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)**

SIXTEENTH 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 Sixteenth 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

[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.

comply with the terms and conditions of the Injunction, and the Company has been responsive in fulfilling the Monitor's requests for information, documents, and interviews with Purdue employees.

INTRODUCTION – STEPS TAKEN SINCE FIFTEENTH REPORT

1. Since the filing of the Fifteenth Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue including the: Vice President, Chief Compliance Officer; Vice President, Legal Strategy and Public Health Initiatives; Vice President of Quality; Associate General Counsel, Head of Corporate Law; Senior Manager, Quality Documentation Systems; Executive Director, Government Affairs; Director, Research and Development Quality; Vice President, Sales & Marketing; Head of Pricing and Contract Administration; Director, Market Access Contracting & Analytics; and Purdue's outside counsel.

2. Since the filing of the Fifteenth 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.

FIFTEENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Fifteenth 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. Following up with the representatives of Medical Affairs after conferences to ascertain if there were any inquiries or interactions relating to Opioid Products. (Fifteenth Report, Paragraph 10.)

b. A continuation from the Eighth Report of reviewing the entirety of the SOPs and corporate policies relating to Opioids and incorporating the requirements of the Injunction where appropriate. (Eighth Report, Paragraphs 53-63; Fifteenth Report, Paragraphs 16-17.)

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

d. Continuing to work with the Company regarding creating and implementing a Standard Operating Procedure to restrict the supply of Opioid Products to certain downstream customers. (Fifteenth Report, Paragraph 32.)

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

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

g. Revisiting and revising the Processing of Product Complaints SOP to correspond with the most recent revisions to the Product Quality Complaint Investigations SOP. (Fifteenth Report, Paragraph 83.)

h. Providing the Monitor with the Key Compliance Indicators, the evaluation of those Indicators, and supporting materials on a quarterly basis. (Fifteenth Report, Paragraph 90.)

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

DISCUSSION AND ANALYSIS

I. BAN ON PROMOTION

A. Attendance at Conferences

4. 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.)

5. 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.)

6. 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.)

7. The Company shared with the Monitor that Medical Affairs intended to have a booth at the upcoming American Society of Health-System Pharmacists Mid-Year conference in early December, to represent Purdue Medical Affairs, address questions, provide a high-level overview of the Public Health Initiatives, and share research priorities.

8. The Company shared details about the booth, as well as educational sessions occurring during the conference relating to Opioids. While there are sessions that would not be appropriate for Company representatives to participate in, such as treatment options for pain management and for managing Opioid and non-Opioid-induced constipation, the information at the Company's booth pertains to the Public Health Initiatives ("PHI") and PHI-related research.

9. The Monitor finds these promotion events consistent with terms of the Injunction.

10. Additionally in the last Report the undersigned recommended following up with representatives of Medical Affairs after conferences to ascertain if there were any inquiries or interactions relating to Opioid Products. (Fifteenth Report, Paragraph 10.) The Company reported that Medical Affairs representatives did not receive any inquiries about Purdue's Opioid Products, nor did anyone directly interact with the Medical Affairs representatives regarding Purdue's Opioid products at the North American Congress of Clinical Toxicology or the American College of Emergency Physicians, where Purdue Medical Affairs also had a booth.

11. **The Monitor recommends that a similar inquiry occur after the American Society of Health-System Pharmacists Mid-Year conference. The Company has agreed to this recommendation.**

B. Marketing Budget and Market Share of Purdue Opioid Products

12. In the Fifth Monitor Report, the undersigned reported on the marketing budget and sales and market share of Purdue Pharma and Rhodes Opioid Products, comparing those factors to 2019, when the Injunction was first entered. (Fifth Report, Paragraphs 28-38.) The following paragraphs update that reporting and compare the last full year of sales to calendar year 2020.

13. Of the entire sales and marketing budget for Purdue Pharma for 2022, approximately nine percent was spent on branded Opioid Products. Of that percentage, approximately 92% was spent on acquisition of data. The costs for data are spread equally across the branded Opioid Products.

14. The balance of the sales and marketing budget for the branded Opioid Products was for website maintenance, storage of data, postage, data transition and savings card expense. None of these investments appears to be used to promote Opioid product sales.

15. Overall, the marketing budget for branded Opioid Products has been decreasing, spending 4% less in 2023 on Opioid Products for sales and marketing than the 2020 expenditures.

16. The Company provided the undersigned internal financial records and National Sales Perspectives and National Prescription Audit data from IQVIA. For Purdue Pharma's branded products:

a. Sales of OxyContin declined in calendar year 2022 by approximately 24% from sales in 2020. OxyContin prescriptions accounted for 10.2% of the market of extended-release opioids in 2022.

b. Sales of Butrans declined in 2022 by approximately 72% from sales in 2020. Butrans prescriptions accounted for 0.7% of the market of extended-release opioids in 2022.

c. Sales of Hysingla decreased by approximately 51% from sales in 2020. Hysingla prescriptions accounted for 0.8% of the market of extended-release opioids in 2022.

