

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), (United States); the State of California, acting through the California Department of Justice, Office of the Attorney General, Bureau of Medi-Cal Fraud and Elder Abuse (California); San Bernardino Medical Orthopaedic Group, Inc., dba Arrowhead Orthopaedics (Arrowhead Orthopaedics); and Arrowhead Orthopaedics' Chief Executive Officer (CEO) Nabil Razzouk (Razzouk); Arrowhead Orthopaedics and Razzouk collectively referred to herein as "Arrowhead"), and relator John Blohm ("Relator") through their authorized representatives. The United States, California, Arrowhead Orthopaedics, Razzouk, and Relator shall be collectively referred to as "the Parties" herein.

RECITALS

- A. Arrowhead Orthopaedics is a California corporation that provides orthopedic services in the San Bernardino and Riverside counties of California. Arrowhead Orthopaedics' corporate office is located at 1901 West Lugonia Avenue, Redlands, CA 92374.
- B. Razzouk is an individual who at all relevant times served as Chief Executive Officer for Arrowhead Orthopaedics.
- C. On April 14, 2014, Relator filed a *qui tam* action in the United States District Court for the Eastern District of California captioned U.S. *ex rel.* Roe v. Orthopedic Associates of Northern California *et al.* 2:14-CV-0917 TLN DAD, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), Cal. Gov. Code § 12650, *et seq.*, and State of Nev. Rev. Code 357.010, *et seq.* (the Civil Action). Relator alleges that: "Defendants knowingly submitted

false and fraudulent claims to government health programs by purchasing and using reimported viscosupplements on their patients, but submitting claims as if the viscosupplements were lawfully obtained from the manufacturer or authorized distributor.” Complaint in Civil Action at ¶ 94.

D. The United States and California contend that Arrowhead submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”); the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”); the FEHBP, 5 U.S.C. §§ 8901-8914; and the Department of Veterans Affairs, Veterans Health Administration, 38 U.S.C. Chapter 17 (collectively, the Federal Health Care Programs). The United States and California contend that engaging in the Covered Conduct and causing the submission of false or fraudulent claims to the above-referenced Programs gives rise to civil liability under the False Claims Act, 31 U.S.C. §§ 3729 - 3733, Cal. Gov. Code § 12650, *et seq.*, and common law.

E. The United States and California contend that they have certain civil claims against Arrowhead arising from the following conduct:

Between January 1, 2008 and November 1, 2014, Arrowhead knowingly purchased discounted versions of viscosupplements, including Synvisc, Orthovisc, and Euflexxa, that were distributed for use in foreign markets (collectively referred to herein as the “Subject Products.”) The Subject Products that Arrowhead purchased: (i) were devices within the meaning of 21 U.S.C. § 321(h); (ii) were Class III devices within the meaning of 21 U.S.C. § 360c(f)(1) that were required to have premarket approval under 21 U.S.C. § 360e; and (iii) were not exempt from premarket approval and were not the subject of United States Food and Drug Administration (“FDA”)

premarket approval since they included labeling that did not receive FDA premarket approval. Specifically, samples reviewed from among the Subject Products included labeling in foreign languages and labeling in English for additional uses not approved in the United States; in addition, the labeling did not include certain patient information, precautions, adverse events, and clinical studies information. Because the Subject Products were reimported, there was no manufacturer assurance that they were stored appropriately and not tampered with. The Subject Products were not covered by Medicare, Medicaid, TRICARE, FEHBP, and the VA because they had not received final marketing approval from the FDA. Arrowhead knowingly submitted claims for payment to Medicare, Medicaid, TRICARE, FEHBP, and the VA for the Subject Products. Because Federal health care programs reimburse viscosupplements at established rates based on the average sales price of domestic product, Arrowhead profited from using the Subject Products.

The conduct described in this paragraph shall be referred to herein as the "Covered Conduct."

F. This Settlement Agreement is neither an admission of liability by Arrowhead nor a concession by the United States, nor California that their claims are not well founded.

