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)**

NINTH MONITOR REPORT

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

EXECUTIVE SUMMARY

This Ninth Monitor Report, and the undersigned's fifth since being appointed on February 18, 2021, will include an outline of actions taken over the last three months to determine compliance with the terms and conditions of the Voluntary Injunction ("Injunction"), discussion of the results of areas of further inquiry or recommendations from the last Report, additional recommendations provided to Purdue Pharma L.P. ("Purdue Pharma" or "the Company"), and the Company's response to those recommendations.

Based on what has been reviewed to date and subject to the recommendations contained herein, Purdue Pharma and the Initial Covered Sackler Persons appear to be making a good faith

[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.

effort to 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 Pharma employees.

INTRODUCTION – STEPS TAKEN SINCE EIGHTH REPORT

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

2. Since the filing of the Eighth 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.

EIGHTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

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

4. The recommendations and areas of inquiry included:

a. Reviewing the circumstances in which Opioid Products are being replaced, as well as the quantities of Opioid Products being replaced (Eighth Report, Paragraph 30);

b. Reporting any issues arising from the Law Department's quarterly review of the Customer Services call logs (Eighth Report, Paragraph 34);

c. Inviting the Monitor to observe at least one of the Injunction training sessions to gain a better understanding as to how the materials are received (Eighth Report, Paragraph 40);

d. Highlighting any changes to processes and policies arising from the Suspicious Order Monitoring ("SOM") team's review of the Customer Service call logs and trainings conducted by the SOM team to employees involved with Product Monitoring, Adverse Effects, Medical Information and Customer Service (Eighth Report, Paragraphs 45-46);

e. Reviewing revised SOPs involving matters impacted by the Injunction (Eighth Report, Paragraphs 58-59);

f. Requesting that the Company review the entirety of the SOPs and corporate policies relating to Opioids and incorporate the requirements of the Injunction where appropriate (Eighth Report, Paragraphs 63); and

g. Establishing policies and procedures for placing restrictions on certain downstream customers (Eighth Report, Paragraphs 58-59).

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

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

DISCUSSION AND ANALYSIS

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

A. Sales Team

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

8. In the Eighth Report, the undersigned reported that the Company intends to use select members of the Commercial department and a limited contractor presence to promote approved Public Health Initiative products to Health Care Providers. (Eighth Report, Paragraph 22.)

9. The Vice President of Ethics and Compliance informed the Monitor that the Company is working to set up its promotion efforts with one the contractors it retained when it had a sales team for Adhansia. As the Company is just now in the process of doing so, the Monitor will include a more robust description of the efforts, and safeguards to ensure compliance with the Injunction, in the next Report.

B. Customer Service Department

1. Refunds and Replacement of Opioid Products

10. As was explained in the Eighth Report, the Company instituted new policies guiding refund and replacement of Opioid Products, clarifying that it would no longer provide any refunds for prescription products, and requests for replacements must be made and are granted only through a pharmacy, not a patient or caregiver. Moreover, any requests for

replacements, when approved by the Company, would be effectuated by giving a credit through the distributor to the pharmacy. (Eighth Report, Paragraph 27-29).

11. Through calendar year 2022 to date, the Company has only granted one credit for replacement of an Opioid Product. The Company provided the Monitor the documentation concerning this credit.

12. In that instance, the patient had a prescription for Butrans. In opening the package and applying the first Butrans patch, the patient discovered that there were only two sealed pouches in the product box, rather than four as would be expected. The patient brought the package back to the pharmacy and the pharmacist opened the second pouch, finding only disposal cards and no Opioid Product. The pharmacist retained the pouch and product box and contacted the Company's Product Complaints Department.

13. Consistent with the Company's revised procedures, the Product Complaints Department transferred the call to the Medical Information Department. An employee within Medical Information worked with the pharmacist to collect the necessary information, including a statement describing what happened, the label showing the patient's name and medication information, and the pharmacy's distributor.

14. Medical Information approved the product credit, and it was then processed by the Customer Service Department.

15. The undersigned Monitor finds that the Company's interactions with the pharmacy and the credit for the replacement of the Butrans product were consistent with the Injunction and the Company's SOP guiding product complaints, replacements and interactions with pharmacies and patients. (See Seventh Report (11/22/21), Paragraphs 35 to 52.)

2. Review of Customer Service and Medical Information Inquires for Consistency with the Injunction and Suspicious Order Monitoring

16. The Seventh Report recommended that the Company agree to have an employee of the Law Department review the Customer Service call and email logs quarterly, along with the comments from the Director of Customer Service and the SOM team. (Seventh Report, Paragraph 89.)

17. The undersigned was informed by the Company that no concerns arose from that review, and the Law Department worked with the Directors of Customer Service and Ethics and Compliance to further define and standardize the process of reviewing the logs by adding a tracker and establishing a meeting schedule between the departments.

18. Also stemming from the log reviews and trainings provided by the SOM team, the Director of Ethics and Compliance reported that they are working with Customer Service, Corporate Security and Product Monitoring to draft and implement a Requirements Document.

19. The Requirements Document will include provisions for when a pharmacy should be reviewed by Corporate Security. In the past, the Company had established thresholds for the number of Opioid pills or patches that would trigger further review by Corporate Security. If one buprenorphine patch or five Opioid pills were reported missing, Corporate Security would conduct a review. Going forward, the Company will aggregate reports of losses/missing products by pharmacy, even if the loss is spread across multiple individual prescriptions.

20. The Requirements Document will also detail the process for identifying and tracking pharmacies that should be reported to the DEA and a state Board of Pharmacy for consistently reporting missing Opioid Products.

21. The Requirements Document will be completed in the upcoming weeks, and the Monitor will review and offer detail in the next Report, if any additional detail is warranted.

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

22. As was observed in the Eighth Report, the Company has updated its training materials regarding the Injunction. The Monitor provided input into the content of that training. (Eighth Report (02/22/22), Paragraphs 36-39.)

23. The training is being conducted by the Company's Vice President, Legal Strategy and Public Health Initiatives, and one of Purdue Pharma's outside counsel, a former Company employee who is very familiar with the Injunction and its terms.

24. To date, there have been 14 training sessions, presented to various departments and business units of the Company.

25. The Monitor observed one of the one-hour virtual training sessions. The training endeavors to use plain language to explain the Injunction and apply its terms to business practices and activities. The training invites ample opportunities for questions and feedback and includes some interactive involvement from those being trained.

26. The Monitor found the presentation of the training to be comprehensive and comprehendible, and done so in a way that is aspirational for working toward best practices, not punitive.

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II. CONTRACT AND PRICING REVIEW

A. Introduction and Overview

27. Prior Monitor reports outlined the elements of the pricing structure of Purdue Pharma's and Rhodes' products, as well as prior actions of the Company and the Monitor in assessing those efforts in light of the Injunction. (Fifth Report (5/20/21), Paragraphs 50-67, 71-73.)

28. To gain a better understanding of the contractual and pricing arrangements and their consistency with the terms of the Injunction, the undersigned Monitor recommended retaining consultants that could assist in undertaking a review, comparing among other things any differences in practices between scheduled and nonscheduled products and the pricing practices of scheduled drugs across the industry. (Fifth Report (5/20/21), Paragraph 74.) The undersigned requested Court approval to hire Pearl Management Consulting to undertake this review. (Sixth Report, Paragraphs 21-23.)

29. Pearl commenced its review and analysis in late August 2021, and the Monitor reported preliminary observations in November 2021. (Seventh Report, Paragraphs 107-122.)

30. Pearl delivered its draft review and analysis to the Monitor in early February 2022. In the intervening months, the Monitor and Pearl have been working closely with the Company to reach a shared understanding of the underlying data, and the recommendations and analysis contained therein.

31. As will be discussed in substantially greater detail below, the review and analysis largely concluded that the Company's pricing and contracting processes have remained consistent from the start of the review period in January 2018 through June 30, 2021. Pearl found those practices to be consistent with industry standards. Moreover, the Company did not

implement changes in these practices to circumvent or adjust to any limitations on the Company's operations as a result of the Injunction. Finally, the review found that the Company's pricing practices conform with the Injunction.

32. In addition to examining the pricing and contracting mechanisms, the review also analyzed the application and outcome of those mechanisms, in terms of both the overall Opioid Product market and the potential to influence distributors', downstream customers', and end users' distribution and use of the Company's Opioid Products. While there are suggested areas of further inquiry, nothing was discovered that suggests an inconsistency with the terms of the Injunction.

33. Pearl's analysis did provide the basis to recommend changes to some of the Company's contractual terms to further support the Company's ongoing efforts to comply with the Injunction.

34. While not directly related to contracting and pricing, the review also brought to light shortcomings in the data reviewed and analyzed for suspicious order monitoring and reporting. These shortcomings have existed since before the Injunction went into effect. An explanation of those shortcomings, as well as recommendations for improvement, are contained herein.

35. The following includes discussion of the Injunction and the framework for analysis; the scope and methodology of review; direct sales and trends; pricing mechanisms and impact on sales; pricing committees and contract terms; and suspicious order monitoring of downstream customers.

B. The Injunction and Framework for Analysis

36. Section II.A of the Injunction states, "The Company shall not Promote Opioids or Opioid Products," and defines "promote" as:

> [...]dissemination of information by the Company to a Third Party that is either likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses and/or strengths of Opioid Products. (Injunction, §I.O.)

37. The Injunction further provides that:

> The Company shall not offer or pay any remuneration directly or through a Third Party, to or from any person in return for the prescribing, sale, use or distribution of Opioid Product. For the avoidance of doubt, this shall not prohibit the provision of rebates and/or chargebacks. (Injunction, §II.B.)

38. Although the terms "remuneration," "person," "rebates" and "chargebacks" are not defined by the Injunction, it follows that while the Company is not allowed to promote nor pay for the prescribing, sale, use or distribution of Opioid Products, the Company is allowed to sell Opioid Products to meet marketplace demand for these products and is allowed to pay chargebacks and rebates in so doing.

