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)**

FIFTEENTH MONITOR REPORT

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

EXECUTIVE SUMMARY

This Fifteenth Monitor Report, and the undersigned's eleventh since being appointed on February 18, 2021, will include an outline of actions taken over the last three months to determine compliance with the terms and conditions of the Voluntary Injunction ("Injunction"), discussion of the results of areas of further inquiry or recommendations from prior Reports, additional recommendations provided to Purdue Pharma L.P. ("Purdue 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 most of the Monitor's requests for information, documents, and interviews with Purdue Pharma employees.

INTRODUCTION – STEPS TAKEN SINCE FOURTEENTH REPORT

1. Since the filing of the Fourteenth Report the undersigned Monitor has continued with a series of interviews and discussions with employees at Purdue Pharma including the: Vice President, Chief Compliance Officer; Vice President, Legal Strategy and Public Health Initiatives; Vice President of Quality; Associate General Counsel, Head of Corporate Law; Senior Manager, Quality Documentation Systems; and Director, Research and Development Quality.

2. Since the filing of the Fourteenth 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.

FOURTEENTH REPORT RECOMMENDATIONS AND AREAS OF FURTHER INQUIRY

3. In the Fourteenth Report, multiple recommendations and areas of inquiry were identified. The Company agreed to all recommendations made. The recommendations and areas of inquiry that warrant further consideration in this Report included:

   a. In assessing whether prescription information obtained for rebate validation purposes can be used to review downstream customers dispensing high-dose prescriptions, the Monitor would seek leave of the Court to contract with counsel or a consultant to explore whether notice can be provided to the SOM Team without violating HIPAA. (Fourteenth Report, Paragraph 37.)

b. The Company agreed that by June 22, 2023, it would approach certain distributors and Group Purchasing Organizations to open contract negotiations regarding restricting chargebacks to high risk downstream customers, and make reasonable attempts to implement recommended changes on commercially reasonable terms. (Fourteenth Report, Paragraph 41.)

c. The Company agreed to provide regular updates whether these changes have been agreed to and implemented. (Fourteenth Report, Paragraph 41.)

d. The Company agreed to request information through the Pharmaceutical Compliance Forum Benchmarking Survey regarding Suspicious Order Monitoring ("SOM") Team size and technology for companies manufacturing and distributing Opioids. (Fourteenth Report, Paragraph 53.)

e. The Company agreed to provide a copy of a proposed climate survey to the Monitor prior to disseminating and share the results of that survey with the Monitor. (Fourteenth Report, Paragraph 63.)

DISCUSSION AND ANALYSIS

I. BAN ON PROMOTION

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

5. The prohibition Purdue Pharma agreed to covers activities relating to sales representatives, outside speakers, medical education programs, websites and social media,

written publications, digital and printed advertisements, Internet search optimization techniques, and Internet marketing. (Injunction, II.A.1.a-h).

6. The Injunction also sets forth activities Purdue Pharma is allowed to do and expressly permits the promotion of products related to the treatment of opioid use disorders, abuse addiction or overdose, and rescue medications. (Injunction, II.A.3-4).

7. During this last reporting period, the Company apprised the Monitor that it intended to have a Medical Affairs booth at the American College of Emergency Physicians Scientific Assembly and the North American Congress of Clinical Toxicity.

8. The Company shared with the Monitor that Medical Affairs intended to have a slide deck about the Company's Public Health Initiatives and prescribing information available upon request, but not visible, for Nalmefene and Buprenorphine/Naloxone. Naloxone is an opioid receptor antagonist that is used to treat acute opioid overdose and Buprenorphine/Naloxone is a used to treat opioid use disorder. The Company also vetted the executive leadership and board members of the sponsoring organizations, and shared agenda topics that may be possibly related to Opioids.

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

10. **The Monitor recommends following up with the representatives of Medical Affairs after the conferences to ascertain if there were any inquiries or interactions relating to Opioid Products. The Company has agreed to this recommendation.**

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

A. Review of Opioid Products Contracts and Agreements

11. In the Ninth Report, the Monitor reviewed the Pricing Consultants' evaluation of the Company's contract terms with Group Purchasing Organizations ("GPO") and Managed Care Organizations ("MCO") for consistency with the promotion and remuneration provisions of the Injunction contained in II.A. and II.B. and made several recommendations for consideration.

