

## **SETTLEMENT AGREEMENT**

### **I. PARTIES**

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS); the Defense Health Agency (DHA), acting on behalf of the TRICARE Program; the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP); and the Indian Health Service (IHS) (collectively, the “United States”); and Purdue Pharma L.P. (“Purdue” and, with the United States, “the Parties”), through their authorized representatives.

### **II. RECITALS**

A. Purdue is a Delaware limited partnership that is headquartered in Stamford, Connecticut.

B. At all relevant times, Purdue, directly or through its subsidiaries, manufactured, marketed, and sold pharmaceutical products in the United States, including OxyContin, Butrans, and Hysingla.

C. OxyContin is a branded, extended-release oxycodone tablet that was reformulated with abuse-deterrent properties in 2010. Oxycodone is an opioid agonist 1.5 times more powerful than morphine with a high potential for addiction, abuse, and misuse. OxyContin is approved by HHS’s Food and Drug Administration (FDA) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. It is classified as a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

D. Hysingla is a branded, extended-release hydrocodone tablet that is formulated with abuse-deterrent properties. Hydrocodone is an opioid agonist as powerful as morphine that exposes users to the risks of addiction, abuse, and misuse. Hysingla is FDA approved for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. It is classified as a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

E. Butrans is a branded buprenorphine patch. Buprenorphine is an opioid partial agonist 12.6 times more powerful than morphine that exposes users to the risks of addiction, abuse, and misuse. Butrans is FDA approved for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. It is classified as a Schedule III narcotic under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

F. On September 15 and 16, 2019, Purdue and twenty-two affiliated entities (collectively, the “Debtors”) each filed a voluntary petition under Chapter 11 of Title 11 of the United States Code (the “Bankruptcy Code”) in the United States Bankruptcy Court for the Southern District of New York (the “Bankruptcy Court”). The Debtors are operating their businesses and managing their properties as debtors in possession pursuant to section 1107(a) and 1108 of the Bankruptcy Code. On September 18, 2019, the Bankruptcy Court entered an order authorizing the joint administration and procedural consolidation of the Debtors’ chapter 11 cases (the “Chapter 11 Cases”) pursuant to Rule 1015(b) for the Federal Rules of Bankruptcy Procedure under the case captioned *In re Purdue Pharma L.P., et al.*, No. 19-23649 (Bankr. S.D.N.Y.) (Jointly Administered).<sup>1</sup>

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<sup>1</sup> 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

G. On July 30, 2020, the United States Department of Justice submitted claim 137848 in the bankruptcy of Purdue on behalf of HHS, DHA, and OPM alleging that, from 2010 to 2018, Purdue knowingly caused false, medically unnecessary claims to be submitted to federal health care programs for Purdue's opioid drugs; from 2008 to 2018, Purdue transferred billions of dollars in distributions and assets to its owners, the Sackler family and their holding companies and trusts, some of which is recoverable as fraudulent transfers; and Purdue's misconduct gives rise to criminal liability and forfeiture of proceeds traceable to Purdue's crimes.

H. On such date as may be determined by the U.S. District Court for the District of New Jersey, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, Purdue will plead guilty to a three-count Information to be filed by the United States in *United States v. Purdue Pharma L.P.*, Criminal Action No. [to be determined] (D.N.J.) that will allege violations of 18 U.S.C. § 371 for: (1) a dual-object conspiracy to defraud the United States and to violate the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331, 353; (2) a conspiracy to violate the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), related to Purdue's payments to health care providers; and (3) a conspiracy to violate the AKS related to Purdue's payments to Practice Fusion, a cloud-based electronic health records platform (hereinafter the "Criminal Action").

I. The United States contends that Purdue, directly or through its subsidiaries, caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"); the Medicaid Program, 42 U.S.C.

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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 Bio Ventures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014).

§§ 1396-1396w-5 (“Medicaid”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); and the FEHBP, 5 U.S.C. §§ 8901-8914; and caused purchases of OxyContin by the IHS on behalf of its federally operated programs, *i.e.*, programs not operated by a tribal health program or an Urban Indian organization, as those terms are defined in the Indian Health Care Improvement Act, 25 U.S.C. § 1603(25), (29) (collectively, the “Federal Healthcare Programs”).

J. The United States contends that it has certain civil claims against the Debtors, as specified in Paragraph III.3 below, for engaging in the conduct set forth in Addendum A from 2010 to 2018. As a result of the conduct set forth in Addendum A, the United States alleges that Debtors knowingly caused false and/or fraudulent claims for OxyContin, Butrans, and Hysingla to be submitted to the Federal Healthcare Programs (hereinafter the “Covered Conduct”).

K. This Agreement is neither an admission of liability by Purdue nor a concession by the United States that its claims are not well founded. Purdue denies that it engaged in the Covered Conduct, with the exception of such admissions that are made in connection with any guilty plea by Purdue in connection with the Criminal Action.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

### **III. TERMS AND CONDITIONS**

1. The Debtors agree that the United States shall have an allowed, unsubordinated, general unsecured claim in the Chapter 11 Cases in the amount of Two Billion Eight Hundred Million Dollars (\$2,800,000,000) (the “Settlement Claim”). Payment on account of the Settlement Claim shall be made as provided for in a Plan of Reorganization as defined in Paragraph 2, or, in the event of liquidation, in accordance with any order of liquidation approved

by the Bankruptcy Court. In either event, only the amount actually paid to the United States shall constitute restitution under this Agreement.

2. Debtors shall propose and obtain confirmation of a plan that (i) provides for a cash distribution on account of the Settlement Claim as soon as reasonably practicable after the effective date of the Plan of Reorganization; (ii) does not provide the United States with an equity stake in the reorganized company or any other structure that emerges from the bankruptcy; (iii) provides that payment shall be made into accounts set forth in the instructions provided to Debtors by the Civil Division of the Department of Justice; (iv) places the Settlement Claim in its own class under the Plan of Reorganization; and (v) provides fair and equitable treatment to the United States and does not unfairly discriminate against the United States (“Plan of Reorganization”).

3. Subject to the exceptions in Paragraph III.7 (concerning excluded claims) below, and conditioned on Paragraphs III.1, 2 and 8 (concerning treatment of claims in the Chapter 11 Cases) below, the United States releases the Debtors from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; the Controlled Substances Act, 21 U.S.C. § 801 et seq.; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, fraud, nuisance, or negligent entrustment. For the avoidance of doubt, this Paragraph III.3 does not release any claims the United States may have against any individual, including without limitation, the Debtors’ current or former owners, shareholders or members of their Boards of Directors. Nothing in this Agreement releases any claims the Debtors’ estates have the ability to bring against any individuals or non-debtor entities, including without limitation, the Debtors’ current or former owners, shareholders

or members of their Boards of Directors, including without limitation fraudulent transfer claims and any other claims that could be brought by the Debtors' estates standing in the shoes of any creditors in the Chapter 11 Cases.

4. Purdue understands and acknowledges that as a result of the guilty plea described in Paragraph H of the Preamble above, it will be excluded pursuant to 42 U.S.C. 1320a-7(a)(1) from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion shall have national effect and, pursuant to 42 U.S.C. § 1320a-7(i), shall be effective after a judgment of conviction has been entered or a guilty plea has been accepted by a Federal, state, or local court. After Purdue is excluded, Federal health care programs shall not pay anyone for items or services, including administrative and management services, furnished, ordered, or prescribed by Purdue in any capacity.

5. DHA expressly reserves all rights to institute, direct, or maintain any administrative action seeking exclusion against the Debtors from TRICARE under 32 C.F.R. § 199.9(f) (mandatory and permissive exclusions).

6. OPM expressly reserves all rights to institute, direct, or maintain any administrative action seeking debarment against the Debtors from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment).

7. Notwithstanding the release given in Paragraph III.3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of any individuals, including but not limited to, present and former owners, shareholders, officers, directors, employees, trustees, and agents of Debtors;
- g. Any liability of any entities other than the Debtors, including consultants, contractors, and Sackler family trusts, trustees, trust protectors, and affiliated entities;
- h. Any liability of non-Debtor individuals, assets, or entities for any claims that could have been or may be brought by, or on behalf of, the Debtors to recover funds or assets transferred from the Debtors;
- i. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- j. Any liability for failure to deliver goods or services due;
- k. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
- l. Any liability for claims 137406, 138509, 137782, 138522, and 137798 filed in the Chapter 11 Cases by the U.S. Department of Justice, U.S. Department of Health and Human Services and the U.S. Department of Veterans Affairs, and no setoff related to amounts paid under this Agreement shall be applied to any claim, action, or recovery in connection with such claims;
- m. Any liability for claims of the states or Indian tribes, and no setoff related to amounts paid under this Agreement to the United States shall be applied to any

recovery in connection with any claim, action, or recovery by the states or Indian tribes;

n. For avoidance of doubt, the United States, except as expressly contemplated by this settlement, retains all rights to recover, pursuant to 42 U.S.C. 1396b(d), the federal share of funds that have been or could be recovered by other entities; and

o. Any liability for the claims or conduct alleged in the following actions:

1. *United States ex rel. Manchester v. Purdue Pharma, L.P., et al.*, No. 1:16-cv-10947 (D. Mass.); and

2. *United States ex rel. [SEALED] v. [SEALED]* (D. Vt.).

No setoff related to amounts paid under this Agreement shall be applied to a recovery, if any, in connection with these actions.

8. In connection with the Chapter 11 Cases, the United States and Debtors agree:

a. The Debtors shall file a motion under Federal Rule of Bankruptcy Procedure 9019 (the “9019 Motion”) no later than 7 business days from the date this Agreement is executed, seeking approval of this Agreement. Before filing such motion and proposed order, Debtors shall obtain the United States’ consent as to form, and the United States and the Debtors acknowledge that this time period may be extended by mutual agreement.

b. The proposed order in respect of the 9019 Motion shall provide that the Settlement Claim shall not be subordinated, disallowed, or reconsidered in these Chapter 11 Cases, including based on 11 U.S.C. §§ 510, 726(a)(4) or for any other reason.

c. The Debtors will not seek releases or exculpation regarding any claims belonging to and currently controlled by the United States against any individuals or non-debtor entities.



d. This Agreement shall not preclude, impair, waive or affect the United States' right to receive, in respect of the Settlement Claim or any other claims filed in the Chapter 11 Cases, its appropriate share under the Plan of Reorganization of any recovery resulting from any actions by the estates in these Chapter 11 Cases or on behalf of the estates that seek to recover assets for the estates, including but not limited to any fraudulent transfer action pursued by the Debtors, or any trustee, person or entity on behalf of the Debtors, against the Debtors' former or current owners, shareholders or any other person, asset or entity.

e. The Debtors will not propose a Plan of Reorganization or liquidation that is inconsistent with this Agreement.

f. If the Bankruptcy Court does not confirm a Plan of Reorganization in the Chapter 11 Cases that provides for the emergence from the Chapter 11 Cases of a public benefit company (or entity with a similar mission), Purdue and the United States each have the option to rescind this Agreement.

g. The United States reserves the right to object to any proposed Plan of Reorganization for any reason not covered by this Agreement.

