

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); Orthopedic Associates of Northern California (OANC); and OANC physicians: Alan Azevedo, Leonard Brazil, William Doherty, Kirk Granlund, David Harwood, Taylor Konkin, Stephen Landaker, Stephen Morris, and Bill Watson (collectively: OANC Physicians); OANC and OANC Physicians collectively referred to herein as “OANC Group”), and John Blohm (“Relator”) through their authorized representatives. The United States, OANC, OANC Physicians, California, and Relator shall be collectively referred to as “the Parties” herein.

RECITALS

A. OANC is a California corporation that provides orthopedic services with offices in Chico and Paradise, California. OANC’s corporate office is located at 131 Raley Blvd. Chico, CA 95928.

B. OANC Physicians are physicians who at all relevant times practiced medicine at OANC.

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 OANC Group 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”); 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 OANC Group arising from the following conduct:

Between January 1, 2008 and September 30, 2013, OANC Group knowingly purchased discounted versions of viscosupplements, including Synvisc, Orthovisc, and Supartz, that were distributed for use in foreign markets (collectively referred to herein as the “Subject Products.”) The Subject Products that OANC Group 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, and the VA because they had not received final marketing approval from the FDA. OANC Group knowingly submitted claims for payment to Medicare, Medicaid, TRICARE, 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, OANC Group 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 OANC Group 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. OANC Group shall pay to the United States and California the total sum of \$814,656, plus accrued interest at the rate of 3% per annum from August 15, 2016, and continuing until and including the day of payment (the “Settlement Amount”), as follows:

a. OANC Group shall pay to the United States the sum of \$805,781 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, OANC Group 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 Effective Date of the Agreement through the date payment is received.

b. OANC Group shall pay to California the sum of \$8,875 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, OANC Group 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 Effective Date of the Agreement through the date payment is received.

2. Conditioned upon the United States receiving the Federal Settlement Amount from OANC Group and as soon as feasible after receipt, the United States shall pay to Relator by electronic funds transfer \$145,040.59 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 OANC Group and as soon as feasible after receipt, California shall pay to Relator by electronic funds transfer \$1,598 plus 18% of any interest paid to the California pursuant to paragraph 1 of this Agreement.

4. OANC Group shall pay Relator's counsel, Lief Cabraser Heimann & Bernstein, LLP, a sum of \$100,000 (the "Fees and Costs Amount") by electronic funds transfer pursuant to written instructions to be provided by Lief Cabraser Heimann & Bernstein, LLP 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, OANC Group shall also pay Relator's counsel interest on the Fees and Costs Amount at a rate of 10% from the Effective Date of the Agreement through the date payment is received.

5. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon OANC Group's full payment of the Federal Settlement Amount, the United States releases OANC Group 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 OANC Group's full payment of the State Settlement Amount, California releases OANC Group 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 OANC Group'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 OANC Group from

any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

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 and California 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 and State 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 OANC Group'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 OANC Group, and its officers, agents, and employees, 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. OANC Group waives and shall not assert any defenses OANC Group 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. OANC Group 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 OANC Group 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.

13. OANC Group, 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 OANC Group 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. OANC Group 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.

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

14. OANC Group 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 OANC Group 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. OANC Group hereby expressly waives all rights they may have by virtue of Section 1542 of the California Civil Code, which provides:

Settlement Agreement between: United States;
California; Orthopedic Associates of Northern CA (OANC);
and OANC Individual Physicians

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.

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

15. OANC Group fully and finally releases the Relator from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that OANC Group 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.

16. 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 OANC Group 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.

17. OANC Group 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of OANC Group, or its present or former officers, directors, employees, shareholders, and agents in connection with: Settlement Agreement between: United States; California; Orthopedic Associates of Northern CA (OANC); and OANC Individual Physicians

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

18. OANC Group 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, OANC Group 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 encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. OANC Group 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.

19. 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 20 (waiver for beneficiaries paragraph), below.

20. OANC Group 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.

21. 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).

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

23. Relator and OANC 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. OANC Physicians, and each of them, acknowledge that they have had the opportunity to seek and obtain 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 OANC Group 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.

