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 of the Department of Health and Human Services ("OIG-HHS") (collectively, the "United States"), StrataDX, formerly Strata Pathology Services, Inc. ("Strata"), and Relator Henry O'Dell ("Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Strata, based in Lexington, Massachusetts, is a pathology laboratory that provides a range of technical and diagnostic pathology services to physician practices on behalf of their patients, including Medicare Program ("Medicare") and Medicaid Program ("Medicaid") beneficiaries.

B. On October 30, 2013, Relator filed an action in the United States District Court for the District of Massachusetts captioned United States ex rel. Henry O'Dell v. Strata Pathology Services, Inc. et al., No. 13-cv-12677-NMG, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). Relator alleges that Strata defrauded federally funded health care programs by, among other things, providing remuneration to physicians to induce referrals of specimens in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Physician Self-Referral Law (also known as the Stark Law), 42 U.S.C. § 1395nn.

C. The United States contends that Strata submitted or caused to be submitted claims for payment to Medicare, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III, and Medicaid, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5.
D. The United States contends that it has certain civil claims against Strata for engaging in the following alleged conduct (the "Covered Conduct"):

1. During the period from January 1, 2009, to December 31, 2014, Strata knowingly submitted to Medicare false claims for pathology services that resulted from its offer and provision of illegal remuneration to physicians in the form of discounts on Strata’s privately insured business to induce the physicians to refer Medicare business to Strata, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Physician Self-Referral Law, 42 U.S.C. § 1395nn. Specifically, between January 1, 2009, and December 31, 2014, Strata engaged in a billing practice, known as "account billing," "direct billing," or "client billing," pursuant to which Strata offered the seven physicians or physician practices listed in Appendix A, and further identified by name in a side letter, discounted prices for pathology services for privately insured patients. Under these arrangements, Strata performed technical slide preparation services, but allowed the physicians or physician practices to bill private insurers directly for those technical services. Strata then split the revenue with the physicians or physician practices by charging the physicians or physician practices discounted prices for the technical services and allowing the physicians or physician practices to retain the reimbursements from the private insurers. Strata offered these account billing arrangements to the seven physicians or physician practices knowing that the practices would refer virtually all of their patients, including Federal health care program beneficiaries, to Strata.

2. During the period January 1, 2008, to December 31, 2014, Strata knowingly submitted to Medicare false claims for pathology services that resulted from its offer and provision of illegal remuneration to physicians in the form of consulting fees to induce the physicians to refer Medicare business to Strata, in violation of the Anti-Kickback Statute, 42
U.S.C. § 1320a-7b(b), and the Physician Referral Law, 42 U.S.C. § 1395nn. Specifically, Strata offered sham consulting arrangements and paid sham consulting fees to the physician and physician practice listed in Appendix B, and further identified by name in a side letter, without that physician and physician practice having provided any services. Both the physician and physician practice listed in Appendix B were sources of Medicare referrals to Strata.

3. During the period January 1, 2008, to December 31, 2014, Strata also received Medicaid revenue in connection with its account billing practices.

E. Strata acknowledges that it committed the following acts:

1. Between January 1, 2009, and December 31, 2014, pursuant to account billing arrangements, Strata offered and provided discounted prices for technical slide preparation services for privately insured patients to the seven physicians or physician practices listed in Appendix A, and further identified by name in a side letter. Strata effectuated these discounts by allowing the seven physicians or physician practices to bill the patients’ private insurers for the technical slide preparation services and to retain the amounts that the private insurers paid to the physicians or physician practices, while charging the physicians or physician practices at a reduced rate for the technical slide preparation services rendered. Strata did not perform any analysis of its account billing practices to determine whether the discounted prices were commensurate with cost savings to Strata or otherwise reflective of any reduction in Strata’s actual costs. Between January 1, 2009, and December 31, 2014, Strata accepted referrals of specimens for Medicare beneficiaries from those seven physicians or physician practices, and Strata billed and accepted payment from Medicare for pathology services rendered in connection with those specimens.
2. Between January 1, 2008, and December 31, 2014, pursuant to a consulting agreement dated February 12, 2008, Strata paid consulting fees to Physician Practice H listed in Appendix B, and further identified by name in a side letter, when Strata did not receive any consulting services in exchange for those fees. Between January 1, 2008, and December 31, 2014, Strata accepted referrals from Physician Practice H specimens for Medicare beneficiaries, and Strata billed and accepted payment from Medicare for pathology services rendered in connection with those specimens.