39. Accordingly, even though chargebacks and rebates are expressly permitted by the Injunction, if the mechanisms used in those contracts are "likely or intended to influence prescribing practices of Health Care Providers in favor of prescribing greater amounts, quantities, doses and/or strengths of Opioid Products," the resulting chargebacks and/or rebates could be construed as inconsistent with the terms of the Injunction

40. Therefore, pricing mechanisms including payment of chargebacks and rebates should be considered in compliance with the Injunction if their use is to appropriately position the product in the competitive marketplace and meet the needs of the overall distribution model for pharmaceuticals. [2]

C. The Scope and Methodology of the Review

41. The Monitor requested that Pearl review the Company's pricing and sales activities from January 1, 2018, long before the Injunction went into effect, to June 30, 2021. The purpose of that timeframe included to ascertain whether the Company changed any of its pricing strategies and activities to adjust or conform to the Injunction. The value of doing so is twofold: First, even if the pricing practices were in effect since 2018 and consistent with industry standards, those practices need to be reviewed in light of the increased obligations placed upon the Company in entering into the Injunction. And second, if the Company had changed pricing practices following the Injunction, those changes deserved scrutiny to ensure that they were not made to address some of the limitations in operations placed on the Company by the Injunction.

42. Pearl reviewed Company pricing practices through analysis of pricing, governance structure, and channel-by-channel outcomes of pricing decisions. Pearl also met with individuals from the Company to gather additional information and context during the review.

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[2] It should be noted that the Company does not agree with the Monitor's conclusion that pricing and contracting practices should be reviewed under both the "promotion" provisions of II.A and the "remuneration" provisions of II.B. The Company believes that pricing and contracting are not implicated by the Injunction's ban on "promotion," as defined in I.O, and in fact are specifically carved out with respect to the market access provisions. Moreover, the Injunction specifically provides that chargebacks and rebates are permitted.

The undersigned believes the Company's construction would mean that rebates and chargebacks would be beyond any scrutiny, no matter the impact on Health Care Providers providing greater amounts, quantities, doses or strengths. Moreover, there are numerous types of payments provided to Third Parties such as inventory and service quality credits, prompt payment discounts, price protection payments and administrative fees. Unlike chargebacks and rebates, this remuneration is not expressly or implicitly excepted from the Injunction's reach, and as a result would presumably violate the remuneration provisions of II.B. E*xpressio unius est exclusio alterius*. Reviewing these various payments and discounts under the promotion provisions of the Injunction affords a construction that this type of remuneration does not violate the Injunction, notwithstanding II.B.

43. Overall, Pearl obtained more than 6,500 files from the Monitor and the Company for analysis, including:

a. Documents relating to pricing activities previously collected by the Monitor;

b. Purchase, rebate, and fee contracts;

c. General pricing terms;

d. Organization charts for Purdue and Rhodes teams involved in pricing, contracting, chargebacks and rebates;

e. Standard Operating Procedures ("SOPs") and Policy documents;

f. Purdue and Rhodes Pricing Committee materials;

g. Contract offer analyses;

h. Wholesale Acquisition Cost/List Prices;

i. Direct and indirect sales, credits, returns and adjustments and other transactions;

j. Product Transfer and Resale (EDI 867) reports;

k. Rebate-related information and supplemental documentation; and

l. Third-party data used in preparing contract offers and analyzing market dynamics.

44. Accordingly, Pearl reviewed all the Company's agreements relating to Opioid Product pricing for 2018 through 2021, totaling more than 142 files consisting of original agreements and amendments to the agreements.

45. To understand the impact of those agreements, Pearl reviewed transactional data covering that timeframe consisting of more than 40 million records across pricing, direct sales, indirect sales, rebates, third party market data, sales tracings, customers, and products.

46. The methodology of review then included:

a. **Contract Review:** analysis of contracts, exhibits and amendments for non-standard terms and conditions, as well as for terms, conditions or other language that may be called into question given the terms of the Injunction. Pearl reviewed pricing components including purchase price discounts, rebate rates, and conditions for concessions.

b. **Contract Modeling and Deal Analysis Review:** Pearl examined assumptions and calculations used in deal models and supporting data the Company used as inputs into the model to generate the contract analysis and presentation of proposed agreements to the relevant Pricing Committee.

c. **Supplemental Documentation Review:** Pearl reviewed organization charts, charters, policies and standard operating procedures, presentations, meeting minutes, work products, payment approval packages and other documents and responses to ad hoc questions provided by the Company relating to pricing activities requested by Pearl. Pearl analyzed the information to understand how the Company approaches contracting, resources required operational activities, structures reviews of pricing activities and overall maintains contract operations of the organization.

d. **Data Analysis:** Pearl analyzed and profiled the Company-provided data to discover, define, analyze, and understand meta data describing its structure, content, and organization. Pearl created and associated additional groupings and classifications of customers and contracts based on Pearl industry expertise, including assigning a “facility type” classification (e.g., Hospital, Pharmacy, Long

Term Care, etc.), to enable thorough examination of the data set. Pearl isolated product codes within the data and augmented them with data available from the U.S. Food and Drug Administration (FDA) and other sources in order to include the following measures in the analysis of the data set:

1. Package: the saleable unit of a product
2. Unit: the dispensable unit within the package
3. MME: Morphine Milligram Equivalents in a package/unit[3]

D. Purdue Pharma Direct Sales and Trends During Period of Review

47. "Direct Sales" are sales by a manufacturer to a distributor. Absent extremely limit circumstances like product donations for research purposes, all the Company's Opioid Products flow through the distributors, who subsequently resell the purchased products to downstream customers.

48. Purdue Pharma has agreements with 15 distributor/customers for their branded products, and Rhodes has 59 agreements.

49. Excluding Avrio Health products,[4] direct sales of Company products totaled $5.95 billion from 2018 through June 30, 2021. Opioids comprised more than 99% of total sales for the Company. Extended-release oxycodone (OxyContin) accounts for 72.5% of sales, followed by extended-release morphine (6.6%), buprenorphine (6.4%), oxycodone & acetaminophen (5.3%), hydrocodone ER (4.9%), immediate release oxycodone (2.2%) and all other products (2.1%).

[3] https://www.hhs.gov/guidance/document/opioid-oral-morphine-milligram-equivalent-mme-conversion-factors-0. MME is the milligrams of morphine an Opioid dose is equal to when prescribed, accounting for differences in Opioid drug type and strength

[4] Avrio Health is a company owned by Purdue Pharma, manufacturing and distributing over the counter products including Betadine, Colace, Senokot, and SlowMag Mg. If the Avrio sales information as included in this analysis, Opioids would comprise 92% of the Company's sales, rather than 99%.

Figure 1. Share of Company Direct Sales Jan 1, 2018 – June 30, 2021

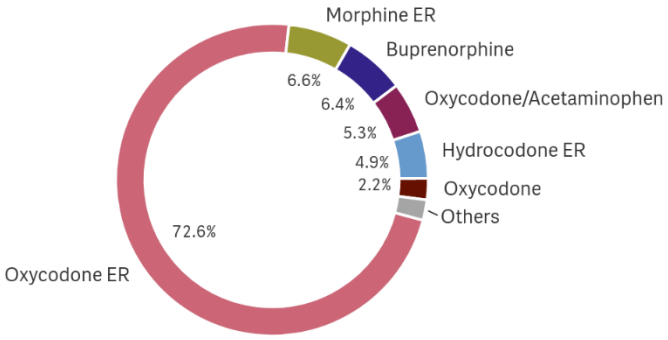


Table 1. Company Direct Sales Jan 1, 2018 – June 30, 2021 (Excluding Avrio Health)

Active Ingredient	Direct Sales ($M)	Percent of Total
Oxycodone ER	4,320.0	72.6%
Morphine ER	392.2	6.6%
Buprenorphine	378.7	6.4%
Oxycodone/Acetaminophen	314.7	5.3%
Hydrocodone ER	290.6	4.9%
Oxycodone	131.7	2.2%
All other products	125.0	2.1%

50. In February 2018, Purdue stopped promoting Opioids through sales representatives visiting physician offices to discuss its Opioid Products.[5] The following quarter showed a 24% drop in sales for OxyContin, the largest quarter-to-quarter drop in sales of OxyContin for the period reviewed. This drop was larger in magnitude than the typical seasonal decline in sales following the first quarter of the year observed in the direct sales data.[6] Following the initial decline, the direct sales trend stabilized, and decline slowed.

[5] "OxyContin maker stops promoting opioids, cuts sales staff," *Reuters*, February 10, 2018, https://www.reuters.com/article/us-usa-opioids-purduepharma-idUSKBN1FU0YL

[6] For OxyContin, the first quarter of 2019 and 2020 had an increase in sales followed by a larger than average decline in the subsequent quarter, though this seasonal pattern did not continue into 2021.

51. Sales for extended-release hydrocodone (Hysingla ER) declined in a similar manner with a 20% decline from 2018 Q1 to 2018 Q2, followed by a stable downward trend.

52. Transdermal buprenorphine (Butrans) showed a 19% decline from 2018 Q2 to 2018 Q3. The sharpest decline in sales of Butrans during the review period was 54% between 2018 Q4 and 2019 Q1, likely due to the introduction of a generic alternative.

53. While quarterly sales trends speak to a challenging business climate and Purdue Pharma's reliance on the OxyContin franchise, the Injunction is specifically focused on limiting activities that increase demand -- greater amounts, quantities, doses and/or strengths -- for Opioids. Therefore, to analyze Company compliance with the Injunction, Pearl focused on analyzing direct sales by Morphine Milligram Equivalents ("MME"). Using MME as the basis for measurement allows direct comparison of sales across different Opioid Products.

