DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
James I. McClammy
Marc J. Tobak
Gerard X. McCarthy

Counsel to the Debtors
and Debtors in Possession

UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF FILING OF MONITOR'S REPORT

PLEASE TAKE NOTICE that Purdue Pharma L.P. hereby files on behalf of Thomas J. Vilsack, in his capacity as Monitor, the *Second Monitor Report* attached as Exhibit A hereto (the "**Second Monitor Report**"). Mr. Vilsack, as Monitor, prepared the Second Monitor Report pursuant to the Voluntary Injunction entered as part of the *Second Amended Order Pursuant to 11 U.S.C. § 105(a) Granting Motion for a Preliminary Injunction*, entered on November 6, 2019

[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 LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

(the "**Preliminary Injunction Order**"),[2] which requires that the Debtors retain a Monitor, and that the Monitor file a report no less than every 90 days regarding compliance by the Company with the terms of the Voluntary Injunction. Purdue Pharma L.P. is filing the Second Monitor Report as a courtesy to the Monitor, who has not retained counsel in connection with these chapter 11 cases.

PLEASE TAKE FURTHER NOTICE that a copy of the Second Monitor Report and any related papers may be obtained free of charge by visiting the website of Prime Clerk LLC at https://restructuring.primeclerk.com/purduepharma. You may also obtain copies of any pleadings by visiting the Court's website at https://www.nysb.uscourts.gov in accordance with the procedures and fees set forth therein.

Dated: August 18, 2020
New York, New York

/s/ Marc J. Tobak

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
James I. McClammy
Marc J. Tobak
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[2] Unless otherwise defined herein, each capitalized term shall have the meaning ascribed to such term in the Preliminary Injunction Order.

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)**

SECOND MONITOR REPORT

Comes now, Thomas J. Vilsack, as duly contracted Monitor for Purdue Pharma L.P. to report to the Court as follows:

EXECUTIVE SUMMARY

This Second Monitor Report will include a description of steps taken since the Initial Monitor Report: to determine compliance with the conditions of the Voluntary Injunction, to review documents and materials relied upon, to retain subject matter experts, to provide an update on the implementation of recommendations from the Initial Monitor Report, to outline additional information relating to a variety of topics germane to the Voluntary Injunction including the ban on promotions, use of remunerations, suspicious order monitoring, lobbying, memberships, and Initial Covered Sackler Persons, and to make recommendations for continued compliance with the terms and conditions of the Voluntary Injunction. Officials at Purdue Pharma L.P. continue to be responsive and cooperative notwithstanding the Covid 19 crisis in

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furnishing information and providing access to key personnel. Based on what has been reviewed to date and subject to the recommendations contained herein Purdue Pharma L.P. and the Initial Covered Sackler Persons appear to be making a good faith effort to comply with the terms and conditions of the Voluntary Injunction.

INTRODUCTION – STEPS TAKEN SINCE INITIAL REPORT

1. Since the filing of the Initial Report the undersigned Monitor has continued with a series of interviews with employees at Purdue Pharma L.P. and its related entities (Purdue) with an emphasis on the staff of the Ethics and Compliance and Market Access Departments.

2. Since the filing of the Initial Report, the undersigned Monitor has continued to request, receive and review a variety of reports and documents that contain lobbying, financial, marketing and suspicious order monitoring information.

3. Since the filing of the Initial Report the undersigned Monitor has retained the expert services, with Court Approval, of Jodi Avergun, former DEA Chief of Staff, who has been instrumental in assisting with the review of the suspicious order monitoring and reporting efforts at Purdue, leading to a series of recommendations contained in this Second Report.

4. Since the filing of the Initial Report the undersigned Monitor is in the process of retaining expert assistance of HealthPlan Data Solutions Inc. to better understand how remunerations, rebates and other financial tools are being used at Purdue.