9. Nothing in this Agreement exempts the United States from or otherwise grants any relief under the bar date order, to the extent applicable, entered in the Chapter 11 Cases on February 3, 2020 and amended on June 3, 2020 with respect to the Debtors.

10. If Purdue defaults on any material obligation under this Agreement; if a Plan of Reorganization consistent with the terms of this Agreement is not confirmed; in the event of dismissal or conversion of the Chapter 11 Cases, voluntary or otherwise; or in the event Debtors' obligations under this Agreement are voided for any reason, the United States may elect, in its sole discretion: (a) to rescind the releases in this Agreement and bring any civil and/or

administrative claim, action, or proceeding against Debtors for the claims that would otherwise be covered by the release provided in Paragraph III.3 above or (b) to have an undisputed, noncontingent, and liquidated, allowed unsecured claim against Debtors for the full amount of the United States' claim 137848 filed in the Chapter 11 Cases. With respect to (a) and (b) in this Paragraph, the United States fully reserves any and all setoff and recoupment rights, claims, and defenses as to the Debtors that the United States may have, and the United States may pursue its claims in the Chapter 11 Cases as well as in any other case, action, or proceeding.

11. If Purdue exercises the option of rescission pursuant to Paragraphs III.8.g of this Agreement or the United States exercises the option of rescission pursuant to any Paragraph of this Agreement, the Agreement will be rescinded except for Paragraphs III.8, 10, 11, 12, 14, and 23. If this Agreement is rescinded for any reason, Debtors will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings that are brought by the United States within 180 calendar days of written notification that the releases have been rescinded, except to the extent such defenses were available on July 18, 2018.

12. In the event of a default by Debtors of any material obligation under this Agreement or rescission of this Agreement, Purdue will agree and stipulate that the automatic stay under 11 U.S.C. § 362(a) does not apply to the United States' claims, actions, or proceedings in connection with the Covered Conduct and, to the extent necessary, will consent to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Purdue further agrees that it will not seek to enjoin the United States' claims, actions, or proceedings pursuant to 11 U.S.C. § 105 or any other bankruptcy authority.

13. The agreed treatment of the Settlement Claim set forth in this Agreement represents the amount the United States is willing to accept in compromise of its civil claims

arising from the Covered Conduct (pursuant to and as set forth more expressly in the terms of this Agreement) due solely to the Debtors' financial condition.

14. The Debtors waive and shall not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

15. The Debtors fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that the Debtors have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution.

16. The Settlement Claim shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Federal Healthcare Program or any state payer related to the Covered Conduct; and Purdue agrees not to resubmit to any Federal Healthcare Program or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

17. The Debtors agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program

directives promulgated thereunder) incurred by or on behalf of the Debtors, their present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) the Debtors' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment the Debtors make to the United States pursuant to this Agreement or the Plan of Reorganization.

are unallowable costs for government contracting purposes and under the Federal Healthcare Programs (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the Debtors, and the Debtors shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by the Debtors or any of its subsidiaries or affiliates to the Federal Healthcare Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: The Debtors further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph)

included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the Debtors or any of their current subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. The Debtors agree that the United States, at a minimum, shall be entitled to recoup from the Debtors any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by the Debtors or any of their current subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the Debtors or any of their current subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine the Debtors' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

18. The Debtors agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, the Debtors shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. The Debtors further agree to furnish to the United

States, upon reasonable request, complete, and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf. For the avoidance of doubt, the Debtors' cooperation is a material condition of this Agreement. The United States will determine in its sole discretion whether information it seeks from the Debtors as part of the Debtors' cooperation is relevant to the United States' investigations. Notwithstanding any provision of this Agreement, (1) the Debtors are not required to request of their current or former officers, agents, or employees that they forgo seeking the advice of an attorney or that they act contrary to that advice; (2) the Debtors are not required to take any action against their officers, agents, or employees for following their attorney's advice; and (3) the Debtors are not required to waive or furnish to the United States any materials subject to any privilege or claim of work product protection, except to the extent stated in an agreement between Purdue and the United States dated June 18, 2019, to the extent such content is privileged, if at all, or to the extent any other waiver, voluntary or otherwise, occurred prior to the date of this Agreement.

19. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph III.20 (waiver for beneficiaries paragraph), below.

20. The Debtors agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

21. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

22. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

23. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey, provided that disputes regarding the implementation of those provisions of this Agreement related to the Chapter 11 Cases may also be heard by the Bankruptcy Court. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

24. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

25. The undersigned counsel for the United States represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below. The undersigned representative of Purdue certifies that he is the Chairman of the Board of Directors of Purdue Pharma Inc., the general partner of Purdue, and that he has been duly authorized by the Board of Directors of the general partner of Purdue to execute this Agreement on behalf of Purdue.

26. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

27. This Agreement is binding on Purdue's successors, transferees, heirs, and assigns, including any reorganized debtor, in any and all forms, or trustee appointed in these Chapter 11 Cases or under a confirmed plan.

28. Purdue consents to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

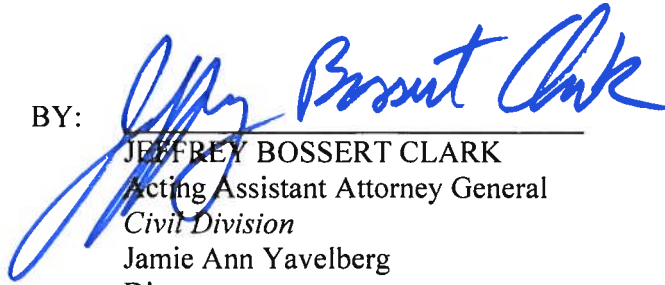
29. This Agreement is effective on the date that the Bankruptcy Court approves the 9019 Motion (Effective Date). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.



THE UNITED STATES OF AMERICA

DATED: 10/21/20

BY:



JEFFREY BOSSERT CLARK  
Acting Assistant Attorney General  
*Civil Division*  
Jamie Ann Yavelberg  
Director  
Natalie A. Waites  
Edward Crooke  
Alicia J. Bentley  
Kelley Hauser  
Christelle Klovers  
Albert P. Mayer  
Kristen M. Murphy  
Claire L. Norsetter  
Attorneys  
*Commercial Litigation Branch*  
*Civil Division*  
*United States Department of Justice*

DATED: \_\_\_\_\_

BY:



RACHAEL HONIG  
Attorney for the United States  
Acting Under Authority Conferred by  
28 U.S.C. § 515  
Nicole F. Mastropieri  
Marihug P. Cedeño  
Assistant United States Attorneys  
*District of New Jersey*

DATED: \_\_\_\_\_

BY:

CHRISTINA E. NOLAN  
United States Attorney  
Owen C.J. Foster  
Assistant United States Attorney  
*District of Vermont*

THE UNITED STATES OF AMERICA

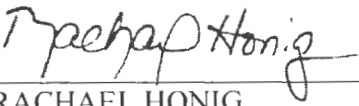
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BY: \_\_\_\_\_

JEFFREY BOSSERT CLARK  
Acting Assistant Attorney General  
*Civil Division*  
Jamie Ann Yavelberg  
Director  
Natalie A. Waites  
Edward Crooke  
Alicia J. Bentley  
Kelley Hauser  
Christelle Klovers  
Albert P. Mayer  
Kristen M. Murphy  
Claire L. Norsetter  
Attorneys  
*Commercial Litigation Branch*  
*Civil Division*  
*United States Department of Justice*


DATED: \_\_\_\_\_

BY: \_\_\_\_\_

  
RACHAEL HONIG  
Attorney for the United States  
Acting Under Authority Conferred by  
28 U.S.C. § 515  
Nicole F. Mastropieri  
Marihug P. Cedeño  
Assistant United States Attorneys  
*District of New Jersey*

DATED: 10/21/20

BY: \_\_\_\_\_

  
CHRISTINA E. NOLAN  
United States Attorney  
Owen C.J. Foster  
Assistant United States Attorney  
*District of Vermont*

DATED: 10/21/2020

BY: Lisa M. Re

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

SALVATORE M. MAIDA  
General Counsel  
Defense Health Agency  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

EDWARD M. DEHARDE  
Assistant Director of Federal Employee  
Insurance Operations  
Healthcare and Insurance  
United States Office of Personnel Management

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DATED: 10/21/2020

BY: /s/ Salvatore M. Maida

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for  
SALVATORE M. MAIDA  
General Counsel  
Defense Health Agency  
United States Department of Defense

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

EDWARD M. DEHARDE  
Assistant Director of Federal Employee  
Insurance Operations  
Healthcare and Insurance  
United States Office of Personnel Management

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

SALVATORE M. MAIDA  
General Counsel  
Defense Health Agency  
United States Department of Defense

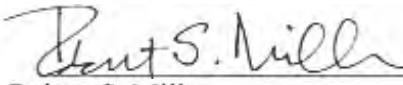
DATED: 10/21/2020

BY:  \_\_\_\_\_

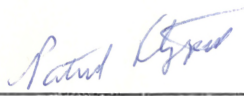
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**Purdue Pharma L.P.**


DATED: 10/20/2020

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DATED: 10/20/2020

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## **Addendum A**

## ADDENDUM A TO SETTLEMENT AGREEMENT

### I. Introduction

1. Purdue Pharma L.P.'s ("Purdue") profits declined precipitously in 2010 after the introduction of its Reformulated OxyContin, which was intended to be more difficult (though not impossible) to crush or manipulate for purposes of abuse and misuse.