17. Purdue's total net sales of branded and generic Opioid Products declined approximately 28% in 2022 compared to 2020 sales.

18. Purdue Pharma and Rhodes Pharmaceuticals products were 10.1% of the overall share of opioid prescriptions in 2022, down from 11.1% in 2020.

19. Purdue Pharma and Rhodes captured 32.1% of the market for extended-release opioids in 2022, down from 36.33% in 2020. Eighteen percent of the share of extended-release opioid prescriptions is for morphine sulfate, a generic sold by Rhodes.

20. The continuing and significant declines in sales and market share of Opioid Products, while not dispositive, are indicative that Purdue is complying with the terms of the Injunction relating to a ban on promotion.

II. REVIEW OF STANDARD OPERATING PROCEDURES

A. Comprehensive Review of SOPs for Consistency with Injunction

21. In the Eighth Report, the Monitor undertook a more comprehensive review of SOPs that in any way involve Opioid Products, recommending that certain SOPs be revisited and that the Company review the entirety of the SOPs and corporate policies relating to Opioids, incorporating the requirements of the Injunction where appropriate. (Eighth Report, Paragraphs 53-63.)

22. The Chief Compliance Officer reported to the undersigned that she and the Ethics & Compliance Department reviewed approximately 50 additional SOPs, and recommended changes to nine of the procedures. The Chief Compliance Officer explained that edits were minor, typically making express references to the Injunction.

23. Revisions to SOPs to reflect the obligations of the Injunction included: Handling DEA Audits/Inspections; Diversion Control in Warehouse; Biennial CS Inventory; Distribution Process Flow; Retained Drug Product Procedure; Pharmacovigilance Agreements; Process for Medical Liaison Electronic Communication for Clinical Information to External Customers; Product Quality Complaint Investigations; Processing of Product Complaints by Product Monitoring; and Diversion Control in in Product Operations to be Produced.

24. Depending upon the SOP, revisions included requirements of: (a) cooperating in fulfilling requests of the Monitor; (b) reporting of suspected theft, abuse or diversion, and concerning customer behavior to Ethics & Compliance, as well as Corporate Security; (c) consideration of the Injunction when entering into pharmacovigilance agreements; and (d) employee responsibility for complying with the Injunction ("All Purdue employees are responsible for ensuring strict compliance with the letter and spirit of the Voluntary Injunction. Any questions referred to the Law Department and Ethics & Compliance Department. Any known or suspected violations of the Voluntary Injunction must be immediately reported to the Law Department and the Ethics & Compliance Department.").

25. The undersigned appreciates the Company's effort in both reviewing the body of SOPs to determine if they touch on matters relating to the Injunction, and expressly including requirements of the Injunction where appropriate.

B. Product Quality Complaints (Including Short Counts)

26. In the Fifteenth Report, the undersigned explained the processes and SOPs relating to Product Quality Complaints and noted that there were minor timeline discrepancies in the "Product Quality Complaint Investigations, SOP (CQA 1-40)," effective March 2023, "Processing of Product Complaints (CQA 7-3)", effective June 2020. (Fifteenth Report, Paragraph 83.)

27. The Company amended CQA 7-3 to correspond with the most recent revisions of CQA 1-40, thereby fulfilling the recommendation from the Fifteenth Report.

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III. GOVERNMENT AFFAIRS AND LOBBYING RESTRICTIONS

A. Government Affairs and Public Policy

28. In the Sixth Monitor Report, the undersigned provided an overview of the Government Affairs & Public Policy Department. (Sixth Report, Paragraphs 89-108.) The following updates that information, explaining more recent staffing and activities.

29. The Government Affairs & Public Policy Department consists of four people, including an administrative assistant. The Executive Director has been with the Company for 15 years and assumed the role leading the Department in late 2021, having previously served as one of three Regional Directors of State Government Affairs. The Director, State Government Affairs has also been with the Purdue for 15 years, and prior to mid-2022 served as a Regional Director of State Government Affairs. The Associate Director, Legislative Alliance joined Purdue mid-2023. The Executive Director reports to the Company's Executive Vice President and General Counsel.

30. Prior to the bankruptcy filing, there were 10 employees in the Government Affairs & Public Policy Department. Since the undersigned became Monitor, the former Executive Director, a Regional Director, and the Director of Federal Affairs and Policy have left the Company.

