

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”), Arthrex, Inc. (“Arthrex”), and Joseph B. Shea (the “Relator”), through their authorized representatives (together, “the Parties”).

RECITALS

A. Arthrex is a medical device manufacturer with its principal place of business in Naples, Florida.

B. On February 4, 2020, Relator filed an action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Joseph P. Shea v. Arthrex, Inc., et al.*, No. 20-cv-10210-ADB, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relator’s complaint alleges, among other things, that Arthrex caused third parties to submit false claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”), by providing remuneration to physicians to induce them to purchase and recommend Arthrex products in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

C. The United States contends that it has certain civil claims against Arthrex arising from Arthrex having caused third parties to submit false claims for payment to Medicare for items and services that Dr. Peter Millett (“Millett”) furnished, ordered, arranged, or recommended. More specifically, the United States contends that Arthrex provided illegal remuneration to Millett, an orthopedic surgeon, to induce him to purchase, order, or recommend the purchasing or ordering of Arthrex medical devices during the period from August 2010 through March 5, 2021 (the “Relevant Period”). The United States contends that Arthrex entered

into a royalty agreement with Millett in August 2010, pursuant to which Arthrex agreed to pay Millett ostensibly for his contributions to the development of the SutureBridge and SpeedBridge kits—two Arthrex product lines that surgeons use in joint repair surgery. In 2006, Arthrex had denied Millett’s request for such royalties. The United States contends that when Millett threatened to realign his loyalty to an Arthrex competitor in 2010, Arthrex not only acquiesced to Millett’s royalty request but also agreed to pay him royalties for past and future sales of SutureBridge and SpeedBridge kits at a higher percentage rate than was the company’s ordinary royalty practice. Pursuant to this agreement, Arthrex paid Millett millions of dollars during the Relevant Period. The United States contends that one purpose of Arthrex’s payments was to induce Millett to purchase, order, or recommend the purchasing or ordering of Arthrex medical devices. The United States’ contentions as described in this paragraph are referred to below as the “Covered Conduct.”

D. 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.

E. Arthrex agrees not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any of the Covered Conduct or creating the impression that the Covered Conduct is without factual basis. Nothing in this paragraph affects Arthrex’s: (i) testimony obligations or (ii) right to take legal or factual positions concerning litigation or other legal proceedings in which the United States is not a party.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Arthrex shall pay to the United States \$16,000,000, plus interest accruing at an annual rate of 1.375% per annum from March 5, 2021, and continuing until and including the day of payment (“Settlement Amount”). Arthrex shall pay the Settlement Amount no later than 10 calendar days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts. Of the Settlement Amount, \$8,000,000 is restitution to the United States.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$2,500,000 plus a 15.625% share of the interest received by the United States from Arthrex to Relator by electronic funds transfer (“Relator’s Share”).

3. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, the United States releases Arthrex from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12, or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 6 below, and upon the United States’ receipt of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Arthrex from any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-33.

5. In consideration of the obligations of Arthrex in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Arthrex, and upon the United States’ receipt of full payment of the Settlement Amount, the OIG-HHS shall release and refrain

from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Arthrex under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Arthrex from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding the releases given in Paragraphs 3 through 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 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. Relator and his 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 his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants with respect to any claims against Arthrex 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 against Arthrex.

8. Conditioned upon payment of the Settlement Amount to the United States and the payment of Relator's attorney's fees, costs, and expenses under 31 U.S.C. § 3730(d) referenced below, Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, fully and finally releases Arthrex, and its officers, agents, and employees, from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Relator has asserted, could have asserted, or may assert in the future against Arthrex related to the Civil Action and the Relator's investigation and prosecution thereof. Arthrex agrees to pay Relator's reasonable attorney's fees, costs, and expenses under 31 U.S.C. § 3730(d) in the amount of \$347,448.65 by electronic funds transfer no later than ten calendar days after the Effective Date of this Agreement pursuant to written instructions by Relator's counsel.

9. Arthrex waives and shall not assert any defenses Arthrex 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.

10. Arthrex fully and finally releases the United States, its agencies, officers, agents, employees, and servants from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Arthrex 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.

11. Arthrex fully and finally releases the Relator from any claims (including for attorneys' fees, costs, and expenses of every kind and however denominated) that Arthrex has asserted, could have asserted, or may assert in the future against the Relator related to the Civil Action and the Relator's investigation and prosecution thereof.

12. 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 Arthrex 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.

13. Arthrex 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 Arthrex, 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) Arthrex's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and 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 Arthrex makes to the United States pursuant to this Agreement and any payments that Arthrex may make to Relator, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

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 Arthrex, and Arthrex 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 Arthrex or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

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

14. 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 15 (waiver for beneficiaries paragraph), below.

15. Arthrex 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.

16. Upon receipt of the payment described in Paragraphs 1 and 8, above, the Relator and the United States shall promptly sign and file in the Civil Action a Stipulation of Dismissal of the Civil Action against Arthrex pursuant to Rule 41(a)(1) and subject to the terms of this Agreement (the "Stipulation"). The Stipulation shall state that: (1) claims for 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 Arthrex shall be dismissed without prejudice as to the United States; and (3) all claims in the Civil Action against Arthrex shall be dismissed with prejudice as to the Relator.

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

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

19. 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 Massachusetts. 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 Arthrex's successors, transferees, heirs, and assigns.


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

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


26. 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: 11/8/2021

BY: 
DAVID J. DERUSHA
CHARLES B. WEINOGRA
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 11/7/21

BY: 
ANDREW JACO
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: **GREGORY DEMSKE**
Digitally signed by GREGORY
DEMSKE
Date: 2021.11.05 16:25:18 -04'00'

For: **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

DEFENDANT ARTHREX, INC.

DATED: 11/4/2021

BY:



JOHN W. SCHMIEDING

Senior Vice President, General Counsel
Arthrex, Inc.

DATED: 11/4/2021

BY:



JACK W. PIROZZOLO

MARK B. LANGDON

JOSEPH R. DOSCH

Counsel for Arthrex, Inc.


Sidley Austin LLP

RELATOR JOSEPH B. SHEA

DATED: 11-4-21

BY:  (JOSEPH B. SHEA)
JOSEPH B. SHEA

DATED: 11-4-21

BY: 
DAVID W.S. LIEBERMAN
SUZANNE E. DURRELL
ROBERT M. THOMAS, JR.
Counsel for Joseph B. Shea