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. Arrowhead shall pay to the United States and California the total sum of \$967,371, plus accrued interest at the rate of 3% per annum from August 1, 2016, and continuing until and including the day of payment (the "Settlement Amount"), as follows:

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a. Arrowhead shall pay to the United States the sum of \$955,288 plus any applicable interest as referenced herein (the "Federal Settlement Amount") by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Eastern District of California no later than the latter of seven (7) business days after the Effective Date of this Agreement or three (3) business days after receiving the above-referenced written instructions. If payment is not timely received, Arrowhead shall also pay the United States interest on the Federal Settlement Amount at a rate of 10% in addition to the 3% noted above (13%) from the date payment was due through the date payment is received.

b. Arrowhead shall pay to California the sum of \$12,083 plus any applicable interest as referenced herein (the "State Settlement Amount") by electronic funds transfer pursuant to written instructions to be provided by California no later than the latter of seven (7) business days after the Effective Date of this Agreement or three (3) business days after receiving the above-referenced written instructions. If payment is not timely received, Arrowhead shall also pay California interest on the State Settlement Amount at a rate of 10% in addition to the 3% noted above (13%) from the date payment was due through the date payment is received.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Arrowhead and as soon as feasible after receipt, the United States shall pay to Relator by electronic funds transfer \$171,952 plus 18% of any interest paid to the United States pursuant to paragraph 1 of this Agreement.

3. Conditioned upon California receiving the State Settlement Amount from Arrowhead and as soon as feasible after receipt, California shall pay to Relator by electronic funds transfer \$2,175 plus 18% of any interest paid to the California pursuant to paragraph 1 of this Agreement.

4. Arrowhead shall pay Relator's counsel, Lief Cabraser Heimann & Bernstein, LLP, a sum of \$60,000 (the "Fees and Costs Amount") by electronic funds transfer pursuant to written instructions to be provided by Relator's counsel after the Agreement is signed by all parties no later than seven (7) business days after receiving the above-referenced written instructions. If payment is not timely received, Arrowhead shall also pay Relator's counsel interest on the Fees and Costs Amount at a rate of 10% from the date payment was due through the date payment is received.

5. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Arrowhead's full payment of the Federal Settlement Amount, the United States releases Arrowhead Orthopaedics and Razzouk 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.

6. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Arrowhead's full payment of the State Settlement Amount, California releases Arrowhead Orthopaedics and Razzouk from any civil claim California has for the Covered Conduct under California's False Claims Act, Cal. Gov. Code § 12651(a)(1)-(3), or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

7. Subject to the exceptions in Paragraphs 8 and 9 below, and conditioned upon Arrowhead's full payment of the Settlement Amount and Fees and Costs Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Arrowhead Orthopaedics from any civil monetary claim the Relator has on behalf of the United States for

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the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and on behalf of California under California's False Claims Act, Cal. Gov. Code § 12651(a)(1)-(3).

8. Notwithstanding the releases given in Paragraphs 5 and 6 of this Agreement, or any other term of this Agreement, the following claims 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, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) or California (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 except as expressly provided herein;
- 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; or
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

9. 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 payment described in Paragraph 2, 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, 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.

10. Conditioned upon Arrowhead's full payment of the Settlement Amount and Fees and Costs Amount, Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Arrowhead, and its officers, agents, employees, heirs, successors, attorneys, and assigns, and Razzouk and his heirs, successors, attorneys, agents and assigns from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.

11. Arrowhead waives and shall not assert any defenses Arrowhead 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. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

12. Arrowhead, together with all present and former affiliates, parents, subsidiaries, divisions and subdivisions, fully and finally release 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 Arrowhead 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 and the United States' investigation and prosecution thereof. Arrowhead hereby expressly waive all rights they may have by virtue of Section 1542 of the California Civil Code, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Arrowhead's releases herein shall be effective whether or not they release claims that are currently known, unknown, foreseen or unforeseen.

13. Arrowhead together with all present and former affiliates, parents, subsidiaries, divisions and subdivisions, fully and finally release California, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Arrowhead has asserted, could have asserted, or may assert in the future against the California, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and California's investigation and prosecution thereof. Arrowhead hereby expressly waives all rights they may have by virtue of Section 1542 of the California Civil Code, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Arrowhead's releases herein shall be effective whether or not they release claims that are currently known, unknown, foreseen or unforeseen.

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14. Arrowhead fully and finally releases the Relator from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Arrowhead has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof.

15. 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, FEHBP Carrier, the United States Department of Veterans Affairs, or any state payer, related to the Covered Conduct; and Arrowhead agrees not to resubmit to any Medicare contractor, TRICARE, FEHBP Carrier, the United States Department of Veterans Affairs, 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.

