

## 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”), THD America, Inc. and its corporate parent, THD SpA, and Amber Arthur (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. THD America, Inc. is a corporation with its principal place of business at 1731 SE Oralabor Road, Ankeny, IA 50021 . THD SpA is the parent company of THD America and is headquartered at Via dell'Industria, 1, 42015 Correggio, Italy . Collectively they are referred to herein as THD. At all times relevant to this case, THD America distributed, marketed, and sold a product in the United States referred to as a THD Slide One Kit ("Kit"). The Kit is a device used during a surgical procedure called transanal hemorrhoidal dearterialization, for the repair of hemorrhoids.

B. On July 14, 2016, Relator filed a qui tam action in the United States District Court for the District of Maryland, captioned *United States ex rel. Arthur v. THD America, Inc.*, 16-cv-2571-ELH, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b). Relator filed a First Amended Complaint (“FAC”) on June 22, 2017 and a Second Amended Complaint (“SAC”) on February 15, 2019 (the “Civil Action”). The United States will file a Notice of Intervention in Part for the Purposes of Settlement in the Civil Action promptly following the execution of this Agreement.

C. The United States contends that THD 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 Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

D. The United States contends that it has certain civil claims against THD arising from conduct whereby THD knowingly caused physicians to submit false claims for payment for the Kit to the Medicare Program and to State Medicaid Programs. Specifically, the United States contends that THD sales representatives, between January 1, 2014 and December 31, 2017, provided information to certain colorectal and general surgeons regarding the following: (1) billing what was then a Category III CPT code – a temporary code or “T-code” assigned for new and emerging services – along with other CPT codes, when the T-code was considered a fully bundled code, meaning that the appropriate code to bill for all components of the procedure was the T-code solely (“upcoding”); and (2) billing for CPT codes OTHER than the T-code when performing the transanal hemorrhoidal dearterialization procedure (“unbundling”). This information caused physicians to submit false claims for payment to the Medicare Program and to State Medicaid Programs. The conduct discussed in this Paragraph D is referred to below as the “Covered Conduct.”

E. This Settlement Agreement is neither an admission of facts or liability by THD nor a concession by the United States that its claims are not well founded. THD denies the United States’ allegations in Paragraph D, above, and denies all claims and allegations by the Relator in the Civil Action that are not included in the Covered Conduct described above.

F. THD has entered or will be entering into separate settlement agreements (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states and

the District of Columbia in settlement of the Covered Conduct. States with which THD executes a Medicaid State Settlement Agreement in the form to which THD and the States have agreed, or in a form otherwise agreed to by THD and an individual state, are referred to herein as “Medicaid Participating States.”

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator’s 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 Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. THD shall pay to the United States and Medicaid Participating States, collectively, the sum of seven hundred thousand dollars (\$700,000) (“Settlement Amount”). The debt shall be discharged by payments to the United States and Medicaid Participating States as follows:

a. THD shall pay to the United States the sum of five hundred ninety-eight thousand one hundred twenty-one dollars and (\$598,121.23) (“Federal Settlement Amount”), by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the Department of Justice by the Effective Date of this Agreement. THD shall make the electronic funds transfer no later than 30 days after the Effective Date of this Agreement. Of the Federal Settlement Amount, \$456,720.26 is restitution.

b. THD shall pay to the Medicaid Participating States the sum of \$101,878.77 (the “State Settlement Amount”) pursuant to the terms and conditions set

forth in the Medicaid State Settlement Agreements that THD will enter into with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount and as soon as feasible after receipt, the United States shall pay \$98,690 to Relator by electronic funds transfer (“Relator’s Share”). No other relator share payments shall be made by the United States with respect to the matters covered by this Agreement.

3. Excluded from this Agreement and reserved by the Relator are any claims against THD pursuant to 31 U.S.C. §§ 3730(d)(4) and 3730(h).

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Federal Settlement Amount, the United States releases THD, together with its current and former parents, direct and indirect subsidiaries, corporate owners, affiliates, successors, transferees, heirs and assigns (the “THD Released Parties”), 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. Subject to the exceptions in Paragraph 3 above and Paragraph 6 below, and upon THD’s full payment of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, fully and finally releases, waives, and forever discharges, and will be deemed to have released and forever discharged the THD Released Parties, as well as THD’s officers and directors, agents, servants, and employees and the assigns of each of them, and the successors and assigns of any of them, from any civil monetary claims the Relator has or may have (a) on behalf of the United States for the Covered Conduct under the False Claims Act, 31

