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) (collectively, the "United States"), and Oxford Diabetic Supply, Inc., U.S. Healthcare Supply, LLC, U.S. Diagnostics, Inc., U.S. Diagnostics NJ, Edward J. Letko, and Jon P. Letko (together, hereafter referred to as the "Oxford/U.S. Healthcare Parties") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

- A. Oxford Diabetic Supply, Inc. and U.S. Healthcare Supply, LLC are or were mail-order suppliers of durable medical equipment based in New York, New York and Milford, New Jersey, respectively. U.S. Diagnostics, Inc. and U.S. Diagnostics NJ are or were entities that provide management support and other services to Oxford Diabetic Supply, Inc. and U.S. Healthcare Supply, LLC. Edward J. Letko is or was the owner and president of Oxford Diabetic Supply, Inc. and U.S. Diagnostics, Inc. Jon P. Letko is the owner and president of U.S. Healthcare Supply, LLC and U.S. Diagnostics NJ.
- B. The United States contends that the Oxford/U.S. Healthcare Parties 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").
- C. The United States contends that it has certain civil claims against the Oxford/U.S. Healthcare Parties arising from the following: from on or about July 21, 2008, to December 31, 2010, the Oxford/U.S. Healthcare Parties set up and controlled an entity called Diabetic Experts, Inc., that they used to make unsolicited telephone calls to suspected Medicare beneficiaries in order to sell durable medical equipment to these beneficiaries in violation of 42 U.S.C. §

1395m(a)(17). The Oxford/U.S. Healthcare Parties billed Medicare for durable medical equipment that was sold pursuant to these unsolicited calls. The conduct described in this paragraph is referred to below as the "Covered Conduct."

D. This Settlement Agreement is neither an admission of liability by the Oxford/U.S. Healthcare Parties 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. The Oxford/U.S. Healthcare Parties shall pay to the United States twelve million dollars (\$12,000,000) ("Settlement Amount") and interest on the Settlement Amount at a rate of 2% from October 2, 2015 through the date of payment, no later than ten days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice. Of the Settlement Amount, Edward J. Letko will personally pay \$6 million, U.S. Healthcare Supply, LLC will pay \$5 million, and Jon P. Letko will personally pay \$1 million. The payments by Edward J. Letko and Jon P. Letko shall come from their personal assets and not from any special distribution from any of the Oxford/U.S. Healthcare Parties.
- 2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon the Oxford/U.S. Healthcare Parties' full payment of the Settlement Amount, the United States releases the Oxford/U.S. Healthcare Parties 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; the common law theories of payment by

mistake, unjust enrichment, and fraud; or any statutory provision creating a cause of action which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 CFR Part O, Subpart I, Sec. 0.45d.

- 3. Notwithstanding the releases given in Paragraph 2 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) for any conduct other than the Covered Conduct;
 - e. Any liability based upon obligations created by this Agreement;
 - f. Any liability of individuals except for Edward J. Letko and Jon P. Letko, who are released as described in this Agreement;
 - g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
 - h. Any liability for failure to deliver goods or services due; and
 - Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. VOLUNTARY EXCLUSION

- a. In compromise and settlement of the rights of OIG-HHS to exclude Oxford Diabetic Supply, Inc. pursuant to 42 U.S.C. § 1320a-7(b)(7), based upon the Covered Conduct, Oxford Diabetic Supply, Inc. agrees to be permanently excluded under this statutory provision from Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). The permanent exclusion shall be effective upon the Effective Date of this Agreement.
- b. Such exclusion shall have national effect. Federal health care programs shall not pay anyone for items or services, including administrative and management services, furnished, ordered, or prescribed by Oxford Diabetic Supply, Inc. in any capacity while Oxford Diabetic Supply, Inc. is excluded. This payment prohibition applies to Oxford Diabetic Supply, Inc. and all other individuals and entities (including, for example, anyone who employs or contracts with Oxford Diabetic Supply, Inc., and any hospital or other provider where Oxford Diabetic Supply, Inc. provides services). The exclusion applies regardless of who submits the claim or other request for payment. Violation of the conditions of the exclusion may result in criminal prosecution and the imposition of civil monetary penalties and assessments. Oxford Diabetic Supply, Inc. further agrees to hold the Federal health care programs, and all federal beneficiaries and/or sponsors, harmless from any financial responsibility for items or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. Oxford Diabetic Supply, Inc. waives any further notice of the exclusion and agrees not to contest such exclusion either administratively or in any state or federal court.
- 5. Oxford Diabetic Supply, Inc. and Edward J. Letko have provided financial disclosure statements (Financial Statements) to the United States (Oxford's Financial Statements are for the corporation, and Edward J. Letko's sworn Financial Statements are for himself