54. Though most attention has been on extended-release oxycodone (OxyContin), oxycodone/acetaminophen was an equal contributor of MME sold by the Company during the study period. The two products together account for 53% of total MME sold. Extended-release morphine (24%), immediate release oxycodone (15%) and all other Opioids (8%) make up the remaining MME sold.

Figure 2. Share of Company Direct MME Sold Jan 1, 2018 – June 30, 2021

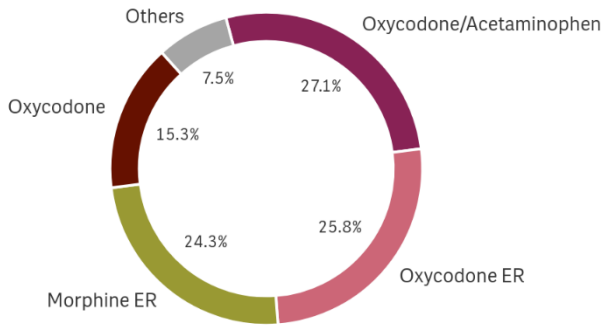


Table 2. Company Direct MME Sold Jan 1, 2018 – June 30, 2021

Active Ingredient	Direct Sales (Millions of MME)	Percent of Total
Oxycodone/Acetaminophen	23,402.4	27.1%
Oxycodone ER	22,298.6	25.8%
Morphine ER	20,928.6	24.3%
Oxycodone	13,175.7	15.3%
Hydromorphone	3,872.6	4.5%
Hydrocodone/Acetaminophen	1,508.8	1.7%
Hydrocodone ER	642.7	0.7%
Buprenorphine	452.9	0.5%

a. The oxycodone/acetaminophen market consists of many different participants, both generic and branded. While oxycodone/acetaminophen is most often prescribed for short durations, like other immediate release ("IR") Opioids, Health Care Providers ("HCPs") also prescribe it to treat patients chronically when the prescriber feels IR Opioids are more appropriate for the patient. Extended-release ("ER") Opioids are often prescribed for longer term use. The amount and range of mg/tablet for oxycodone/acetaminophen are lower (5mg to 10mg) than both immediate release oxycodone (5mg to 30mg) and extended-release oxycodone (10mg to 80mg).

55. Company quarterly sales by MME declined from 7.95 billion MME in the first quarter of 2018 to 4.87 billion MME in the second quarter of 2021, a 39% decline overall. This decline in quarterly MME sold is not reflected uniformly across Opioid presentations, though all but two presentations declined.

56. Compared to first quarter 2018, quarterly sales by MME in second quarter 2021:[7]

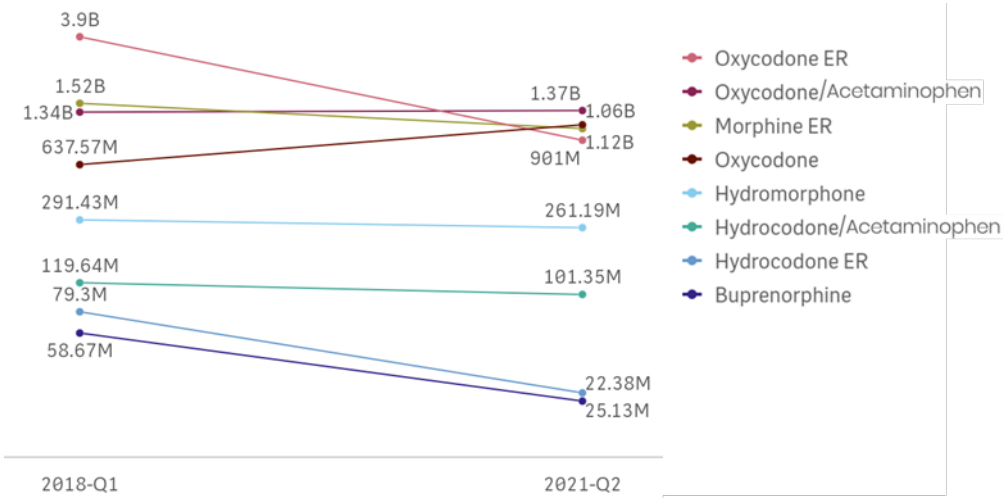
a. Extended-release oxycodone (OxyContin), extended-release hydrocodone (Hysingla ER), and buprenorphine transdermal (Butrans) declined significantly by 77%, 68%, and 62%, respectively;

b. Extended-release morphine (MS Contin and generic together) and hydrocodone/acetaminophen declined by 30% and 15%, respectively;

c. Hydromorphone (Dilaudid and generic together) declined by 10%; and

d. Oxycodone/acetaminophen and immediate release oxycodone grew by 2.3% and 76%, respectively.

Figure 3. Change in Quarterly Sales by MME, 2018 Q1 to 2018 Q2



[7] January 2018 to June 30, 2021 encompasses the entire period of Pearl's review. To the extent there are concerns about comparing separate quarters of the respective years due to seasonality in distributor purchasing, a comparison of the first quarters of 2018 and 2021 demonstrate: OxyContin: -74%; Hysingla ER: -64%; Butrans: -64%; Morphine: -23%; Hydrocodone/APAP: -26%; Hydromorphone: -23%; Oxycodone/APAP: +25%; and IR Oxycodone: +67%.

Table 3. Quarterly Sales for 2018 Q1 and 2018 Q2

Active Ingredient	2018 Q1 Direct Sales (Millions of MME)	2018 Q2 Direct Sales (Millions of MME)	Percent Change
Oxycodone ER	3,901.3	901.0	-77%
Hydrocodone ER	79.3	25.1	-68%
Buprenorphine	58.7	22.4	-62%
Morphine ER	1,520.5	1,062.4	-30%
Hydrocodone/Acetaminophen	119.6	101.4	-15%
Hydromorphone	291.4	261.2	-10%
Oxycodone/Acetaminophen	1,342.0	1,372.4	2%
Oxycodone	637.6	1,121.2	76%

57. For Opioids with large declines, period-to-period changes within the timeframe reviewed shows the most significant decline occurred in 2018, though for Butrans the decline continued for a longer period, reflecting the entry of generic and other competition. In all cases, the rate of decline has flattened.

58. For oxycodone/acetaminophen, sales by MME grew by 56% from the second to the third quarter of 2018. Sales by MME remained steady until the second quarter of 2021 when they declined by 18% to a level similar to that of the first two quarters of 2018.

59. Third party data for total prescriptions provides additional insights. For the overall market from 2018 to mid-2021:

a. Immediate Release Opioids are 90% of the overall market prescriptions for Opioid Products;

b. Overall, Opioid prescriptions declined, and the market continued to contract;

c. As the dominant extended-release oxycodone product in the market, the oxycodone market trend largely tracks with the decline in OxyContin;

d. Purdue immediate-release oxycodone and buprenorphine gained share; and

e. Purdue lost market share across all extended-release product classes.

E. Pricing Mechanisms, Impact on Sales, and Recommendations

60. There are various agreements in the pharmaceutical industry that establish what the manufacturer ultimately receives for distribution of its product. This includes the Wholesale Acquisition Cost set by the manufacturer, negotiated purchase contracts that result in discounts to downstream customers reflected in distributor chargebacks, negotiated rebate contracts that results in payments to intermediaries such as Pharmacy Benefit Managers ("PBMs") for use of product by insured patients, and government pricing calculations that establish statutory product pricing and rebates. Each will be discussed in turn.

1. Wholesale Acquisition Cost

61. Wholesale Acquisition Cost ("WAC") serves as the basis for most pricing, and the structure of WAC price list is fundamental to market reception of a product. Pearl analyzed WAC pricing for the Company products to: (a) quantify period-to-period price increases or decreases; and (b) compare prices within product families to quantify differences in pricing across product strengths or presentations.

62. WAC for Company branded products increased over the period, typically on an annual basis, while WAC for Company generic products stayed the same or decreased. There is no standard across all products in the marketplace to compare with, but Pearl found that Purdue Pharma's WAC dynamics are consistent with general WAC dynamics in the market where branded products' WAC increase over time while generic products' WAC are stable or decrease over time.[8]

[8] See for example, "The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025." IQVIA Institute for Human Data Science, May 2021. (https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us)

63. Analysis of WAC within product families across strengths (e.g., WAC/mg oxycodone for 10mg OxyContin vs 80mg OxyContin) shows two distinct approaches.

a. Constant package WAC price regardless of strength: Used for branded ADHD products, this approach to WAC keeps cost of treatment constant regardless of product strength required to treat. As noted in the FDA label, long term use of amphetamines can lead to tolerance and result in the need for an increased strength to achieve the desired effect. Because cost for treatment does not change by strength, this approach does not directly lead to increasing cost to treat over time. If WAC increases over time, cost to treat will increase but increases will not differ by product strength.

b. Increasing package WAC with increasing strength: Used for all branded Opioids, this approach increases cost to treat as the strength required to treat increases. As noted in the FDA label, long term use of Opioids can lead to tolerance and results in the need for an increased strength to achieve the desired effect. Because cost for treatment increases by strength, this approach tends to increase cost to treat over time. If WAC increases over time, increases in cost to treat from increasing strength are compounded.

64. WAC increasing as strength increases results in a downward demand pressure acting against increasing product strength for treatment.[9] However, this impact can be tempered or amplified depending on the proportion of the increase in WAC to the increase in product

[9] To the patient, WAC pricing has a reduced impact on demand pressures because the end user typically does not pay the WAC price. However, to the extent patients increasingly pay co-insurance instead of a fixed co-pay, WAC pricing impacts the patient more. Moreover, this is dependent on patients being sensitive to price, i.e., that the product has an elastic demand curve. The more inelastic the curve (e.g., one must take the product, there is no other alternative product, one is addicted to the product), the less price sensitive the patient. To the PBM, if it is more expensive for a patient to increase strength, the PBM might be more focused on finding ways to control that cost by reducing demand.

strength.[10] If WAC increases at a faster rate than product strength, the downward demand pressure is increased. Alternatively, if WAC increases at a slower rate than the increase in active ingredient, the downward pricing pressure is lessened.