16. Arrowhead 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Arrowhead, or 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) Arrowhead'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 attorney's fees);

- (4) the negotiation and performance of this Agreement; and
- (5) the payment Arrowhead makes to the United States pursuant to this Agreement and any payments that Arrowhead may make to Relator, 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 by Arrowhead, and Arrowhead 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 Arrowhead or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, VA or FEHBP Programs.

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

17. Arrowhead agrees to cooperate fully and truthfully with the United States' and California's investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Arrowhead shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and to encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Arrowhead further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody,

or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

18. 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 19 (waiver for beneficiaries paragraph), below.

19. Arrowhead 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 payers based upon the claims defined as Covered Conduct.

20. Upon receipt of the payment described in Paragraph 1, above, the United States, California, and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

21. Unless otherwise stated 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.

22. Relator and Arrowhead warrant that they have been represented by, and have sought and obtained the advice of, independent legal counsel with regard to the nature, purpose, and effect of this Settlement Agreement. The Settlement Agreement was negotiated by the Parties and their respective counsel, each of whom had the opportunity to participate in the drafting thereof. Relator and Arrowhead hereby declare that the terms of this Settlement Agreement have been completely read, fully understood, and voluntarily accepted following opportunity for review by legal counsel of their choice.

23. Each of the Parties and each signatory to this Agreement warrants and represents that it freely and voluntarily enters into this Settlement Agreement without any degree of duress or compulsion whatsoever, after having been apprised of all relevant information and data by its legal counsel. Each of the Parties further warrants and represents that no other Party or its representative has made any promise, representation or warranty, express or implied, except as expressly set forth in this Settlement Agreement, and that no Party has relied on any inducements, promises, or representations made by any Party to this Settlement Agreement, or its representatives, or any other person, except as expressly set forth herein.

24. 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 Eastern 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.

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

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

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

28. This Agreement is binding on Arrowhead's successors, transferees, heirs, and assigns.

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

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

31. 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

PHILLIP A. TALBERT
Acting United States Attorney
Eastern District of California

DATED: 9/23/16

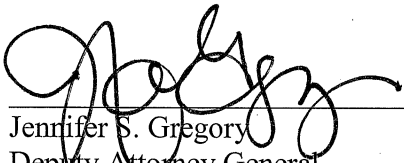
BY: CJ Swann
Catherine J. Swann
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of California

DATED: 9/21/16

BY: Robert K. Deconti
Robert K. Deconti
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

CALIFORNIA

DATED: 9/23/16

BY: 

Jennifer S. Gregory
Deputy Attorney General
Bureau of Medi-Cal Fraud and Elder-Abuse
Office of the Attorney General
California Department of Justice

San Bernardino Orthopaedic Medical Clinic, Inc., and Nabil Razzouk, M.D.

DATED: _____

BY: _____
James D. Matiko, M.D.
President of Arrowhead Orthopaedics
For San Bernardino Orthopaedic Medical Group, Inc.

DATED: _____

BY: _____
Nabil Razzouk

WALLER LANSDEN DORTCH & DAVIS, LLP

DATED: _____

BY: _____
Jennifer Weaver
Counsel for Arrowhead

CALIFORNIA

DATED: _____

BY: _____

Jennifer S. Gregory
Deputy Attorney General
Bureau of Medi-Cal Fraud and Elder-Abuse
Office of the Attorney General
California Department of Justice

San Bernardino Medical Orthopaedic Group, Inc., and Nabil Razzouk, Ph.D.

DATED: 9-21-16 BY: _____

James D. Matiko, M.D.
President of Arrowhead Orthopaedics
For San Bernardino Medical Orthopaedic Group, Inc.

DATED: 9-21-16 BY: _____

Nabil Razzouk
Nabil Razzouk

WALLER LANSDEN DORTCH & DAVIS, LLP

DATED: 9-22-16 BY: _____

Jennifer Weaver
Jennifer Weaver
Counsel for Arrowhead

JOHN BLOHM - RELATOR


DATED: 9/23/2016

BY: 

John Blohm

LIEFF, CABRESER, HEIMANN, BERNSTEIN, LLP

DATED: 9/23/16

BY: 

Nimish R. Desai
Counsel for John Blohm