

SETTLEMENT AGREEMENT

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) (collectively, the “United States”), and Sentynl Therapeutics, Inc. (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Sentynl Therapeutics (“Sentynl”) is a specialty pharmaceutical company located in Solana Beach, California. From December 1, 2015 through August 31, 2016 (the “relevant time period”), Sentynl marketed and sold prescription controlled substances Abstral and Levorphanol Tartrate (“Levorphanol”). Sentynl no longer markets and sells these products.

B. Abstral, a sublingual tablet, is a Transmucosal Immediate-Release Fentanyl (“TIRF”) medication designed to administer an immediate dose of fentanyl. Abstral is approved by the United States Food and Drug Administration (“FDA”) for the treatment of breakthrough pain in opioid-tolerant cancer patients (referred to as “breakthrough cancer pain”). Abstral is a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

C. Levorphanol, a controlled substance tablet, is approved by the FDA for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Levorphanol is a Schedule II narcotic under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*

D. Schedule II narcotics have a high potential for abuse and, if abused, may cause severe psychological and physical dependence. 21 USC § 812(b)(2).

E. The United States contends that Sentynl submitted or 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”).

F. The United States contends that it has certain civil claims against Sentynl arising from the conduct described in this Paragraph F under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-33. The United States alleges that during the relevant time period Sentynl engaged in the following conduct:

- Sentynl knowingly caused the submission of claims for Abstral and Levorphanol medications to Medicare in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). These claims resulted from remuneration Sentynl provided to a physician and physician’s girlfriend in South Florida.
- Specifically, Sentynl hired the girlfriend of a physician who was a top prescriber of Transmucosal Immediate Release Fentanyl (“TIRF”) medications to act as a sales representative in South Florida – the same region in which her boyfriend physician practiced. Sentynl hired, employed, and made salary and bonus payments to the physician’s girlfriend to induce the physician to prescribe its Abstral and Levorphanol medications.

That conduct is referred to below as the “Covered Conduct.”

G. This Settlement Agreement is neither an admission of liability by Sentynl nor a concession by the United States that its claims are not well founded. Sentynl denies the United States’ allegations in Paragraph F.

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:

TERMS AND CONDITIONS

1. Sentynl shall pay to the United States (\$750,000) (“Settlement Amount”), of which [\$375,000] is restitution, plus interest at a rate of 4.42% from November 22, 2023 to **January 15, 2024** (“Interest”) [\$4,972.50], no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the **United States Attorney’s Office for the District of New Jersey**. The Settlement Amount plus Interest as described above shall **hereafter be referred to as the “Settlement Proceeds.”**

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Proceeds, the United States releases Sentynl together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them 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 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, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights 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 or enforcement right, 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 individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

4. Sentynl waives and shall not assert any defenses Sentynl 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.

5. Sentynl fully and finally releases 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 Sentynl has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare

Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Sentynl agrees not to resubmit to any Medicare contractor 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.

7. Sentynl agrees 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Sentynl, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Sentynl's 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 attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Sentynl makes to the United States pursuant to this Agreement

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Sentynl, and Sentynl 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 Sentynl or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Sentynl further agrees that within 90 days of the Effective Date of this Agreement it 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 Sentynl or any of its 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. Sentynl agrees that the United States, at a minimum, shall be entitled to recoup from Sentynl 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 Sentynl or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this

paragraph) on Sentynl or any of its 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 Sentynl's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

8. Sentynl agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Sentynl shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its 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. Sentynl further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

9. 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 10 (waiver for beneficiaries paragraph), below.

10. Sentynl agrees that it waives 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.

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

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

13. This Agreement is governed by the laws of the United States. The exclusive venue for any dispute relating to this Agreement is the United States District Court for the District of New Jersey. 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.

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

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

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

17. This Agreement is binding on Sentynl's successors, transferees, heirs, and assigns.

18. All Parties acknowledge the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 2/7/24

BY: *Susan Pappy*
SUSAN J. PAPPY
ROBERT L. TOLL
Assistant United States Attorneys
United States Attorney's Office for the
District of New Jersey

DATED: 2/1/2024

BY:

**SUSAN
GILLIN**

Digitally signed by SUSAN
GILLIN
Date: 2024.02.01 11:21:22
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SUSAN E. GILLIN

Assistant Inspector General for Legal Affairs


Office of Counsel to the Inspector General

Office of Inspector General

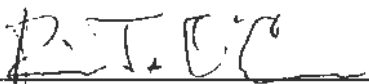
United States Department of Health and Human Services

SENTYNL THERAPEUTICS, INC.

DATED: 1/15/2024

BY: 
C4381FF94B614AC...
Matthew Heck
President & Chief Executive Officer
Sentynl Therapeutics, Inc.

DATED: 1/15/2024

BY: 
Brian T. O'Connor
Kendall V. Dacey
Ropes & Gray LLP

Christopher J. Walsh
McLane Middleton PA