31. In addition to overseeing and setting direction for the Department, the Executive Director participates in federal and state government affairs. At the federal level, the Executive Director monitors activity that could impact the Company. The Department is not involved in every interaction the Company may have with an agency or employee of the federal government but is involved if requests come to the Company from federal elected officials or their staff.

32. Working with the Executive Director, the Director of State Government Affairs is responsible for the entire country, as well as oversight of 24 contract firms retained at the state and federal level. In addition to quarterly reports, the Director speaks with the contract firms at least monthly, and more frequently if an issue arises in an individual state.

33. Post-Covid, the Executive Director and the Director are separately attending gatherings of state officials at conferences of the Council of State Governments, the State Legislative Leadership Foundation, and the Republican State Legislative Committee. Participation affords the opportunity to meet with leaders and representatives from multiple states in one place, or collectively hear what the agenda or trends might be. The Executive Director reported that questions directed to Purdue are most often about the bankruptcy, and when and how much money a particular state will receive if the settlement is approved.

34. If a request comes to the Company from a state elected official, it will be responded to by the Executive Director or the Director, depending on whether there are existing relationships between the official and the Department employee. While most of their interaction with state legislators and officials has been responsive since entry of the Injunction, the Executive Director anticipates more active interaction as the Public Health Initiatives more fully mature.

35. The Associate Director, Legislative Alliance, is principally tasked with matters relating to the Public Health Initiatives. Though the Associate Director just started in June, she is responsible for developing relationships and forming alliances with national, regional, and local organizations addressing substance and opioid use disorder, and assisting in identifying potential legislative or regulatory initiatives to help address the opioid crisis. As part of a "listening and learning initiative," she has been attending conferences including the Association

for Addiction Professionals, and the Oklahoma Association for the Treatment of Opioid Dependence and Addiction Medicine, and will soon be attending conferences of the Association for Behavioral Health and Wellness and the American Academy of Addiction Psychiatry.

36. The Department also tracks and can become involved in issues that any pharmaceutical company might face unrelated to Opioids or the topics of the Injunction, such as matters involving pricing and transparency laws.

37. While the Department does not actively work to influence legislative or administrative outcomes relating to topics covered by the Injunction, it focuses on monitoring legislative and administrative activity, and getting information to those in the Company who might need the information.

38. As explained by the Executive Director, 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.

39. Using information gathered from contract lobbyists and other industry sources, the Government Affairs & Public Policy Department produces monthly summary reports regarding issues facing the industry. Recent reports included state legislative proposals covering topics such as opioid antagonists, opioid taxation, drug pricing transparency, substance abuse, drug takeback and disposal programs, prescription drug importation, and opioid litigation and abatement funds. The reports will also include summaries of significant federal activity. The Executive Director explained that the report is for the use of any interested employee, and it provides broader perspective of what is happening in the states, but only a snapshot and does not reflect every piece of legislation that the Department may be tracking.

40. In addition to responsive and information-gathering activities, the Department is 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.

B. Membership and Participation in Outside Organizations

41. Purdue 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.

42. At the end of 2022, the Company ended its memberships in the Association for Accessible Medicine ("AAM"), which advocates to advance policies and regulations that make accessibility to generic drugs easier for the consuming public, and the Healthcare Distribution Alliance ("HDA"), the national organization representing healthcare distributors. Membership in AAM was not renewed after leadership changes in Rhodes, and HDA because the Company has not been working on opioid tax issues. The Executive Director noted that she still can get access to information the various associations disseminate, but both because the Company does not actively participate and because of budget sensitivities, the Company determined that further membership was unwarranted.

43. Purdue also asked all 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.

44. 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.

45. Purdue participates in the Republican State Legislative Committee, the Council of State Governments, and the State Legislative Leadership Foundation, with the first one being a partisan organization, and the latter two educational-based nonpartisan organizations.

46. Purdue is also a dues-paying member of the Connecticut Business & Industry Association, an organization that provides information and advocacy on matters such as labor laws, biosciences, and proposals that could affect the Company as a business in the state of Connecticut.

47. While the Injunction provides fairly prescriptive limitations on what lobbying is permitted, the Injunction does not prohibit "[r]esponding to an unsolicited request for the input on the passage of legislations or the promulgation of any rule or regulation," and "[c]ommunications by the Company, including to elected or appointed officials, federal or state legislative or administrative bodies, committees or subcommittees regarding (1) mechanisms for preventing opioid abuse and misuse, including abuse deterrent formulations and the use of blister packaging for opioid medications, (ii) the prevention, education and treatment of opioid use disorders or opioid abuse, addiction or over, including medication-assisted treatment for opioid addiction; and/or (iii) rescue medications for opioid overdose." (Injunction, II.D.4.)