FIRST REPORT RECOMMENDATIONS

5. In the Initial Report filed by the undersigned Monitor a series of recommendations were made and agreed upon by Purdue. Included in those agreed upon recommendations was the requirement for the third party sales force personnel hired by Purdue to market non-opioid products to certify that they have read the Preliminary Voluntary Injunction

dated November 6, 2019 (Injunction)[2], that they have provided a list of any health care provider or customer called upon that inquired about opioids or opioid products, and that they acknowledge they have directed any such inquiry by the health care provider or customer to the Medical Affairs Department of Purdue (Paragraph 48 of the Initial Report). The undersigned Monitor received and reviewed the certifications provided by Purdue and found them in compliance with the agreed upon recommendations.

6. Included in those agreed upon recommendations was the requirement that in the event data from studies identified in detail in the Initial Report (Paragraphs 49-55 of the Initial Report) was published in a scientific journal, and that data was linked to a website controlled by Purdue, the company would accompany the publication of the data with a disclaimer drawing attention to the risks of misuse, abuse and overdose of opioids and opioid products (Paragraph 55 of the Initial Report). The undersigned Monitor has been advised that no such publication of data nor linkage has yet taken place.

7. Included in the agreed upon recommendations was the requirement that Purdue insert the same cautionary language contained in the Purdue Pharma L.P. website on the Rhodes Pharmaceuticals L.P. website (Paragraph 58 of the Initial Report). The undersigned Monitor reviewed the website which now contains consistent language concerning the risks of misuse, abuse or overdose associated with opioids or opioid products.

8. Included in the agreed upon recommendations was the requirement that Purdue update its LinkedIn account to reflect the correct number of employees and to alert followers to

[2] On November 6, 2019, the Bankruptcy Court entered a Preliminary Injunction as part of this Bankruptcy Proceeding. The Preliminary Injunction Order included, as Appendix A, a Voluntary Injunction (Injunction). The Injunction has been entered numerous times and remains unchanged from the version entered on November 6, 2019.

the existing bankruptcy proceeding (Paragraphs 63 of the Initial Report). This recommendation has been followed.

9. Included in the agreed upon recommendations was the requirement that Purdue certify that for the Market Access Incentive Compensation Plan that in the corporate performance element neither top-line opioid product sales or volume specifically would be used as a factor in calculating salaries or bonus (Paragraph 101 of the Initial Report). The undersigned Monitor has received the certification Purdue agreed to provide.

10. Included in the agreed upon recommendations was the requirement that lobbyists working at the federal and state levels have contracts that spell out in detail the prohibitions on lobbying and an agreement to abide by those prohibitions (Paragraphs 156, 169 of the Initial Report), a requirement that lobbyists provide a list of all issues and matters worked on and positions taken with respect to each such issue or matter (Paragraphs 159, 170 of the Initial Report) and a requirement that lobbyists certify compliance with those prohibitions (Paragraphs 159,171 of the Initial Report). The undersigned Monitor has received the reports and certifications requested.

11. Included in the agreed upon recommendations was the requirement that Purdue would provide written notice to the undersigned Monitor before any effort to lobby against an opioid tax (not including legislation on how a tax might be structured or administered) (Paragraph 173 of the Initial Report). To date no such written notice has been provided indicating no such effort has been undertaken.

BAN ON PROMOTION

12. Based on the information received and documents reviewed the undersigned Monitor concluded that Purdue continues to sell its branded opioid products without the use of a sales force.

13. The undersigned Monitor examined information detailing Drug Enforcement Agency (DEA) established procurement and manufacturing quotas granted to Rhodes Technologies for active pharmaceutical ingredients and manufacturing quotas granted to Purdue Pharmaceuticals L.P. for finished dosage forms of opioids and opioid products for sale covering the years 2018, 2019, and 2020. The records provided reflected quotas that either remained steady or declined over that three-year period.

14. The undersigned Monitor examined the most recent Purdue financial reports. These financial records represented that the current dollar sales of Purdue's branded opioid products for 2020 remain in line with 2019 sales and reduced from 2018 sales.

15. The market access of generic opioid products is very dependent on competitive pricing. Rhodes Pharmaceuticals L.P. conducted a review of its pricing for generic opioid products. The review found that several products were being sold at a loss. In response to the review Rhodes Pharmaceuticals L.P. increased its price on those products to provide for a small profit margin. The undersigned Monitor found that this action was not designed to promote the use or sale of opioid products and therefore was not contrary to the terms and conditions of the Injunction.