12. Recommendations included making a good-faith effort to negotiate certain provisions relating to carve-outs for Opioid Products from sales-based payments in its distributor GPO contracts and inclusion of prescription-level data in its MCO contracts, and keeping the Monitor apprised of those efforts. (Ninth Report, Paragraphs 123, 131, 141.)

13. As of the date of the filing of this Report, the Company has successfully negotiated the recommended changes in all but two of the managed care rebate agreements. The Company reported that the remaining two contracts come up for renewal at the end of 2023, and the Company intends to negotiate these terms in the fourth quarter of this year.

14. Regarding the recommendation to remove failure-to-supply penalties in the distributor GPO agreements, in the last Report the undersigned explained that there were three contracts remaining that include this provision. (Fourteenth Report, Paragraphs 10-11.) Since the filing of the last Report, the Company reported to the undersigned that it successfully executed an agreement with one of the GPOs. The other two continue to refuse to consider changes.

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III. REVIEW OF STANDARD OPERATING PROCEDURES

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

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

17. The Monitor has not yet received and reviewed these SOPs but will report on changes in the next Report.

IV. LOBBYING RESTRICTIONS

18. Since the filing of the Thirteenth 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 April 1 to June 30, 2023.

19. One contracted state firm reported contacts with a state department of health and tribal agencies relating to the Company's Public Health Initiatives. One contracted firm reported participating in legislative roundtable meetings where addiction and mental health issues were discussed, but those roundtables were hosted by a state sheriff's association, another client of the firm, and there was no reference to Purdue Pharma.

20. In all other instances, the state and federal contracted firms only monitored legislation and legislative, executive, and administrative activities relating to Opioids, Opioid Products, Opioid antagonists, substance use disorder, and other related matters.

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

V. BAN ON HIGH DOSE OPIOIDS

22. 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).

23. 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. Atypical/Excessive Quantity Thresholds

24. In the last Report, the Monitor detailed the history behind the effort to utilize information in the Company's possession about atypical Opioid prescriptions for SOM purposes, the contractual and legal issues raised by the Company in utilizing this information, and an explanation that the Monitor intended to seek leave of the Court to contract with counsel or a consultant to further explore whether notice can be provided to the SOM Team without violating the Health Insurance Portability and Accountability Act ("HIPAA"). (Fourteenth Report, Paragraphs 22-33.)

25. The undersigned has recently contracted with Deven McGraw as the Monitor's HIPAA Consultant. Ms. McGraw was the Deputy Director for Health Information Privacy at the

HHS Office for Civil Rights ("OCR") from 2015-2017, where she was the career federal official in charge of policy and enforcement of HIPAA privacy, security, enforcement, and breach notification regulations. During her tenure, OCR issued policy guidance on a number of topics related to HIPAA compliance and settled 26 HIPAA enforcement cases. During 2017, she also served as the Acting Chief Privacy Officer for the HHS Office of the National Coordinator for Health.

26. The undersigned will work with the Company and the undersigned's HIPPA Consultant and provide further information in the next Report.

B. Restricting Supply of Company Opioid Products to Downstream Customers

27. The issue of "establishing policies and procedures for placing restrictions on certain downstream customers" has been a staple element of the Monitor Reports for the past eighteen months. (*See* Eighth Report, Paragraphs 80-86; Ninth Report, Paragraphs 198-199; Eleventh Report, Paragraphs 96-98; Twelfth Report, Paragraphs 92-94; Thirteenth Report, Paragraphs 58-65; Fourteenth Report, Paragraphs 34-41.)

28. In filing the Fourteenth Report, on May 22, 2023, the Monitor was under the impression that a SOP was close to being finalized. After discussion with the Company, the undersigned included in the last Report the following:

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

terms. The Company further agrees to provide regular updates whether these changes have been agreed to and implemented.

(Fourteenth Report, Paragraph 41.)

29. The Company provided a draft of the SOP on June 6, and the undersigned provided input five days later. The Company provided another draft on June 21, met with the Monitor and the undersigned's SOM consultant, and the undersigned and SOM consultant provided relatively minor comments two days later. A revised SOP was provided by the Company to the undersigned on August 15, three days prior to filing the Fifteenth Report.

30. The Company informed the Monitor that on or prior to June 22, (i) notices were sent out to three of Purdue Pharma's distributors and (ii) contract amendments were sent to four of Rhodes's distributors and twelve GPOs of Purdue Pharma and Rhodes that are responsible for 90% of the chargebacks generated from sales of branded and generic Opioid Products by Purdue Pharma and Rhodes.