2. Purdue attributed the majority of the decline to two trends: (i) individuals abusing opioids moving from OxyContin to opioids that were easier to abuse through insufflation or injection and (ii) increased scrutiny of prescribers, pharmacists, and other actors in the opioid distribution chain.

3. Purdue sought to recapture lost sales and increase Purdue's share of the opioid market.

4. As a result, from 2010 through approximately February 2018, Purdue developed and implemented several strategies to ensure that the revenues generated from its opioid prescriptions, including those that Purdue knew or should have known were not medically necessary, would continue to flow to Purdue.

5. At the center of these strategies was Purdue's aggressive marketing program that focused on detailing over 100,000 doctors and nurse practitioners nationwide each year, including thousands of prescribers that Purdue knew or should have known were prescribing opioids for uses many of which were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and/or were diverted for uses that lacked a legitimate medical purpose. By 2013, Purdue intensified its detailing of the very highest-volume prescribers, *i.e.*, those writing "25 times as many OxyContin scripts" as their similarly situated peers, because it knew that its detailing was highly effective in causing these prescribers to write



more prescriptions for Purdue's opioids. This strategy was referred to as the "Evolve to Excellence" or "E2E" program.

6. Purdue also rewarded and induced prescriptions from some of its most lucrative prescribers by paying kickbacks through its Key Opinion Leader corporate advisor and speaker programs. Indeed, some of the prescribers whom Purdue paid through these programs were poor speakers, showed indicia of abuse and diversion, or, in at least one case, requested an express *quid pro quo* from Purdue employees.

7. Increasingly concerned that pharmacies would not fill OxyContin prescriptions as pharmacies and regulators increased safeguards against the filling of medically unnecessary prescriptions, Purdue developed and implemented a strategy to detail the pharmacies of its highest volume prescribers, including those that Purdue knew were writing medically unnecessary prescriptions, to ensure that Purdue opioids would be dispensed. Further, after Purdue determined that a large number of its prescriptions were still being rejected, Purdue considered an "alternative distribution strategy" and later developed a program focused on Hysingla through which it paid kickbacks to three specialty pharmacies to dispense prescriptions for Purdue's opioids that traditional pharmacies refused to fill.

8. Finally, from April 2016 through December 2016, Purdue paid kickbacks to Practice Fusion, an electronic health records company ("EHR"), to induce it to recommend and arrange for prescriptions of opioids by creating alerts that would appear within Practice Fusion's software while providers were seeing patients. Purdue did so with the intent that these alerts would cause more prescriptions for extended release opioids like those manufactured and sold by Purdue.

9. Through its marketing and kickbacks, from 2010 through 2018, Purdue knowingly caused the submission of false and fraudulent claims to Federal healthcare programs for its opioid drugs that were: (1) prescribed for uses that were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and that were often diverted for uses that lacked a legitimate medical purpose; or (2) tainted by illegal kickbacks.

## **II. Prior Resolution**

10. In 2007, The Purdue Frederick Company, Inc. (“Purdue Frederick”), an affiliate of Purdue, pled guilty to misbranding OxyContin by falsely marketing it as less addictive, less subject to abuse and diversion, and less likely to cause dependence and withdrawal than other pain medications. Purdue and Purdue Frederick also agreed to pay more than \$600 million, of which over \$100 million was paid to settle civil False Claims Act liability for knowingly causing the submission of false claims to Federal healthcare programs for OxyContin. In conjunction with the resolution, Purdue entered into a five-year Corporate Integrity Agreement with the Department of Health and Human Services, Office of Inspector General (OIG-HHS). OIG-HHS closed the corporate integrity agreement in January 2013.

## **III. Organization of Purdue Pharma**

11. Purdue Pharma L.P. carries on operations, including distributing and selling the extended-release opioid drugs OxyContin, Butrans, and Hysingla. Prior to February 2018, it employed a sales force of, at times, over five hundred representatives to market its opioid drugs.

12. Purdue was owned (through trusts) and controlled by members of the Sackler family. Several members of the Sackler family served on the Board of Directors of Purdue

Pharma Inc., which oversaw Purdue and certain related companies during the relevant time period.<sup>1</sup>

13. The Sacklers, as members of the Purdue Board, exercised substantial oversight over management's operations of Purdue. For instance, in February of 2011, a memorandum observed: "There seems to be a consensus that the role of the board and that of the management is blurred compared with the distinctions made by other major corporations," and, historically, certain members of Sackler family functioned as "executives, management, board, and shareholders all-in-one [and] worked collaboratively with other managers on a daily basis."

14. As late as 2017, a high-level Purdue executive commented: "Three distinct business types (branded Rx [including Purdue]/biosimilars, consumer/OTC, generics) are being run through four separate regions (five if Rhodes is included), with the Board of Directors serving as the 'de-facto' CEO."

#### **IV. The Opioid Drugs Purdue Manufactured, Marketed, Promoted, and Sold**

##### **A. *OxyContin***

15. Oxycodone is an opioid agonist with a morphine milligram equivalent ("MME") of 1.5 and a high potential for abuse similar to other opioids including fentanyl, hydromorphone, methadone, morphine, and oxymorphone.

16. It is classified as a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* ("CSA").

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<sup>1</sup> The following reflects the tenures of the Sackler family members on the Purdue Pharma Inc. Board of Directors: Richard S. Sackler (10/2/1990 – 7/24/2018); Jonathan D. Sackler (10/2/1990 – 12/8/2018); David A. Sackler (7/19/2012 – 8/14/2018); Kathe A. Sackler (10/2/1990 – 9/27/2018); Mortimer D.A. Sackler (1/15/1993 – 1/16/2019); Theresa E. Sackler (1/15/1993 – 9/7/2018); Ilene Sackler Lefcourt (10/2/1990 2/4/2005; 5/16/2008 – 10/9/2018); and Beverly Sackler (approximately 1993 –10/2017).

17. Purdue manufactured, marketed, promoted, sold, and distributed OxyContin, an extended-release oxycodone tablet, nationwide, including by sending sales representatives to prescribers' offices and pharmacies, to persuade healthcare providers to prescribe and pharmacists to dispense OxyContin.

18. In April 2010, Purdue received FDA approval to market a reformulated version of OxyContin.

19. Reformulated OxyContin was more difficult to crush or dissolve, but FDA cautioned that Reformulated OxyContin "is not completely tamper-resistant and those intent on abusing this new formulation will likely find a means to do so. In addition, the product can still be misused or abused and result in overdose by simply administering or ingesting larger than recommended oral doses."

20. In August 2010, Purdue discontinued the original version of OxyContin.

**B. *Butrans***

21. Buprenorphine is an opioid partial agonist with an MME of 12.6 that exposes users to the risks of addiction, abuse, and misuse. It is classified as a Schedule III narcotic under the CSA.

22. In June 2010, Purdue received FDA approval to market Butrans, a buprenorphine patch, and began manufacturing, marketing, promoting, and selling Butrans nationwide.

**C. *Hysingla***

23. Hydrocodone is an opioid agonist with an MME of 1.0 that exposes users to the risks of addiction, abuse, and misuse. It is classified as a Schedule II narcotic under the CSA.

24. In November 2014, Purdue received FDA approval to market Hysingla, an extended-release hydrocodone tablet, which is formulated with abuse-deterrent properties, and began manufacturing, marketing, promoting, and selling Hysingla nationwide.

V. **Purdue Knowingly Caused Medically Unnecessary Prescriptions to be Submitted to Federal Healthcare Programs**

25. From 2010 to February 2018, Purdue engaged in strategies that resulted in prescriptions of its drugs for uses that were not for a medically accepted indication, were unsafe, ineffective, and medically unnecessary, and that were diverted for uses that lacked a legitimate medical purpose. Such prescriptions are not reimbursable by Federal healthcare programs.

26. The paragraphs below describe the fraudulent scheme to cause extreme high-volume prescribers to write medically unnecessary OxyContin prescriptions for Federal healthcare program beneficiaries.

A. ***“Calling On” and “Detailing” Prescribers Causes Them to Write More Prescriptions***

27. Until it stopped marketing opioids in February 2018, Purdue sought to increase and maintain opioid sales by sending sales representatives to prescribers’ offices and pharmacies to meet with prescribers in person; deliver company-developed messaging; give the prescribers meals (such as coffee, breakfast, and lunch) and marketing materials (such as articles, brochures, posters, and other media); and provide information about pharmacies stocking Purdue opioids and prescription coverage, including coverage under Federal healthcare benefit programs.

28. This practice is known in the pharmaceutical industry as “calling on” or “detailing” healthcare providers and pharmacies.

29. Purdue knew that calling on or detailing healthcare providers and pharmacies caused them to prescribe and dispense, respectively, more of Purdue’s opioid drugs.

30. In September 2010, at a presentation to Purdue's sales supervisors, a Purdue executive explained: "As I have stated several times, we know increases in the prescriber call average will have the single largest impact of anything you can do to increase prescriptions of Purdue products with our core and super core prescribers."

31. Additionally, presentations related to E2E recognized: "Increased calls have a significant impact on OxyContin TRx."

32. Likewise, Purdue prepared return-on-investment analyses comparing the cost of detailing as compared to the OxyContin prescriptions that would not have been written but for Purdue's in-person marketing, as well as "sensitivity" analyses showing the impact of Purdue's detailing on OxyContin prescribing.

**B. *The Sales Revenue Purdue Calculated from Federal Healthcare Programs***

33. Purdue knew that Federal healthcare programs paid claims for Purdue's opioid drugs, including OxyContin, and those payments accounted for a significant percentage of Purdue's revenue.

34. For example, an April 11, 2012, budget presentation to Purdue's Board of Directors showed that certain Federal healthcare programs accounted for over 30% of Purdue's revenue from sales of OxyContin.

35. Additionally, Purdue developed messaging and marketing materials associated with prescription coverage for OxyContin, including Federal healthcare program coverage, to induce prescribers to write OxyContin prescriptions for Federal healthcare program beneficiaries.

36. Purdue knew that it was reasonably foreseeable that its promotional activities for its drugs were a substantial factor in claims being submitted to Federal healthcare programs.

**C. *Purdue's Marketing of OxyContin After Reformulation.***

37. Shortly after the introduction of Reformulated OxyContin, Purdue's profits declined, in large part, because some individuals who abused OxyContin moved to more easily manipulated opioids.