U.S.C. §§ 3729-3733, and (b) on behalf of any state for the Covered Conduct under comparable provisions of applicable state statutes including, but not limited to, all state statutes referenced in the Civil Action, and from any and all liability, claims, demands, actions, rights, suits, debts, obligations, losses, damages (including treble damages and any civil penalties), punitive damages, costs, expenses, or causes of action of any kind, character, or nature whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statutes or regulations, or in common law or otherwise, that Relator, her heirs, successors, attorneys, agents, and assigns otherwise would have standing to bring as of the date of this Agreement, including, but not limited to, any liability to Relator arising in any way out of, relating in any way to, or connected in any way to the claims Relator asserted or could have asserted in the Civil Action, the facts, claims and circumstances alleged in, arising under, arising from, or relating to the filing of the Civil Action, or any past activities, actions, or inactions of the THD Released Parties. Relator represents and warrants that she and her counsel are the exclusive owner of the rights, claims, and causes of action herein released and none of them have previously assigned, reassigned, or transferred or purported to assign, reassign or transfer, through bankruptcy or by any other means, any or any portion of any claim, demand, action, cause of action, or other right released or discharged under this Agreement except between themselves and their counsel.

6. Notwithstanding the releases given in Paragraph 4 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.

7. Relator and her 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 Relator's receipt of the Relator's Share, Relator and her 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. THD waives and shall not assert any defenses THD 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. THD fully and finally releases 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 THD has 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 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 THD 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.

11. THD 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 THD, 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(s) of the matters covered by this Agreement;

- (3) THD's 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 THD makes to the United States or any State pursuant to this Agreement and any payments that THD may make to Relator, including costs and attorney's 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 by THD, and THD 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 THD or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: THD 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 THD 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. THD agrees that the United States, at a minimum, shall be entitled to recoup from THD 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 THD or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on THD 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 THD's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

12. 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 other persons or entities are expressly released in Paragraphs 4 through 9 of this Agreement, and except to the extent provided for in Paragraph 13 (waiver for beneficiaries paragraph), below.

13. THD 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.

14. Upon receipt of the Federal Settlement Amount described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Notice of Dismissal of all claims and defendants in the Civil Action pursuant to Rule 41(a)(1), except for those claims retained by the Relator against THD in paragraph 3. The Notice of Dismissal shall state that: (1) claims arising from the allegations described in the Covered Conduct are dismissed with prejudice as to the United States; (2) all other claims in the Civil Action against all defendants in the Civil Action, including but not limited to claims arising outside the time period of the Covered Conduct, shall be dismissed without prejudice as to the United States; and (3) all claims in the Civil Action against all defendants in the Civil Action shall be dismissed with prejudice as to the Relator, except for those claims retained by the Relator against THD in paragraph 3.

15. Except as provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

17. 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 Maryland. 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.

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

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

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

21. This Agreement is binding on THD's successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

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

24. 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.


[Signature Pages Follow]

THE UNITED STATES OF AMERICA

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

BY: JAY MAJORS Digitally signed by JAY MAJORS  
Date: 2024.08.28 15:01:47  
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JAY D. MAJORS  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

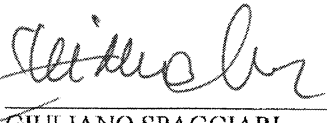
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Date: 2024.08.28 14:40:58 -04'00'  
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TARRA DESHIELDS  
Assistant United States Attorney  
District of Maryland


DATED: 08/19/24

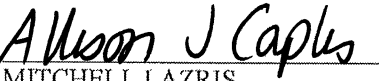
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SUSAN E. GILLIN  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DEFENDANTS

DATED: Aug 26, 2024 BY:   
GIULIANO SPAGGIARI  
THD America  
Director

DATED: 8/27/2024 BY:   
MITCHELL LAZRIS  
ALLISON J. CAPLIS  
Hogan Lovells US LLP  
Counsel for THD America

DATED: Aug 26, 2024 BY:   
ALESSANDRO SPAGGIARI  
THD SpA  
Chairman of the Board of Directors


DATED: 8/27/2024 BY:   
MITCHELL LAZRIS  
ALLISON J. CAPLIS  
Hogan Lovells US LLP  
Counsel for THD SpA

Amber Arthur - RELATOR

DATED: Aug 13, 2024

BY:   
Amber Arthur (Aug 13, 2024 12:09 CD)  
AMBER ARTHUR

DATED: Aug 14, 2024


BY:   
VINCENT MCKNIGHT  
Counsel for Amber Arthur

Amber Arthur - RELATOR

DATED: 8/21

BY:   
Amber Arthur (Aug 22, 2024 16:14 CDT)  
AMBER ARTHUR

DATED: 8/21

BY:   
Vince McKnight (Aug 22, 2024 21:12 EDT)  
VINCENT MCKNIGHT  
Counsel for Amber Arthur