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), the Defense Health Agency (DHA), acting on behalf of the TRICARE program, the Office of Personnel Management (OPM), which administers the Federal Employees Health Benefits Program (FEHBP) (collectively the "United States") and Bruce Wolf, M.D., Kiro John Yun, M.D., and Wolf and Yun, P.S.C., (collectively "W&Y"), through their authorized representatives. The United States and W&Y hereafter collectively are referred to as "the Parties."

RECITALS

A. W&Y is a medical practice group of otolaryngologists specializing in allergy, asthma and immunology with offices located in Bardstown, Elizabethtown and Leitchfield, Kentucky. Drs. Wolf and Yun are the sole shareholders of W&Y. W&Y provided services to Medicare, TRICARE and FEHBP beneficiaries.

B. The United States contends that W&Y 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 TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE"); and the FEHBP, 5 U.S.C. §§ 8901-8914.

C. The United States contends that it has certain civil claims against W&Y arising from improperly billing Medicare, TRICARE and FEHBP for Sublingual Immunotherapy serum preparation and overstated units of serum preparation for injection vials, under CPT Code 95165, and for testing under CPT Code 95024 during the following time periods:

1. For Medicare between January 1, 2010, and October 31, 2015;

2. For TRICARE between June 1, 2010, and September 30, 2015; and

3. For FEHB, between January 1, 2010, and August 31, 2015.

Said conduct is hereinafter referred to as the "Covered Conduct."

D. This Agreement is neither an admission of liability or wrongdoing by W&Y nor a concession by the United States that its claims are not well-founded.

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. W&Y, jointly and severally, agree to pay the United States SEVEN HUNDRED FORTY THOUSAND FIVE HUNDRED SEVENTY-EIGHT DOLLARS (\$740,578.00) (the "Settlement Amount") within 15 days after the Effective Date of this Agreement. Payment of the Settlement Amount shall be by electronic funds transfer pursuant to written instructions to be provided by the U.S. Attorney's Office for the Western District of Kentucky.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon W&Y's full payment of the Settlement Amount, the United States releases W&Y 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.

3. Notwithstanding the releases provided in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States 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 State or Federal health care programs;
- d. OPM expressly reserves all rights to institute, direct, or maintain any administrative action seeking debarment against W&Y from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment) or (c) and (d) (permissive debarment);
- e. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and
- f. Any liability based upon obligations created by this Agreement.

4. W&Y waive and shall not assert any defenses W&Y 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.

5. W&Y 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 W&Y has asserted or could have asserted against the United States and its agencies, officers, agents, employees, and servants related to the United States' investigation and prosecution of the Covered Conduct.

6. 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 or FEHBP carrier or payer or any state payer, related to the Covered Conduct; and W&Y agree not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

7. W&Y agree to the following:

a. <u>Unallowable Costs Defined</u>: 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 W&Y, their officers, directors, employees and agents in connection with:

- i. the matters covered by this Agreement;
- ii. the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- W&Y'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);

iv. the negotiation and performance of this Agreement; and

v. the Settlement Amount

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. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by W&Y, and W&Y 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 W&Y or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: W&Y further agree that within 90 days of the Effective Date of this Agreement they 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 W&Y or any of their subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. W&Y agree that the United States, at a minimum, shall be entitled to recoup from W&Y 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 right to disagree with any calculations submitted by W&Y or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on W&Y or any of their 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 W&Y's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. 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 9 (waiver for beneficiaries paragraph), below.

9. W&Y agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

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

11. Each party and signatory to this Agreement represents that they freely and voluntarily enter into this Agreement without any degree of duress or compulsion.

12. 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 Western District of Kentucky. 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.

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

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

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

16. This Agreement is binding on W&Y's successors, transferees, heirs, and assigns.

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

18. 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

JOHN E. KUHN, JR. United States Attorney, Western District of Kentucky

DATED: 6/9/17

BY: **BENJAMIN S. SCHECTER**

Assistant United States Attorney

DATED: 6/2/17

Disall. Re LISA M. RE BY:

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

DATED: _____

BY:

LEIGH A. BRADLEY General Counsel, Defense Health Agency United States Department of Defense

DATED: _____ BY:

EDWARD M. DEHARDE Acting Assistant Director of Federal Employee Insurance Operations Healthcare and Insurance United States Office of Personnel Management 16. This Agreement is binding on W&Y's successors, transferees, heirs, and assigns.

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THE UNITED STATES OF AMERICA

JOHN E. KUHN, JR. United States Attorney, Western District of Kentucky

DATED: _____ BY:

BENJAMIN S. SCHECTER Assistant United States Attorney

DATED:

BY:

BY:

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

DATED: 31 May 2017 BY:

Bryan T. Wheeler

Deputy General Counsel, Defense Health Agency United States Department of Defense

DATED: _____

EDWARD M. DEHARDE Acting Assistant Director of Federal Employee Insurance Operations Healthcare and Insurance United States Office of Personnel Management

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THE UNITED STATES OF AMERICA

JOHN E. KUHN, JR. United States Attorney, Western District of Kentucky

DATED: _____ BY:

BENJAMIN S. SCHECTER Assistant United States Attorney

DATED: _____

BY:

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

DATED: _____ BY:

LEIGH A. BRADLEY General Counsel, Defense Health Agency United States Department of Defense

DATED: 5/30/2017 BY:

EDWARD M. DEHARDE Acting Assistant Director of Federal Employee **Insurance** Operations Healthcare and Insurance United States Office of Personnel Management

WOLF AND YUN, P.S.C.

DATED6/5/14.

DATED: 6

BY STEPHANIE P. FRANCKEWITZ Counsel for Wolf and Yun, P.S.C.

BRUCE WOLF, M.D.

DATED: 5-30-2017

BY: Bruce Wolf, M.D. MD

DALEN:

DI STEPHANIE P. FRANCKEWITZ Bruce Wolf, M.D.

KIRO JOHN YUN, M.D.

DATED: 6

DATED;

BY: o John Yun BY STEPHANIEP, FRANCKEWITZ Kiro John Yun, M.D.