

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice (“DOJ”) and on behalf of the Office of Inspector General of the Department of Health and Human Services (“HHS-OIG”) (collectively, the “United States”), and Dr. Gerald M. Sacks (“Dr. Sacks”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Dr. Sacks is a physician specializing in pain management, with an office in Santa Monica, California, who has prescribed medications to patients including beneficiaries of the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”).

- B. The United States contends that it has certain civil claims against Dr. Sacks for:
- prescribing the medications Butrans, Hysingla, and OxyContin, which are opioid medications for the treatment of pain, to Medicare beneficiaries in part in exchange for receiving paid speaking and consulting work from their manufacturer, Purdue Pharma LP (“Purdue”), in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1), thereby causing the submission of false and fraudulent claims to Medicare between December 13, 2010 and October 31, 2021;
 - prescribing the medications Gralise, which is a nerve-pain medication, and Lazanda and Nucynta, which are opioid medications for the treatment of pain, to Medicare beneficiaries in part in exchange for receiving paid speaking and consulting work from their manufacturer, Depomed Inc. (“Depomed”), in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1), thereby

causing the submission of false and fraudulent claims to Medicare between January 1, 2016 and December 31, 2016; and

- unjust enrichment based on Purdue's and Depomed's payments to Dr. Sacks during the respective time periods referenced above.

This conduct is referred to below as the "Covered Conduct."

C. Dr. Sacks denies the United States' allegations in Paragraph B.

D. This Settlement Agreement is neither an admission of liability by Dr. Sacks, nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of 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. Dr. Sacks shall pay to the United States two hundred and seventy thousand, five hundred and eighty-two dollars, and sixty-three cents (\$270,582.63) ("Settlement Amount") plus interest on the Settlement Amount at a rate of 2% per annum from June 2, 2022, of which two hundred and two thousand, nine hundred and sixty-three dollars, and eighty-three cents (\$202,963.83) is restitution, no later than ten days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the DOJ.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount plus any interest due under Paragraph 1, the United States releases Dr. Sacks 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. 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 other than Dr. Sacks;
- 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; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Dr. Sacks waives and shall not assert any defenses he 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. Dr. Sacks 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 Dr. Sacks 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 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 Dr. Sacks 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. Dr. Sacks 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 Dr. Sacks in connection with:
- (1) the matters covered by this Agreement;
 - (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

- (3) Dr. Sacks' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Dr. Sacks 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 Dr. Sacks, and he 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 Dr. Sacks or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: Dr. Sacks further agrees that within 90 days of the Effective Date of this Agreement, he 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 Dr. Sacks or any of his 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. Dr. Sacks agrees that the United States, at a minimum, shall be entitled to recoup from him 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 Dr. Sacks or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Dr. Sacks 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 Dr. Sacks' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

8. Dr. Sacks agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Dr. Sacks shall encourage, and agrees not to impair, the cooperation of others, consistent with the rights and privileges of such individuals. Dr. Sacks shall furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents related to the Covered Conduct.

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. Dr. Sacks agrees that he 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 Central District of California. 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.

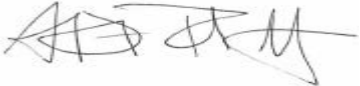
17. This Agreement is binding on Dr. Sacks' successors, transferees, heirs, and assigns.

18. All Parties consent to 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.

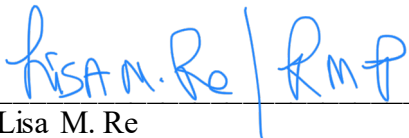
THE UNITED STATES OF AMERICA

DATED: 7/6/2022

BY: 

Albert P. Mayer
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 7/15/2022

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

DR. GERALD M. SACKS

DATED: _____

BY: _____
Gerald M. Sacks, M.D.

DATED: _____

BY: _____
Brian T. Rafferty
BAKER HOSTETLER LLP
Counsel for Dr. Sacks

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
Albert P. Mayer
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

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

DR. GERALD M. SACKS

DATED: July 5, 2022

BY:

Gerald M. Sacks, M.D.
Gerald M. Sacks, M.D.

DATED: _____

BY: _____
Brian T. Rafferty
BAKER HOSTETLER LLP
Counsel for Dr. Sacks

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Albert P. Mayer
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

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

DR. GERALD M. SACKS

DATED: _____

BY: _____

Gerald M. Sacks, M.D.

DATED: 7/6/22

BY: 

Brian T. Rafferty
BAKER HOSTETLER LLP
Counsel for Dr. Sacks