3. Between January 1, 2013, and December 31, 2014, pursuant to a consulting agreement dated March 1, 2013, Strata paid consulting fees to Physician I listed in Appendix B, and further identified by name in a side letter, when Strata did not receive any consulting services in exchange for those fees. Between January 1, 2013, and December 31, 2014, Strata accepted referrals from Physician I of specimens for Medicare beneficiaries to Strata, and Strata billed and accepted payment from Medicare for pathology services rendered in connection with those specimens.

F. Strata has entered or will enter into a separate settlement agreement, described in Paragraph 1.b below (the “Medicaid State Settlement Agreement”) with Massachusetts in settlement of the Covered Conduct.

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 attorneys’ fees and costs and reasonable and necessarily incurred expenses.
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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. No later than seven days after the Effective Date of this Agreement, Strata shall pay to the United States and the Commonwealth of Massachusetts, collectively, $558,793.20, plus interest at a rate of 2% from August 12, 2015, through the day before full payment (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and Massachusetts on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and Massachusetts under the following terms and conditions:

   a. Strata shall pay to the United States the sum of $540,900.29, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than seven (7) days after the Effective Date of this Agreement.

   b. Strata shall pay the sum of $17,892.91, plus accrued interest as set forth above ("State Settlement Amount"), to Massachusetts in accordance with the terms of the Medicaid State Settlement Agreement, which Strata has entered or will enter into with Massachusetts.

2. Conditioned upon the United States receiving the Federal Settlement Amount from Strata, the United States agrees that it shall pay $102,773.25, plus nineteen percent (19%) of the actual accrued interest paid to the United States by Strata on the Federal Settlement Amount, to Relator by electronic funds transfer as soon as feasible after receipt.
3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Strata’s full payment of the Settlement Amount, the United States releases Strata, together with its current and former parent corporations, direct and indirect subsidiaries, its current Chief Executive Officer Pat Noland, its current Chief Financial Officer James Agnello, its current Controller Robin Feeney, 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.

4. Subject to the exceptions in Paragraph 5 below, and conditioned upon Strata’s full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Strata 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.

5. Notwithstanding the releases given in Paragraphs 3 and 4 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 and the suspension and debarment rights of any Federal agency;
   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. Except as explicitly stated in this Agreement, any liability of individuals.

6. 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.

7. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, fully and finally releases Strata, and its officers, agents, and employees, from any liability to Relator arising from any claims that the Relator has asserted, could have asserted, or may in the future assert against Strata, related to the claims alleged in the Civil Action including a claim for unlawful retaliation. As to attorney’s fees and costs, Strata and the Relator have reached an agreement as to the payment of fees and costs as memorialized in the “Attorney’s Fees and Costs Settlement Agreement.”

8. Strata waives and shall not assert any defenses Strata 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.

9. Strata fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney’s fees, costs, and expenses of every kind and however denominated) that Strata 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.

10. Strata, together with its current and former parent corporations, direct and indirect subsidiaries, and its current and former officers, agents, and employees, fully and finally releases the Relator and his heirs, successors, attorneys, agents, and assigns from any claims (including for attorney’s fees, costs, and expenses of every kind and however denominated) that Strata has asserted, could have asserted, or may assert in the future against the Relator, related to the Civil Action and the Relator’s investigation and prosecution thereof.

11. 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 Strata agrees not to resubmit to any Medicare contractor 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.