16. The sales figures to date of opioid products, the static or declining product quotas, and the decision to raise prices on generic opioid products support a conclusion that Purdue is in

compliance with the ban on promotion contained with Part II, Section A (1, 3 and 5) of the Injunction.

REMUNERATION: REBATES, CREDITS, DISCOUNTS, CHARGEBACKS, ADMINISTRATIVE FEES AND DATA PURCHASES

17. Under Part II, Section B (2) of the Injunction, Purdue agreed not to offer any remuneration directly or through a Third Party to any person in return for the sale, use or distribution of opioid products. This agreement expressly did not prohibit the use of rebates and/or chargebacks. However, the terms remuneration, person, rebates and chargebacks were not defined in the Part I of the Injunction.

18. Purdue sells opioid products to a variety of entities including to wholesale distributors, government agencies, states, group purchasing operations, pharmacy benefit managers, and hospitals.

19. Purdue sells opioid products by virtue of a variety of negotiated contracts and agreements and/or pursuant to a number of government programs operated by federal or state agencies.

20. With the wholesale distributors, they earn a fee for the services they perform for Purdue which are issued as a credit against the purchase of branded opioid products. There are a number of credits given or earned by the wholesalers that are credited against the purchase of branded opioid products that include the following:

a. a credit for maintaining a certain level of inventory,

b. a credit for maintaining a certain level of service quality,

c. a credit for limiting excess inventory,

d. a credit for an administrative fee for distributing product through a centralized location,

e. a credit for the difference between the wholesaler acquisition cost from Purdue (prior to prompt pay and fee credits) and the price that the wholesaler sells to Purdue's end contract customer, which can be lower (referred to as a "chargeback"), and

f. a credit for providing data on inventory levels and sales to end customers.

21. In addition to the foregoing credits earned and given, Purdue also purchases general commercial prescription data and trade market access data from its wholesalers and third-party vendors that is allocated as an expense against branded opioid products. The data purchased includes national sales and inventory data from a variety of sources which is used by Purdue to track and/or forecast products and markets, plan production/manufacturing, to determine distributor performance, and to assess formulary performance.

22. With Pharmacy Benefit Managers, Managed Care Entities and Group Purchasing Organizations there are a number of credits negotiated in part to maintain formulary status or retain exclusivity for the use of Purdue opioid products within the various plans offered by Managers, Entities and Organizations including:

a. rebates,

b. price protection payments to restrict the impact of price increases that occur from time to time, and

c. administrative fees.

23. With federal and state programs, rebates and discounts are fixed by law, by regulation or by negotiated agreement to ensure that prices paid for opioids and other pharmaceutical drugs remain low.

24. The rebates, credits, discounts, chargebacks, price protection payments, and data purchase amounts vary from customer to customer and from month to month. The payments, credits and discounts that are negotiated are approved by a multi-disciplinary committee of Purdue executives that includes representatives from the finance, law, ethics and compliance, commercial and pricing functions. The systems used to evaluate the extent of payments, credits and discounts and as well as the amounts of each are considered to be proprietary by Purdue and other pharmaceutical manufacturers that offer similar incentives.

25. The varied and proprietary nature of payments, credits and discounts make it difficult to determine if any payment, credit, discount or data purchase is outside a normal range that might suggest non-compliance with the prohibitions of Part II, Section B (2) of the Injunction.

26. Additional effort needs to be conducted to review the reasonableness and appropriateness of the payments, credits, and discounts offered by Purdue and fees paid to wholesalers for data purchased by Purdue. To assist in that evaluation the undersigned Monitor has requested permission to hire a subject matter expert, subject to Court Approval.

27. The nature of the aforementioned evaluation and any and all conclusions from it related to compliance with the Injunction shall be reported in the Monitor's Third Report.

28. Purdue conducted a study in late 2019 to determine if the administrative fees it was paying were within the norm for the industry. The study concluded that the fees were in line with industry standards and not contrary to the requirements of the Part II, Section B (2) of the Injunction.

