to a customer." The thresholds are used as integral part of the Suspicious Order Monitoring process. A more through discussion of thresholds, as well as how they are calculated and how they are used, is contained within the Fifth Monitor's Report, Paragraphs 171 through 182.

146. Thresholds are calculated for all 10 drug families for each distribution center, requiring the calculation by the Ethics and Compliance Department of approximately 1,500 thresholds each year.

147. Since the Fifth Report, the Company undertook an effort to embed the formulas used to calculate thresholds into a template spreadsheet workbook, and that template is then tailored to each individual distributor center/customer.

148. Accordingly, while prior to this last quarter, the Associate Director would manually calculate each of the 1,500 thresholds, a process that would take months, using this template the Associate Director can now calculate the thresholds by electronically cutting from the customer's annual review the number of downstream customers specific to that distributor, and pasting it into the spreadsheet workbook created for that distributor. The calculated

threshold numbers are then cut from the spreadsheet and pasted into the SOM cloud-based system.

149. The Associate Director spent significant time testing the spreadsheet template and comparing it to the process and outcome of manually calculating the same and, after finding it satisfactory, to date has converted and transferred approximately 20% of thresholds created each year to the spreadsheet workbook template. The Ethics & Compliance Department is targeting October 2021 to convert the remaining 1,200 threshold calculations.

150. Consistent with the recommendation contained in the Fifth Report, the undersigned interviewed the Director and Associate Director of the Ethics and Compliance Department and reviewed an electronic version of the spreadsheet as well as an updated copy of the SOP explaining how the thresholds are calculated.

151. The undersigned Monitor finds that embedding the formulas improves the process of calculating thresholds, both making it more efficient and eliminating some of the risk of human error.

152. **Accordingly, the Monitor encourages full implementation and use of the spreadsheet templates for each customer.**

153. Finally, as noted by both the Prior Monitor and the undersigned, the Company's practice had been that one individual, the Associate Director, individually calculated and implemented each customer's thresholds, as well as performed many other duties related to SOM. Currently and going forward, both the Director and Associate Director will be calculating thresholds, and cross-reviewing to ensure no errors are made.

C. Schedule or Standards for Site Visits and Due Diligence and Annual Reports

154. As discussed in the prior Report, Purdue Pharma's policy requires that a virtual site visit occur prior to accepting orders from a new customer, a physical site visit of each wholesaler occur at least one time to corroborate the information obtained from the Due Diligence Questionnaire, or "as needed to address SOM compliance concerns or substantial changes in the customer's business model or SOM program." (Fifth Report, Paragraphs 153 and 154). The undersigned recommended that (a) no orders be taken until the virtual site visit is complete; and (b) that the Company establish guidelines for assessing under what circumstances and how often it conducts site visits to current customers and consider whether in person site visits should be conducted after a certain amount of time has elapsed from the last in person inspection. (Fifth Report, Paragraphs 164 and 165).

155. Since filing the last report, five site visits of existing customers have been conducted. All were conducted virtually, and it may be into 2022 before physical site visits resume.

156. The Company sent out requests for its customers to complete due diligence and annual review reports in early July. As responses come in, they are being review by the Company and provided to the undersigned; to date, five responses have been provided.

157. As to the frequency and regularity of the site visits, in addition to the site visit occurring in onboarding a new customer, going forward the Company will visit each customer at least once every three years. Doing so is consistent with the current practices of the Drug Enforcement Administration, which has diversion investigators conduct inspections of each distributor on a three-year rotation basis.

158. Accordingly, with 56 distributor/customers, Purdue Pharma intends to conduct at least 18 inspections each year. Currently, 18 of 56 have not been visited in at least three years, so those 18 will be given priority. It should be noted that site visits at the three largest distribution company customers occur only at the customer's national licensing center and not every individual distribution center each customer operates.

159. The Company intends that these be physical, not virtual, visits, upon the further easing of COVID restrictions and concerns. Either the Director or the Associate Director will participate in every site visit.