31. Immediately prior to filing of this Report, the undersigned received information on the status of contract modifications. To date, seven GPOs of Purdue Pharma and Rhodes have agreed to terms or have executed the requested contract modifications, while one of the Rhodes's GPOs has refused the proposed contract modifications. Discussions are ongoing with the distributors.

32. The Monitor will continue working with the Company with the expectation that the SOP will be implemented early in this reporting period, and provide additional detail in the next Report.

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C. Suspicious Order Monitoring Staffing

33. In the Thirteenth Report, the undersigned recommended that "the Company undertake a survey or assessment of other Opioid Manufacturers to better understand the personnel dedicated to Suspicious Order Monitoring by those other manufacturers." (Thirteenth Report, Paragraphs 70-74.) The Fourteenth Report detailed steps the Company had taken to meet that recommendation. (Fourteenth Report, Paragraphs 42-46.)

34. In the last Report, the Monitor reported that the Company had recently filled a data analytics position on the SOM Team responsible for retrieving, aggregating, and interpreting data to aid the SOM Team, and was in the process of recruiting a Senior Manager position, requiring prior experience working for the Drug Enforcement Administration, and with responsibilities including investigating downstream customers using open source and publicly available databases and sites, as well as managing the setting of direct customer thresholds. (Fourteenth Report, Paragraphs 47-48.)

35. The Chief Compliance Officer reported that the latter position is now filled, and the new employee will be joining the Company later this month. The successful applicant had served for the past 25 years as a Special Agent with the Drug Enforcement Agency, including working with the Company's Director, Ethics & Compliance during his service and tenure with the Agency. Throughout his tenure with the DEA, the successful applicant has been involved in matters relating to prescription drug diversion and abuse, including efforts relating to awareness and prevention.

36. In the last Report, the Monitor also recommended that the Company avail itself of a membership benefit of the Pharmaceutical Compliance Forum ("PCF"), by requesting information through the PCF's quarterly Benchmarking Survey regarding SOM Team size and

technology for companies manufacturing and distributing Opioids. (Fourteenth Report, Paragraphs 44, 52.)

37. In fulfilling this recommendation, the Company provided the Monitor with a draft of its survey for input. Upon incorporation of that input, the Company requested that PCF send out the survey. The survey inquired about both the nature of the respondents, as well as particulars about their SOM programs, including what division in the company the program is housed, the number of employees dedicated to SOM and reporting, the frequency, content, and automation of review of downstream customer information, and whether the respondents would be willing to participate in an open forum discussion about SOM practices.

38. However, due to its concerns about the survey length, the PCF would not distribute the survey to its members. Given the complexity of the issue, there is no way to limit the survey questions to meet the PCF format that would result in gathering meaningful and potentially actionable information.

39. The Chief Compliance Officer then identified those PCF member companies that distribute controlled substances, and individually requested that they fill out an anonymous survey, with a response target of early August.

40. Of the twenty companies receiving the survey, only three responded, with one company stating that it does not manufacture controlled substances. Accordingly, the Company has concluded the paucity of information gathered is not instructive to use to evaluate or compare to Purdue Pharma's SOM processes.

41. In the two and one-half years serving as Monitor, the undersigned continues to be surprised and disappointed that neither the industry nor the regulators are collaboratively focused upon establishing and implementing best practices when it comes to Suspicious Order Monitoring and Reporting.

42. Admittedly, the undersigned has little direct insight into the operating practices of other manufacturers and distributors of Opioid Products. However, because of these Monitor reports and the reports of other Opioid manufacturers operating with monitors, not only are those companies with monitors continually pushed to further improve their practices, but also the other manufacturers and regulators can reap the benefit of insight into improved practices that the transparency of a monitorship affords. While this has led the undersigned to believe that, given the resources invested, Purdue Pharma is now one of the industry leaders in suspicious order monitoring and reporting, because of the lack of transparency and collaboration in the industry and with the regulators, that belief cannot be verified.

D. Suspicious Order Monitoring Review of Savings Card Information

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

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

45. The Company has represented to the Monitor that it is beginning the process of negotiating amendments to the contracts with the Savings Card program vendors to allow the information to be shared with the SOM Team, and the Monitor will report the status of those efforts in the next Report.

VII. REPORTING, ANALYSIS, AND RESOLVING: 1) REPORTS OF CONCERN; 2) SHORT COUNTS; AND 3) SUSPECTED VIOLATIONS OF LAW OR POLICY

46. In the Thirteenth Report, the Monitor recommended that that the Company "develop processes to identify, track, and capture: (1) short counts and missing product; (2) known or suspected abuse or diversion of a Company-marketed controlled substance; and (3) known or suspected violations of law or policy." (Thirteenth Report, Paragraph 86.)