65. In the case of OxyContin, the cost per milligram of oxycodone decreases as the amount of oxycodone increases. For example, WAC for a single OxyContin 80 mg tablet is more than 30% less than the WAC of eight OxyContin 10 mg tablets, and this difference did not change over the project period.

66. Discussions with Purdue Pharma contract operations revealed that prior to 2018, the differences between cost per milligram for product strengths changed, but decreasing cost per milligram has always been the WAC price structure in place for OxyContin.

67. In the Seventh Report, the Monitor highlighted this decrease in cost per milligram but reserved making any recommendations until Pearl had completed its review. (Seventh Report, Paragraphs 118-120.)

a. Pearl modeled the impact of increasing WAC for higher strengths to equalize per mg cost across package strengths to 10 mg level ($0.4437/mg).
b. Approximately 10% of prescriptions for extended-release Opioids and 13% of prescriptions for immediate-release Opioids go through cash and non-benefit channels. Accordingly, for this section of the market it is at least conceivable that an increase in price would decrease the utilization of the higher milligram tablets.
c. However, price increases to customers covered by managed care contracts would be offset in large part by increases in rebates, due to price protection language in contracts for nearly all managed care entities.

[10] If WAC increase is exactly proportional to increase in product strength, there is no modulation of the impact.

d. Moreover, increasing WAC increases the Average Manufacturer Price ("AMP"), further driving down 340B price due to increasing the Inflation Penalty as a result of widening the spread between Baseline AMP indexed for inflation and current AMP.[11]

e. In most cases, 340B price is already at "penny pricing" (i.e., the Company receives $0.01 for each dispensable unit sold to eligible entities) and increasing AMP will only ensure it stays there. 340B penny pricing could be a potential driver of increased Opioid sales.

f. Accordingly, when considering all the channels, standardizing WAC per mg across package strengths by increasing WAC price for higher strengths could lead to greater use of higher dosage Opioid Products, not less.

68. Therefore, the Monitor does not recommend any changes to the methodology the Company uses in setting WAC price. Pearl found the Company's practices consistent with industry practices, and not intended to or resulting in prescribing greater amounts, quantities, doses and/or strengths of Opioid Products.

2. <u>Chargebacks and Indirect Sales Trends</u>

69. "Indirect Sales" are sales by a distributor on behalf of a manufacturer to a customer that has a contract with the Company setting the price for the product. These contracts are between the Company and Group Purchasing Organizations ("GPOs").

[11] The AMP is the average price paid to the manufacture for a drug covered by Medicaid, as set forth in 42 C.F.R. 447.50. A more detailed discussion of AMP, the Inflation Penalty, Baseline AMP and 340B pricing can be found in the discussion of government pricing at pages 33-36, *infra.*

70. During the review period, Purdue Pharma had contracts with nine different hospital/alternate care GPOs and one staff model HMO that included branded Opioid Products, and Rhodes contracted with 14 different distributor GPOs for generic Opioid Products.

71. The Indirect Sales customer does not interact directly with the Company as part of the sale, and the Company is only aware of the indirect sale upon submission of a claim by a distributor for the difference in price between the distributor's acquisition cost, or WAC, and the amount charged to the Indirect Sale customer, which is the contract price between the Company and the GPO.

72. This submission is commonly referred to as a "chargeback" transaction, and represents a payment made by the Company to make up the difference between the WAC price and the contract price. Rather than the Company making a payment to cover the difference, the distributor is credited that amount on their account.

73. As is typical across the industry, the Company's indirect sales packages and MME for generic Opioid Products are 90% or more of the Company's direct sales packages or MME for each respective generic Opioid Product in all the quarters that Pearl reviewed. This means nearly all generic sales of Opioid Products are ultimately made at a price lower than the WAC price at which a product is sold to wholesalers/distributors for resale.

74. Indirect sales for the Company's generic Opioid Products are to both retail pharmacies and institutional/inpatient facilities, resulting in the Company having good visibility to downstream customers for generic Opioid Products through chargeback data.

75. For the Company's branded Opioid Products, indirect sales packages account for 19% or less of direct sales packages by product overall.

Table 4. Opioid Product Indirect Sales as Percentage of Direct Sales

Brand	Percent of Direct Sales Packages	Percent of Direct Sales MME
Hysingla ER	3%	3%
OxyContin	19%	7%
Butrans	19%	18%
Oxycodone (Generic)	89%	90%
Morphine ER (Generic & Branded)	93%	92%
Hydrocodone/Acetaminophen (Generic)	93%	91%
Hydromorphone (Generic)	97%	96%
Oxycodone/Acetaminophen (Generic)	99%	99%

76. Otherwise stated, there are chargebacks and attendant downstream customer visibility for less than one-fifth of the packages or MME of branded Opioid Products sold.

a. OxyContin represents 26% of the total direct MME sold by the Company. For OxyContin, the Company has visibility to the end customer via chargebacks for less than one in five packages or one in 14 MME sold.

b. Company branded products indirect sales are made to institutional/inpatient facilities or alternate care sites, and not to retail pharmacies.[12] Therefore, the Company has limited or no visibility through chargebacks to most retail pharmacy sales for branded Opioid Products.

77. For the Company's branded Opioid Products, MME sold at a negotiated price to an entity other than a distributor (non-retail, typically inpatient sales) declined from early 2018 to the present. Despite this decline, the portion of the Company's direct sales resold at a negotiated contract price increased.

[12] The one exception is a portion of 340B purchases that are to retail pharmacies acting as "contract pharmacies" for 340B entities entitled to the 340B statutory discount.

78. The sales data suggests a faster decline in retail (pharmacy/outpatient) use of Company products than in institutional settings. While it is likely that the decrease in retail sales is attributable at least in part to the Company's decision to no longer promote Opioid Products, this is also a continuation of broader market trends identified by, among others, the FDA in 2018.[13]

79. To review the relationship between price and quantity and to compare across product lines, the sales price was converted to price per MME of the product. To account for differences in how long a price was available, calculations were performed to calculate "MME/day" (total MME of a product purchased at a price divided by the number of days the price was available). Plotting the relationship between price and quantity sold shows low correlation until price approaches zero (i.e., 340B Penny Pricing), at which point the quantity sold increases. Otherwise stated, decreases in contracted price per MME do not appear to lead to increases of contracted sales of the Opioid Product.

80. Based on Pearl's review of the negotiated chargebacks and indirect sales, the following conclusions can be drawn:

a. Across the industry, branded product contracting dynamics vary by therapeutic area and product. Pearl found that the Company's branded product contracting dynamics are not out of the ordinary based on Pearl's exposure to brand contracting.

b. In those instances where the Company agreed to provide branded Opioid Products at a negotiated price that was below the WAC, Pearl did not find any meaningful

[13] *See* FDA Analysis of Long-Term Trends in Prescription Opioid Analgesic Products: Quantity, Sales, and Price Trends, FDA White Paper, March 1, 2018 https://www.fda.gov/files/about%20fda/published/FDA-Analysis-of-Long-Term-Trends-in-Prescription-Opioid-Analgesic-Products--Quantity--Sales--and-Price-Trends.pdf

correlation between the negotiated price and increased or decreased use of its branded Opioid Products, and thereby nothing to suggest that these pricing strategies are inconsistent with the terms of the Injunction.

c. For the Rhodes generic products, Pearl found that the Company's product contracting dynamics for both pharmacies and inpatient setting are not out of the ordinary based on Pearl's exposure to generic pricing practices.

81. Accordingly, the Monitor does not recommend any changes.

3. Managed Care and Pharmacy Benefit Manager Rebates

82. Another mechanism by which the Company can provide lower or discounted prices is by paying rebates directly to a PBM or Managed Care Organization ("MCO") when Purdue Pharma products are used by the customers of the PBM or MCO.

83. There are 15 active or pending agreements with PBMs and MCOs across the commercial and Medicare Part D channels.

84. During the period analyzed, Purdue Pharma contracted with PBMs for all branded Opioid Products. Almost all rebates paid were for Opioid Products and over 80% of Opioid rebates were for OxyContin.

85. Total rebate payments have significantly declined, from approximately $134 million for the first quarter of 2018 to approximately $55 million for the second quarter of 2021.

86. For every quarter analyzed, more than 67% of rebates are paid to Medicare Part D payors, although Part D rebates declined significantly in 2021.

87. The Company rebate contracts are intended to provide patients in the PBM access to Purdue Pharma's products through placement on the PBM formulary. Formulary positions and terminology can be highly technical and include many conditions, but generally products can be

positioned as "Exclusive" or "Parity" (sometimes referred to as "1 of X"). If a product is Exclusive, it is the only presentation of that product type that can be purchased by the consumer under the PBM at a particular co-pay level. Parity allows the consumer to choose between the Company's product and at least one other branded product manufactured by a different company.

88. PBMs often employ additional levels of management and cost containment, including labeling a particular set of products as "Preferred" with a lower co-pay than "Non-Preferred" products. The benefit of being in a Preferred status level in a formulary is that the co-pay paid by the consumer is less than it would be if the drug were in a Non-Preferred status.

89. Products may also be designated by PBMs as Not on Formulary, or "Excluded," where the product is not covered by the PBM.

90. Health Plans for whom the PBM is managing the prescription benefit may or may not always follow the main formulary of the PBM, and a PBM may have multiple formulary options.

91. There were several changes in formulary position of the Company's products with PBMs from 2018 to 2021. Those changes provide natural experiments to review the impact of formulary position on utilization of Opioids.