38. Purdue executives closely analyzed Purdue's internal data, including data purchased from vendors, in order to target high-volume prescribers and monitor their prescriptions.

39. Purdue ranked the prescribers based on their aggregate opioid prescriptions in deciles from numbers 1 through 10, with 10 being the highest.

40. From 2010 to 2013, Purdue instructed its sales force to primarily focus on the top three deciles of prescribers.

41. The purpose of focusing the sales force on these highest deciles of prescribers was to cause an even higher volume of prescriptions to be written by them.

42. Purdue knew, at that time, that the three highest deciles of prescribers combined accounted for only 1.5% of all opioid prescribers nationwide, but wrote 80% of all OxyContin prescriptions nationwide. Purdue also knew that these prescribers were the most responsive to Purdue's detailing.

43. Specifically, in June 2010, Purdue executives discussed instructing sales representatives to "build their target list with a focus on the highest prescribers across all three categories (Tier 1), and then fill in target list with the next highest potential and keep in front of OER [opioid extended release] high prescribers." They estimated that "the top three deciles drive closer to 80% of all Rx's."

44. An October 6, 2013 update to Purdue’s 2013 annual marketing plan included a graphic, showing the breakdowns of the deciles.

▪ **Prescribers**

In 2012: 209,066 healthcare providers (HCP) wrote at least one prescription for OxyContin.  
 For the first 6 months of 2013: 165,137 HCPs wrote at least one prescription for OxyContin.

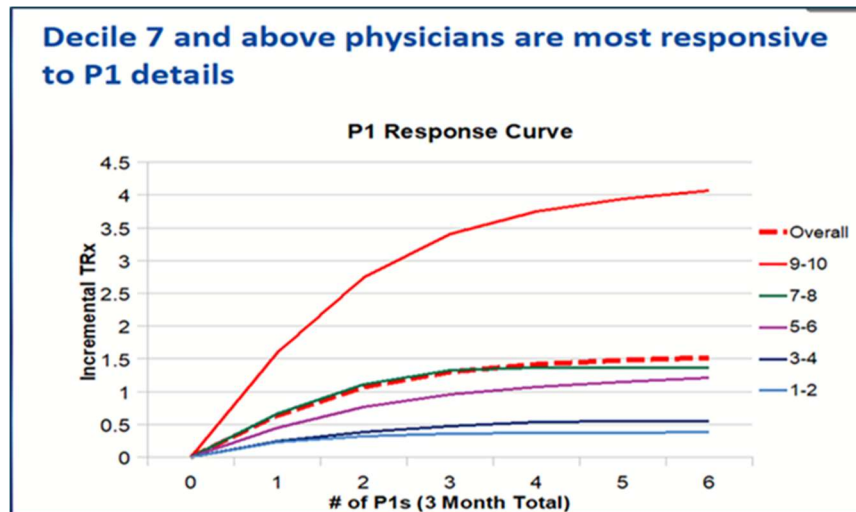
**January – July 2013 Prescribers**

TRx Decile	# Physicians	% Physicians	# Rx	Mean Rx / Physician/Month
10	358	0.2%	617,887	246.6
9	778	0.5%	617,624	113.4
8	1,500	0.8%	617,149	67.8
7	2,182	1.4%	617,248	40.4
6	3,613	2.3%	617,056	24.4
5	5,668	3.5%	617,075	15.6
4	8,668	5.4%	617,056	10.2
3	13,636	8.5%	617,048	6.5
2	24,399	15.2%	617,331	3.6
1	99,825	62.2%	620,667	0.9

45. While the targeting strategies and terminology differed over time, from 2010 through 2013, sales representatives were instructed to develop call plans around these high volume prescribers and detail them with the most frequency. In turn, sales representatives were rewarded with incentive compensation tied to the volume of OxyContin prescriptions generated from the health care providers they had detailed and faced corrective action plans, such as performance improvement plans, when they did not meet their sales goals.

46. A July 2012 Purdue PowerPoint, “OxyContin Marketing Mix Modeling Result,” depicts the high degree of responsiveness to detailing by extreme high-volume prescribers (deciles 7 and above) – with deciles 9 and 10 (the very highest of the high volume prescribers) demonstrating the greatest responsiveness to Purdue’s marketing.





47. Purdue also found that, if it stopped detailing those extreme high-volume prescribers, the number of Purdue prescriptions written by them would not just have stayed stagnant – it would have declined. For example, on September 16, 2011, a Purdue executive stated that high-volume prescribers’ OxyContin prescriptions decreased between 23 to 28% without detailing.

48. Approximately a year later, on July 13, 2012, a Purdue executive advised others that “OxyContin base sales will most likely erode with time when marketing programs are removed” and that incremental prescription lift was 32% after detailing by Purdue sales representatives.

**D. Declining Sales and Higher Sales Goals**

49. From 2010 to 2018, Purdue’s profits were almost entirely driven by its success in selling OxyContin.

50. On January 25, 2010, Richard Sackler emailed other members of Purdue’s Board: “By way of background, the most important driver of our sales growth or decline is the performance of all the oxycodone extended release forms in the market (called OER); this is comprised of OxyContin® tablets plus all the generics in the space.”

51. By virtue of OxyContin's importance, certain of the Sacklers placed pressure on executives to meet OxyContin sales goals set by the Board and participated in decision-making regarding Purdue's sales strategies for OxyContin, at times overruling the targets set by Purdue's executives.

52. For example, in January 2010, Purdue executives and certain of the Sacklers engaged in an exchange regarding the executives' proposed 2010 budget.

53. The executives proposed that OxyContin growth should be pegged at 3%. Richard Sackler thought this target was too low and would "lead to an OxyContin[] tablets forecast that is almost the same as our sales in 2009." A Purdue executive informed Richard Sackler that "in looking at the recent [oxycodone extended release] prescription growth trends and knowing the overall dynamics of the market OxyContin competes in – I just can't see a way of the prescription growth tracking to a level substantially higher than the 3% on which this budget is based" and that the higher target suggested by Richard Sackler would "be interpreted as an imposition as opposed to an action that will stimulate the type of business building behaviors we want to encourage."

54. In response, Richard Sackler, who believed that Purdue's OxyContin growth target should be much higher, told a Purdue executive "... I'm disappointed and don't agree with you. This is a matter that the Board will have to take up and give you a settled direction."

55. Later that month, on January 25, 2010, Richard Sackler emailed the Board and informed them that he had "engaged management on this subject," referring to the proposed 2010 budget, and explained his view that management's number was "unduly conservative."

56. On the same day, Mortimer D.A. Sackler followed up with Theresa Sackler regarding Richard's proposal, stating "we should push management to agree to a higher target."

57. After the release of Reformulated OxyContin in August 2010, OxyContin sales immediately began to decline.

58. Purdue management presented information regarding the slipping demand for Purdue's OxyContin to Purdue's Board in December 2010, showing that the total weekly kilograms dispensed of branded OxyContin declined from August to November 2010.

59. This downward trend continued the following year. On or about June 15, 2011, a Purdue executive prepared a memorandum to a Purdue executive, among others, identifying an expected budget shortfall of over \$1 billion. The memorandum stated that "Kilograms dispensed have declined since the transition to the reformulated, primarily due to fewer 40mg and 80mg tablets being dispensed."

60. In or around June 20, 2011, a Purdue executive shared this information with the Board in a presentation stating, "Since the transition, 40 and 80mg tablet prescriptions have decreased significantly. The 10mg and 20mg tablet prescriptions initially increased, but given their lower value not enough to offset the higher strength decline." The presentation went on to revise the forecast of projected OxyContin sales from \$3.9 billion to \$2.8 billion.

61. Sales continued to trend downward in 2012.

62. On April 15, 2012, Richard Sackler emailed a Purdue executive, stating, "We should . . . discuss the sudden decline in [OxyContin] sales in the past year or two. What are we doing to identify corrective actions?" The following day, a Purdue executive forwarded Richard Sackler's email to another Purdue executive, among others, stating, "I am surprised that Dr. Richard is asking this. . . . Since the decline is related to reformulation I'm not sure how to proceed with him."

63. On July 17, 2012, Mortimer D.A. Sackler emailed fellow Purdue Board members stating that Purdue should “start a search asap for a new CEO” and consider “replacing the head of sales and marketing.”

64. In November 2012, looking back at the time period since Reformulated OxyContin replaced original OxyContin, a Purdue executive reported to Purdue’s Board of Directors that there was a “Decline in OxyContin [Prescriptions] From Late 2010 Through 2011.” The executive added that 2012 gross sales of OxyContin were “3.7%[] below budget” and 2012 net sales of OxyContin were “4.3% below budget due to lower prescription demand, , lower trade inventory, and higher returns than budgeted.”

65. In October 2013, Mortimer D.A. Sackler inquired directly with Purdue’s leadership to request additional data concerning the downward trend in sales by dosage, requesting a chart to “show the breakdown of the OxyContin market share by strength against competitors. I would like to understand more the recent dynamics of the market and where the patients are shifting to that we are losing.” Later that same day, responses to Mortimer’s questions explained that the loss of sales was due to “the recent dynamics of the market,” the pressures of increased government regulation, and that there were “fewer patients titrating to the higher strengths from the lower ones.”

**E. *Post-Reformulation Decline Attributed, in Large Part, to Medically Unnecessary Prescriptions***

66. Purdue studied the drivers of the post-reformulation OxyContin sales decline, and it attributed the decline, in large part, to a reduction in prescriptions written for individuals who abused OxyContin through insufflation or injection and increases in safeguards intended to hinder medically unnecessary prescribing.

67. Purdue also conducted a number of post-marketing studies of Reformulated OxyContin.

68. Purdue's studies and analyses showed that the decline in overall OxyContin prescriptions was most pronounced among both extreme high-volume opioid prescribers and its highest dosage tablets, the 40 mg and 80 mg tablets.

69. Purdue also attributed approximately 40% of the decline in OxyContin prescriptions in 2010 to 2011 to "Region Zero" prescribers. Region Zero prescribers were prescribers that Purdue instructed sales representatives not to call on because, based on information maintained by its Abuse and Diversion Detection ("ADD") Program, Purdue determined that "there is a concern about potential abuse or diversion related activities" by them. Purdue had detailed information (down to the number of prescriptions written, product, and dosage) of Purdue products prescribed by all prescribers, including Region Zero doctors from which it could determine that Purdue had been making substantial profits from these prescriptions.