47. Since the filing of the Thirteenth Report, the Monitor has received additional detail and information, identifying both the substantive matters in each of the aforementioned categories, and the processes involved in identifying, tracking, capturing and resolving these reports and concerns.

48. In all instances, business practices were already in place to ensure that reports are not only captured, but also tracked through to resolution. Having reviewed and analyzed this level of detail, the undersigned understands the systems to be comprehensive and complete, and has limited recommendations for improvement, as detailed in the paragraphs that follow.

A. Reports of Concern

49. In the Fourteenth Report, the undersigned provided detail on the substance of the Reports of Concern ("ROC") received by the Company between October 2021 and March 2023, and noted that additional detail about the process for tracking ROCs would be included in this Report. (Fourteenth Report, Paragraphs 67 and 68.)

50. During this last reporting period, the Company implemented "Processing of Potential Reports of Concern (CS-SBP-17)," a new Standard Business Practice ("SBP"), which is functionally like a Standard Operating Procedure ("SOP"), to identify, capture, track and investigate potential ROCs. The Company provided the undersigned the opportunity to review and comment on the SBP prior to its adoption.

51. As discussed in previous Reports, there has been, at times, confusion over what constitutes a ROC. (Thirteenth Report, Paragraphs 84 and 85.) The SBP defines ROC as "[a] specific alleged occurrence of suspected Diversion of a Purdue marketed controlled substance," and "Diversion" is defined as "[a]ny intentional act that results in transferring a Purdue-marketed controlled substance from lawful to unlawful distribution or possession."

52. The SBP details that Corporate Security ("CS") receives information about potential ROCs from various sources, including reports from Drug Safety & Pharmacovigilance, Product Monitoring, and reports to the Integrity Helpline. Within five business days of receipt of a notification of a potential ROC, CS-SBP-17 requires that CS log and capture the details of the potential ROC onto a spreadsheet.

53. The SPB further provides that CS then evaluates the details of the potential ROC to determine whether to conduct an investigation. If CS determines that an investigation is warranted, this can include interviewing the person or party that brought the ROC to the attention of the Company, and reviewing any available evidence, such as video recordings.

54. If CS determines there was Diversion, the SBP provides that CS will work with the SOM Team to notify and refer the matter to applicable law enforcement and/or regulators. The SBP sets forth that CS must notify the SOM Team within two business days of determining

there has been Diversion, and that the SOM Team must notify the appropriate law enforcement and regulators within two business days of notice from CS.

55. Corporate Security also updates the ROC spreadsheet to ensure it captures the higher level details of the ROC, including: a unique identifier for the complaint; the department receiving the complaint; the date received; the identity of the complainant (if known); a determination of whether the matter is related to Opioids; a short description of the matter; the lot number, if known; the activities performed by CS, the SOM Team, and Quality Assurance; a conclusion; and a determination if the matter is a ROC. The SBP further provides that CS must update the ROC spreadsheet within five days of completing an investigation.

56. While the SBP does not include an expected timeframe for the investigation and conclusion, the Monitor's analysis of ROCs reported between October 2021 and March 2023 found that most investigations are completed within four to six weeks. Given that each investigation can be different, and the Company is typically relying upon the responsiveness of third parties, the undersigned does not think it would be particularly constructive to include an expected timeframe.

57. The SBP further provides that CS and the SOM Team will review the ROC Spreadsheet with the Chief Compliance Officer on a quarterly basis.

58. The Monitor finds that the CS-SBP-17, and the process it sets forth, is thorough and consistent with the terms of the Injunction. While a spreadsheet might at first blush appear to be a rudimentary system for capturing and reporting ROCs, given the limited number of such reports and that the reports are also captured in the various systems from where the report originated, the Monitor is satisfied that all ROCs and potential ROCs are identified and tracked.

59. **Going forward, the Monitor recommends that the Company provide the undersigned with the ROC spreadsheet on a quarterly basis. The Company has agreed to this recommendation.**

B. Product Quality Complaints (Including Short Counts)

60. Regarding Product Quality complaints, the undersigned interviewed the Vice President of Quality, responsible for the quality assurance/quality control functions, the Director, Research and Development Quality, and the Senior Manager, Quality Documentation Services. The undersigned also reviewed relevant SOPs and policies.