29. Information examined by the undersigned Monitor documented that a number of the managed care entities and/or pharmacy benefit managers recently changed the formulary

status of Purdue's branded opioid products. In some cases, an effort by Purdue to forestall these changes by offering to increase rebates was unsuccessful. In most cases, these formulary changes will likely result in a loss of market share.

30. The fact that formulary changes in fact occurred suggests that the offered rebates were not alone enough to maintain the past formulary status.

31. **A recommendation is to have an expert retained to review the use of fees, credits, incentives, price protection mechanism, discounts and data purchases, to verify that any or all are being used consistent with the normal course of business and within industry standards. Purdue agrees to this recommendation.**

SUSPICIOUS ORDER MONITORING

32. Under 21 CFR §1301.74(b) Purdue is required to design and operate a system to detect suspicious orders of controlled substances and to inform the Field Division Office of the Drug Enforcement Administration (DEA) in its area when a suspicious order is discovered.

33. Under the Controlled Substances Act, 21 U.S.C. § 804 (57) and 21 CFR §1301.74(b) a suspicious order is defined as an order of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.

34. Because neither the Controlled Substance Act ("CSA") nor DEA provide definitive instructions concerning how CSA registrants must structure their SOM programs, these programs are individualized and company-specific.

35. Under the Injunction, Purdue must: (i) analyze reasonably available direct and downstream customer data to identify potentially suspicious orders; (ii) analyze any other information that Purdue has that indicates a potential for an unreasonable risk of diversion by a direct customer or downstream customer; and (iii) upon request, report to the relevant state

agency (a) any direct customer or downstream customer that Purdue has identified in that state through its monitoring and (b) any customers Purdue has terminated because of an unreasonable risk of diversion or potential diversion.

36. Purdue established a Standard Operating Procedure (SOM-SOP) that sets forth the design of the system Purdue would use to identify, evaluate and report suspicious orders.

37. There are indicators that may suggest a particular order is suspicious given its size, frequency, or pattern or where a downstream customer may be engaging in suspicious activities given the nature of its ordering history.

38. Under the SOM-SOP, suspicious orders are orders determined to be orders of unusual size, orders deviating substantially from a normal pattern or orders of unusual frequency adopting the same definition as in 21 U.S.C § 804 (57) and 21 C.F.R. §1301.74 (b).

39. Under the SOM-SOP an order of unusual size, frequency, and/or that deviates substantially from a normal pattern is one that is "pended" by a SOM Tool or by other means and is then considered by Purdue to be an "Order of Interest".

40. For each Order of Interest (i.e., pended), Purdue then reviews the order to determine if there may be reasonable explanations for the deviations (e.g., a customer has low product inventory, two distributors merge and require larger orders).

41. Under the SOM-SOP, the SOM Tool is a cloud-based IT program that uses both an algorithm and custom rules/thresholds to identify and pend Orders of Interest.

42. In the development of the cloud-based SOM Tool, Purdue contracted with a third-party vendor that uses a series of purchasing data sets to compare a customer's monthly orders across a variety of matrices enabling the vendor to identify orders of unusual size, unusual frequency and/or that deviate from a normal pattern. The algorithm is tailored for Purdue's use

and based, in part, on an analysis of national sales data. The software compares the specific order against a range of statistical information about other orders to determine if the order at issue deviates in terms of usual size, pattern, and/or frequency.

43. In addition to the algorithm described above, starting in 2017, Purdue implemented a customer threshold review. Threshold levels are established for each individual customer and drug family, and all orders are reviewed against the customer-specific threshold to determine if they are exceeding the customer's set limits for order volume.

44. Under the SOM-SOP, the threshold to be used is defined as the monthly maximum quantity in dosage units for each DEA controlled substance base code and/or strength unique to a customer and which caps the total number of doses a customer may order for a controlled substance base code in any calendar month. The threshold is calculated by using national data representing sales for each product to establish a baseline. That baseline number is multiplied by a store count provided by each customer, in part from information obtained from the Customer Due Diligence Questionnaires and the Annual Customer Questionnaire, broken down by the type of enterprise (retail, long term care etc.). The final step in the process is to multiple that number by a fraction based on the contract status of each customer. Based on the material provided to date and the interviews conducted it is unclear what the basis is for each one of the last multipliers used in fixing the threshold.

