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) and the Defense Health Agency (DHA), which administers the TRICARE program (collectively the "United States"); Olympus Corporation of the Americas, ("Olympus"), and John Slowik ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Olympus is the United States subsidiary of Olympus Corporation, a Japan based company. Olympus sells and distributes medical optics and imaging equipment, including endoscopes, ultrasound systems, and clinical microscopes throughout the United States including New Jersey. Olympus's corporate headquarters are located at 3500 Corporate Parkway, Center Valley, Pennsylvania, 18034.

B. On or about November 15, 2010, John Slowik (Relator) filed a *qui tam* action in the United States District Court for the District of New Jersey captioned <u>United</u> <u>States ex rel. Slowik et al. v. Olympus America, Inc., et al.</u>, Case No. 10-cv-5994 (D.N.J.) pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), and the analogous provisions of a number of state False Claims Act statutes (the "Civil Action"). Relator's complaint alleged that Olympus and several of its affiliates paid kickbacks to healthcare providers, in violation of the False Claims Act, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Relator filed amended complaints on July

22, 2011, and October 24, 2012, and a corrected Second Amended Complaint on February 4, 2016.

C. Olympus has entered into 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, defined in Paragraph F, below. States with which Olympus executes a Medicaid State Settlement Agreement in the form to which Olympus and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by Olympus and an individual State, shall be defined as "Medicaid Participating States."

D. Olympus and its subsidiaries that market, sell, or lease medical and surgical products, including but not limited to endoscopes will contemporaneously enter into a Deferred Prosecution Agreement ("DPA") with the United States Attorney's Office for the District of New Jersey. The United States has filed or will file a Criminal Complaint in the United States District Court for the District of New Jersey (the "Court") charging Olympus with conspiracy to commit violations of the Anti-Kickback Statute, contrary to Title 42, United States Code, Section 1320a-7b(b), in violation of Title 18, United States Code, Section 371, during the years 2006 through 2011 (the "Criminal Complaint"). The United States and Olympus will file with the Court the DPA, which states that the Department of Justice will recommend to the Court that prosecution of Olympus for the conduct charged in the Criminal Complaint be deferred for a period of three (3) years and that the Department of Justice will seek dismissal with prejudice of

the Criminal Complaint thereafter if Olympus is in compliance with all of its obligations under the DPA.

E. The United States contends that Olympus submitted or caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1; the TRICARE Program, 10 U.S.C. §§ 1071-1110b; and the Medicaid Program (Medicaid), 42 U.S.C. §§ 1396-1396w-5.

F. The United States contends that from January 1, 2006 through December 31, 2011, Olympus provided kickbacks to physicians and to hospital employees and representatives, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), in order to induce them to purchase Olympus endoscopes and other Olympus medical and surgical equipment. The United States contends that these kickbacks took the form of grants, fellowships, consulting payments, free trips to desirable locations, payment for recreation and leisure activities, gifts and no-charge loans of equipment, and free use of equipment. For example, Olympus paid for a number of physicians to take week-long trips to Japan, where Olympus provided sightseeing excursions and lavish entertainment. Also, Olympus provided one physician with approximately \$400,000 in endoscopes and other equipment to use without charge in his private practice, and that doctor played a major role in a hospital's decision to purchase millions of dollars worth of Olympus products. The United States contends that it has certain civil claims against Olympus arising from this conduct, which is referred to in this Agreement as the Covered Conduct.

G. Except for those facts admitted in connection with the criminal DPA, this Settlement Agreement is neither an admission of liability by Olympus nor a concession by the United States or the Relator that their claims are not well founded.

H. 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. Olympus agrees to pay to the United States and the Medicaid Participating States, collectively, the total amount of three hundred and six million dollars (\$306,000,000) plus accrued interest at the rate of 2.25% per annum from June 20, 2015, and continuing until and including the day of payment (the "Settlement Amount"). The Settlement Amount is to be paid to the United States and the Medicaid Participating States as follows:

a. Olympus shall pay to the United States the sum of \$263,160,000 plus accrued interest in the amount of 2.25% per annum earned on that amount beginning on June 20, 2015 and continuing through the day before full payment ("the Federal Settlement Amount"). Olympus shall pay the Federal Settlement Amount by electronic funds transfer pursuant to instructions from the United States Attorney's Office for the District of New Jersey. Olympus shall make this electronic funds transfer no later than ten days after (1) the Effective Date of this Agreement, or (b) the date of the filing of the criminal complaint, whichever is later.

b. Olympus shall deposit the sum of \$42,840,000 plus accrued interest as set forth above (the "Medicaid State Settlement Amount") into one or more interest-bearing money market or bank accounts that are held in the name of Olympus, and make payment from these accounts to the Medicaid Participating States pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Olympus will enter into with the Medicaid Participating States.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Olympus and as soon as feasible after receipt, the United States shall pay \$43,421,400, plus accrued interest in the amount of 2.25% per annum earned on that amount beginning on June 20, 2015 and continuing through the day before full payment by Olympus, to Relator by electronic funds transfer in accordance with the instructions provided by Relator's Counsel.

3. Relator and Relator's counsel acknowledge receipt of Olympus's full and complete payment of Relator's attorneys' fees and costs pursuant to 31 U.S.C. §3730(d) incurred in connection with the Civil Action. No additional attorneys' fees or costs shall be paid to or claimed by Relator or his counsel.

4. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon Olympus's satisfaction of the payment and deposit obligations in Paragraph 1 above, the United States releases Olympus, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and affiliates; and the successors and assigns of any of them, 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. In consideration of the obligations of Olympus in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and Olympus, and conditioned upon Olympus's satisfaction of the payment and deposit obligations in Paragraph 1 above, the OIG-HHS agrees to 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 Olympus 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 8 (concerning excluded claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Olympus 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 8, below.