61. In total, there are 78 employees working in the Quality Department, though not all deal with Product Complaints. The Department is broken into four main groups: (1) the quality control group, responsible for testing of internally-produced product and the market product stability program, which assesses the quality, safety, purity and efficacy up to the product's expiration date; (2) the quality group, supporting the internal manufacturing and product transfer of materials into the Company's manufacturing facility in Wilson, NC; (3) the corporate quality group, overseeing research and development, drug safety pharmacovigilance, and other regulatory-type support functions; and (4) a third-party quality group involved in third-party product development, manufacturing and packaging, and auditing of suppliers.

62. The "Product Quality Complaint Investigations, SOP (CQA 1-40)," effective March 2023, sets forth the process for conducting Product Complaint investigations of finished products manufactured by the Company, Purdue Pharma products manufactured or packaged by a third party, and all reports of possible suspect or illegitimate products. There is also a SOP for "Processing of Product Complaints (CQA 7-3)", effective June 2020, and White Papers setting forth standards for count-related manufacturing or packaging defects ("Count White Paper (+/-

1),” effective July 2022, “Legacy Packaging Product Complaints-Count White Paper,” effective September 2022, and “Butrans Short Count White Paper,” effective September 2015) that all relate to CQA 1-40.

63. The Company internally packages approximately 75% of its Opioid Products; it has third-party packagers for all Company Opioid products distributed in blister packs and for some distributed in bottles. Of the Company’s Opioid Products, buprenorphine patches and Hydromorphone Oral Solution are not manufactured and packaged by the Company.

64. Upon receipt of a purported Product Complaint, the Company’s third-party Product Monitoring Group, tasked with fielding external calls and emails to Purdue Pharma, conducts an initial assessment, or triage, of the complaint.

65. In some instances, the report is not a Product Quality complaint. The Processing of Product Complaints SOP (CQA 7-3) details that: reports involving Reports of Concern are forwarded to the Law Department and Corporate Security; reports of adverse events are forwarded to the Drug Safety and Pharmacovigilance Department; and complaints not directly implicating the quality of the product, such as the size of the label printing, are assigned to the appropriate department.

66. While CQA 1-40 does not expressly define what constitutes a Product Complaint, CQA 7-3 provides that a report is classified as a Product Complaint if: the reported defect doesn’t meet product specifications, such as a broken tablet, unsealed bottle, or a missing or illegible lot number; the reporter requests that a product be tested or investigated; or a physical characteristic is present that is not inherent to the product, as per the prescribing information.

67. Additionally, the Product Quality Complaint Investigations SOP (CQA 1-40) includes a multi-page table that more discretely defines each category of complaint, and its applicability to the various Purdue Pharma products.

68. The defects are classified by the third-party Product Monitoring Group as either Critical or Non-Critical, based upon that table of defects included in CQA 1-40. The Vice President of Quality explained that impact to patient safety is the most important factor in determining whether a Product Complaint is considered Critical. Identifying and listing the factors determining criticality is a collaborative effort between the Company's Quality Assurance, Drug Safety, Pharmaceutical Technology, and Analytical Services departments.

69. Examples of Critical defects for Opioid Products include overfills of bottles, open or missing seals, broken tablets, discoloration, incorrect products, and unusual odor, texture or taste. Short counts are deemed Non-Critical for Opioid Products, except for complaints reporting an empty bottle.

70. All Critical complaints must be triaged and assigned to the manufacturing site within one business day. Non-Critical reports must be assigned within three business days.

71. The third-party Product Monitoring Group enters the complaint into a database and creates a case file. Information includes: a detailed description of the complaint; type of defect; reporter contact details; lot number and/or expiration date, if available; and whether a product sample is available for return.

72. The Company's Quality Assurance Group also determines whether Purdue Pharma must file a Field Alert with the Food and Drug Administration ("FDA"). A Field Alert is a notification to the FDA that the Company has become aware of something unusual with a

product in commerce that could have a potential safety risk to patients, and that the Company is in the process of investigating it.

73. The decision whether to file a Field Alert must be made within three business days of receiving a report of a complaint. Accordingly, unless the Company can immediately determine that the Product Complaint would not impact patient safety, a Field Alert is filed.

74. After the investigation is complete, Purdue Pharma informs the FDA of the results of the investigation, corrective actions taken to prevent a reoccurrence, and, if there's a serious enough patient safety risk, a recommendation to the FDA regarding recalling the product and at what level the recall should occur.