45. Each threshold is primarily established by a single employee who calculates the threshold manually on an annual basis unless it needs to be adjusted during the year when circumstances require (e.g., change in contract status, change in number of customers). An order is pended if (i) it is determined to be out of the normal range in terms of size, frequency, and pattern based on an algorithm and/or (ii) it exceeds the customer's threshold level.

46. Under Purdue's procedure, once an order is pended due to the algorithm, the threshold or both, the order is further reviewed by SOM personnel to determine if the order should be cleared for review or rejected and reported to the DEA. This review process may include, among other things, review of the customer's order history and/or discussions with the customer. Any concerns regarding a customer that cannot be resolved are discussed with the VP of Ethics & Compliance to determine the next steps, which may include an additional on-site customer visit.

47. Under the SOM-SOP, if an order is pended additional manual review and intervention is required by SOM personnel.

48. Under the SOM-SOP, the purpose of the review is to determine if an order is to be cleared for processing and delivery or rejected and reported to the DEA. Under Purdue's system, only rejected orders get reported as suspicious to the DEA despite being flagged by an algorithm based on multiple matrices that are designed to identify orders that fit the definition of suspicious order under 21 U.S.C §804 (57) and 21 C.F.R. § 1301.74 (b).

49. The SOM-SOP manual review and intervention triggered by an order being "pended" from the time of the entry of the Injunction to the present has been conducted primarily by a single individual in Ethics and Compliance which is entirely independent of the Commercial organization. The reviewing employee also calculates the threshold.

50. From time to time, the reviewing employee has been assisted in a limited way by two other individuals. They primarily act as a second reviewer for orders from Ohio since by that state's law those orders require that a second person also review the order. They also serve as a back-up for the reviewing employee when that employee is unavailable. A third individual has

been identified to assist with inspections at some point in the future but has not yet been trained in the system.

51. The SOM-SOP sets forth steps that can be taken but are not required to be taken when an Order of Interest has been pended which include: determining why the Order of Interest was pended, reviewing the customer order history, checking the customer threshold, looking at the customer file, inquiring with Customer Service at Purdue, or contacting the customer. These additional steps, if taken, would also be conducted by the reviewing employee.

52. A Suspicious Monitoring Report (SOM) is prepared each month listing each order, listing all Orders of Interest that have been cleared and the reason why they have been and also identifying the Orders of Interest that have been rejected.

53. The undersigned Monitor reviewed the SOM Reports for March, April, and May of 2020 containing information on more than 15,000 orders processed through the SOM Tool. Of that number the system, using the algorithm designed to identify orders of unusual size, unusual frequency and/or substantially deviating from normal patterns, flagged over 300 orders that met those criteria. After an additional review required under the SOM-SOP all but 2 orders of the more than 300 flagged orders were cleared and processed. One rejection was a duplicate order due to an IT error. The other was due to a customer's non-compliance with SOM Policy. Specifically, the customer had 2 DEA registration numbers, but only provided one number for the orders. This order was reported to the DEA.

54. The SOM Reports reviewed also contained a note or journal entry identifying the reason or reasons for clearing orders for further processing. In nearly 90% of the cleared orders the reason recorded in the note or journal was that the order was within limits or within the threshold. These notes combined with times recorded in the note or journal suggest that the

review occurred within a matter of minutes at a minimum suggests that the threshold alone might have been used to override the IT based SOM tool's flagging of orders as being of unusual size, unusual frequency, and/or deviating from a normal pattern. However, Purdue represents that the clearing of orders only occurs if issues raised by the SOM Tool have been reasonably explained as a result of an additional investigation that includes but is not necessarily limited to a review of the threshold.