160. In interviewing the Director and Associate Director, the Associate Director noted that she is unaware of any manufacturer conducting as many site visits as does Purdue Pharma, both on an initial and ongoing basis.

161. **The undersigned Monitor agrees with the proposal that each direct customer will be visited during an official site visit at least once every three years, and recommends that the Company update its SOP to reflect these changes. The Company agrees to this recommendation.**

D. Independent Corroboration of Customer's Justifications for Pended Orders

162. In the Fifth Report, the undersigned Monitor detailed the review of Pended Orders and their justification for release, and recommended a further review of whether there is a better way to capture or ensure some degree of corroboration of the customer's representations, if the representation is an observable fact. (Fifth Report, Paragraphs 187-193).

163. As a general matter, while there are thousands of orders reviewed by the SOM system each month, with over 6,000 in the month of June alone, the justifications for clearing orders that were pended by the SOM system are a fairly discrete universe, ranging from a new

award status, supply chain disruptions from other manufacturers, increases due to the demand of one customer, and weather disruptions, as examples.

164. The undersigned provided the Company a sampling of 12 pended orders and requested the corroboration justifying the release of those orders.

165. Of the 12 pended and cleared sample orders provided to the Company, the undersigned received and reviewed backup material for each of the orders. In all instances, the Director or Associate Director would reach out to the distributor, seeking an explanation of the order, or would rely on recent correspondence with the distributor regarding the same product family. In at least once instance, because the distributor's typical point of contact was on vacation, Purdue Pharma held the pended order until the customer's point of contact returned.

166. In at least two instances in the sample, Purdue Pharma requested materials further corroborating the customer's representation, such as forecasts from the downstream customer. The Director and Associate Director explained that, at times, they will place an order on hold until such forecasts or projections are received. The Ethics and Compliance team stated that they would take further steps and call the customer's head of DEA compliance and/or national accounts to get a better sense of the shortages or disruptions, but that was not evident in the materials reviewed.

167. Additionally, in reviewing the orders of interest from July 2021, the undersigned noted that there were many instances where the Ethics and Compliance team requested from the distributor additional projections, inventories, and details relating to the orders that had been pended.

168. **The undersigned Monitor acknowledges that there isn't necessarily any formulaic process for seeking independent corroboration or justifications relating to**

pended orders, but encourages the Company to continue to work to ensure that every order that is released based on a customer's representations has some degree of corroboration attached to that released order. For example, if a manufacturing issue of one product causes an increased order pattern for Purdue Pharma products, that manufacturing or supply chain issue should be documented with information that is independent of a customer's statement that there are supply chain issues. Such corroboration could include industry news about supply chain issues, or evidence that a manufacturer has sent notice to its customers about likely shortages. There should be some independent review on a regular basis (monthly or quarterly) to verify that the supply chain issue remains. Similarly, justifications involving an increase resulting from a distributor having added customers or product lines should consist of some sort of proof, such as an invoice, or an email between the distributor and its new direct customer verifying the new account. It is not sufficient for Purdue to simply rely on a distribution company customer's statement that it has a new customer and that new customer caused a change in ordering patterns. The Company agrees to this recommendation.

E. Review of Downstream Customers

169. Under the terms of the Injunction, the Company must "reasonably utilize available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of a Company Opioid Product," and "[a]nalyze all information that the Company received that indicates an unreasonable risk of diversion activity of a Company Opioid Product or an unreasonable potential for a diversion activity of a Company Opioid Product, by a direct or downstream customer. . .". (Injunction, Paragraph II.G.1.a.-b.).

1. Identification of Downstream Orders and Customers of Interest

170. The primary way in which the Company assesses the activities of its downstream customers and any material, unreasonable or potential risk for diversion activities is through a review of all chargeback data, comparing each individual order to the average order for downstream customers, based upon their relative size and the type of customer or patient services that the downstream customer provides. Those that have a significantly larger number of chargeback units than other customers are flagged as customers of interest, or "outliers," and then are more extensively reviewed by the Ethics and Compliance department. (Fifth Report, Paragraphs 194-204).