48. Additionally, the prior Monitor made a number of recommendations relating to lobbying and advocacy, which were accepted by the Company. Those recommendations included:

a. That the agreements with the state and federal consultants be in writing and spell out the terms of the injunction and that those lobbyists both provide quarterly reports of the issues they are engaged in and certifications that they are abiding by the terms of the Injunction.

b. That the Company refrain from lobbying against the passage of an opioid tax, absent written notice to the Monitor.

c. That Purdue provide the Monitor a quarterly report of all political contributions that related to an agreement reached between all interested parties and the court relating to certain political contributions.

d. That any Purdue employee serving on the board of an organization that engages in lobbying or educating state and federal officials on policies that could promote the use of opioids or opioid products must recuse from any board discussions relating to opioids, and refrain from participating in any working groups that focus on issues prohibited by the Injunction.

(Second Report, Paragraph 90.)

49. The undersigned Monitor finds that the Government Affairs & Public Policy Department is performing in a manner consistent with the terms of the Injunction and the recommendations of the prior Monitor. Almost all the Opioid-related activities involve monitoring legislative and administrative activities, with some activities around Opioid use disorders and rescue medications. Moreover, there are no longer any Purdue employees serving in organizations engaging in lobbying or educating state and federal officials on policies that could promote the use of Opioids or Opioid Products, and no political contributions have been given. Additionally, the 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.

C. Contracted Firms

50. Since the filing of the Fifteenth 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 July 1 to September 30, 2023.

51. Contracted firms monitored legislation relating to various topics involving opioids, prescription monitoring programs, opiate settlement advisory committees and foundations, pricing transparency, opioid antagonists, substance use disorder, drug importation, PBMs, liability protections, and Medicaid expansion, among other topics. At the federal level the topics ranged from opioid and substance use disorder, bankruptcy reform, pricing, PBMs, and other matters. In all instances, the firms were only monitoring legislative, executive, and administrative activities, and all firms certified compliance with the terms and conditions of the Injunction.

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

IV. BAN ON HIGH DOSE OPIOIDS

53. 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).

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

V. SUSPICIOUS ORDER MONITORING AND REPORTING

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

55. The Monitor has been working with the Company since the Ninth Report on matters relating to using rebate information for SOM purposes. (Ninth Report, Paragraphs 134-138.) While the undersigned is close to reaching conclusions and making recommendations, the Company has requested additional time to consider those conclusions and recommendations.

56. The undersigned will work with the Company and provide further information in the next Report, or an interim Report filed before the end of the next quarter.

B. Restricting Supply of Company Opioid Products to Downstream Customers

57. In the Eighth Report, the undersigned recommended that "the Company establish policies and procedures for placing restrictions on certain downstream customers and provide the Monitor the opportunity to review these policies and procedures prior to implementation." (Eighth Report, Paragraph 86; *see also* Ninth Report, Paragraphs 198-199; Eleventh Report, Paragraphs 96-98; Twelfth Report, Paragraphs 92-94; Thirteenth Report, Paragraphs 55-66; Fourteenth Report, Paragraphs 34-41; Fifteenth Report, Paragraphs 27-32.)

58. The Company involved the Monitor in reviewing, revising and finalizing the SOP and related materials for fulfilling this recommendation. Presentation of the SOP, in summary form, follows.

59. The purpose of the SOP is "to discourage distribution of Purdue controlled substance products to Downstream Customers who pose a risk of diversion, and to enhance compliance with the Drug Enforcement Administration's ('DEA') Know Your Customers' Customer due diligence requirements." The SOP defines a "Customer of Interest" as a "customer of a Direct Customer that displays one or more Indicators of Potential Diversion

('IPD')." Purdue's Direct Customers are wholesalers or distributors who purchase products directly from Purdue and sell them to the Downstream Customers.

60. Through existing Suspicious Order Monitoring processes, the SOM Team identifies potential Customers of Interest by analyzing Chargeback Data,[2] EDI Data,[3] and other information received by the Company. The SOP provides that a potential Customer of Interest will be identified using data analytics including, but not limited to, total number of chargebacks, the location, size and business type of the Downstream Customer, and a zip code analysis.

61. For Downstream Customers identified as potential Customers of Interest, the SOM Team undertakes the same analysis as it has been applying to chargeback outliers (*see* Twelfth Report, Paragraph 111), and also considers IPD's including whether the Downstream Customer: (i) has significantly higher chargeback units or bottle counts of controlled substances compared to their peers in the region; (ii) has three or more controlled substance suppliers in the DEA's Automated Reports and Consolidated Ordering System ("ARCOS") database; and (iii) whether the Downstream Customer or persons under its authority received federal or state disciplinary action or criminal/administrative sanctions related to controlled substances within the past five years. The SOM Team also conducts an open-source analysis of instances where media or publicly available information within the past 24 months suggests that Downstream

[2] Chargeback Data is "[i]nformation detailing an amount credited or to be credited to a Direct Customer for the difference between the invoice price paid to Purdue by the Direct Customer for a Covered Product and the negotiated contract price that the Downstream Customer pays for that Covered Product." It is found through Electronic Data Interchange ("EDI") 844 and 849 Reports. EDI 844 Reports reflects requests by a wholesaler to receive a credit or debit from a manufacturer. EDI 849 Reports reflect whether the manufacturer accepts or disputes the chargeback and rebate details.