92. The following four formulary changes occurred with four different PBMs during the period of time that Pearl reviewed:

(1) <u>Commercial PBM 1: OxyContin "Preferred" to "Excluded" (January 2020)</u>[14]

93. Extended-release Opioid prescriptions had been declining for Commercial PBM 1 since before 2018. In January 2020, OxyContin was moved from Preferred to Excluded from most commercial formularies, with a branded competitor extended-release oxycodone product placed in the Preferred position. Although this was also the beginning of the COVID-19

[14] So as not to include confidential or business-sensitive information, the Monitor agreed to the Company's request not to disclose the names of the PBMs, and instead have given each an anonymized descriptive name.

pandemic, extended-release Opioid prescription trends stayed stable. The market for immediate release Opioids experienced large disruptions due to COVID-19.

94. As would be expected following this type of formulary change, OxyContin prescriptions and market share declined significantly. The competitor product would be expected to increase prescriptions and market share in a roughly inverse relationship to the decline in OxyContin. However, the decline in OxyContin prescriptions was not completely offset by increases in competitor product prescriptions for any extended-release Opioid.[15]

95. The market share for the competitor product still had not exceeded that for OxyContin as of the third quarter of 2021. A detailed look at plans under the PBM show some remained with OxyContin on formulary, while others did not. For those that kept OxyContin on formulary, prescription trends were stable. For those that did not, total extended-release Opioid Product prescriptions declined due to OxyContin losing a significant number of prescriptions that were not picked up by competitor products.

96. Accordingly, the change in formulary appears to have had an impact on both Purdue Pharma and total extended-release Opioid prescriptions for this commercial PBM customer.

(2) Part D PBM 2: OxyContin "Exclusive" to "Excluded" (January 2021)

97. Extended-release oxycodone prescription trends had been consistent, though declining, for Part D PBM 2 since before 2018, with OxyContin prescriptions falling steadily in favor of a branded competitor product. In January 2021, the branded competitor extended-release oxycodone product took over Exclusive status from OxyContin, which was moved to Excluded status.

[15] As the volume of immediate release Opioid prescriptions is nine times that of extended-release Opioids, it is difficult to either identify or definitively rule out OxyContin prescriptions switching to immediate release Opioids.

98. As would be expected, the competitor product took market share when the change was made, and there was a transitory decline in total Opioid prescriptions. However, by the second quarter of 2021 the competitor product had effectively swapped market share with OxyContin.

99. At a plan level, the largest plan under Part D PBM 2 had the largest impact. For the next two largest plans, prior formulary changes in 2018 had already shifted share to the branded competitor oxycodone product, which continued to grow market share and prescriptions since that time.

100. Accordingly, while the change in formulary appears to have had an impact on Purdue Pharma, there was no appreciable impact on total extended-release Opioid prescriptions for this Part D PBM customer.

(3) Commercial PBM 3: OxyContin "Exclusive" to "Parity" (July 2020)

101. Led primarily by a decline in OxyContin prescriptions, extended-release Opioid prescriptions had been declining steadily for Commercial PBM 3 since 2018. In July 2020, OxyContin was moved from Exclusive to Parity status with a branded competitor extended-release oxycodone product. Following the change, the decline in extended-release oxycodone prescriptions continued with no significant inflection, as did the individual trends for each product within the market.

102. Accordingly, the change in formulary from Exclusive to Parity did not appear to have had an impact on either Purdue Pharma or total extended-release oxycodone prescriptions for this commercial PBM customer.

(4) Part D PBM 4: OxyContin "Preferred" to "Non-preferred" (January 2021)

103. Led by OxyContin, extended-release oxycodone prescription trends had been declining consistently for Part D PBM 4 since before 2018. In January 2021, OxyContin status shifted from "Preferred Exclusive" to "Non-Preferred Exclusive" which resulted in a significant increase in patient cost for OxyContin.[16]

104. Following the change in formulary, utilization of OxyContin broke trend and dropped sharply in the first quarter of 2021. The change in patient cost had a significant downward impact on demand for OxyContin, which is a classical response to an increase in price.

105. At the same time, demand for the branded competitor oxycodone product increased, though there was a temporary reduction in the number of extended-release oxycodone prescriptions. As of the end of the third quarter 2021, the two products had nearly the same number of prescriptions.

106. Accordingly, while the change in formulary appears to have had an impact on Purdue Pharma, there was no appreciable impact on total extended-release Opioid prescriptions for this Part D PBM customer.

4. Recommendations on Formulary Positioning

107. The Opioid market is contracting as manufacturers, distributors, prescribers, and the public change behaviors. That is not to suggest there is no legitimate need for Opioid Products, including those sold by the Company. While the Company no longer actively promotes Opioid Products, it does seek to fill the legitimate market need for the Company's Opioid Products.

108. Access to medication is facilitated in large part by PBMs and MCOs and the formulary actions they and their member plans take. Pearl's analysis suggests these formulary

[16] For Low Income Subsidy ("LIS") patients (approximately 65% of covered lives), the co-pay increased $5; for non-LIS patients, co-pay increased by at $140 plus 38% coinsurance.

decisions can impact both individual manufacturers and the overall market. When OxyContin is in an Exclusive position and subsequently placed in Excluded position, it appears that not only does the Company's market share change as would be expected, but there is also break in trend for extended-release oxycodone prescriptions, followed by a continued trend downward.

109. While such a finding -- having OxyContin in exclusive formulary position keeps demand for extended-release oxycodone higher than it would be with OxyContin in Excluded position -- seems to implicate the Injunction's prohibition on activities likely to increase the "amounts, quantities, doses and/or strengths of Opioid Products," these impacts appear to be transitory as the competitor extended-release oxycodone product, now in Exclusive position, eventually picks up, and often, exceeds the lost prescriptions as the trend stabilizes.

110. Therefore, the undersigned Monitor does not recommend any changes to the Company practices in managed care contracting. Pearl found the Company's practices not fundamentally changed since the Injunction was put in place, the Company managed care contracts are consistent with industry practices, and do not in practice result in prescribing greater amounts, quantities, doses and/or strengths of Opioid Products.

111. **Continued analysis by the Company over time will likely indicate further evolution of the market for Opioids, including a likely steady state where Opioid prescriptions are no longer falling. At that time, the undersigned recommends that the Company again evaluate contracting for Exclusive formulary position.** To remain consistent with the Injunction, the Company should show that while Exclusive formulary position of its Opioid Products might increase the Company's market share, it does not increase overall demand as reflected in prescriptions and MME of the relevant Opioid market.

112. The Monitor notes that competitors might see or be actively pursuing a perceived opportunity to gain Exclusive position and aggressively promote their own Opioid Products, as not every manufacturer of Opioids is presently operating under similar promotion restrictions as is Purdue Pharma. However, ongoing and recently resolved actions against various other parties involved in the manufacture and sale of Opioids,[17] as well as what, from the Monitor's perspective, ought to be continued pressure on all manufacturers of Opioid Products to limit aggressive promotion, should lessen the appeal of such a perceived advantage.

5. Government Pricing

113. The term "Government Pricing" is used to refer to the statutory requirements for the Medicaid Drug Rebate Program, the 340B Program and the Veteran's Administration ("VA") Federal Supply Schedule. Requirements include calculation of average prices based on transactional data, determining lowest offered and achieved prices, and rebate rates or contracted prices based on these prices. All calculations must be performed in compliance with extensive statutory and regulatory requirements and guidelines. Key terms for these programs are presented in brief below.

[17] See, e.g., https://www.law360.com/texas/articles/1466380/key-opioid-cases-to-watch-as-massive-wave-of-trials-looms; https://www.mass.gov/news/drug-company-ends-face-to-face-marketing-for-its-opioid-product-to-massachusetts-doctors-in-ag-settlement; https://ag.ny.gov/press-release/2021/attorney-general-james-victorious-new-yorks-opioid-trial; https://www.mallinckrodt.com/about/news-and-media/news-detail/?id=26966; https://nationalopioidsettlement.com/wp-content/uploads/2022/04/Janssen-agreement-03302022-FINAL2.pdf; https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kapoor.html; https://www.nasdaq.com/articles/amerisourcebergen-cardinal-health-and-mckesson-agree-to-settle-opioid-lawsuits; https://news.bloomberglaw.com/health-law-and-business/ex-pharma-ceo-found-guilty-of-aiding-opioid-sales-to-addicts.

a. **Medicaid Drug Rebate Program (MDRP):** Federal program requiring manufacturers to enter into a national rebate agreement with the Department of Health and Human Services to receive federal funding for covered drugs dispensed to eligible patients.[18]

b. **Average Manufacturer Price (AMP):** Under the MDRP, AMP is a required monthly and quarterly calculation of average price paid to the manufacturer for a covered drug in the United States by certain types of customers, as outlined in regulations.[19]

c. **Baseline AMP:** The AMP designated as the index price in determining the "Inflation Penalty" portion of the Medicaid per unit rebate amount (see URA, below).[20]

d. **Best Price:** Under the MDRP, Best Price is the lowest price to most types of customers, as outlined in the Medicaid Drug Rebate Program statute and regulations.[21]

e. **Unit Rebate Amount (URA):** Under the MDRP, URA is the rebate amount per unit to be paid by a manufacturer for units invoiced by a State Medicaid agency. The URA consists of (i) a "base rebate" calculated as the greater of (a) the difference between AMP and BP and (b) AMP multiplied by a statutory discount percentage, and (ii) an "inflation penalty" calculated as the difference between AMP and Baseline AMP indexed for inflation.[22]

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18 See Pub. L. No. 101-508, 104 Stat. 1388 (1990) for details.
19 See 42 C.F.R. § 447.504 for details.
20 See 42 U.S.C. 1396r-8(c)(2)(B) and Manufacturer Release #97 (April 15, 2016) for details, but generally, the index period is the first full quarter following market introduction for branded products and the fifth quarter following market introduction for generic products.
21 See 42 U.S.C. 1396r-8 (c)(1)(C); 42 C.F.R. § 447.505 for details.
22 See 42 C.F.R. § 447.509(a)(1)(ii)(B)(3) for details.

f. **340B Program:** Established under section 340B of the Public Health Service Act, the program requires pharmaceutical manufacturers as a condition of participating in the MDRP to sell outpatient drugs to specific health care organizations (as determined eligible for the program by the Health Resources and Services Administration ("HRSA")) that care for uninsured and low-income patients at a discounted price reflecting the MDRP rebate.[23] While there is no restriction on the way in which savings from the program are spent, covered entities are expected to use savings to provide free care for uninsured patients, offer free vaccines, and other services. The 340B program purchase price is determined by subtracting URA from AMP.

g. **340B Penny Pricing:** Occurs when URA exceeds AMP, in which case the 340B program purchase price is set to $0.01 per dispensable unit of product (e.g., a bottle of 100 units would have a price of $1.00).[24]

h. **VA Federal Supply Schedule (FSS):** The FSS consists of multiple award contracts for medical equipment, supplies, pharmaceuticals, and services. Under the Veterans Healthcare Act of 1992, pharmaceutical products are listed in schedule 65 I B at a price not to exceed basis. Annually, pricing is updated through calculation and submission of non-Federal Average Manufacturer's Price (non-FAMP) and Federal Ceiling Price (FCP).[25]

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[23] These organizations include community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations. See 42 U.S.C. § 256b(a)(4) for details.