personally) and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. Oxford Diabetic Supply, Inc. and Edward J. Letko warrant that the Financial Statements are complete, accurate, and current. If the United States learns of assets in which Oxford Diabetic Supply, Inc. and/or Edward J. Letko had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or if the United States learns of any misrepresentation by Oxford Diabetic Supply, Inc. and/or Edward J. Letko on, or in connection with, the Financial Statements, and if such nondisclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by \$600,000 or more, the United States may at its option: (a) rescind this Agreement and file suit against Oxford Diabetic Supply, Inc. and/or Edward J. Letko based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount from Oxford Diabetic Supply, Inc. and/or Edward J. Letko plus one hundred percent (100%) of the value of the net worth of Oxford Diabetic Supply, Inc. and/or Edward J. Letko previously undisclosed. The United States agrees to provide written notice to Oxford Diabetic Supply, Inc. and Edward J. Letko, and to provide 20 days for Oxford Diabetic Supply, Inc. and Edward J. Letko to respond to the United States, before undertaking a collection action pursuant to this Paragraph. Oxford Diabetic Supply, Inc. and Edward J. Letko agree not to contest any collection action undertaken by the United States pursuant to this provision, and immediately to pay the United States all reasonable costs incurred in such an action, including attorney's fees and expenses.

6. In the event that the United States, pursuant to Paragraph 5 (concerning disclosure of assets), above, opts to rescind this Agreement, Oxford Diabetic Supply, Inc. and Edward J. Letko agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to Oxford Diabetic

Supply, Inc. and/or Edward J. Letko that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on June 23, 2014.

- 7. The Oxford/U.S. Healthcare Parties waive and shall not assert any defenses the Oxford/U.S. Healthcare Parties 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.
- 8. The Oxford/U.S. Healthcare Parties 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 the Oxford/U.S. Healthcare Parties have 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.
- 9. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and the Oxford/U.S. Healthcare Parties agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.
 - 10. The Oxford/U.S. Healthcare Parties 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 the Oxford/U.S. Healthcare Parties, their present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement;
 - (2) the United States' audits and civil and any criminal investigations of the matters covered by this Agreement;
 - (3) the Oxford/U.S. Healthcare Parties' investigation, defense, and corrective actions undertaken in response to the United States' audits and civil and any criminal investigations in connection with the matters covered by this Agreement (including attorney's fees);
 - (4) the negotiation and performance of this Agreement;
 - (5) the payment the Oxford/U.S. Healthcare Parties make to the United States pursuant to this Agreement; and
 - (6) the negotiation of and obligations undertaken pursuant to the CIA entered into by U.S. Healthcare Supply, LLC, U.S. Diagnostics, Inc., U.S. Diagnostics NJ, Edward J. Letko, and Jon P. Letko 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 10.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 the Oxford/U.S. Healthcare Parties.

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the Oxford/U.S. Healthcare Parties, and the Oxford/U.S. Healthcare Parties 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 the Oxford/U.S. Healthcare Parties or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: The Oxford/U.S. Healthcare Parties 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 the Oxford/U.S. Healthcare Parties 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. The Oxford/U.S. Healthcare Parties agree that the United States, at a minimum, shall be entitled to recoup from the Oxford/U.S. Healthcare Parties 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 the Oxford/U.S. Healthcare Parties or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on the Oxford/U.S. Healthcare Parties 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 the Oxford/U.S. Healthcare Parties' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 11. 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 12 (waiver for beneficiaries paragraph), below.
- 12. The Oxford/U.S. Healthcare Parties 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.
- 13. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 14. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.
- 15. 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.

- 16. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 17. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 18. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 19. This Agreement is binding on the Oxford/U.S. Healthcare Parties' successors, transferees, heirs, and assigns.
- 20. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 21. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: <u>9/7/16</u>

BY:

Trial Attorney
Commercial Litigation Branch

Civil Division

United States Department of Justice

PAUL J. FISHMAN United States Attorney District of New Jersey

DATED: 9/7/16

BY:

CHARLES GRAYBOW

Assistant United States Attorney United States Attorney's Office for the 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: 8/30/16

BY: Poblit L. 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

OXFORD/U.S. HEALTHCARE PARTIES - DEFENDANTS

DATED: 8/19/2016

BY:

EDWARD J. LEPKO

For himself individually and as president and owner of Oxford Diabetic Supply and

U.S. Diagnostics, Inc.

DATED: <1/4/2016

BY:

JON P. LETKO

For himsel kindividually and as president and owner of U.S. Healthcare Supply, LLC and

U.S. Diagnostics NJ

DATED: 0/26/16

BY:

JOSEPH SAVAGE, JR

Goodwin Procter

Exchange Place, 53 State Street

Boston, MA 02109

JURA C. ZIBAS

Wilson Elser

150 East 42nd Street

New York, NY 10017

Counsel for the Oxford/U.S. Healthcare Parties