75. Depending on where the product is manufactured and/or packaged, the complaint is either assigned to the Wilson Quality team, if internally manufactured, or is assigned to a Single Point of Contact ("SPOC") within Purdue Pharma responsible for oversight of a third-party manufacturer/packager to conduct the investigation. The assignee also reviews the third-party Product Monitoring Group's classification of each Product Complaint as Critical or Non-Critical.

76. Tasks required by the SOP for complaint investigations include: setting out the details of the investigation; conducting a historical review to determine if there have been other valid complaint reports of a similar nature for a single lot and defect; conducting an impact and risk assessment; reviewing, as applicable, the information regarding the batch or lot; evaluating any samples received; identifying the root cause or contributing factors leading to the Product Quality issue; and reaching a conclusion. The investigator may also request review of security video footage of the filling and packaging process.

77. These tasks are the same whether the complaint is identified as Critical or Non-Critical, except that an impact and risk assessment is not required for Non-Critical defects, as there is no impact to patient safety.

78. CQA 1-40 further provides that the Company may perform a reduced investigation when: the subject lot was expired at the time the reporter detected the complaint; the associated sample, photo or description invalidates the reported complaint condition; an investigation was previously completed for the reported lot and defect; or, subject to management discretion, the reported lot number is invalid. The investigator must justify the decision to conduct a reduced investigation, and still must perform an historical review, an evaluation of the returned sample (if provided), an impact assessment if critical defects are reported, and a conclusion.

79. In instances such as where the complaint falls within the applicable White Papers (Count White Paper (+/-1), Legacy Packaging Product Complaints-Count White Paper), no investigation is required unless there are five complaints relating to an individual packaging batch. Consistent with the Butrans Short Count White Paper, the threshold number for determining whether an investigation is required ranges from two to 17 complaints, depending on the batch size.

80. Investigations are deemed either inconclusive, invalid, or valid. To the extent that there is sufficient evidence that the reported defect is the responsibility of the Company's manufacturing site or an associated company, the investigation is deemed valid. Where there is insufficient evidence that the reported defect is the result of activities under the responsibility of the Company's manufacturing site or an associated company, the investigation is deemed inconclusive. If the defect has been verified to not be the result of activities under the

responsibility of the Company's manufacturing site or an associated company, the investigation is deemed invalid.

81. The Company requires in CQA 1-40 that the investigation be completed and closed within 30 calendar days if manufactured or packaged by the Company, and 45 days if by a third party. Up to three extensions can be granted, but over three-fourths of the complaint investigations are concluded in the prescribed period. The Vice President of Quality explained that the 30-day timeframe is considered industry standard for internal investigations, though some companies are now shifting to a 60-day time frame for completing investigations of Product Complaints involving third-party manufacturers or packagers.

82. The undersigned finds that the Product Quality Complaint Investigations SOP, CQA 1-40, is consistent with the Injunction and thorough in its exposition and detail.

83. There are minor disparities between the two SOPs, such as the timeframes for case closure, and the undersigned assumes that the recently revised CQA 1-40 applies. **The Monitor recommends that the Company revisit and revise the Processing of Product Complaints SOP, CQA 7-3, to correspond with the most recent revisions of CQA 1-40. The Company has agreed to this recommendation.**

C. Review and Analysis of Product Quality Complaints

84. More than just the procedures for processing and investigating Product Complaints, the Company undertakes a rigorous review and analysis of those complaints and their resolution.

85. On a monthly and quarterly basis, Products Quality evaluates the total of their complaints against 13 identified Key Compliance Indicators. These indicators range from the confirmed, valid critical Product Complaints as a percentage of the total complaints received, to

the types of complaints, to the timeliness of completing the investigation, to the percentage of complaints in which the Company identified the root cause of the defect problem.

86. For each Key Compliance Indicator, the Company also sets compliance targets it strives to meet or exceed. The Vice President of Quality explained that the Key Compliance Indicator targets aren't metrics that the Company must meet, but more so indicators to determine compliance risks. This analysis is prepared for and used by the relevant Company departments, as well as the Executive Committee.

87. The Company set the compliance targets approximately eight years ago. The Vice President of Quality explained that these targets are not typically adjusted or changed, so that the Executive Team and Product Quality Department can gain a sense of performance over time. The Company sets acceptable quality levels by reaching out to other industry participants, and has consultants, or external auditors, periodically review the performance of the Company.

