

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; Edward W. Leahey M.D. P.A. and Edward W. Leahey (collectively, the “Leahey Defendants”); and Jasjit Walia and Preet Randhawa (collectively, “Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives arising from the action filed by Relators captioned, *United States ex rel. Walia v. [SEALED]*, Case No. [SEALED] (the “Civil Action”).

RECITALS

A. Leahey is a cardiologist practicing primarily in Baytown, Texas. Edward W. Leahey M.D. P.A. is a cardiology practice owned and controlled by Leahey.

B. On March 5, 2018, Relators filed the Civil Action pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b).

C. The United States contends that it has certain civil and administrative claims against the Leahey Defendants arising from the following alleged conduct. The actions, transactions, occurrences, and alleged wrongdoing set forth in this Paragraph are herein collectively referred to as the “Covered Conduct.”

i. The United States contends that the Leahey Defendants 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”).

ii. Specifically, the United States contends that it has certain civil claims against the Leahey Defendants arising from the overbilling of radiopharmaceuticals used in cardiac stress tests during the period from 2012 through 2022.

iii. In Medicare Jurisdictions H and L (which cover Arkansas, Colorado, Delaware, District of Columbia, Louisiana, Maryland, Mississippi, New Jersey, New Mexico, Oklahoma, Pennsylvania, and Texas), health care providers are required to bill Medicare for diagnostic radiopharmaceuticals, including sestamibi and tetrofosmin, based on their acquisition cost. 42 U.S.C. § 1395kk-1(a)(1), (a)(4)(A); Pub. L. 108-173, title III, § 303(h), Dec. 8, 2003, 117 Stat. 2253.

iv. The United States contends that from January 2012 through August 2022, the Leahey Defendants submitted or caused to be submitted claims to Medicare that sought reimbursement for radiopharmaceuticals above the actual acquisition cost incurred by Edward W. Leahey M.D. P.A., resulting in excess payments by Medicare.

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

E. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees, and costs.

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. The Leahey Defendants shall pay to the United States the total sum of eight hundred ninety-four thousand, six hundred seventy-nine dollars, and seventeen cents (\$894,679.17) (the "Settlement Amount"), of which four hundred forty-seven thousand, three hundred thirty-nine dollars, and fifty-eight cents (\$447,339.58) is restitution, within thirty days of the Effective Date of this Agreement. Payment to the United States shall be made by electronic funds transfer

pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay one hundred fifty-six thousand, five hundred sixty-eight dollars, and eighty-five cents (\$156,568.85) ("Relators' Share") to Relators by electronic funds transfer pursuant to instructions to be provided by the undersigned Relators' counsel.

3. Within thirty days after the Effective Date of this Agreement, Defendants shall pay to Relators sixty thousand dollars (\$60,000) by electronic funds transfer pursuant to wiring instructions to be provided by Relators' counsel as full and complete payment of Relators' attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d).

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the Leahey Defendants' full payment of the Settlement Amount, the United States releases the Leahey Defendants 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.

5. Conditioned upon the Leahey Defendants' full payment of the Settlement Amount specified in Paragraph 1 above and fees and cost payments specified in Paragraph 3 above, Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release the Leahey Defendants and their predecessors, together with current and former parent companies, direct and indirect subsidiaries, affiliated companies, brother and sister corporations, divisions, current or former corporate owners, all of their directors, officers, employees, general and limited

partners, heirs, successors, attorneys, agents, and representatives, and the successors and assigns of any of them from any and all claims, of every kind and however denominated, for damages, fines, and penalties, that any of them has asserted, could have asserted, or may assert in the future, for themselves or on behalf of the United States, under the False Claims Act, 31 U.S.C. §§ 3729-3733, with respect to the allegations set forth in the Civil Actions and the Covered Conduct.

6. Notwithstanding the releases given in Paragraphs 4 and 5 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; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relators' receipt of the Relators' Share, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. The Leahey Defendants waive and shall not assert any defenses the Leahey Defendants 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.

9. The Leahey Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that the Leahey Defendants 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 or the United States' investigation or prosecution thereof.