70. Purdue knew that the remainder of prescribers who experienced a significant drop in sales post-reformulation were not on Purdue's Region Zero do-not-call list, meaning representatives could continue detailing them.

71. At the December 2010 Board briefing, a Purdue executive discussed a chart stating that "Region 0 Accounts For Much Of The TRx Decline At The Regional Level."

72. In April 2011, Purdue prepared an excel sheet showing prescribers who experienced significant drops in prescriptions post-reformulation. Among the 134 prescribers listed in the prescription change analysis, Purdue was continuing to detail about one-third of

them. The spreadsheet specifically identified substantial declines in prescriptions for 80 mg tablets.

73. On October 25, 2011, Purdue's Board received a copy of Purdue's September Executive Committee Meeting Notes & Actions, which provided Board members with information regarding the impact of Reformulated OxyContin on abuse.

74. Among the Board materials was a presentation stating that there was a "[d]ecline in 80 mg prescriptions, esp[ecially] among 'Do not Call' prescribers," and a "[s]hift in routes of abuse, especially injecting and snorting."

75. The study, which surveyed individuals being treated for opioid use disorder who reported abusing OxyContin through any route, also found that while the overall rate of OxyContin abuse decreased, some users continued to abuse Reformulated OxyContin through insufflation or injection—albeit with more difficulty—and that the percentage of users who reported abusing OxyContin through oral ingestion increased from 54% to 76% following the introduction of Reformulated OxyContin.

76. The materials provided to the Board in October 2011 also included a study, "Changes in Prescribing Patterns Following Introduction of Reformulated OxyContin: A Window into Diversion." The study examined a two-year period, August 2009 to July 2011, and found that data for Region Zero prescribers showed an 86% decline in their OxyContin prescriptions after Purdue's introduction of its reformulated version, and especially at the highest dosages, 40 and 80 mg tablets. The study found that prescribers suspected of abuse and diversion also prescribed the highest dose (80 mg) of OxyContin more frequently than other prescribers.

77. The study also found that Region Zero prescribers accounted for only 38.4% of the overall decline in sales post-reformulation, which Purdue attributed to reduced abuse of OxyContin. The remaining 61.6% of the decline was among other prescribers that were not on Purdue's Region Zero lists, meaning that sales representatives either were continuing to call on these prescribers or were permitted to do so.

78. Figures in the presentation further showed that immediate-release oxycodone prescribing increased at a similar rate (an approximately 32% increase) to the decline in 80 mg and 40 mg tablets of Reformulated OxyContin prescriptions (which experienced a 24% decrease and 26% decrease, respectively) among the non-Region Zero comparator prescribers, indicating that patients who had been abusing OxyContin may have been shifted to a non-reformulated oxycodone product that they could continue to misuse.

79. Versions of the presentation, including at least one provided to Richard Sackler in August 2013, repeated key findings, including: "Greater declines for doctors that were potentially problematic prescribers"; "Greater declines for high versus low dosage strengths"; "A small number of prescribers contribute to a large proportion of potential diversion of opioids from legal to illegal channels"; and "there were doctors in the [Purdue's] database who were prescribing painkillers 'for what appears to be the wrong reasons.'"

80. In sum, Purdue knew that, after the release of its Reformulated OxyContin, the product continued to be abused, but the method of abuse shifted to abuse through oral ingestion. Furthermore, Purdue knew that abuse and diversion appeared concentrated among a cohort of

high-volume prescribers. As described below, certain of Purdue's marketing efforts were concentrated on extreme high-volume prescribers.

**F. *Decline in OxyContin Revenue Also Attributed to Safeguards Intended to Curb Abuse and Diversion.***

81. At the same time, Purdue also attributed declines in OxyContin prescription revenue post-reformulation to safeguards intended to reduce medically unnecessary opioid sales, including increased scrutiny of opioid prescribing by law enforcement, wholesalers, distributors, and retail pharmacies.

82. For example, a Business Condition Report from a May 2-3, 2013 Board of Directors Meeting described sales as being "\$144mm behind Q12013 budget" with "\$36mm attributed to lower Rx demand" and stated that "[p]ossible causes of fewer tabs/Rx in the market" include "Increased State Regulations"; "Anti-opioid environment"; and "Increased DEA/law enforcement scrutiny of physicians, pharmacies and wholesalers."

83. A consulting company that worked for Purdue since approximately the mid-2000s similarly attributed the decline in sales, in large part, to both the reformulation and safeguards against medically unnecessary prescriptions.

84. In 2013, the consulting company informed Purdue and its Board, that "[t]he retail channel, both pharmacies and distributors, is under intense scrutiny and direct risk."

85. More specifically, the consulting company explained "[t]here are reports of wholesalers stopping shipments entirely to an increasing number of pharmacies," "[m]any wholesalers are also imposing hard quantity limits on orders based on prior purchase levels," and "[p]harmacy chains are implementing guidelines for which patients can fill opioid prescriptions."



86. Later, Purdue's 2014 budget presentation to the Board listed these safeguards – intended to prevent medically unnecessary prescriptions of opioids, including OxyContin – among the “challenges” to achieving revenue goals.

**G. *Re-catalyzing Medically Unnecessary Prescriptions: Turbocharging Sales through E2E.***

87. On May 25, 2013 Richard Sackler had a call with a senior executive from the consulting company to discuss various business opportunities, including opportunities related to OxyContin.

88. On May 28, 2013, Purdue entered into a contract with the consulting company to “conduct a rapid assessment of the underlying drivers of current OxyContin performance, identify key opportunities to increase near-term OxyContin revenue and develop plans to capture priority opportunities.”

89. Between July 18 and August 8, 2013, the consulting company provided several reports to a Purdue executive, at least two of which were provided to the Board, including the Sacklers.

90. The consulting company proposed that Purdue adopt what was later referred to as the “Evolve to Excellence” initiative, or “E2E.”

91. The reports concluded that there existed a “significant opportunity to improve sales through better targeting.”

92. “Better targeting” meant focusing sales calls on extreme high-volume opioid prescribers and removing sales representative discretion with respect to call plans.

93. Purdue and the consulting company analyzed Purdue prescription data and other Purdue data sources broken down by deciles based on, primarily, their opioid prescribing. According to Purdue and the consulting company's deciling calculations, the prescribers writing

“25 times as many OxyContin prescriptions as” other providers – those within the top five deciles – comprised less than seven percent of all prescribers nationwide, but wrote approximately as many opioid prescriptions as the remaining 93 percent of prescribers combined.

94. The consulting company contended that, in contrast to the decile ranking undertaken by Purdue from 2010 to 2012, its rankings focused on “value deciles,” which purported to be qualitatively different. In practice, the value decile ranking only enhanced Purdue’s marketing focus on extreme high-volume prescribers and ensured a focus on Federal healthcare program beneficiaries.

95. The “value decile” analysis purported to use the following metrics: (1) overall opioid prescriptions, including number of branded versus generic prescriptions; (2) whether the prescriber had rules in place prohibiting sales representatives from calling on them; (3) managed care access, including access to Federal healthcare program beneficiaries; and (4) the number of the prescriber’s new to brand prescriptions (including new opioid patients and switches from other opioid products).

96. The consulting company reports showed that the highest-volume prescribers were the most susceptible to marketing: detailing resulted in a 53% increase in prescriptions compared to only 33% for the middle decile prescribers. They also showed that, in the absence of detailing, high-volume prescribers’ Purdue prescriptions would decline considerably.

97. The consulting company told Purdue and its Board that its proposed marketing plan would slow or reverse that decline and recapture those sales.

98. The memoranda asked Purdue to “make a clear go or no go decision on Turbocharging the Sales Engine,” meaning implementing E2E.

99. On August 15, 2013, two Purdue executives discussed the consulting company's progress on evaluating growth opportunities for OxyContin with the Board. Their presentation noted that the analysis would include an examination of "relatively more sudden declines in tablets per prescriptions and prescriptions for 40 mg and 80 mg strengths" and "prescriber segmentation and targeting."

100. Later that same day, Richard Sackler emailed Mortimer D. A. Sackler: "The 'discoveries' of [the consulting company] are astonishing."

101. Richard Sackler subsequently arranged for a face-to-face meeting for the Board with the consulting company outside of the presence of Purdue executives.

102. On August 23, 2013, certain Sackler family members met with the consulting company and examined its "unvarnished" findings and recommendations.

103. Following the meeting, one of the consulting company partners that led the meeting with the Sacklers memorialized in an email: "[T]he room was filled with only family, including the elder statesman Dr. Raymond [Sackler]. . . . We went through exhibit by exhibit for about 2 hrs. . . . They were extremely supportive of the findings and our recommendations . . . and wanted to strongly endorse getting going on our recommendations."

104. Another consulting company partner further remarked in the email correspondence that their "findings were crystal clear to" the Sacklers "and [the Sacklers] gave a ringing endorsement of 'moving forward fast.'"

105. After the "ringing endorsement" by the Sacklers, Purdue, in collaboration with the consulting company, implemented many of the consulting company's recommendations.

106. The Board received a presentation on E2E's implementation at the September 2013 Board meeting.

107. In September 2013, Richard Sackler emailed an advisor asking when Purdue could reach out to a newly-hired Purdue executive to brief him on E2E.

108. E2E took a multifaceted approach to increasing OxyContin prescribing and Purdue's profits. The consulting company recommended, among other strategies, refreshing Purdue's marketing messaging – particularly around titration to higher, more lucrative dosages -- and undertaking strategies to ensure prescriptions would be filled. At its core, however, E2E focused on intensifying marketing to the very highest-volume prescribers in the country by targeting them with increased frequency and minimizing sales representative discretion in identifying prescribers to target. The E2E call plans targeted the highest-volume prescribers in the country, and the program demanded stricter adherence with call plans than had existed in years past.

109. In late 2013, the Board received a 2014 Budget presentation again reviewing E2E's implementation. Board notes show the Board discussed ensuring E2E's funding at that meeting.

110. In sum, Purdue understood E2E's core strategies, namely, that it relied on generating prescriptions from extreme high-volume prescribers, and implemented it anyway.