88. Each of the Product Complaints are individually tracked. In calendar year 2022, the Company received, processed, and tracked approximately 1,650 Product Complaints, with 1,520 relating to controlled substances. Of the complaints involving controlled substances, 106 were categorized as Critical.

89. In reviewing the materials and discussing Company practices with the Vice President of Quality and his staff, the Monitor finds them consistent with the Injunction, and is impressed with the systems in place to capture, resolve and analyze all Product Complaints. The only potential concern is that identified by the Vice President of Quality when pressed: that there isn't future significant staff attrition within the workgroup. The Monitor has no recommendations for improvement.

90. **Going forward, the Monitor recommends that the Company provide the undersigned with the Key Compliance Indicators, the evaluation of those Indicators, and supporting materials on a quarterly basis. The Company has agreed to this recommendation.**

D. Integrity Helpline and Suspected Violations of Law or Public Policy

91. There are three primary SOPs and one Working Practices Document ("WPD") guiding the Integrity Helpline, and capturing, investigating and resolving ethics concerns and reports of known or potential violations of law or policy: "Operations of the Integrity Helpline (CC-SOP-0010 v.6 (Jan. 2023))"; "Ethics & Compliance Investigations (CC-SOP-000007 v.4 (Nov. 2022)"; "Producing Incident Reports (CC-SOP-000025 v.2 (Mar. 2023)"; and "Convercent Incident Report Management (CC-WPD-000033 v.2 (Mar. 2023))".

92. The Operations SOP details that the Helpline "has been established to provide a confidential process for reporting ethics concerns and known or potential violations of laws, regulations, the Voluntary Injunction under which the Company is operating, and/or Company policies or procedures…." It makes clear the Helpline is available to both Company employees and individuals outside the Company, and that the Helpline is but one avenue to report concerns. Other avenues for employees include "reporting directly to their supervisor, another supervisor, a member of Human Resources, Law, Corporate Security or Ethics & Compliance, or internal reporting mechanisms such as SMS/text reporting and the Ethics & Compliance Portal."

93. During this reporting period, the Company provided the Monitor with a listing of all contacts with the Integrity Helpline and suspected violations of law or policy from November 2021 to April 2023. The undersigned also reviewed the relevant SOPs and interviewed the Chief Compliance Officer and Vice President, Legal Strategy and Public Health Initiatives.

94. There were 60 "incidents" from November 2021 to April 2023, defined in the WPD as "a matter, investigation, question or concern that was raised to Ethics & Compliance for handling." Thirty-one of the incidents originated from the Integrity Helpline call center, one by text message, and 28 were created by proxy, meaning that it was entered by a member of Ethics & Compliance. Only 20 of the 60 entries were related to Opioids, and many of those were only tangentially related, dealing with matters such as seeking payment assistance or information about the litigation and settlement.

95. The Working Practices Document requires that all incidents must include the following: description of the incident; who was involved; company location; date of occurrence; all relevant documents (photos, emails, etc.); and information about the reporting party.

96. Nineteen of the reports were substantiated, meaning that the matter raised was confirmed through the review; substantiated incidents relating to Opioids, of which there were six, included matters like an employee inquiring whether a family relation could cause a conflict of interest, and an order that had been rejected by the SOM Team being inadvertently shipped to a customer. Fourteen incidents were inquiries, three of which related to Opioids, ranging from calls about product pricing and copayments. Twenty-two had undetermined substantiation, 11 of which related to Opioids, defined in the WPD as "matters that are referred to other departments for handling," and include matters like Product Complaints and questions about the litigation against the Company. There were no incidents relating to Opioids that were unsubstantiated, meaning that the incident was not confirmed through the investigation to be either accurately reported or of concern.

97. There are minor matters, such as inquiries to the Ethics & Compliance Department as to where to find a specific policy, that would not be entered on the list as a proxy.

98. The Ethics & Compliance member that enters the information ranks the severity of the incident as high, medium, or low. Most incidents were ranked as low, and no incidents were ranked as high severity. The Chief Compliance Officer noted that the matter would have to be a something like a threat to person, product, or property to be ranked high, and that has only happened five or six times in her career.

99. The database captures the number of days the review or investigation is open. Incidents passed on to another department often will be closed in a matter of days. Significant investigations can be open 100 days or longer. The undersigned does not view the lack of a required time frame as a shortcoming or limitation in process. Given that incidents coming through the Helpline or entered by proxy can be vary in content and complexity, and the reviews are often also dependent upon getting information from other Company departments or third parties, it is unsurprising that matters can be open for varying amounts of time.