6. In consideration of the obligations of Olympus set forth in this Agreement, conditioned upon Olympus's satisfaction of the payment and deposit obligations in Paragraph 1 above, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program

against Olympus, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and the successors and assigns of any of them, under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 8 (concerning excluded claims), below, and as reserved in this Paragraph. DHA expressly reserves authority to exclude Olympus from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

7. Conditioned upon Olympus's satisfaction of the payment and deposit obligations in Paragraph 1 above, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Olympus, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; and affiliates; and the successors and assigns of any of them, from any 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 4 through 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:

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 exclusion from Federal health care programs.
- d. Any liability to the United States (or its agencies) or the StatePlaintiffs for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
- i. Any liability of individuals.

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 and 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 Olympus's satisfaction of the payment and deposit obligations in Paragraph 1 above, Relator, with Relator's heirs, successors, attorneys, agents, and assigns, fully and finally releases, waives, and forever discharges Olympus, together with its current and former parent corporations; direct and indirect subsidiaries or affiliates; brother or sister corporations; divisions; predecessors; current and former directors, officers, agents, and employees; along with the successors and assigns of any of them, from any and all claims, demands, controversies, actions, obligations, liabilities, or demands for damages of any nature, character, or amount whatsoever, whether known or unknown, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law that each would have had standing to bring as of the date of this Agreement, including but not limited to claims under 31 U.S.C. § 3730(d)(1) for attorneys' fees, costs, and expenses. Provided however, nothing in this paragraph shall release, waive, or discharge Relator's rights to seek a relator's share of any settlement under state law.

11. Olympus waives and shall not assert any defenses it 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. Olympus fully and finally releases the United States and its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Olympus 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. In consideration of the obligations of the Relator set forth in this Agreement, Olympus, together with any successors and assigns, fully and finally releases, waives, and forever discharges Relator and Relator's heirs, successors, attorneys, agents, and assigns from any and all claims, demands, controversies, actions, obligations, liabilities, or demands for damages of any nature, character, or amount whatsoever, whether known or unknown, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law that each otherwise would have had standing to bring as of the date of this Agreement, including but not limited to claims for attorneys' fees, costs, and expenses.

14. 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 or TRICARE contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Olympus agrees not to resubmit to any Medicare or TRICARE contractor or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Olympus 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 Olympus, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and the DPA;
- (2) the United States' audit(s) and civil and criminal investigation(s)of the matters covered by this Agreement;
- Olympus's investigation, defense, and corrective actions
 undertaken in response to the United States' audit(s) and civil and
 any criminal investigation(s) in connection with the matters
 covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement and the DPA;
- (5) the payment Olympus makes to the United States pursuant to this Agreement and any payments that Olympus 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). However, nothing in paragraph 15.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Olympus.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Olympus, and Olympus 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 Olympus or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

16. Olympus agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Olympus 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. Olympus 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.

17. 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 Paragraphs 4-7 above and paragraph 18, below.

18. Olympus 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.

19. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1), dismissing the Civil Action with prejudice to the Relator as to all claims, with prejudice to the United States for the Covered Conduct, and without prejudice to the United States for all other claims.

20. Except as provided in the separate agreement between Relator and Olympus described in Paragraph 3, above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

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

22. 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 New Jersey. 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.

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

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

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

26. This Agreement is binding on Olympus's successors, transferees, heirs, and assigns.

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

28. All parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED:

BY:

David T. Cohen Senior Trial Counsel Commercial Litigation Branch Civil Division

DATED: 3/1/16

BY:

David E. Dauenheimer Deputy Chief, Civil Division United States Attorney's Office District of New Jersey

3/1/16

BY: Jacob T. Elberg

Chief, Health Care and Government Fraud Unit United States Attorney's Office District of New Jersey

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

DATED: _____

BY: ____

Paul J. Hutter General Counsel Defense Health Agency United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: 3/1/16 BY: David I. Cohen

Senior Trial Counsel **Commercial Litigation Branch** Civil Division

DATED:

BY:

David E. Dauenheimer Deputy Chief, Civil Division United States Attorney's Office District of New Jersey

BY:

Jacob T. Elberg Chief, Health Care and Government Fraud Unit United States Attorney's Office District of New Jersey

DATED: 2/26/16

BY: Robert & Delonti

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

DATED:

BY:

Paul J. Hutter General Counsel Defense Health Agency United States Department of Defense

THE UNITED STATES OF AMERICA

DATED:

BY:

David T. Cohen Senior Trial Counsel Commercial Litigation Branch Civil Division

DATED:

BY:

David E. Dauenheimer Deputy Chief, Civil Division United States Attorney's Office District of New Jersey

BY: ____

Jacob T. Elberg Chief, Health Care and Government Fraud Unit United States Attorney's Office District of New Jersey

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

DATED: 23566 6

Deputy b.C. BY: Paul J. Hutter for

General Counsel Defense Health Agency United States Department of Defense

DATED: 2/29/16

OLYMPUS R

Nacho Abia President and CEO, Olympus Corporation of the Americas

2/29/16

BY: M. Gallagier

Jeremy D. Frey Pepper Hamilton LLP Counsel for Olympus RELATOR JOHN SLOWIK

DATED: 2/23/16 BY: John Slowik Relator

DATED: 2.24.16 BY:

M. Tavy Deming Kenney McCafferty Counsel for Relator

Schilling DATED: 2-24-16BY: Kathryn Schilling

Kathryn Schiffing Kenney McCafferty Counsel for Relator