55. The SOM reports also contained notes identifying the reason or reasons for clearing orders for further processing. In nearly 90% of the cleared orders the reason given was that the order was within limits or within the threshold. This determination is made only if the issues raised by the SOM Tool have been reasonably explained. Purdue represents that if an order is pended under the algorithm function of the SOM Tool for unusual size, but the customer has a pattern of ordering greater quantities at year-end, SOM personnel will review the dosage history (i.e., for the past 12 months), the active ingredient listing (i.e., looking back to 2017), DEA journal entries, historical correspondence with the customer, and/or communication(s) with the customer regarding the pended order and current contract status. Additionally, since the order pended based on the algorithm, SOM personnel will also review the order vis a vis the threshold. If the order clears the threshold (i.e., the order is less than the anticipated maximum order), the SOM Report notes will indicate that the order was cleared under the threshold.

56. Purdue also has a system in place to review and monitor downstream customers who are purchasing product from a Purdue customer and dispensing it to their customers. The purpose of the system is to identify downstream customers of interest who may be ordering quantities that may be exceeding national or customer dispensing levels.

57. Purdue established a Standard Operating Procedure for monitoring and reporting Downstream Customers (Downstream – SOP). Under the Downstream-SOP, Ethics and Compliance is required to review on a quarterly basis available 867 and/or chargeback data to identify orders that appear to exceed national or customer dispensing averages.

58. Orders so identified require a due diligence review that may include, according to the Downstream – SOP: an internet search for basic information about the customer, a review of other purchase data, a contact with the Purdue customer to place the order in context, the conduct of other due diligence steps including outreach to the downstream customer, and possible initiation of background checks or site visits.

59. A typical monthly chargeback report contains approximately 5,000 customers' chargebacks that reflects the number of units to be credited for each downstream customer.

60. The reviewing employee, in addition to the responsibilities in connection with direct customer suspicious order monitoring, also does the quarterly review of chargebacks.

61. The method used for the chargeback review is manual. No IT cloud-based system, algorithm or threshold is used in the chargeback review. The list of chargebacks is examined to locate a downstream customer that has a significantly larger number of chargeback units than other customers contained in the same report. The Company has entered into a contract with a third party vendor to implement a due diligence tool that will automate downstream customer data review and enhance the review of various data sets including chargeback data.

62. During the last chargeback review approximately 20 chargeback entries were reviewed.

63. Purdue also requires that their customers provide a Wholesaler Due Diligence Report which requests information from the customer as to its system for detecting suspicious orders. The reviewing employee also reviews these Due Diligence Reports.

64. One of the Wholesale Due Diligence Reports that was reviewed was for a company suggesting it was solely in the business of exporting pharmaceutical drugs to markets in other countries. In the Report this customer represented that its SOM system responsibility was satisfied merely by the United States Government providing permission for it to export. The company's registration number did not identify the customer as being an exporter and in fact the company was engaged in selling domestically pharmacy products, vitamins and dietary supplements, medical supplies and sports supplements online in the United States. Despite providing false, insufficient and inadequate detail of its business and its SOM program the company was able to obtain one shipment of opioids and opioid products from Purdue. Recently, Purdue rejected an additional order placed by this customer, reported it to the DEA and determined it would no longer ship products to the company.

65. Under Part II, Section G of the Injunction, Purdue agreed in part to operate an "effective monitoring and reporting system" that was designed with process and procedures that would "reasonably analyze" collected direct customer data and downstream customer data to identify a suspicious order.

66. Part I, Section Q of the Injunction adopts the same definition of suspicious order as in 21 U.S.C. § 804 (57).

67. The analysis of whether Purdue is in compliance with the requirements of Part II, Section G of the Injunction rests upon a determination of the reasonableness of the Company's efforts after an order is flagged. Purdue's cloud-based IT system is designed to identify orders

that are of unusual size, unusual frequency, and/or deviate from the normal pattern which fit the definition of suspicious orders under the law and Purdue's policy. Absent a detailed explanation of why an order is unusual or deviates from a normal pattern Purdue by law, by its own regulation and by Injunction such an order ought to be reported to the DEA.

68. A review of the SOM reports and of the explanation given for clearing hundreds of orders flagged by the cloud-based IT system and the algorithm reveals that nearly 90% of the orders are noted to have cleared because of threshold review only. However, Purdue represents that these orders were also subject to the additional reviews of dosage history, active ingredient history and other queries (although these factors may not all be noted in the notes).

