

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); the Defense Health Agency (DHA), acting on behalf of the TRICARE program; (collectively, the “United States”), and Edward Lubin (“Defendant”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Defendant is a medical doctor currently practicing in Tampa, Florida. From in or about 2013 through in or about September 2016, Dr. Lubin practiced at the Gessler Clinic Professional Association in Winter Haven, Florida.

B. On September 21, 2021, the United States filed an action against Defendant in the Tampa Division of the United States District Court for the Middle District of Florida captioned *United States v. Lubin*, Case No. 8:21-cv-02231 (the “Civil Action”).

C. On July 26, 2023, Defendant filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code, commencing a bankruptcy case styled *In re Edward Lubin*, Case No. 8:23-bk-03168 (the “Bankruptcy Case”), in the Tampa Division of the United States Bankruptcy Court for the Middle District of Florida (hereinafter, the “Bankruptcy Court”).

D. The United States contends that Defendant 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”) and the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”).

E. The United States contends that it has certain civil claims against Defendant arising from the submission, or causing the submission, of false claims to Medicare and

TRICARE during the time period from August 1, 2013, through October 31, 2016. Defendant wrote prescriptions for Subsys, a fentanyl spray manufactured by Insys Therapeutics, Inc.

(“Insys”). In the Civil Action, the United States alleges that Defendant participated in Insys’ sham speaker program, in which he was paid to purportedly speak at sham “events” that either lasted a few minutes, never occurred, or had repeat attendees, including seven sham “events” with the same single attendee, despite the lack of any rationale to present to the same person more than one time. The United States alleges that, once he became an Insys speaker:

(1) Defendant immediately began prescribing Subsys in exchange for speaker fees regardless of medical necessity; (2) over the course of three years, Insys paid Defendant \$159,580.00; and (3) during this time period, Defendant caused the submission of prescriptions of Subsys that were paid by Medicare and TRICARE. Accordingly, Defendant knowingly and willfully received remuneration from Insys in return for prescribing Subsys in violation of the federal anti-kickback statute and caused the submission of claims that were tainted by kickbacks and/or medically unnecessary.

The United States contends that it has certain civil claims against Defendant, arising from the conduct described in paragraph E, above, which is referred to below as the “Covered Conduct.”

F. Defendant denies as untrue the allegations made by the United States as described above.

G. This Agreement is neither an admission of liability by Defendant nor a concession by the United States that its claims are not well founded.

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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendant shall pay to the United States one million five hundred thousand dollars (\$1,500,000.00) (“Settlement Amount”), which constitutes restitution to the United States. Payment shall be made by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Middle District of Florida.

Payments shall be made as follows:

- a. Defendant shall pay to the United States \$187,500.00, no later than December 31, 2023;
- b. Defendant shall pay to the United States \$500,000.00, no later than the earlier of (1) October 15, 2024, or (2) thirty days after any distribution paid to Defendant pursuant to his ownership interest in CMG Corporation resulting from the anticipated sale of CMG Corporation.
- c. Defendant shall pay to the United States \$250,000.00, no later than October 15, 2024;
- d. Defendant shall pay the remaining \$562,500.00 of the Settlement Amount to the United States through three annual payments of \$187,500.00, plus interest (“Annual Installment Payments”). Defendant shall pay each of the Annual Installment Payments on or before the following dates: October 15, 2025; October 15, 2026; October 15, 2027, until paid in full. If the Defendant prepays any portion of the Annual Installment Payments on or before October 15, 2024, the Defendant shall not pay any interest on those payments. Any portion of the Annual Installment Payments that the Defendant does not prepay on or before October 15, 2024, shall accrue interest at a rate of 4.75% per annum from the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 4 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1(d), the United States releases Defendant 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. In consideration of the obligations of Defendant set forth in this Agreement, and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1(d), DHA shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Defendant under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 4 (concerning reserved claims), below. DHA expressly reserves authority to exclude Defendant from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the releases given in Paragraph 2 and Paragraph 3 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 for which the statute of limitations has not expired;

- 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;

5. Defendant waives and shall not assert any defenses Defendant may have to any 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 administrative action.

6. Defendant 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 Defendant 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.

7. 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), TRICARE carrier or payer, or any state payer, related to the Covered Conduct; and Defendant agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, 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.