[24] Under the Patient Protection and Affordable Care Act (ACA) § 2501(e), Pub. L. No. 111-148, 124 Stat. 119, 309 (2010), URA was capped at 100% of AMP. However, the American Rescue Plan Act of 2021 (the Rescue Plan) eliminates the cap as of 2024. [S. Amend. 891, 117th Cong. § 9816 (2021) (amending American Rescue Plan Act of 2021, HR 1319, 117th Cong. § 3106 (2021))]

[25] 38 U.S. Code § 8126

i. **Non-Federal Average Manufacturer's Price (non-FAMP):** Under the FSS, non-FAMP is the weighted average price of a drug paid by wholesalers, net of cash discounts and other similar price reductions, for sales not including the federal government.[26] Non-FAMP is calculated quarterly and annually to be used in the calculation of Federal Ceiling Price (FCP).

j. **Federal Ceiling Price (FCP):** Under the FSS, FCP is the lower of (i) the current FSS price indexed for inflation or (ii) 76% of annual non-FAMP less an annual inflation penalty if the third quarter non-FAMP for the current year exceeds the third quarter non-FAMP for the prior year, indexed for inflation.[27]

114. Medicaid Rebates, 340B sales and FSS sales reflect upstream pricing activity inputs to the statutorily defined rates and prices in accordance with the Company policies put in place to interpret them. In reviewing, Pearl found that the Company policies and procedures for Government Pricing are clear and in line with relevant statutory and regulatory requirements.

115. Government Pricing rates and prices can be broadly affected, and indeed steered, by pricing decisions regarding WAC and prices offered to eligible entities, but exact and direct manipulation of rates and prices is nearly impossible. Analysis of contracting agreements by Pearl found no evidence that the Company's pricing activities were used to manipulate Government Pricing outcomes.

116. Penny Pricing in the 340B program is the byproduct of years of WAC price increases above inflation. As noted, this is a potential area of concern regarding increasing the amount and/or strengths of Opioids in the marketplace. However, Penny Pricing is a specific feature of the 340B program and not up to the discretion of the Company.

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[26] 38 USC § 8126(h)(5)

[27] 38 U.S.C. 8126(d)(1) and 38 U.S.C. 8126 (d)(2), (a)(2) & (c)

F. Pricing Committees and Contract Terms

117. As was noted at the outset, in addition to analyzing the impact of the agreements on the sales of Opioid Products, Pearl also analyzed the structure and procedures by which agreements are entered into, as well as the substantive terms of those agreements. From that review, the following observations and recommendations are made.

1. Pricing Committee Charter and Structure

118. In the Seventh Report, the Monitor recommended, and the Company accepted that it incorporate considerations of the Company's requirements under the Injunction into the Pricing Committee charters, and thereby the committees' decisions. (Seventh Report, Paragraphs 113-117.)

119. During discussions with the Company regarding the Pearl analysis, the Monitor further recommended that the Company should consider whether it is necessary to have multiple pricing committees. Pearl recommended that absent business or regulatory reasons not to do so, consolidation of the pricing committees of Rhodes and Purdue into one consolidated pricing committee may improve operational efficiency and identify situations where contracting activities in the generic Opioid market may impact decisions being made on branded Opioid Products. The Company communicated to Pearl that there is no required separation between Purdue Pharma and Rhodes Pharmaceuticals and the Monitor is aligned with the process now underway at the Company to combine the pricing committees.

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2. GPO Contracts Terms Review

120. Pearl's review concluded GPO contracts are overall in line with industry standards.

121. However, with respect to the distributor GPO contracts of Rhodes, certain contract terms merit ongoing diligence on the part of Rhodes when considering the prohibitions set forth in the Injunction to further support compliance with those prohibitions.

122. While Rhodes has amended a number of its distributor GPO contracts to exclude Opioid Products from fees and other payments, not all of Rhodes Distributor GPO contracts exclude Opioid Products from Failure to Supply Penalties, Initial Order Discounts, and Volume Service Fees that are tied to sales of a product. These types of payments could potentially be construed as payments to incentivize sales.

123. **The Monitor recommends that the Company continue to make commercially reasonable, good faith efforts to negotiate carve-outs for Opioid Products from sales-based payments in its distributor GPO contracts in the normal course of the contract renewal process for distributor GPO contracts.**

124. **The Monitor further recommends that the Company provide the undersigned with a schedule detailing when each GPO contract is scheduled for renewal, and whether the individual GPO contract includes the recommended carve-outs from sales-based payments. In the event that the Company negotiates or renews a GPO contract that does not contain the recommended carve-outs from sales-based payments, the Monitor requests that the Company inform the undersigned promptly after contract completion or renewal.**

125. **For all distributor contracts that include Opioid Products, the Monitor further recommends that the Company not accept any distributor requests for fees, rebates, or discounts intended to incentivize the sale of Opioid Products.**

126. Notwithstanding the above, the Company may pay a distributor for data or services when the Company has a legitimate business need for Opioid Products data, such as sales data for monitoring diversion or other suspicious activity, or Opioid Products services, such as maintaining secure storage. These payments must be fair market value, bona fide payments intended only to reimburse the distributor for data and services necessary to the sale and monitoring of Opioid Products.

3. Managed Care Contracts Terms Review

127. Pearl's review concluded that, overall, managed care contracts are in line with standard industry practices. However, there are some areas for improvement.

128. **Validation Terms:** not all managed care contracts have explicit language regarding what government utilization the Company may exclude from payment as Duplicate Claims.[28] Specifically:

a. Managed Medicaid and Fee for Service Medicaid specific exclusions. This exclusion requires collection of Medicaid claim details from State Medicaid agencies to compare to received managed care prescription data.

b. Exclusion of claims originating from a 340B service provider. This exclusion requires continual tracking of 340B entities and comparison to the received managed care prescription data.

[28] "Duplicate claims" used in this context means prescriptions: (a) submitted for rebate by more than one managed care customer; (b) submitted for rebate more than once by the same customer; or (c) submitted for rebate by customers in different channels. "Duplicate claims" does not mean a prescription that is filled more than once. Duplicate claims can be identified within a claim, across the current claim and previous claims, and across claims from multiple providers or multiple channels.

129. The Company notes the following:

a. While contracts may not have specific Medicaid exclusion terms, most contracts have language that allows recovery of Medicaid duplicate claims, which validation the Company routinely performs. The Company requests prescription data from State Medicaid agencies for Medicaid submissions meeting a particular dollar threshold that has been adjusted over time and may be further adjusted depending on business conditions and cost/benefit analysis of the activity.

b. The Company currently performs 340B entity validation on all managed care submissions. However, due to limitations inherent in the 340B program implementation, the Company may negotiate the parameters of this exclusion with its customers, as commercially reasonable.

130. To address this, the Company is making a concerted effort to negotiate more detailed rebate validation language into its managed care contracts through the addition of a rebate validation exhibit or corresponding language in the body of the agreement that specifically lays out mutually agreed upon exclusions and data validations permitted under the agreement.

131. **The Monitor recommends that the Company, in the normal course of the contract renewal/amendment process for managed care rebate agreements, make commercially reasonable, good faith efforts to include such a validation exhibit or language in all managed care agreements.**

132. **The Monitor further recommends that the Company provide the undersigned with a schedule detailing when each managed care rebate agreement is scheduled for renewal or amendment, and whether the individual managed care agreement includes a**

validation exhibit or corresponding language in the body of the agreement. In the event that the Company negotiates or renews a managed care rebate agreement that does not contain such a validation exhibit or language, the Monitor requests that the Company inform the undersigned promptly after agreement completion, amendment or renewal.

133. **Furthermore, the Monitor recommends that the Company prepare a presentation of the business conditions and cost/benefit analysis for collecting the Medicaid claim details from State Medicaid agencies willing to provide claims data.**

134. **Atypical/Excessive Quantity Thresholds:** Current thresholds used in contract operations to exclude claims for prescriptions of excessively large quantities of Opioids from rebate payment do not take into account product strength (OxyContin, Hysingla and Butrans) or days' supply (OxyContin, Hysingla).

135. While in the context of rebate validation, these thresholds are typically intended to identify keystroke errors, Pearl's analysis identified that states generally require prior authorizations from 50 to 90 MME/day, with many states implementing hard caps from 200 to 360 MME/day and/or days' supply.[29] Moreover, many states have enacted laws restricting dispensing Opioids and other Schedule II Controlled Substances to a 30- or 90-day supply.

136. An Atypical Quantity Threshold that does not consider product strength (i.e., MME) and/or days' supply pays a rebate without further investigation of prescriptions with very different total MME and MME/day. For example, a hypothetical 480 tablet threshold would allow prescriptions ranging from 7,200 to 57,600 MME and 80 to 1,920 MME/Day.