**H. *E2E's Aggressive OxyContin Sales and Marketing Strategies.***

111. E2E was overseen by the consulting company and some of Purdue's top executives through the creation of the E2E Executive Oversight Team ("EOT") and Project Management Office ("PMO").

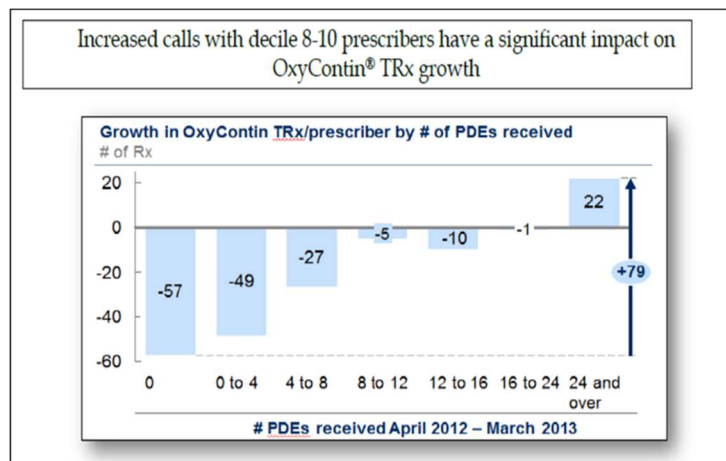
i. ***Increasing the Frequency of Calls on Extreme High-Volume Prescribers***

112. Based on a study showing that providers in deciles 7-10 were most responsive to sales calls and were the most prolific writers, the E2E call plans instructed sales representatives to call on the very highest deciles of high-volume prescribers with the most frequency.

113. Specifically, Purdue instructed its sales representatives to call on the highest volume OxyContin prescribers (*i.e.*, those in so-called “deciles” 7 through 10) at least 24 times a year and “heavily favor” promoting OxyContin over other Purdue opioids in their messaging.

114. Purdue executives also emphasized the focus of E2E at national sales meetings: “The single core objective of E2E...is to make sure that we’re making calls on the highest potential customers with the right frequency to maximize prescribing potential.”

115. An email between two Purdue executives dated October 23, 2013, entitled “S&P Final Version” attached Board presentations, a 2014 Budget Presentation to the Board on OxyContin Tablets, which reflected that the extreme high-volume prescribers that E2E targeted were most sensitive to Purdue’s marketing:



116. Speaker notes to this presentation discussed focusing on these top tier prescribers because “Increased calls with decile 8-10 prescribers have a significant impact on OxyContin®

TRx growth” – an over 39% increase as compared to a decline of approximately 17% among prescribers receiving fewer calls.

**ii. *Messaging to Cause High Volume Prescribers to Get More Patients on OxyContin and Titrate Patients to Higher Dosages***

117. Purdue’s sales and marketing departments prepared scripts, visual aids, brochures, and messaging for representatives to use with the providers they called on. A large part of this marketing was intended to cause the highest volume prescribers in the nation to “commit” to writing more OxyContin prescriptions.

118. At the same time, Purdue also refined its marketing message through the S.T.A.R.T. (Supplement, Titrate, Adjust, Reassess, Tailor) initiative by focusing sales conversations with prescribers on titrating patients to dosages.

119. The goal of the program was to discourage patient discontinuation of OxyContin due to perceived lack of pain relief by encouraging providers to increase the OxyContin dosage, or “titrate up.”

120. For example, a 2011 script stated: “We discussed the discontinuation rate of extended-release opioids by day 35. One of the potential reasons for discontinuation is the lack of efficacy perhaps as a result of lack of titration.” E2E created a refreshed 2014 version of the script that stated: “According to an analysis ... 57% of patients initiated on some commonly prescribed extended-release opioids are no longer on those products by day 35,” “Assuming a patient discontinues therapy by day 35 due to their perceived lack of pain relief, what is the impact on your patient, you and your staff? (pause for effect),” and then “Doctor, working with you and your staff, I can provide support to you when initiating and titrating dosages on my products.”

121. In addition, representatives were trained to “[o]vercome . . . objection[s]” raised by providers and get physicians to “commit” to prescribe more Purdue products. Specifically, representatives were trained to pivot from legitimate physician concerns about addiction to statements about “dependence” and opioid “tolerance.” When asked about the safety of high dosages, representatives were instructed to respond that OxyContin “does not have a ceiling dose.”

122. The Board received information concerning “OxyContin strength Rx history as well as statistical projections” that attributed the decline in sales of the high dosage tablets to “DEA pressures and ‘good faith dispensing policies’ at large chain pharmacies, *fewer patients switching into the ERO market from other products*, and there are *fewer patients titrating to the higher strengths from the lower ones*” (emphasis in original).

123. At the November 2013 meeting concerning Purdue’s 2014 budget, a Purdue executive discussed with the Board the company’s plan to “refine the message” of the company’s titration up marketing campaign and specifically referenced the “Individualize the Dose” campaign, a Conversion & Titration Guide, and the S.T.A.R.T. principles to “highlight important elements of titration throughout the course of treatment.”

124. Briefings to the Board also showed that the E2E marketing pushed by sales representatives in these calls specifically discussed titrating to higher dosages, initiating opioid naïve patients on opioid therapy, and switching patients from immediate release opioids to Reformulated OxyContin.

125. In December 2013 correspondence, a Purdue executive told the Board that “[t]he E2E sales force focus/effectiveness initiatives [that] are being implemented starting October 2013 through April 2014 are already showing positive results.”

**I. *Purdue's Internal Systems Confirm that E2E Caused Medically Unnecessary Prescribing***

126. Purdue's Abuse and Diversion Detection ("ADD") program and Region Zero list contain examples of high-volume prescribers detailed during E2E that Purdue's own employees suspected were writing medically unnecessary prescriptions.

127. At all relevant times, Purdue maintained an ADD program, through which Purdue had the means and ability to identify prescribers suspected of engaging in abuse and diversion.

128. The ADD program began in or around 2002 and ended in or around February 2018. It was governed during most of that time period by Standard Operating Procedure ("SOP") 1.7.1.

129. SOP 1.7.1 instructed Purdue employees to refer prescribers who displayed indicia of abuse and diversion to ADD. Employees referred these prescribers to ADD by issuing a Report of Concern ("ROC").

130. The indicia of abuse and diversion in SOP 1.7.1 were amended over time and included, among other things, excessive numbers of patients; brief or nonexistent contact with patients; high numbers of cash pay patients; information that a prescriber or his or her patients may be diverting opioids; allegations of patient overdoses; allegations of unauthorized individuals signing prescriptions; large numbers of patients traveling long distances; and allegations that a prescriber is under investigation.

131. After prescribers were referred to ADD, Purdue reviewed information concerning the prescribers to determine whether Purdue should continue to market its opioids to them.

132. If Purdue determined a sales representative should not continue to call on a prescriber, the prescriber was placed on the Region Zero list.



133. Purdue was aware that Region Zero providers were responsible for a major drop in sales after Reformulated OxyContin was released, and that there were also declines among prescribers that were not on Region Zero that Purdue sales representatives could continue to detail.

134. Purdue sales representatives were trained to report prescribers suspected of abuse and diversion to ADD, and some sales representatives did so.

135. However, high-volume prescribers were often not reported and, even if they were, they were sometimes not added to Region Zero until they lost the ability to prescribe through legal or medical board action. In addition, certain Purdue policies resulted in high-volume prescribers not being reported to ADD, and thus not being added to Region Zero. For example, Purdue trained its sales representatives to only report clear instances of abuse and diversion, and sales representatives were instructed to discuss the reports with their district managers prior to filing. In addition, although Purdue's policy stated that it required timely reporting, Purdue had few, if any, effective compliance measures to address an employee's failure to report, and very few sales representatives were penalized for failing to timely report.

136. Purdue's Sales and Marketing Department tracked prescribing of opioids by all health care providers, including providers included in ADD and Region Zero, placing them into deciles as described above. ADD contained a field that reflected whether a health care provider was a high-volume prescriber. When the sales force petitioned for a prescriber to be removed from Region Zero so that detailing of him or her could resume, and when ADD reviewed such petitions, both the sales force and ADD were aware of the volume of sales generated by that prescriber.

137. From 2002 through the end of 2012, Purdue conducted various data analyses to identify prescribers with red flags for abuse and diversion. The red flags included prescribers with high numbers of prescriptions for 80mg tablets; prescribers with large numbers of patients that used multiple prescribers or pharmacies; and prescribers with large numbers of cash paying patients.

138. Purdue also evaluated prescribers whose prescriptions declined sharply following reformulation.

139. Although the analyses identified many red flag prescribers, only a fraction were reviewed as part of the ADD program and Purdue knowingly continued detailing others without any further scrutiny.

140. Further, even for those prescribers who were placed on Region Zero, Purdue engaged in other practices to increase those prescribers' opioid prescriptions.

- a. Purdue permitted sales representatives to continue calling on other members of the exact same practice, although doing so could increase the prescriptions of the Region Zero prescriber;
- b. Purdue detailed its highest-volume prescribers' pharmacies in order to increase the likelihood that Region Zero prescriptions would be filled; and
- c. Purdue permitted sales representatives and managers to petition to have Region Zero status reversed so they could resume calling on Region Zero prescribers. These petitions were sometimes granted.

141. For example, in 2012, Purdue employees petitioned for over 180 mid to high-decile Region Zero providers to be reinstated.

142. Purdue also failed to maintain updated and complete Region Zero lists.

143. Purdue knowingly continued detailing prescribers suspected of abuse and diversion, including at times after a ROC was filed with ADD.

**Doctor-1**

144. From January 2010 through May 2018, Purdue representatives detailed Doctor-1 at least 300 times, although calls after February 2018 did not promote opioid products. During this time, the doctor caused the submission of a high number of OxyContin claims to Medicare.

145. Purdue knew that Doctor-1 was prescribing medically unnecessary opioids. From 2009 through 2011, Purdue received at least three different ROCs about Doctor-1.

146. In October 2009, a Purdue sales representative reported: “Pharmacist . . . says they’ve had all kinds of problems with abuse and diversion of Oxycontin . . . [Pharmacist] said [he] and [other doctor] are too loose [sic] when writing prescriptions of Oxycontin. He says of the patients he thinks are selling their prescriptions, he has notified the doctors, but nothing has changed.”