69. The cloud-based IT system and its algorithm uses 8 different screens to determine a flagged order review.

70. **A recommendation is made to Purdue that it re-evaluate whether thresholds should be used and if continued, to develop best practice standards for their use. Purdue agrees to this recommendation.**

71. **A recommendation is made to Purdue to provide more documentation setting out why a decision was made to clear an order. Although documentation does exist, it would be preferable to include the documentation in one place, explaining, for example, whether a customer was contacted about an order and what information was then provided or what further investigation was conducted. Purdue agrees to this recommendation.**

72. **A recommendation is made that on or before October 1, 2020 Purdue commence for a period of 90 days to begin reporting to the DEA all orders identified and flagged by the cloud-based IT system that is designed to identify and flag orders that are of unusual size, unusual frequency, and/or deviate from the normal pattern based on the 8**

matrices through which each order is compared. Orders flagged solely because the state of Ohio requires a second review would not be subject to this recommendation. Furthermore, it is recommended that between the filing of this report and October 1, 2020, Purdue work with the undersigned Monitor to identify any issues, barriers, and problems that might arise from the implementation of this recommendation and to work to resolve any such issue, barrier, or problem. Purdue agrees to this recommendation and states that it looks forward to working with the Monitor toward ensuring implementation of a rational reporting system that does not overburden the DEA, but meets the agency's practical needs.

73. The analysis of whether Purdue is in compliance with Part II, Section G of the Injunction also depends upon the "reasonableness" of its effort to monitor downstream customers through a quarterly review of chargeback data.

74. The effort to identify suspicious orders from direct customers uses a cloud-based IT system with an algorithm involving multiple screens done daily. While the downstream customer effort is based on a review of chargeback data by the reviewing employee who simply scans quickly quarterly data and selects somewhat arbitrarily a very small number of customers orders and accounts to review.

75. The limited nature of the downstream customer monitoring effort, in comparison to the cloud-based IT system in place for direct customer monitoring efforts, raises concerns about whether the downstream monitoring system is sufficient to ensure compliance with the Injunction as currently structured.

76. **The recommendation is for Purdue to re-evaluate the downstream customer monitoring and reporting system and to establish more robust mechanisms for review and**

reporting that ought to include: a monthly review instead of a quarterly review of chargeback data, an expanded use of the chargeback data to determine, for example, if orders flagged by the cloud-based IT system should be shipped, review of data to identify customers that consistently have a large volume of chargebacks meriting further investigation and the development of a more objective method for identifying chargeback units that merit further review. Purdue agrees to this recommendation.

77. **The recommendations above will likely require additional qualified and trained staff being added to the current team dedicated to monitoring and reporting functions. A strong recommendation would be to add sufficient staff so that the monitoring can be more robust, the review of customer provided questionnaires can be more thorough, the documentation of all decisions can be more thorough and complete. Purdue agrees to this recommendation.**

LOBBYING AND MEMBERSHIP

78. Under Part II, Section D Purdue agreed to certain restrictions on its lobbying activities at both the federal and state level. A review of lobbying reports for over 20 states and for the federal government involving Purdue and its lobbyists and consultants reinforced and supported the representation made in the certifications received from Purdue officials and their lobbyists and consultants that Purdue is in direct compliance with Part II, Section D of the Injunction.

79. Under Part II, Section C (5) of the Injunction no officer of Purdue may concurrently serve as a director of an entity that engages in the promotion of opioid products or opioids. There is no definition of entity in Part I of the Injunction. Purdue certified that it

queried all executives and represents that none serves as a director, board member, employee, agent or officer of any entities that engages in promotion relating to opioids or opioid products.

80. At the request of the undersigned Monitor Purdue furnished a list of memberships held by Purdue and its officers. However, Purdue also belongs to certain organizations that lobby federal and state officials on a variety of bills being considered in either the federal Congress or state legislative bodies. One such organization is the Association for Accessible Medicine (AAM). The mission of AAM is in part to advance policies and regulations that make accessibility to generic drugs easier for the consuming public. In that regard AAM educates elected officials and lobbies with and on behalf of its members at the federal and state government levels.