[3] The EDI Information consists of the EDI 852, or Product Activity Data report, which contains date related to inventory positions and movements (i.e., sales and restocking), between suppliers and retailers, and the EDI 867, or Product Transfer and Resale report, which is sent from a wholesaler/distributor to a manufacturer to advise the manufacturer in order to know about product movements, including sales, change in location, and returns.

Customer is likely involved in diversion, and reviews information it receives from employees/contractors, law enforcement, regulatory agencies, or a Direct Customer.

62. If, after this review, the SOM Team continues to harbor concerns about potential diversion, the Team notifies Purdue's Direct Customer of the identity of its Downstream Customer of Interest and requests that, within 60 days, the Direct Customer conduct a due diligence review and provide a report of findings. The SOM Team may, at their discretion, also inform the Direct Customer of Purdue's concerns and identified IPDs relating to the Customer of Interest.

63. If the Direct Customer fails to respond after 30 days, the SOM Team will once again request the due diligence review and may also attempt to directly send the notification to the Downstream Customer of Interest.

64. The due diligence review conducted by the Direct Customer may include analysis of IPDs from the Direct Customer's SOM program, or the results of a comprehensive site visit conducted by the Direct Customer or an independent third-party vendor approved by the Direct Customer.

65. At a minimum, the due diligence review should include an in-depth analysis of the following IPDs:

a. Cash to non-cash ratio: The percentage of cash payment to total purchases of both controlled and non-controlled substances. A ratio of 20% or greater of controlled substances purchased in cash, or a variance of 10% or more between controlled substances and non-controlled substances purchased in cash, may be considered an IPD.

b. Single-entity ratio: The percentage of single-entity prescriptions to total prescriptions. A ratio of 20% or higher of single-entity prescriptions may be considered an IPD.

c. Unusual Formulation Purchasing: Ordering of high-risk formulations, including but not limited to formulations of methylphenidate, dexmethylphenidate, amphetamine salts, hydromorphone, oxycodone, hydrocodone, morphine, dronabinol and buprenorphine (without naloxone), may be considered an IPD. The SOP also provides that the SOM Team may add, remove, or revise the list of high-risk formulations based on various factors including regulatory guidance and abuse/diversion trends.

d. Prescriber to Pharmacy Distance: Greater than or equal to 20 miles between the controlled substance prescribers and the Downstream Customer of Interest may be considered an IPD, unless located in rural/sparsely populated areas or areas lacking in available practitioners. Lesser distances may also be an IPD in urban/densely populated areas or areas with no shortage of practitioners.

e. Pharmacy to Patient Distance: Greater than 20 miles between the patient and the Downstream Customer of Interest may be considered an IPD, unless located in rural/sparsely populated areas or areas lacking in available practitioners. Lesser distances may also be an IPD in urban/densely populated areas or areas with no shortage of practitioners.

f. Prescriber Activity and Licensure: Prescribers conducting suspicious activity such as prescribing controlled substances incongruent with practitioner specialty may be an IPD. In addition, disciplinary, regulatory, or other verifiable derogatory

information against the primary prescriber of controlled substances may be considered an IPD.

g. Irregular Activity of the Downstream Customer: Activities may be an IPD such as: dispensing only controlled substances; requiring customers to utilize an intercom to enter the premises; taking overly cautious security precautions indicative of law enforcement counter-surveillance; offering little to no front-of-store items; dispensing overlapping prescriptions issued by different prescribers; and the owner of the retail pharmacies also owning pain clinics in the area.

66. The SOM Team will compile information received from the Direct Customer and/or Customer of Interest, and the file and related documentation will be reviewed to determine whether the IPDs have been resolved. To the extent additional information is needed from the Direct Customer, it will be requested.

67. If the Company is unable to resolve the IPDs, the Downstream Customer will be deemed a "Designated Downstream Customer," defined in the SOP as "[a] Customer of Interest who, pursuant to this SOP, is determined to pose a risk of diversion of Covered Products," which are controlled substances marketed and sold by Purdue.