147. In June 2010, the sales representative further reported: “the pharmacy manager, says [the doctor] is known as the “Candyman” . . . because she will immediately put every patient on the highest dose of narcotics she can, whether it’s Oxycontin or another product. He says when he goes to local pharmacist meetings, when her name comes up everyone in the room cringes and moans because of her practices. He says she is doing all kinds of wacky dosing and tablet strengths. He says he feels like she is not doing what she should be doing with medications. On occasion he has refused to fill prescriptions from her office . . . . He said he’s been seeing some crazy dosing of Oxycontin coming in, especially from [Doctor-1].”

148. In July 2010, a Purdue sales representative reported: Another physician “said he had a patient . . . from [the doctor] who was on 80 mg 5 times per day. He thought this was over

the top and asked me today what the maximum dose was. He felt this patient was definitely exceeding it. I told him since it was a single entity opioid, there is no ceiling dose. It is only limited by side effects. He said he would not continue this type of dose.”

149. The same representative “became concerned on March 18, 2010, when she realized that patients were being treated by . . . a registered nurse without prescribing privileges, in [the doctor’s] absence. According to [the representative], this ‘was not an isolated incident.’”

150. The representatives’ call notes showed other instances where Doctor-1 was absent during business hours, including a February 2010 incident when the doctor left in the middle of the day to get a tattoo.

151. The ADD program placed Doctor-1 on Region Zero and instructed sales representatives to cease calling on the doctor in August 2010.

152. However, in October 2011, Purdue informed sales representatives that they may resume calling on Doctor-1, and the sales representatives did so until the spring of 2018.

153. Purdue’s detailing caused Doctor-1 to write medically unnecessary prescriptions for OxyContin, claims for which were submitted to Federal healthcare programs.

#### **Doctor-2**

154. From January 2010 to May 2018, Purdue representatives detailed Doctor-2 at least 260 times, although calls after February 2018 did not promote opioid products.

155. During this time, Doctor-2 caused Medicare claims for OxyContin, the overwhelming majority of which were for OxyContin 80mg tablets.

156. On September 23, 2003, a Purdue employee flagged Doctor-2 for ADD review stating, “Have you looked at the doctor with [the doctor’s ME number]? This person is in specialty decile 7 and has about twice the volume as anyone else in that decile.”

157. Purdue performed an ADD review in July 2004 after reviewing information showing the doctor had abnormally high opioid volume and a high percentage of cash-paying patients, and receiving reports that the doctor was under investigation for his opioid prescribing. The ADD team did not place Doctor-2 on the Region Zero list at that time.

158. Doctor-2's name came up again in 2008 and 2009 in connection with Purdue's internal investigation of a diverting pharmacy. The investigation revealed, in part, the following red flags regarding the pharmacy, including: it was a high traffic pharmacy; cars observed at the pharmacy had out of state plates; it had pharmacy clients loitering outside; it had pharmacy clients entering and exiting vehicles not their own; and it had pharmacy clients exchanging prescription drugs. As part of the investigation, Purdue identified Doctor-2 as one of the "Three (3) Main Doctors who prescribe for [pharmacy]," but undertook no further review of the doctor after this event.

159. Purdue sales representatives' call notes also identified ongoing concerns regarding abuse by the doctor's patients. For example, a 2010 call note stated: "Had a patient that died this week that was taking OxyContin (2 tablets of 80mg at Q12h). She was 45-48 years old and had been seen by [the doctor] for 10 years. The patient had complained previously (was reported) that the reformulation made her sick and tried to get a refund for the reformulation (the pharmacy refused). She did find generic OxyContin. Patient was found dead sitting at the kitchen table with a syringe beside her. It has been ruled as an accidental death by the police."

160. Following the reformulation of OxyContin, Doctor-2 was flagged for review by a December 2010 data analysis due to the doctor's drop in Reformulated OxyContin prescription rates. Months after the analysis, on August 1, 2011, Purdue completed an ADD review, deciding

to take no action based on Doctor-2's explanation for why he stopped prescribing Reformulated OxyContin

161. In early 2013, the state Board of Medical Examiners filed a complaint against Doctor-2 outlining his practice of prescribing OxyContin and other opioids outside the course of legitimate medical practice, which detailed the excessive amounts of OxyContin he prescribed to certain patients.

162. On February 27, 2013, a Purdue sales representative filed a ROC that Doctor-2 was subject to disciplinary action by the Board of Medical Examiners. On April 5, 2013, Doctor-2 was placed on the Region Zero list. Purdue representatives had detailed Doctor-2 146 times between 2007 and his addition to Region Zero in April 2013.

163. Although under ADD review since February 27, 2013, Purdue sales representatives called on Doctor-2 several more times until April 5, 2013.

164. Four months later, on August 26, 2013, a Purdue sales representative requested to resume calling on the doctor. In response, the ADD program wondered if it was "[t]oo soon to put him back on the list." It initially recommended a "resume call" status due to a "lack of progress on the resolution of the board's complaint and the doctor's continuation in practice," but, after further discussion, kept him on Region Zero.

165. In February 2015, the same Purdue sales representative again requested that the doctor be removed from the Region Zero list. The doctor was removed from the list on March 2015 after an "Expedited Review" of requests to resume calling on several high-volume doctors. Purdue sales representatives detailed Doctor-2 an additional 117 times between March 2015 and spring 2018, although calls after February 2018 did not promote opioid medications.

166. In sum, Purdue's detailing caused Doctor-2 to write medically unnecessary prescriptions for OxyContin, claims for which were submitted to Federal healthcare programs.

**Doctor-3**

167. From January 2010 through March 2013, Purdue sales representatives detailed Doctor-3, who was, at one time, the highest volume Medicare prescriber of opioids in the nation, over 100 times. The majority of Doctor-3's prescriptions were for 80 mg tablets.

168. Doctor-3 surrendered his medical and DEA licenses in 2013. In October 2016, Doctor-3 pled guilty to distribution of a controlled substance and healthcare fraud.

169. Over the course of a little over a year, Purdue's ADD program received at least five ROCs concerning Doctor-3. Additionally, Doctor-3's practice had numerous, easily identifiable indicia of abuse and diversion, including large numbers of high dosage patients, long lines of patients waiting outside his clinic, brief or nonexistent patient examinations, and drug transactions in the parking lot. Yet, Doctor-3 was not placed on Region Zero during this time period and sales representatives were directed to continue calling on him.

170. In fact, Doctor-3 was not placed on Region Zero at all until he lost his medical license and could no longer prescribe Purdue's opioids.

171. Purdue's detailing caused Doctor-3 to write medically unnecessary prescriptions for OxyContin, claims for which were submitted to Federal healthcare programs.

**J. *Purdue Detailed the Pharmacies of Region Zero Prescribers to Cause More Medically Unnecessary Prescriptions to be Filled***

172. From 2010 through 2012, Purdue trained its sales force to call on pharmacies that dispensed a "high volume of opioid scripts" and were near a "[l]arge pain practice."

173. In 2013, the same consulting company that developed E2E identified pharmacist scrutiny as a hurdle to sales and told the Board: "Access to OxyContin for some patients has

become quite challenging in specific local markets. This is due to a combination of factors including: regulations, DEA initiatives, [Physicians for Responsible Opioid Prescribing], wholesaler initiatives and local pharmacist perceptions. . . While the wholesaler issues are quite visible and real, we believe the daily decisions being made at local pharmacies, while less publicly visible, are in fact creating far greater access issues.”

174. On November 18, 2013, Purdue received a presentation from a vendor that identified the top twenty OxyContin prescribers whose OxyContin prescriptions declined as a result of a pharmacy’s “good faith dispensing” policy designed to hinder the dispensing of medically unnecessary prescriptions.

175. In 2014, a Purdue regional manager similarly wrote that “[t]he retail pharmacist is an integral part of our business. As the old adage in pharmaceutical sales goes, ‘The pharmacist isn’t likely to generate business, but they sure can kill it.’”

176. To ensure that prescriptions from extreme high-volume prescribers would be filled, Purdue engaged in certain strategies, including instructing its sales representatives to detail pharmacies and paying kickbacks to specialty pharmacies to fill red flag prescriptions, which is discussed further below.

177. Purdue also sought to encourage the pharmacists to “reach out to a Prescriber to recommend that a patient be switched from immediate release oxycodone to OxyContin.” In other words, Purdue’s pharmacy calls both functioned to assuage pharmacists’ concerns about filling prescriptions for OxyContin and at times served as a proxy or indirect call on the very Region Zero prescribers Purdue allegedly precluded the sales force from directly contacting.

178. At the same time, Purdue had the means and ability to detect suspicious pharmacies through its Order Monitoring System (OMS). Like Purdue’s ADD team (and



comprised of many of the same personnel), the OMS Committee was empowered to flag suspicious pharmacies, instruct distributors to pause or cancel orders to those pharmacies, and instruct sales representatives not to call on the pharmacies.

179. In addition to identifying suspicious pharmacies through referrals and data analyses, the OMS team also had the ability to see which pharmacies were filling prescriptions from Region Zero prescribers. Despite having this data, Purdue continued knowingly marketing to the pharmacies that filled the prescriptions of Region Zero and other red flag providers, which led those prescribers' medically unnecessary Purdue prescriptions to be filled.

180. For example, in or around 2010, Purdue's OMS Committee reviewed a Florida pharmacy based on a report from a district manager that the pharmacy was "filling primarily from 1.7.1 physicians," referring to prescribers reported to ADD for displaying indicia of abuse and diversion. The report stated that the Florida pharmacy's "parking lot is filled with cars with license plates from other states including Kentucky. They are ordering and filling prescriptions for primarily OxyContin 80mg. . . . [They are also filling prescriptions] from 1.7.1 physicians. He asked the pharmacist if he had any concerns about filling prescriptions from these physicians, and the Pharmacist (owner) stated that he was not going to question what a physician writes for his/her patient."

181. Despite Purdue's knowledge of the red flags indicating the pharmacy was engaged in abuse and diversion, the OMS Committee voted to "continue to monitor" the pharmacy, and allowed the sales representatives to continue to call on the pharmacy for the next five years through 2015.

**VI. Kickbacks to Doctors to Induce and Reward Prescriptions**

182. As an additional means to induce doctors to prescribe Purdue's opioid drugs, from 2010 through at least March 2018, Purdue paid kickbacks to certain prescribers in the form of speaker programs, advisory board memberships, research programs and honoraria.