81. In 2020, AAM reached out to the Trump Administration by letter to encourage the Administration to oppose H.R. 938 and Section 205 of S 1895 also known as the "Blocking Act".

82. The "Blocking Act" is a proposal that would remove the current incentive in the law for generic drug makers to contest a brand name drug patent by which the initial and successful challenging generic is given some exclusivity in marketing before all other generics marketing the same product.

83. AAM on behalf of generic drug manufacturers opposed the "Blocking Act" for the reason that it would have chilling effect on challenges to brand name drug patents delaying doctors and their patients access to more affordable generic drugs which could include opioid products.

84. The letter sent to the Trump Administration included the names of the AAM board of directors which included an officer of Rhodes Pharmaceuticals L.P. suggesting support for the action outlined in the letter.

85. The use of a membership in an organization that lobbies combined with a board seat held by a Purdue officer that has a say in what gets lobbied blurs the line between lobbying that might be technically compliant with the Injunction if done by that officer of Purdue through a membership organization that Purdue belongs to and in which its officer is a board member but not compliant with the Injunction if with a Purdue official were to lobby directly on behalf of Purdue.

86. From time to time board members of AAM also decide and prioritize what bills AAM should lobby and what position the organization on behalf of its members should be taken through a "working group" of member companies of AAM. A "working group" agrees to undertake and to finance lobbying efforts directly and in conjunction with the staff of AAM.

87. Most recently one such "working group" of AAM members was organized to advocate and lobby against bills and issues surrounding the assessment of opioid taxes in a number states.

88. The range of issues that AAM may support directly or through "working groups" related to opioids and opioid products is extensive and creates an expanded opportunity for Purdue, through membership and a board position, to further blur the line on lobbying.

89. A similar concern arises with Purdue's membership in the Healthcare Distribution Alliance and membership fees paid by Purdue that supports a variety of positions on opioid product taxes and other key issues surrounding improper diversion of opioid products.

90. **A recommendation is for Purdue to ensure that any employee serving on the board of any organization, including the AAM, that engages in lobbying or educating state and federal officials on policies and regulations, the impact of which would be to more easily enable or promote the use of opioids or opioid products, recuse himself/herself from any board discussion or decisions relating to opioids, including any determinations the organization may make related to lobbying efforts with respect to opioids. Further, employees will refrain from participation in any working group of such organization that focus on the promotion of opioid or opioid products or which focus on issues that would otherwise not be permitted under the Voluntary Injunction. Purdue agrees to this recommendation.**

INITIAL COVERED SACKLER PERSONS

91. Under Part II, Section I of the Injunction the Initial Covered Sackler Pearson's were not to be actively engaged in the opioid business in the United States or interfere with compliance with the Injunction. Since the filing of the Initial Report one of the Initial Covered Sackler Persons, Jonathan D. Sackler, has died. Under Part II, Section I of the Injunction the Estate of Jonathan D. Sackler will be substituted for Jonathan D. Sackler as an Initial Covered Sackler Person.

92. The undersigned Monitor received signed certifications from all the named Initial Covered Sackler Persons or their representatives certifying that none of the named Initial Covered Sackler Persons actively engaged in the opioid business in the United States and that each one has taken no action to interfere with compliance of the provisions of the Injunction.

MISCELLANEOUS

93. An issue arose during the time following the filing of the Initial Monitor's Report involving contributions made by the company to a number of political organizations including associations representing the interest of governors, state attorney generals and state legislative leaders as well as organizations involved in policy formulation and advocacy. The Court and all interested parties reached an agreement that prohibits Purdue from making certain political contributions, limiting contributions that can made, and calling the total amount of such contributions in any given year.

94. **A recommendation is for Purdue to provide the undersigned on a quarterly basis all political contributions that fall within the agreement so that performance of the agreement can be monitored. Purdue agrees to this recommendation.**

Wherefore, the undersigned Monitor respectfully submits this Second Report with the recommendations contained therein.

Thomas J. Vilsack
Monitor