Designated Downstream Customers, except for 340B and Federal Supply Schedule ("FSS") Customers

68. Except for 340B and FSS customers, for those Customers of Interest identified as Designated Downstream Customers, Purdue will:

a. Request that the Direct Customer not distribute controlled substances marketed and sold by Purdue to the Designated Downstream Customer;

b. Report the Designated Downstream Customer to the DEA;

c. Notify Purdue's other Direct Customers of the Designated Downstream Customer, and request that they not ship controlled substances marketed and sold by Purdue to the Designated Downstream Customer; and

d. If permitted in the contracts between Purdue and its Direct Customers and GPOs, terminate the Designated Downstream Customer from participation in the Purdue Chargeback Program.

69. In addition to the steps taken immediately after a Customer of Interest is identified as a Designated Downstream Customer, the SOM Team will quarterly provide all Purdue's Direct Customers a list of Designated Downstream Customers.

70. Each Designated Downstream Customer will be monitored for 12 months from the date of designation, to verify that Direct Customers are no longer shipping controlled substances marketed and sold by Purdue to that Designated Downstream Customer. In the event shipments are being made, an additional request to cease shipment will be sent to the Direct Customer, and the DEA will also be notified.

71. Designated Downstream Customers may seek reinstatement by commissioning, at their own cost, a third-party review of their program and implementing controls to identify and mitigate potential diversion of controlled substances. The third-party reviewer must be drawn from an approved list of vendors.

72. In the event a determination is made to reinstate a Customer of Interest, Purdue will notify the Direct Customer that it is no longer requesting that controlled substances not be shipped and will prospectively allow the Downstream Customer back into the Purdue Chargeback Program. Notice of reinstatement will also be included in the quarterly notification to all Direct Customers, as well as to relevant contracting partners.

73. If a Downstream Customer, after being reinstated, is subsequently again deemed a Designated Downstream Customer, it cannot be reinstated for a second time.

74. The SOP also provides prescriptive timelines for each step of information gathering and determination, processes for notifications internal to the Company, and form letters and notifications covering each communication with a Direct Customer and Customer of Interest, where applicable.

340B/FSS Designated Downstream Customers

75. Under Section 340B of the Public Health Service Act ("PHSA"), pharmaceutical manufacturers wanting to take part in Medicaid "must offer" their "covered outpatient drugs" for outpatient use at steeply discounted prices to healthcare providers, known as "covered entities," that care for low-income and rural patients.

76. While these organizations include federal grantee organizations and several types of hospitals, including critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate share hospitals serving low-income and indigent populations, the covered entities can also contract with outside/independent pharmacies ("contract pharmacies") to provide services to the covered entity's patients.

77. For 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.

78. The Company is concerned that, if it requests distributors not to ship to 340B covered entities and contract pharmacies, it could risk non-compliance with the PHSA's "must offer" requirement, which requires a manufacturer to make its Medicaid "covered outpatient drugs" available for sale to a designated covered entity or its contract pharmacy.

79. The Health Resources & Services Administration ("HRSA") has issued nondiscrimination guidance requiring that manufacturers not treat 340B entities any worse than other commercial entities or providers (*See* https://www.hrsa.gov/sites/default/files/hrsa/opa/non-discrimination-05-23-2012.pdf). In the undersigned's estimation, if Purdue requests Direct Customers not to ship Covered Products to 340B contract pharmacies that are Designated Downstream Customers, just as it does with other pharmacies, the 340B entity is not being treated any worse than other providers.

80. To mitigate against the risk of noncompliance with the PHSA, the Company recently provided HRSA notice of its intent to request that distributors not distribute its controlled substances to Designated Downstream Customers otherwise eligible for 340B prices. If HRSA does not object to the policy change within four weeks of receipt of the policy, Purdue will amend the SOP to include 340B entities and contract pharmacies, when requesting Direct Customers not to ship to Designated Downstream Customers.

81. For generic products, 10% of all pharmacies are either 340B covered entities or serve as contract pharmacies for 340B covered entities; for branded products, 20% of customers eligible for contracted price discounts (whether purchasing direct or indirect) are 340B contract pharmacies or covered entities. Stated otherwise, a Designated Downstream Customer could serve patients under the 340B program and other commercial agreements and, because it has a 340B contract, Purdue will not request that its Direct Customer stop shipping to that Designated

Downstream Customer. Given the limitations of linking chargeback data to other wholesaler reports, it is unknown what percentage of pharmacies will be excepted from the program until this is resolved, although the percentage would be less than 20%.

82. For Federal Supply Schedule contracts, the Veterans Health Care Act requires that manufacturers enter into a Master Agreement, which requires the covered outpatient drugs to be put on the Federal Supply Schedule for government purchasers and to be sold at the Federal Ceiling Price ("FCP"). Manufacturers have statutory and contractual obligations to make their products available at the FCP. Like the issues around 340B contracts, the Company is concerned that, if it requests distributors not to ship controlled substances, the Veterans Administration could determine it was not fulfilling its statutory and contractual obligations. Accordingly, the Company is providing the Veterans Administration notice prior to implementation.