137. It is the Company's position that day's supply is not a reliable metric because pharmacies do not always provide day's supply data, and if provided, the day's supply data is

[29] "Report to Congress on Opioid Prescribing Limitations." Department of Health and Human Services, https://www.fda.gov/media/147152/download.

sometimes inaccurate. With respect to product strength and state laws, this is not commercially reasonable or practical to implement from a customer and from a validation system framework. In addition, the Company receives no information in the individual claims to determine the reasonableness of a prescription. Thus, the Company reviews large prescriptions in the context of identifying potential keystroke errors by a pharmacist. The Company has stated it will continue to analyze relevant data to review, and adjust if appropriate, its thresholds for large quantity exclusions.

138. **The Monitor recommends that the Company prepare an analysis and presentation of: (i) the availability, accuracy, and reliability of days' supply data in managed care rebate submissions; (ii) the reasons why strength, days' supply, and/or MME cannot be implemented as a threshold validation in Company contracts; and (iii) possible approaches to implement a threshold based on MME and/or MME/day.**

139. **Prescription Level Data:** The Company currently receives prescription level data from its managed care customers that includes, at a minimum, Fill Date, Provider NPI/NABP ID, Prescription ID, Fill Number, Quantity Dispensed, and Days Supplied for each dispensing record supporting the invoiced rebate amount, regardless of whether these fields are mandatory in the format the Company requires for managed care rebate submissions. The Company should ensure all these fields are contractually required to be provided in support of the validations noted above and all other managed care rebate claim validations, processing, and payment under the Company's contracts.

140. **The Monitor recommends that the Company, in the normal course of amendments to managed care rebate agreements make commercially reasonable, good**

faith efforts to include language in all managed care agreements explicitly making these fields mandatory in submission of claim data with all current rebate customers.

141. **The Monitor further recommends that the Company provide the undersigned with a schedule detailing when each managed care rebate agreement is scheduled for renewal or amendment, and whether the individual managed care agreement explicitly makes these fields mandatory. In the event that the Company negotiates or renews a managed care rebate agreement that does not, the Monitor requests that the Company inform the undersigned promptly after agreement completion, amendment or renewal.**

G. Suspicious Order Monitoring of Downstream Customers

142. Another issue that arose through the review and analysis was the lack of visibility into the downstream customers' distribution of branded Opioid Products, and the impact on that lack of visibility in fulfilling the obligations for Suspicious Order Monitoring.

143. For decades, the Drug Enforcement Administration has required that registrants with the DEA, including Opioid manufacturers, design and operate a system to disclose suspicious orders:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 CFR 1301.74(b); *see also* 21 U.S.C. § 823(b)(1)

144. The manufacturer's requirement to operate the SOM system initially focused on direct customers, which are principally the distributors.

145. Since the 2017 settlement in Mallinckrodt, PLC, et al. v. State of Connecticut, et al., the DEA has also made its view known that manufacturers have the same obligations as

distributors, when it comes to suspicious order monitoring and reporting of downstream customers.

146. In the release announcing the Mallinckrodt settlement, the Department of Justice declared:

> The resolution advances the DEA's position that controlled substance manufacturers need to go beyond "know your customer" to use otherwise available company data to "know your customer's customer" to protect these potentially dangerous pharmaceuticals from getting into the wrong hands.

(https://www.dea.gov/press-releases/2017/07/11/mallinckrodt-agrees-pay-35-million-record-settlement-failure-report)

147. In that same release, the DEA Special Agent in Charge explained, "This investigation let's [sic] all DEA registrants know that they need to use all of their resources and tools to detect and report suspicious orders."

148. The Memorandum of Agreement entered between Mallinckrodt and the DEA provided that "Mallinckrodt's suspicious order system will be designed to utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."

149. Specific to chargebacks, it provided:

> As part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants. Mallinckrodt receives this type of data only after it is submitted to Mallinckrodt by the direct customer, which is after the controlled substance has already been distributed. Mallinckrodt will report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.

(https://www.justice.gov/usao-edmi/press-release/file/986026/download)

150. In addition to the federal regulatory language, the Injunction also guides and defines the Company's obligations to review the actions of downstream customers.

151. The Injunction provides:

> The Company shall operate an effective monitoring and reporting system that shall include processes and procedures that:
>
> . . .
>
> (b) Reasonably utilize available downstream customer data to identify whether a downstream customer poses a material risk of diversion of a Company Opioid Product;
>
> (c) Analyze all information that the Company receives that indicates an unreasonable risk of diversion activity of a Company Opioid Product or an unreasonable potential for diversion activity of a Company Opioid Product, by a direct customer or a downstream customer, including reports by employees and customers of the Company, Health Care Providers, law enforcement, state, tribal or federal agencies, or the media;

(Injunction, II.G.1)

152. And, included within the definition of Health Care Providers are pharmacies and those "engaged in the business of providing health care services and/or prescribing an Opioid Product." (Injunction, I.H.)

H. Use and Limitations of Chargeback Data for Suspicious Order Monitoring

153. From the entry of the Injunction until the Summer of 2021, the Company fulfilled its obligations to monitor downstream customers primarily through review of the chargebacks. (See Fifth Report, Paragraphs 194-198.)

154. In the Sixth Report, the undersigned observed:

> The primary way in which the Company assesses the activities of its downstream customers and any material, unreasonable or potential risk for diversion activities is through a review of all chargeback data, comparing each individual order to the

> average order for downstream customers, based upon their relative size and the type of customer or patient services that the downstream customer provides. Those that have a significantly larger number of chargeback units than other customers are flagged as customers of interest, or "outliers," and then are more extensively reviewed by the Ethics and Compliance department. (Fifth Report, Paragraphs 194-204).

(Sixth Report, Paragraphs 170.)

155. The Sixth report also detailed some of the improvements to the review of downstream customers that the Company was implementing, including incorporating the review of detailed sales reporting information, or 867 data. (Sixth Report, Paragraph 177.)

156. Through the Pricing review, the Monitor became aware that the vast majority of sales and distribution of Purdue Pharma's branded Opioid Products – OxyContin, Hysingla, and Butrans – are not included in the chargeback process.

157. Specifically, the Chargeback review process only includes between 2% to 24% of Purdue's Branded Opioid Products packages or 2% to 22% of Company branded Opioid Product MME, with the disparity from month to month and product to product:

a. 2% to 4% of Hysingla ER packages and MME;

b. 11% to 24% of OxyContin packages, or 4% to 10% of OxyContin MME, indicating indirect sales of OxyContin tend to be for blister packs, not bottles, and for lower strength forms of the product (83% of blister pack MME are sold indirect compared to 6% for bottles, and 12% of 10 mg OxyContin is sold indirect compared to 6% for 80mg OxyContin); and

c. 14% to 24% of Butrans packages, or 13% to 22% of Butrans MME.[30]

[30] For one quarter, 2019 Q1, Butrans indirect sales reached 30% of packages (28% of MME) due to slowed direct sales in response to introduction of generic versions of the product. This is an outlier in the data and not reflective of general sales practices.

158. Given that 85% of the Company's revenues and 27% of the total MME sold over the reviewing period were branded Opioid Products, there is no insight into a substantial amount of Purdue's downstream sales and distribution through the chargeback review process.

159. Prior to the review undertaken by Pearl, neither the prior Monitor nor the undersigned Monitor were aware that such a small percentage of downstream sales and distribution of branded product is reviewed by relying on chargebacks.

160. The Company and the SOM team report that they were aware throughout the term of the Injunction that the chargeback review process only provided visibility into a small percentage of downstream sales and distribution of branded Opioid Products. This was never raised with the undersigned.

161. Through Pearl's review, it became evident why a chargeback review might be sufficient for companies like Mallinckrodt, but not Purdue Pharma and perhaps other manufacturers of Opioid Products. Mallinckrodt only manufactures generic oxycodone and almost all their Opioid Products are unbranded, the vast majority of which are sold to downstream customers like pharmacies for a negotiated price below the WAC price given to distributors. Similarly, the generic or unbranded products manufactured by Rhodes are also delivered to pharmacies at a negotiated price below the WAC price.

162. For branded products, however, the only distribution that would be captured by a review of chargebacks are those contracted indirect sales to institutional/inpatient facilities or alternate care sites, and not to retail pharmacies.

163. Accordingly, and as noted above, while the Company had visibility to 100% of its direct sales of all its Opioid Products, the Company did not have visibility into the movement

of 76% to 98% of the branded Opioid products to downstream customers for purposes of SOM and reporting, from the time the Injunction went into effect, until at least mid-year 2021.

I. Use and Limitations of EDI 867 Data

164. EDI 867, also known as a Product Transfer and Resale Report, is data sent from the distributor to the manufacturer, giving the Company insight into product movements, including sales, changes in location, and returns. Specifically, once the distributor sells its product to a downstream customer, like a pharmacy chain, Purdue is given notice how much of its Opioid products were transferred to the pharmacy chain, which individual pharmacies received the Opioid Product, and the date the Opioid Product is dispensed to the end customer.

165. In the Sixth Report, filed in August 2021, the undersigned reported that the principal limitation in using chargeback data for SOM purposes is that it typically is not available for six to eight weeks after the dispensing to the end user had occurred. (Sixth Report, Paragraph 172.) As earlier noted, the Monitor was not aware of limitations in visibility of downstream sales and distribution of the Company's branded Opioid Products when using chargeback data.

166. In the Sixth Report, the undersigned wrote:

> [T]he Undersigned recommends that the Company explore whether systematically incorporating historical sales and inventory data into the analysis and processes – or even making sales and inventory information the primary data source analyzed – might provide more effective and timely identification of orders and customers of interest than the analysis of chargeback data currently does. In particular, the Undersigned encourages the Company consider using the information that is available to it in its newly implemented Due Diligence Plus system with regard to the final destination of Purdue products to evaluate whether a downstream customer poses a threat of diversion.