8. 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 9 (waiver for beneficiaries paragraph), below.

9. Defendant 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.

10. In the event that Defendant fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Defendant shall be in Default of Defendant's payment obligations ("Default"). In the occurrence of Default:

a. The United States will provide a written Notice of Default, and Defendant shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Agreement up to the date of payment. Notice of Default will be delivered to Defendant, or to such other representative as Defendant shall designate in advance in writing. If Defendant fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule ("Uncured Default"), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 4.75% per annum from the date of default.

b. In the event of Uncured Default, Defendant agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Defendant for the claims that would otherwise be covered by the releases provided in

Paragraph 2 and Paragraph 3 above, with any recovery reduced by the amount of any payments previously made by Defendant to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Defendant by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, the United States is entitled to seek a ten-percent (10%) surcharge of the amount collected, as authorized by 28 U.S.C. § 3011(a).

c. In the event of Uncured Default, OIG-HHS may exclude Defendant from participating in all Federal health care programs until Defendant pays the Settlement Amount, with interest, as set forth above (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Defendant. Defendant waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7) and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Defendant wishes to apply for reinstatement, he must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Defendant will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

11. Defendant agrees that the Settlement Amount is non-dischargeable under 11 U.S.C. §§ 523(a)(2) and (a)(7) in the Bankruptcy Case and any future bankruptcy cases filed by the Defendant.

12. Within ten business days of the Effective Date of this Agreement, Defendant shall file in the Bankruptcy Court a Joint Motion to Approve Agreement. The Joint Motion shall submit this Agreement for approval by the Bankruptcy Court. Within ten business days of the Bankruptcy Court entering an Order approving the Agreement (1) the United States shall file a Notice withdrawing the United States' Objection to the Debtor's Subchapter V Plan of Reorganization (Bankruptcy Case, Docket Entry 90); (2) the United States shall file a Notice that the United States withdraws its joinder in the United States of America and Gessler Clinic's Joint Motion to Dismiss Bankruptcy Petition or Convert to Chapter Petition for Cause Due to Bad Faith Filing (Bankruptcy Case, Docket Entry 99); and (3) so long as the Defendant's Bankruptcy Plan includes the applicable terms of this Agreement, the United States will seek authority to vote to accept Defendant's Bankruptcy Plan under 11 U.S.C. § 1126(a); however, the United States' failure to obtain authority to vote to accept Defendant's Bankruptcy Plan shall not impair or effect this Agreement.

13. Upon receipt of the payment described in Paragraph 1(a), above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1)(A)(ii). Such Dismissal shall be subject to the terms of the Agreement.

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

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

16. 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 Middle District of Florida. 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.

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

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

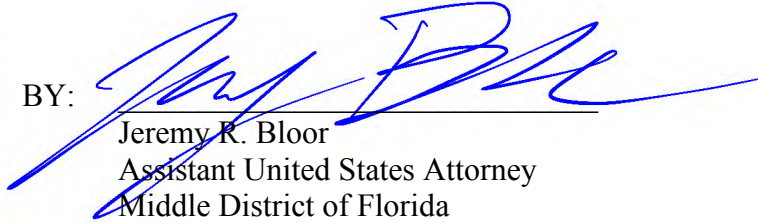
19. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

20. This Agreement is binding on Defendant's successors, transferees, heirs, and assigns.

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

22. 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: 10/13/23 BY: 
Jeremy R. Bloor
Assistant United States Attorney
Middle District of Florida

DATED: _____ BY: LISA RE
Digitally signed by
LISA RE
Date: 2023.10.13
10:15:22 -04'00'
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

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
Jeremy R. Bloor
Assistant United States Attorney
Middle District of Florida

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: 10/12/2023


BY: _____
BLEY.PAUL.NICHOLAS.1099873821
LAS.1099873821
SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

Digitally signed by
BLEY.PAUL.NICHOLAS.1099873821
Date: 2023.10.12 16:39:03 -04'00'


for

EDWARD LUBIN - DEFENDANT

DATED: 10/12/2023

BY: 
Edward Lubin, M.D.

DATED: 10/12/2023

BY: 
Dale Sisco
Robert Aranda
Counsel for Edward Lubin