24. 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 or have had the opportunity to seek and obtain the advice of independent legal counsel with regard to all relevant information and data. 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.

25. 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.

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

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

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

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

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

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

32. 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: 9/23/2016 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: _____

BY: _____

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

Orthopedic Associates of Northern California and Individual Physicians

DATED: _____

BY: _____

Bill Watson, M.D.
On behalf of Orthopedic Associates of Northern California

DATED: _____

BY: _____

Alan Azevedo, M.D.

DATED: _____

BY: _____

Leonard Brazil, M.D.

DATED: _____

BY: _____

William Doherty, M.D.

DATED: _____

BY: _____

Kirk Granlund, M.D.

DATED: _____

BY: _____

David Harwood, M.D.

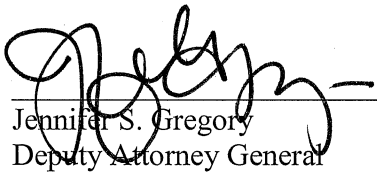
DATED: _____

BY: _____

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: 9/23/14

BY:  _____

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

Orthopedic Associates of Northern California and Individual Physicians

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Office of Counsel to the Inspector General
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CALIFORNIA

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Orthopedic Associates of Northern California and Individual Physicians

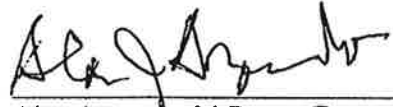
DATED: 9/23/16

BY: _____


Bill Watson, M.D.
On behalf of Orthopedic Associates of Northern California

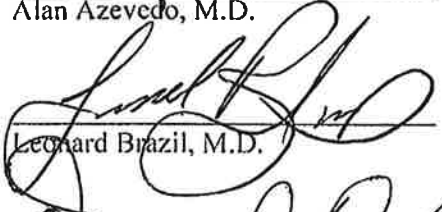
DATED: 9/21/16

BY: _____


Alan Azevedo, M.D.

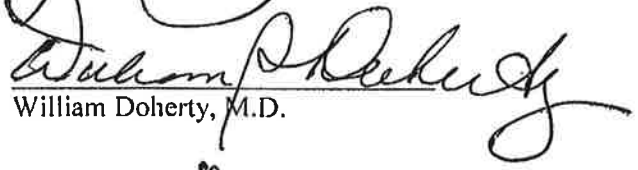
DATED: 9-22-16

BY: _____


Leonard Brazil, M.D.

DATED: 9/23/16

BY: _____


William Doherty, M.D.


DATED: 9/21/16

BY: _____


Kirk Granlund, M.D.

DATED: 9/22/16


BY: _____


David Harwood, M.D.

Settlement Agreement between: United States;
California; Orthopedic Associates of Northern CA (OANC);
and OANC Individual Physicians


DATED: 9/22/16

BY:


Taylor Konkin, M.D.

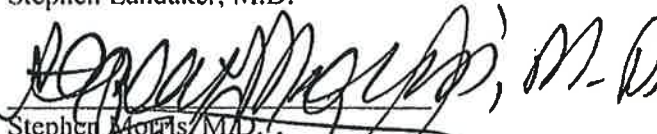
DATED: 9/22/16

BY:


Stephen Landaker, M.D.


DATED: 9/22/16

BY:


Stephen Morris, M.D.

DATED: 9/23/16


BY:


Bill Watson, M.D.

WASHINGTON & HEITHECKER

DATED: 9/24/2016

BY:


Peter G. Washington
Counsel for OANC

JOHN BLOHM - RELATOR

DATED: _____

BY: _____

John Blohm

LIEFF, CABRESER, HEIMANN, BERNSTEIN, LLP

DATED: _____

BY: _____

Nimish R. Desai
Counsel for John Blohm

DATED: _____ BY: _____
Taylor Konkin, M.D.

DATED: _____ BY: _____
Stephen Landaker, M.D.


DATED: _____ BY: _____
Stephen Morris, M.D.

DATED: _____ BY: _____
Bill Watson, M.D.


WASHINGTON & HEITHECKER

DATED: _____ BY: _____
Peter G. Washington
Counsel for OANC

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