12. Strata 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. §§ 1395-1395III and
1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Strata, and its present or former officers, directors, employees, shareholders, and agents in connection with:

i. the matters covered by this Agreement;

ii. the United States’ audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

iii. Strata’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);

iv. the negotiation and performance of this Agreement;

ev. the payment Strata makes to the United States pursuant to this Agreement and any payments that Strata may make to Relator, including costs and attorney’s 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 will be separately determined and accounted for by Strata, and Strata shall not
charge such Unallowable Costs directly or indirectly to any contract 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 Strata or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

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

14. 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 15 (waiver for beneficiaries paragraph), below.
15. Strata 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.

16. Upon receipt of the Federal Settlement Amount described in Paragraph 1.a and the State Settlement Amount described in Paragraph 1.b, above, and receipt of Strata’s payment of fees and costs as memorialized in the “Attorney’s Fees and Costs Settlement Agreement,” the Relator shall promptly sign and file in the Civil Action a Notice of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

17. Except as otherwise provided 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.

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

19. 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 Massachusetts. 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.

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

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on Strata’s successors, transferees, heirs, and assigns.

24. This Agreement is binding on Relator’s successors, transferees, heirs, and assigns.

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

26. 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: 9/30/15
BY: Abraham George
Deana K. El-Mallawany
Assistant United States Attorneys
United States Attorney’s Office
District of Massachusetts

DATED: 9/30/15
BY: Robert K. DeConti
Assistant Inspector General for Legal Affairs
Office of the Counsel to the Inspector General
U.S. Department of Health and Human Services

STRATA

DATED: ______________
BY: Pat Noland
Chief Executive Officer
Strata

DATED: ______________
BY: Jonathan L. Kotlier
Nutter McClennen & Fish LLP
Counsel for Strata

RELATOR

DATED: ______________
BY: Henry O’Dell

DATED: ______________
BY: Thomas J. Poulin
Simmer Law Group PLLC
Counsel for Henry O’Dell
THE UNITED STATES OF AMERICA

DATED: _______________  
BY: _______________________
    Abraham George
    Deana K. El-Mallawany
    Assistant United States Attorneys
    United States Attorney's Office
    District of Massachusetts

DATED: _______________  
BY: _______________________
    Robert K. DeConti
    Assistant Inspector General for Legal Affairs
    Office of the Counsel to the Inspector General
    U.S. Department of Health and Human Services

STRATA

DATED: 9-29-15  
BY: _______________________
    Pat Noland
    Chief Executive Officer
    Strata

DATED: 9-30/15
BY: _______________________
    Jonathan L. Kotlier
    Nutter McClennen & Fish LLP
    Counsel for Strata

RELATOR

DATED: _______________  
BY: _______________________
    Henry O'Dell

DATED: _______________  
BY: _______________________
    Thomas J. Poulin
    Simmer Law Group PLLC
    Counsel for Henry O'Dell
THE UNITED STATES OF AMERICA

DATED: ________________
BY: _________________________
   Abraham George
   Deana K. El-Mallawany
   Assistant United States Attorneys
   United States Attorney's Office
   District of Massachusetts

DATED: ________________
BY: _________________________
   Robert K. DeConti
   Assistant Inspector General for Legal Affairs
   Office of the Counsel to the Inspector General
   U.S. Department of Health and Human Services

STRATA

DATED: ________________
BY: _________________________
   Pat Noland
   Chief Executive Officer
   Strata

DATED: ________________
BY: _________________________
   Jonathan L. Kotlier
   Nutter McClennen & Fish LLP
   Counsel for Strata

RELATOR

DATED: 9/29/15
BY: _________________________
   Henry O'Dell

DATED: 9/30/15
BY: _________________________
   Thomas J. Poulin
   Simmer Law Group PLLC
   Counsel for Henry O'Dell
APPENDIX A

1. Physician Practice A in Chicago, Illinois
2. Physician Practice B in Marietta, Georgia
4. Physician D in Fairfax, Virginia
5. Physician Practice E in Edina, Minnesota
6. Physician Practice F in Colchester, Vermont
7. Physician G in Anchorage, Alaska
APPENDIX B

1. Physician Practice H in Stoneham, Massachusetts
2. Physician I in Marietta, Georgia