171. From an industry perspective, the manufacturers' use of chargeback information to review downstream orders or customers of interest largely grew out of a 2017 settlement between the Drug Enforcement Administration and Mallinckrodt, plc. (https://www.justice.gov/usao-edmi/press-release/file/986026/download).

172. The chargeback data has some limitations. As the Director and Associate Director noted, the rebate and chargeback data are typically not available, complete nor accurate until six to eight weeks after a transaction has occurred. Accordingly, by the time the Company conducts its review and makes a referral based on chargeback data, it can relate to an order several months past. This issue is not unique to Purdue Pharma, and other manufacturers reviewing downstream customers face the same data lag.

173. As was noted in the prior Report, "To date, the method used for the chargeback review has been manual, and no IT cloud-based system, algorithm, or threshold is used in the review. As part of the Company's efforts over the past seven months and at the request of the Monitor, Purdue Pharma is in the process of implementing a new IT program that will aggregate

and enhance the information gathered in order to more effectively and assess the actions of downstream customers. While it is not evident the proposed system identifies downstream orders of interest, it moves away from a spreadsheet review and may provide better information for the Ethics & Compliance Department to identify the outliers." (Fifth Report, Paragraph 205).

174. The Company has taken significant strides since the last Report to more effectively analyze chargeback data, and is also considering other streams of information within and available to the Company that might be of assistance in identifying registrants that may pose a risk of diversion.

175. For example, in the June report, there were over 430,000 individual chargeback entries, downloaded into a single spreadsheet. In the past, orders of interest were identified by sorting the spreadsheet by drug family and type of customer or patient services that the downstream customer provides, determining the average number of chargebacks for that drug family and customer type, then identifying those downstream customers having chargebacks above that month's average. To further explore the downstream customer's ordering history, Purdue Pharma would need to review spreadsheets from prior months.

176. The chargeback entries are now downloaded into an IT system that generates reports identifying those downstream customers having chargebacks above average. It can also generate historical or trend information relating to an order of interest, or any downstream customer.

177. More than just reviewing chargeback information, the new system also provides the SOM Team detailed sales reporting information, or "867 data", and product inventory information, or "852 data". Among other functions, the SOM Team can view this information

both at the distributor and downstream customer level, as well as compare sales and inventory to the prior 11 months for that distributor or downstream customer.

178. The Director, Associate Director and Manager of Ethics and Compliance are working with the IT vendor to fully understand the capabilities of this new system, explore whether there are enhancements to the system that would make it even more useful and effective, as well as exploring other data sources and programs.

179. The technology, staffing and measures taken to identify downstream orders and customers of interest have been substantially improved since the prior Monitor's First Report. The undersigned Monitor notes that these improvements are not all being driven by the Injunction or the process of having an outside Monitor, and frequently occur at the initiative of the Company's Ethics and Compliance employees overseeing the suspicious order monitoring and reporting.

180. **The undersigned Monitor recommends that, over the next quarter, the Company continue to work with its outside vendor, the undersigned, as well as other data sources and programs to further explore measures that can more effectively and timely identify downstream orders and customers of interest. The Company agrees to this recommendation.**

181. **Notwithstanding the DEA/Mallinckrodt settlement language, which was not explicit or fulsome in directing how chargeback data be used, the undersigned Monitor encourages the Company to not limit itself to chargeback information. Rather, the Undersigned recommends that the Company explore whether systematically incorporating historical sales and inventory data into the analysis and processes – or even making sales and inventory information the primary data source analyzed – might provide more**

effective and timely identification of orders and customers of interest than the analysis of chargeback data currently does. In particular, the Undersigned encourages the Company consider using the information that is available to it in its newly implemented Due Diligence Plus system with regard to the final destination of Purdue products to evaluate whether a downstream customer poses a threat of diversion. The Company agrees to this recommendation.