83. The Company hopes that this will be an interim measure, and recently sent letters to both HRSA and the Veterans Administration. Unless one of the federal agencies objects, the Company intends to revise the SOP by the end of December, treating 340B/FSS Designated Downstream Customers the same as other Designated Downstream Customers.

Limitation in Influencing Distribution of Branded Products

84. As has been explained in earlier reports, a limitation in creating a program that relies upon restricting chargebacks to prevent a Designated Downstream Customer from distributing Purdue controlled substance is that chargebacks are predominantly paid on generic, not branded products. For branded products, chargebacks are paid only on contracted indirect sales to institutional/inpatient facilities or alternate care sites, and not to retail pharmacies. The vast majority -- between 76 and 98 percent – of Purdue Pharma's branded Opioid Products are sold through pharmacies. (*See, e.g.,* Ninth Report, Paragraphs 156-161.)

85. The undersigned asked the Company to explore whether a process could be implemented restricting rebates for branded products similar to the processes for restricting chargebacks, thereby making it less likely that Designated Downstream Customers would have access to Purdue's controlled substances. The Monitor met with the Vice President, Legal Strategy and Public Health Initiatives; the Vice President, Sales & Marketing; the Head of Pricing and Contract Administration; the Director, Market Access Contracting & Analytics; and the Company's outside counsel.

86. The Monitor has been convinced that a similar process would not work.

87. A chargeback is a credit paid by the manufacturer to the distributor, covering the difference between the invoice price paid to Purdue by the distributor and the negotiated contract price that the Downstream Customer pays the distributor for the product. A rebate, however, is paid by the manufacturer to a Pharmacy Benefit Manager ("PBM") based on utilization by eligible health plans. The PBM acts as an intermediary between a health insurance plan and the manufacturer, and the rebate is paid in exchange for formulary placement.

88. Once rebates are paid from the manufacturer to PBM, the PBM shares some percentage of the rebate with the health plan. The PBMs do not typically share any portion of the rebate with the pharmacies and, while a pharmacy receives a small percentage markup over the cost of purchasing the product plus a dispensing fee, that payment is not impacted by whether a rebate is paid.

89. Nor do the PBMs share any portion of the rebate with the Direct Customer/distributor. Accordingly, unlike a chargeback restriction, where the Direct Customer would be financially impacted if it shipped Purdue's products to a Designated Downstream

Customer, restricting rebates would not financially impact the Direct Customer or the Designated Downstream Customer.

90. While experience operating under the new SOP will be the ultimate test, the inability to financially impact Direct or Downstream Customers distributing and selling branded Opioid Products to Designated Downstream Customers will hopefully not adversely impact the effectiveness of the processes established.

91. First, the request to Direct Customers not to distribute Purdue controlled substances to Designated Downstream Customers, with notification to the DEA, should act as the primary incentive to restrict supply, more so than restricting chargebacks.

92. Second, if a Direct Customer will not receive chargeback credits relating to a Designated Downstream Customer for generic Opioid Products, it appears highly improbable that the Direct Customer would continue distributing branded Opioid Products to that Designated Downstream Customer.

93. Finally, as discussed below, if the Distributors will simply agree to restrict distribution to Designated Downstream Customers based upon Purdue's request, the additional steps that would allow restriction of chargebacks becomes unnecessary.

Results to Date

94. The Company implemented the SOP on October 2, 2023. Already, three Downstream Customers of Interest have been identified, and information has been sought from the Direct Customers. The 60-day period for the Direct Customers to provide due diligence information has not yet expired.

Contract Negotiations

95. In the Fourteenth Report, the undersigned included the following recommendation with respect to updating customer contracts to facilitate implementation of the SOP:

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

(Fourteenth Report, Paragraph 41.)

96. Immediately prior to filing this Report, the undersigned received information on the status of contract modifications. Since the undersigned's last Report, no additional Group Purchasing Organizations ("GPOs") of Purdue Pharma or Rhodes have agreed to terms or have executed contract modifications. However, one of the three main distributors for Purdue has: (i) advised that under its SOM program it will honor requests from Purdue Pharma and Rhodes to cease distribution of their controlled substances to downstream customers that become Designated Downstream Customers under Purdue's SOP; and (ii) agreed to an amendment to Purdue Pharma's chargeback policy t allowing for termination of prospective chargebacks on branded products for downstream customers that become Designated Downstream Customers.

97. The Company explained to the undersigned that they are now attempting to advance the negotiations by arranging cross functional meetings, including the SOM and legal teams, rather than just focusing on those responsible for commercial and contracting functions.