10. The Leahey Defendants fully and finally release Relators, their attorneys, and their respective heirs, successors, assigns and agents, for all time and to the fullest extent allowed by law, from any claims (including attorney's fees, costs, and expenses of every kind and however

denominated) that the Leahey Defendants have asserted, could have asserted, or may assert in the future against Relators related to the Covered Conduct or the investigation and prosecution of the Civil Action.

11. 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 the Leahey Defendants agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

12. The Leahey Defendants 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Leahey Defendants, their 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(s) of the matters covered by this Agreement;
- (3) Defendants' 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 the Leahey Defendants make to the United States pursuant to this Agreement and any payments that the Leahey Defendants may make to Relators, including costs and attorneys' fees,

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 in non-reimbursable cost centers by the Leahey Defendants, and the Leahey Defendants 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 Leahey Defendants or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: The Leahey Defendants further agree that within ninety days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and 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 Leahey Defendants or any of their 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 Leahey Defendants agree that the United States, at a minimum, shall be entitled to recoup from the Leahey Defendants 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 the affected agencies. The United States reserves its rights to disagree with any calculations submitted by the Leahey Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the Leahey Defendants or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

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

13. 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 5 (Relators' release), Paragraph 10 (Leahey Defendants' release), and Paragraph 14 (waiver for beneficiaries paragraph), below.

14. The Leahey Defendants 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.

15. Upon receipt of the payments described in Paragraph 1 above, Relators and the United States shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the claims against the Leahey Defendants pursuant to Rule 41(a)(1). The dismissal shall be with prejudice to the United States and the Relators with respect to the Covered Conduct. The dismissal shall be without prejudice as to the United States and with prejudice as to the Relators with respect to all other claims against the Leahey Defendants set forth in the Civil Action.

16. Except as set forth in Paragraph 3, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

18. This Agreement is governed by the laws of the United States.

19. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Columbia. 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.

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

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

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

23. This Agreement is binding on the Leahey Defendants' successors, transferees, heirs, and assigns.

23. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

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

25. 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.

<REMAINDER OF PAGE LEFT BLANK; SIGNATURE PAGES TO FOLLOW>

UNITED STATES OF AMERICA

DATED: _____

BY: _____

James Nealon
Trial Attorney, Commercial Litigation Branch
Department of Justice

DATED: _____

BY: _____

Stephen DeGenaro
John C. Truong
Assistant United States Attorneys
U.S. Attorney's Office for the District of Columbia

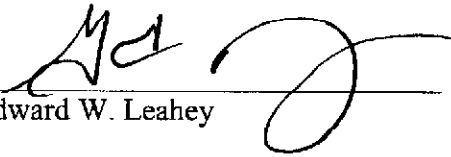
DATED: _____

BY: _____

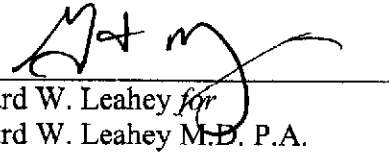
Susan Gillin
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DEFENDANTS

DATED: _____

BY: 
Edward W. Leahey

DATED: 10/31/24

BY: 
Edward W. Leahey *for*
Edward W. Leahey M.D. P.A.

DATED: _____

BY: _____
Sean Cenawood
Gadi Weinreich

Attorneys for the Leahey Defendants

DEFENDANTS

DATED: _____

BY: _____
Edward W. Leahey

DATED: _____

BY: _____
Edward W. Leahey *for*
Edward W. Leahey M.D. P.A.


DATED: 10/31/24

BY: Sean Cenawood
Sean Cenawood
Gadi Weinreich

Attorneys for the Leahey Defendants

RELATORS

DATED: 11/02/2024

BY: 

Jasjit Walia

DATED: 11/3/2024

BY: Preet Randhawa

Preet Randhawa

DATED: _____

BY: _____
Henry F. Furst
Daniel R. Miller
Jonathan Z. DeSantis
W. Scott Simmer

Attorneys for Relators