100. The Incident Report database is maintained by a member of the Ethics & Compliance Department, and CC-SOP-000025 provides that the Chief Compliance Officer meets with the members of the Department on a quarterly basis to review the Report and all matters opened in the prior quarter and that remain open from earlier quarters. The SOP also provides that Department members will review the Incident Report or conduct a live review of incidents not yet closed during periodic Ethics & Compliance Department Team Meetings.

101. The undersigned asked the Chief Compliance Officer about several of the individual entries on the Incident Report, and was satisfied and impressed with her substantive responses, and command of the level of detail that went into investigations of the Incidents.

102. In reviewing the materials and discussing Company practices with the Chief Compliance Officer, the Monitor finds them consistent with the Injunction, and is impressed

with the systems in place to capture, investigate and resolve matters raised to the Ethics & Compliance Department and alleged violations of law, regulation, Company policy or the Injunction.

103. **Going forward, the Monitor recommends that the Company provide the undersigned with the Incident Report database on a quarterly basis. The Company has agreed to this recommendation.**

E. Climate Survey

104. In the Fourteenth Report, the Monitor requested that the Company provide a proposed climate survey of employees regarding the corporate culture surrounding compliance and the reporting of concerns to the undersigned prior to disseminating, as well as share the results of that survey. (Fourteenth Report, Paragraph 63.)

105. The Company provided the Monitor with a draft of the proposed anonymous climate survey and attendant materials, and afforded opportunity for input. The survey had 33 questions, covering areas including: the employee's awareness of ethics-related polices and the Injunction; whether the employee has been provided sufficient resources to perform their job in an ethical and complaint manner; adequacy of training; belief in whether reports of unethical or illegal behavior are taken seriously; whether the employee had reported actions considered to be unethical or illegal, or been asked by someone senior to take action the employee considered to be unethical or contrary to state policies; whether peers, managers and the Executive Committee act in accordance with the Company's ethics and compliance policies; whether Company employees who demonstrate a commitment to high ethical standards of behavior are valued and are recognized, whether employees who act in an unethical manner will face negative consequences; and comfort in reporting unethical or illegal behavior without fear of retaliation.

106. The Ethics & Compliance Department sent out several notices requesting employees complete the anonymous survey and asked Executive Committee members to encourage employees within their reporting structure to do the same. In total, 47% of Company employees completed the survey, a response rate that, according to the Chief Compliance Officer, is approximately four times greater than most surveys sent to Company employees.

107. The results of the survey indicated that 100% of the Company respondent employees reported that their ethics and compliance responsibilities had been clearly communicated to the employee, 98% knew where to find the Company's Code of Ethics and the Healthcare Law Compliance Policy, and outside of annual training, almost 20% of the respondents had reason to refer to these policies over the last year. Additionally, approximately 98% of respondents reported knowing where or who to go to address the concern if the respondent observed unacceptable behavior on the job.

108. Questions were also included about the Injunction, and the respondents were asked to reply on a scale of one through ten. Seventy-two percent ranked as a 10 out of 10 understanding how the terms of the Injunction apply to their role in the Company, with an overall average ranking of 9.5 out of 10.

109. Sixty-four percent of responding employees ranked as a 10 out of 10 that reported matters will be handled discreetly and without fear of retaliation, and 56% ranked as a 10 out of 10 that the Company employees who demonstrate a commitment to high ethical standards are valued and are recognized; in aggregate, the average rankings were 9.1/10 and 8.7/10 for these questions, respectively. Only three percent of responding employees stated that they have been made aware in the last year that someone else in the Company has been asked by

someone senior to them to take action that would be considered unethical or contrary to stated policies.

110. Many of the questions also provided respondents the opportunity to provide feedback or freeform comments in response to questions. In reviewing those responses, an insufficient number of the respondent employees provided additional comments for the undersigned to offer any meaningful conclusions.

111. In sum, the aggregate numbers are highly encouraging, suggesting that employees are aware of the policies relating to ethics and compliance, follow them, and believe that the Company not only takes such concerns seriously, but also values the commitment of employees to do so.

112. The undersigned commends the Company for undertaking such a comprehensive climate survey, as well as for the efforts of the Chief Compliance Officer and Executive Committee in encouraging employees to respond.

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VIII. INITIAL COVERED SACKLER PERSONS

113. The undersigned has requested but not yet received all 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. Upon receipt, the Monitor will supplement this Report if any issues arise.

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

STEPHEN C. BULLOCK
Monitor