2. Reporting of Downstream Orders of Interest or Customers of Interest to the Distributor and/or Drug Enforcement Administration

182. In the Fifth Report, the undersigned wrote that "there is nothing in the [Standard Operating Procedure] or on the Outlier Report that would indicate when a downstream customer should be reported to the DEA, or even when the downstream customer's distributor should be contacted, and that the undersigned would "evaluate and assess the updates to the Chargeback system and make recommendations to the Company, if warranted." (Fifth Report, Paragraphs 206-207).

183. The Director noted that, in reviewing the outliers, they are effectively doing an investigation as best they can while lacking police powers, and that there is no mathematical formula for when to report a downstream customer to the DEA or to its distributor.

184. Both the Director and Associate Director have significant experience in law enforcement. The concern regarding when to report orders of interest is not to suggest that they aren't committed to reducing diversion or the risk of diversion, more so the fact that a pharmacy or other downstream customer dispensing to an end-user customer is a point in the distribution process where diversion is more likely to occur compared to Purdue Pharma's direct customer. Yet, it is also the point over which Purdue Pharma has the least amount of control.

185. Notably, the DEA has not provided any meaningful guidance on this issue.

186. In addition to its normal suspicious order reporting process, Purdue has referred seven orders received by downstream customers to the DEA in 2021, with six of the seven referrals occurring in July of this year. The July referrals were based upon a review of orders placed in May of this year. The Company referred one order received by a downstream customer to the DEA in 2020, and five such orders in 2019. The Company has also referred 15 orders to the downstream customer's distributor this year, four in 2020, and one in 2019.

187. To date, the undersigned Monitor has received and reviewed Outlier reports through June 2021. Every one of orders reported to the DEA or a distributor were identified through the process of identifying and analyzing the outliers. The numbers are as follows:

a. In January 2021 there were 23 outliers identified, four of which were then reported to the Parent. One report was made to the DEA in January, based on a November chargeback.

b. In February 2021 there were six outliers, one of which was reported to the DEA and Parent.

c. In March 2021 there were 6 outliers, one of which was reported to the Parent.

d. In April 2021 there were five outliers, two of which were reported to the Parent.

e. In May 2021 there were nine outliers, four of which were reported to the DEA and to the Parent.

188. It is important to note that a referral to the DEA or to the downstream customer's Parent/distributor does not necessarily mean that there has been diversion or a risk of diversion. When the Company makes a report to a distributor about its customer, the transmittal includes: "This is not a report of a suspicious order, but a referral of a registrant that based on the limited information at our disposal, may be of interest to the DEA. We will be making this referral as

part of our due diligence efforts to comply with the DEA's know your customer's customer requirement. We are notifying [the Parent] in order for you to remain informed and take whatever action you deem necessary."

189. The notification to the distributor, or Parent, entails more than simply providing the distributor with a report. Purdue Pharma's Ethics & Compliance team often follows up with the distributor, to gain an understanding or justification from the distributor of the downstream customer's order of interest, and follows up with the distributor when that understanding isn't provided to the Company.

190. At times, the DEA and/or Parent is notified just based on the chargeback order. Often, however, the outlier review uncovers additional information of interest that the Company determines is significant enough to report the downstream customer to the parent and/or DEA, ranging from: chargebacks combined with the number of suppliers to the downstream customer for the Opioid; address discrepancies; prior DEA sanctions or judicial actions against the pharmacy or pharmacists; and other disciplinary histories at the state level.

191. The undersigned Monitor discussed with the Director and Associate Director of Ethics and Compliance the merits of reporting all downstream orders of interest, or outliers, to the Parent and DEA.

192. A consideration in doing so is that if the Company reports too many outliers because of high chargebacks, it could become "white noise" to the customers and/or the DEA. Understandably, the issue is whether potentially overreporting diminishes the impact of the referrals to the DEA and/or the parent distributors. As noted above and based on the information the Company provided to the undersigned, to date the distributors appear to take reports from the Company seriously.

193. From January to May 2021, out of literally tens of thousands of orders, 62 of those orders would be reported to the DEA and the downstream customer's distributor if all outliers had been reported.