98. Faced with a similar situation, Mallinckrodt, another manufacturer, proposed a letter agreement to the three largest distributors, seeking further cooperation in suspicious order monitoring and reporting. In April 2022, one of the three distributors agreed to:

> (1) Terminate supply to customers Mallinckrodt identifies as posing a diversion risk; (2) inform Mallinckrodt of [the distributor's] restriction of downstream registrants; (3) respond to Mallinckrodt's requests for information; and (4) submit timely chargeback requests.

Eighth Mallinckrodt Monitor Report, Paragraph 11.47 (https://www.mallinckrodt.com/globalassets/documents/corporate/41654555-v1-eighth-mallinckrodt-monitor-report.pdf)

99. It is disappointing that, after over two years of efforts, it appears that only one of the three largest distributors has entered into this agreement with Mallinckrodt. However, the fact that one distributor did agree is meaningful, and perhaps if other manufacturers request similar arrangements, it is more likely the distributors will understand the value to the manufacturers, to the distributors, and to prevent unlawful use and diversion of controlled substances.

100. Reaching agreements with Purdue's principal Direct Customers would alleviate many of the obstacles to fully implementing the SOM. First, if a Direct Customer agrees to terminate supply, contract amendments with the Direct Customer and GPO to accept chargeback restrictions become less important as no chargebacks on the Company's controlled substance

products arising from a sale to the Designated Downstream Customer should occur. Second, it would ensure that Purdue Pharma's branded Opioid Products, which are for the most part not subject to chargebacks, would also not be distributed to or by Designated Downstream Customers. And third, as both manufacturers and Direct Customers have independent suspicious order monitoring and reporting obligations, the information flowing from the Direct Customer to the Company could certainly be beneficial for Purdue in fulfilling its SOM obligations.

101. **The undersigned recommends that 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. The Company has agreed to this recommendation.**

102. Moreover, five months after the Monitor recommended negotiations with the distributors and GPOs commence with the objective of having those contracts amended within three months, progress has been slower than the Monitor expects. The Company reports that its efforts to negotiate these amendments have not in certain instances been met with receptivity by the distributors and GPOs.

103. The Monitor has become increasingly convinced that, if left to the devices of those in each contracting party typically responsible for commercial and contracting functions, the changes necessary to fully effectuate the SOP are unlikely. The terms requested, and greater underlying policy reasons for seeking these amendments, are unlike what is covered in routine contract negotiations.

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104. **Accordingly, the Monitor recommends that 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. The Company has agreed to this recommendation.**

Conclusion

105. In the Eighth Report, filed February 22, 2022, the Monitor recommended "that the Company establish policies and procedures for placing restrictions on certain downstream customers…." (Eighth Report, Paragraph 86.) Policies and procedures have been in force since October, and hence the Monitor finds that the recommendation as set forth in the Eighth Report has been met. While it certainly has been a long and arduous journey to get to this point, the matters covered are not without significant complexity and, to the undersigned's knowledge, only one other manufacturer is employing processes even remotely similar.

106. In the Fourteenth Report, the undersigned detailed that "the Company recently reported to the undersigned that it has concluded that, absent amendments to its agreements with the distributors and GPOs, the Company could not restrict the supply of Opioid Products to downstream High-Risk Customers of Concern." (Fourteenth Report, Paragraph 37.) Accordingly, absent either (a) the Company amending its agreements with the distributors and/or GPOs; (b) the Company revisiting its legal conclusions concerning the necessity of those amendments; or (c) distributors honoring Purdue's request to restrict supply even if amendments aren't made, the newly implemented SOP will not restrict supply of Purdue's controlled substances to Downstream Customers that Purdue believes pose a risk of diversion. The DEA

could certainly take action, however, as it will be notified of Purdue's concerns. (*See, supra, Paragraphs 68 and 70.)*

107. The Monitor will report further in the next Report.

C. Suspicious Order Monitoring Review of Savings Card Information

108. In the Eighth Report, the undersigned reported that "[t]he SOM team also commenced reviewing the information gathered from the Opioid Product Savings Card program, to assess whether patients are receiving medications prior to when they should, whether there are patterns that might suggest doctor shopping, and anything else that could present a risk of or potential for diversion." (Eighth Report, Paragraph 89.)

109. During the last Reporting period, the Company reported to the undersigned that this information has not been consistently provided to the SOM Team, because of contractual limitations on the use of the data collected by the third-party vendor administering the Savings Card program. (Fifteenth Report, Paragraph 44.)

110. The Company has successfully negotiated amendments to the contracts with the Savings Card program vendors to allow the information to be shared with the SOM Team, and is now in the process of evaluating how to best incorporate this date into the SOM process.

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VI. INITIAL COVERED SACKLER PERSONS

111. 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 Sixteenth Report with the observations and recommendations contained herein.

STEPHEN C. BULLOCK
Monitor