183. Purdue allowed its sales and marketing personnel, who had data on each doctor's prescribing of Purdue's drugs and whose compensation depended on increasing their assigned doctors' prescribing of Purdue's drugs, to select speakers instead of Purdue's medical education staff.

184. Purdue also allowed its sales representatives to relay and endorse doctors' requests to be retained, and the doctors could be selected even if they had not been identified by the consulting company Purdue had retained for this purpose. Within Purdue, these were known as "unsolicited requests."

185. Purdue vested final authority to select doctors in Purdue's Marketing department, which had data on each doctor's Purdue prescriptions.

186. Purdue's list of speakers included providers that Purdue knew or should have known were writing prescriptions that were not for a medically accepted indication; for uses that were unsafe, ineffective, and medically unnecessary; and/or that were diverted for uses that lacked a legitimate medical purpose.

187. Under the processes described above, Purdue knowingly and willfully selected doctors to retain as paid corporate advisors and speakers specifically to induce them to prescribe and reward them for prescribing Purdue's drugs in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS).

188. For example:

- a. Purdue paid the highest-volume OxyContin prescriber in the United States over \$160,000 between 2013 and May 2018 because he was, in the words of Purdue's employees, "the biggest prescriber in CT," "the #3 prescriber of opioids nationally," and "very important to our success," even after he indicated that if he stopped receiving speaking assignments from Purdue, "the love may be lost."
- b. Purdue paid the highest-volume OxyContin prescriber in Medicare approximately \$475,000 between 2013 and January 2017 to deliver speeches and advice even though Purdue observed he was "not a strong speaker or presenter" and "attendees couldn't follow him," he engaged in "heavy prescribing, particularly in large doses for long periods of time," and was excluded by Florida Medicaid.
- c. Purdue paid more than \$110,000 to a high-volume prescriber who demanded speaking assignments or else he would "re-evaluate the use of [Purdue's] products."

**VII. Kickbacks to an Electronic Health Records Vendor for Prescriptions**

189. Practice Fusion, Inc. ("Practice Fusion") is a company that provides EHR services to medical providers. Practice Fusion provided EHR services to tens of thousands of healthcare providers in the United States, which were used during millions of patient visits each month.

190. Practice Fusion's EHR system included the capability to prompt prescribers during a patient visit to take certain clinical actions based on particular personal health information and circumstances relayed by the patient. These prompts were known as clinical

decision support (“CDS”) alerts and were meant to aid the prescriber in making treatment decisions by providing unbiased information consistent with medical practice guidelines.

191. On January 27, 2020, Practice Fusion entered into a deferred prosecution agreement with the United States and admitted that it solicited and received kickbacks from an unnamed pharmaceutical company—Purdue – in exchange for using CDS alerts within its EHR software to influence the prescribing of opioid pain medications.

192. Beginning in or around spring 2014, Purdue discussed paying Practice Fusion to create a CDS alert (“Pain CDS”) to prompt providers using Practice Fusion’s EHR to take certain clinical actions that Purdue believed would increase prescriptions for Purdue’s extended release opioid products (“EROs”), which included OxyContin, Butrans, and Hysingla.

193. From the beginning, the primary purpose of the program was to increase Purdue’s ERO prescriptions.

194. On May 4, 2014, a Purdue executive wrote regarding a potential deal with Practice Fusion that “[t]he key is understanding how it grows or protects [prescriptions].”

195. On March 23, 2015, a Practice Fusion employee emailed colleagues in preparation for an upcoming meeting at Purdue and described the opportunity to sell a CDS program to Purdue. The Practice Fusion employee explained that Purdue “has communicated that the average dosage of OxyContin is declining,” and that “[p]roviders are hesitant about using high dosages to combat pain.” The Practice Fusion employee further explained that, “[a]s a result, Purdue is toying with the idea of using Pain Assessment tools with the provider at every visit and before every [prescription].”

196. In a September 2015 presentation to Purdue’s marketing personnel, Practice Fusion touted that the Pain CDS would increase Purdue’s prescriptions of OxyContin, Butrans,

and Hysingla by delivering “clinical patient-centric provider messages” targeted at healthcare providers with “opioid naive patients with chronic pain,” and with patients currently receiving immediate release oxycodone and hydrocodone.

197. Practice Fusion and Purdue determined the amount of payment – nearly \$1 million – by considering Purdue’s anticipated return on investment, rather than on the fair market value of the services. Purdue’s last payment to Practice Fusion occurred in December 2016.

198. In March 2016, Practice Fusion’s recap of the kickoff of the Pain CDS project with Purdue began with the statement, “Primary goal of the project is to increase Rx for Purdue’s medications.”

199. In May 2016, Practice Fusion again heard that the CDS alert program was not for research purposes, and that “I keep hearing the client revert back to ‘Rx lift’ as the primary objective of the program, this came up in the kickoff meeting and again during last week’s meeting when we were talking about the objectives of the prospective and retrospective analyses.”

**B. *Purdue Designed the Pain CDS to Increase Its ERO Sales***

200. Purdue participated in the design of the Pain CDS alert. It approved the types of patients the Pain CDS would target and what guidance the alert would provide healthcare providers.

201. The Pain CDS was presented to providers as a neutral medical standard. However, Purdue’s primary objective in designing of the CDS alert was to increase its ERO sales, and the Pain CDS deviated from medically accepted standards, CDC guidelines, and FDA-approved labels for Purdue’s EROs.

202. In creating a list of treatment plan options for addressing pain, Purdue employees pulled from a list of alternatives treatments to opioids in a New England Medical Journal article on opioid abuse in chronic pain. That article described several concerns about opioid use, including “ concerns about overdosing and abuse by patients” and “ [f]actors associated with the risk of opioid overdose or addiction.” Despite this, Purdue employees added opioids to the list within the CDS of potential therapies for chronic pain.

203. Although the written contract between Purdue and Practice Fusion expired in mid-2017, the Pain CDS alert was live on Practice Fusion's EHR platform from on or about July 6, 2016 to the spring of 2019. The Pain CDS alerted more than approximately 230 million times during this period.

204. Purdue knew that Federal healthcare programs paid for EROs marketed by it and other pharmaceutical companies, and that the CDS alert was designed to prompt providers (including those who treated patients whose drug prescriptions were paid by government healthcare programs) to focus on patients’ pain and create care plans. Purdue further knew that the CDS Pain alert was designed to increase prescriptions of EROs.

#### **VIII. Alternative Distribution Strategy**

205. As an additional means to circumvent safeguards intended to prevent the filling of suspicious prescriptions, from October 2015 through 2018, Purdue and certain of the Sacklers sought to find a pharmacy mechanism to fill OxyContin prescriptions that other traditional pharmacies had rejected.

##### **A. *Purdue Caused Specialty Pharmacies to Dispense Medically Unnecessary Prescriptions.***

206. As noted above, in July 2013, as part of the E2E program, the consulting company relayed to Purdue and the Board that OxyContin revenues were down because, among

other things, “entire pharmacies [are] being shut off by distributors, pharmacies themselves imposing tablet limits, decreases in channel inventory leading to greater stockouts, and pharmacies choosing to not stock OxyContin.” The consulting company proposed creating an “alternative model for how patients receive OxyContin. This model would bypass retail, likely through a third party vendor who would provide adjudication and direct distribution to patients.”

207. On August 16, 2013, one day after the Board briefing on E2E discussed above, Mortimer D. A. Sackler emailed a Purdue executive and others asking what ideas management had for creating a new distribution system “to help relieve this problem of product access for legitimate chronic pain patients,” which would use “an independent service to verify the legitimacy of [the patients’] prescriptions.” Two days later, Mortimer D.A. Sackler reiterated, “I do think there may be an opportunity here for us to set up a complimentary business to handle this for Purdue as well as other controlled drug manufacturers. Do we have a team who could explore this possibility?”

208. On August 18, 2013, Richard Sackler responded that he had the same idea and expressed it to a Purdue executive after a Board meeting. That Purdue executive responded three days later confirming Mortimer D.A. Sackler’s interest in exploring an “alternative distribution process for all or essentially all opioid formulations.” Mortimer D.A. Sackler responded on the same day, “To be clear, I was thinking about selling to pharmacies.”

209. Shortly thereafter, the Sacklers approved E2E, and the E2E program went on to develop “multiple tactics to address these issues,” including “alternative supply channels.” In 2015, the Company entered agreements with three specialty pharmacies.

210. Some of the prescriptions that were filled by the specialty pharmacies had been rejected by traditional retail pharmacies and displayed indicia that the prescriptions were not for

a medically accepted indication; for uses that were unsafe, ineffective, and medically unnecessary; and that were often diverted for uses that lacked a legitimate medical purpose.

211. Purdue's ADD program data further confirms that some of these prescriptions lacked medical necessity. From mid-2015 through 2018, the specialty pharmacies filled Medicare prescriptions for Purdue opioids written by approximately 100 prescribers. Nearly one-fourth of those prescribers were referred to ADD on suspicion of engaging in abuse and diversion.

**B. *Purdue Paid Kickbacks to Specialty Pharmacies.***

212. From October 2015 through 2018, Purdue paid the specialty pharmacies over \$100,000 in kickbacks to fill prescriptions that other traditional pharmacies had rejected.

213. By October 2013 and in connection with Purdue's alternative distribution model strategies, Purdue had approached six potential partners, but all six rejected Purdue's offer because they were "not comfortable with mail fulfillment" and were concerned with the "risk associated with dispensing OxyContin" under that model. Purdue updated the Sacklers on status at the Board meeting that month: "What is Purdue Considering? Includes exploring opportunity to distribute directly; exploring existing channels (Specialty pharmacies, independent pharmacy networks)."

214. In May 2015, Purdue hired a vendor to assist with this project. A presentation by the vendor stated that Purdue could expect a "100% fill rate" and was structured so that the pharmacy was paid a fee each time it dispensed a prescription for Hysingla.

215. The agreements Purdue ultimately entered into with three specialty pharmacies made payments at above fair market value that were tied to the volume of Hysingla the pharmacy dispensed.



216. Purdue's sales representatives and Medical Affairs department employees referred prescribers and patients that were having difficulty filling prescriptions for any Purdue opioids, including OxyContin, to the specialty pharmacies.