(Sixth Report, Paragraph 181.)

167. Consistent with this recommendation, the 867 data for Purdue Pharma branded Opioid Products is now loaded each month into the Company's IT Cloud based SOM system, Due Diligence Plus. The Company has been working with its vendor over the past six months to refine and enhance how this data is presented and used. The Due Diligence Plus system now compares the pharmacy's monthly order of each Opioid Product to that downstream customer's orders from the prior month, identifying those pharmacies that have increased their monthly receipt of an Opioid Product. The system can also generate heat maps, by state and soon by zip code.

168. As noted in the Eighth Report, the SOM team is now also receiving 867 reports from the principal distributors on a weekly basis. (Eighth Report, Paragraphs 76-77.) The SOM team receives approximately 25 different spreadsheets each month from the distributors for branded and unbranded products and conducts a review similar to that performed with chargebacks.

169. The percentage increases identified by Due Diligence Plus and the spreadsheet review do not automatically lead to the Company reporting out downstream purchasers as a customer of concern, but rather provides the SOM team information to further review the order to determine if the downstream customer should be reported to the DEA and distributor.

170. While the 867 data set is more robust than the chargeback data, it still lacks visibility into all the product movement.

171. Four large pharmacy chains "blind" their data, meaning that the manufacturer does not receive any information about the identity or location of the downstream customer that dispensed the Opioid Product to an end user.

172. The blinding of the data occurs as a result of the contractual agreement between the distributor and the pharmacy chain. A pharmacy chain's reasons for blinding can include the concern their data may give the manufacturers a competitive advantage in current or future negotiations, that their data may be leaked to competitors, or that the pharmacy chain (not the distributor) should receive the financial benefit of selling data related to their purchase activity.

173. If the pharmacy buys the drug from its principal distributor, the 867 data is blinded. If, however, the pharmacy chain must purchase from a secondary wholesaler or distributor, that information is often reported out.

174. Depending on the product and the month, Pearl determined 35 to 45 percent of the 867 package sales of the Company's branded Opioid Products were "blinded" between 2018 and June 30, 2021, meaning the Company had no visibility into the product movement beyond the distributor level. Recently, the Company placed that estimate as between 33 and 37 percent.

175. Accordingly, even with the 867 data that the Company is in the process of further incorporating into its SOM processes, Purdue Pharma has no visibility into downstream customer distribution for at least one third of the Company's branded Opioid Products.

176. This problem is presumably not unique to Purdue Pharma. Any pharmaceutical manufacturer that only relies on chargebacks would lack visibility into the great majority of the downstream customer transactions of its branded products. And, even if the manufacturer incorporates 867 Data into its review as Purdue Pharma is now doing, it is likely the manufacturer would face the same problem with the blinding of a substantial percentage of the downstream customer transactions for branded products.

177. As relates to downstream customers, the Injunction provides that "[t]he Company shall operate an *effective* monitoring and reporting system that shall include processes and procedures that . . . "utilize *available* downstream customer data" and "[a]nalyze all information that the Company *receives*..." (Injunction II.G.1(b) and (c), emphasis added).

178. Now that the 867 data have been incorporated into the SOM review, the Monitor finds that the Company is utilizing available downstream data and analyzing all information that the Company receives, and accordingly is in compliance with the Injunction.

179. Though consistent with the Injunction, the effectiveness of that monitoring and reporting system is undermined by the Company lacking visibility into between 33 and 45 percent of the downstream sales and distribution of branded Opioid Products. This is the case for Purdue Pharma, as is presumably the case for any manufacturer distributing branded Opioid Products, absent other arrangements being made.

180. There are four pharmacy chains that, through their contractual relationship with distributors, blind the downstream data that Purdue Pharma receives. **In conversations with the Company, the Monitor has requested that the Company endeavor to gain visibility into these transactions, including seeking to obtain the pharmacy chains' permission have their 867 Data unblinded for SOM purposes.**

181. **The Monitor recommends that the Company report to the Monitor the process undertaken and success of these efforts within 30 days of the filing of this Report. In instances where these efforts do not succeed, the undersigned recommends that the Company confer with the Monitor to explore potential alternative strategies to obtaining the blinded data.**

III. REVIEW OF STANDARD OPERATING PROCEDURES

182. In the Eighth Report, the Monitor recommended that the Company revise certain SOPs and policies to incorporate requirements of the Injunction, as well as take a more comprehensive review of the entirety of the SOPs relating to Opioids. (Eighth Report, Paragraphs 58-63.)

183. The Vice President, Ethics and Compliance explained to the Monitor that SOPs identified by the undersigned and the Code of Ethics have been updated.

184. To date, the Monitor has reviewed updated SOPs covering: Ethics & Compliance Investigations; Hotline Operations; Ethics & Compliance Committees; Ethics & Compliance Training; Enterprise Risk Management; and Ethics & Compliance Monitoring Program.

185. The updated SOPs received and reviewed by the Monitor thus far have sufficiently incorporated considerations relating to the Injunction.

186. The Vice President, Ethics and Compliance further reported that the Company has contracted with an outside vendor to create the policy portal, and Ethics and Compliance is in the process of rewriting one of its foundational documents, the healthcare law compliance policy. Ethics and Compliance is also working with the various business units and divisions in the Company, with the expectation that all SOPs will be reviewed and revised when appropriate in calendar year 2022.

187. The Monitor will continue to report progress in the next Report.

IV. LOBBYING RESTRICTIONS

188. Since the filing of the Eighth 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 January 1 to March 31, 2022

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

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

V. BAN ON HIGH DOSE OPIOIDS

191. Under Section II.E of the Injunction, Purdue Pharma agreed to abide by whatever decision is made by the Food and Drug Administration (FDA) on the pending Citizens Petition dated September 1, 2017, concerning a ban on high doses of prescription and transmucosal Opioids exceeding 90 morphine milligram equivalents (FDA-2017-P-5396).

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

VI. SUSPICIOUS ORDER MONITORING AND REPORTING

A. Customer Due Diligence and Annual Review Reports.

193. Earlier Reports detailed the due diligence and annual review reports the Company requires each year of its distributors. (Fifth Report, Paragraphs 143-152.)

194. In the past, requests to complete the reports have been sent by the Company to its customers in July. (Sixth Report, Paragraph 156.)

195. This year, the SOM team sent out the requests in April, and the Associate Director, Ethics and Compliance reported that 31 of the 48 distributor/customers have already returned the completed reports.

196. Although not all reports have been produced for review as of the filing of this Report, the Monitor reviewed the due diligence and annual review reports that were produced

and finds them complete and in compliance with the Injunction and SOPs and policies guiding this process.

197. The SOM team has also conducted four site visits of distributors in 2022. All site visits continue to be conducted virtually. The Monitor has reviewed these site visit reports and finds them to be consistent with the Company's policies and the Injunction.

B. Restricting Supply of Company Opioid Products to Downstream Customers

198. 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." The undersigned also noted, "It is evident that there is not meaningful sharing of best industry practices relating to Suspicious Order Monitoring and compliance." (Eighth Report, Paragraphs 86-87.)

199. The Director of Ethics and Compliance reported to the undersigned that the SOM team continues its investigation into the systems and standards other Opioid manufacturers employ for restricting sales or chargebacks to downstream customers, as well as the standards employed for reinstituting sales to those downstream customers. The other manufacturers have not been forthcoming in the processes they use, so the Company is speaking to various vendors to determine the best path forward.

200. The undersigned Monitor will continue to report progress in the next Report.

C. External Source Review for Suspicious Order Monitoring

201. In addition to monitoring sales, chargeback and product movement data, the Injunction requires that the Company "[a]nalyze all information that the Company receives . . .

including reports by employees and customers of the Company, Health Care Providers, law enforcement, state, tribal or federal agencies, or the media." (Injunction, II.G.1(c))

202. Since the last Report, the Monitor requested an explanation from the Company about information it receives or reviews that isn't necessarily tied to a specific distributor or downstream customer's orders.

203. The Director and Associate Director of Ethics and Compliance explained that the Company reviews information from various external sources, including:

a. Email communications from the DEA and US Department of Justice regarding diversion, prescription fraud, and Medicaid and Medicare fraud;

b. Email communications from law firms that put out information regarding pharmaceutical industry litigation;

c. Health and Human Services Office of Inspector General Reports; and

d. Corporate security loss reports.

204. The SOM team also regularly reviews RX Patrol (https://www.rxpatrol.com/) and state regulatory board agendas and minutes.

205. Additionally, the Associate Director has media search terms, or "google alerts" set for approximately 10 different terms or phrases, to identify HCPs that could warrant further review.

206. The Monitor finds these additive efforts to be consistent and compliant with the terms of the Injunction.

D. Other Measures Implemented by Suspicious Order Monitoring

207. In the Eighth Report, the undersigned reported that the SOM team was working with Corporate Security so that SOM will now receive all reports of counterfeiting, loss, or theft.

(Eighth Report, Paragraph 88.) The Director of Ethics and Compliance informed the undersigned that the SOM team had not previously been receiving these reports. The SOM team is now reviewing each Corporate Security report and determining whether any should be submitted to the DEA and/or state Boards of Pharmacy. To date, no such reports have been made to the DEA or a state Board of Pharmacy.

208. The SOM team also commenced reviewing the information gathered from the Opioid Product Savings Card program, to assess whether patients are receiving medications prior to when they should, whether there are patterns that might suggest doctor shopping, and anything else that could present a risk of or potential for diversion. (Eighth Report, Paragraph 88.) To date, the SOM team has not found anything of concern.

VII. INITIAL COVERED SACKLER PERSONS

209. The undersigned has received signed certifications from the Initial Covered Sackler Persons or their representatives certifying that they have not actively engaged in the Opioid business in the United States and have taken no action to interfere with Purdue Pharma's compliance with the Injunction.

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

STEPHEN C. BULLOCK
Monitor