194. **Based on discussions with the Company, Purdue Pharma will now report all reportable downstream customer's orders of interest, both to the customer's distributor/Parent and to the DEA. This reporting first occurred in July 2021.**

195. **The undersigned Monitor recommends that the Company continue reporting all reportable outliers to both the Parent and DEA over the next three months. Prior to the next Report, the undersigned will discuss with the Company whether this increased reporting has diminished the responsiveness of the Parents and DEA to these reports, and determine whether it should be a practice incorporated into the SOP. The Company agrees to, and has already implemented, this recommendation.**

VII. INITIAL COVERED SACKLER PERSONS

196. 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 Sixth Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor

Appendix A
Customer Service Letter, August 16, 2021

August 16, 2021

Dear Governor Bullock:

The Voluntary Injunction ("VI") requires Purdue to “fully, completely and promptly cooperate with the Monitor.” Purdue takes this obligation seriously. In the spirit of such cooperation, Purdue provides this summary of a matter recently brought to its attention. Purdue's Law Department became aware that the Customer Service department, which is part of the Commercial group, may have attempted to resolve certain opioid product complaint issues directly with pharmacies. Under a broad reading of the Voluntary Injunction, it is possible that the issues should have been directed to Medical Services.

Upon learning of a potential contact between Customer Service and a pharmacy, the Law and Ethics & Compliance departments immediately engaged Skadden to review and help remediate the issue. The Company provided Skadden a call log reflecting opioid-related calls received by Customer Service since November 1, 2019. In addition, the Company scheduled several informational calls with Customer Service.

By its terms, the VI prohibits the Company from promoting opioids. Promotion is defined broadly by the VI as "the dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of [HCPs] in favor of prescribing greater amounts, quantities, doses, and/or strengths of Opioid Products." HCP is defined as “any U.S.-based physician, nurse practitioner, physician assistant, dentist, pharmacist, podiatrist, nurse, or other person engaged in the business of providing health care services and/or prescribing an Opioid Product and any medical facility, practice, hospital, clinic, or pharmacy engaged in providing health care services and/or prescribing an Opioid Product in the United States." Thus, if the Company disseminates information to a pharmacy, and that dissemination would have the effect of “influenc[ing] prescribing practices,” then that dissemination would run afoul of the promotion ban in the VI.

For background, the Customer Service has historically received calls from wholesalers, patients, HCPs, and others with an unknown affiliation. The Customer Service department adjudicates those calls by answering the questions or transferring the caller to another department. One function of the Customer Service department was to handle requests for refunds and replacements of opioid products. For instance, a pharmacy might contact Customer Service to inform them that an order of Butrans patches is not adhering properly. The review found that, at times, after receiving a request from a pharmacy or patient for a refund or replacement of an opioid product, Customer Service contacted pharmacies in an effort to try to resolve the issue.

This meant that Customer Service personnel sometimes discussed refunds related to and replacements of opioids with pharmacies. The Director of Customer Service indicated that the group did not consider pharmacists to be HCPs, and therefore did not realize that the better course would have been to direct this

outreach to Medical Services. However, as these calls were from the commercial organization to pharmacies, and as these calls could have had the effect of influencing the pharmacy and the patient to maintain a prescription, the contacts might be considered promotional in nature under the broadest reading of the VI.

With respect to remediation efforts, the Company has now put into place the Customer Service Call Handling Response and Logging Process standard operating procedure ("SOP"). The SOP requires, among other things, that Medical Services – not Customer Service – handle discussions about refunds related to or replacements of opioid products, as appropriate. It also formalizes the requirement that Customer Service transfer medical or general product related questions to Medical Services. The SOP went into effect on July 14, 2021, and training for the Customer Service department on the new SOP was launched on July 20th, 2021.

Purdue takes seriously the obligations in the Voluntary Injunction, and provides the above information in the spirit of complying with the letter and the spirit of the Voluntary Injunction. We are happy to discuss any questions you may have.

Very truly yours,

Marc L. Kesselman
EVP, General Counsel & Corporate Secretary

Cc: Sheila Birnbaum, Dechert LLP
Danielle Gentin Stock, Dechert LLP
Richard Silbert, Purdue Pharma LP