

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among (a) 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); (b) OC Genetic Consultants Inc. (OC Genetic); and (c) George Carralejo (Carralejo), through their authorized representatives. Collectively, all of the above will be referred to as the Parties.

RECITALS

A. George Carralejo, of Yorba Linda, California, is the sole owner and Chief Executive Officer of OC Genetic Consultants Inc., a sales and marketing company based in California.

B. The United States contends that OC Genetic and Carralejo caused claims for payment to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare).

C. The United States contends that it has certain civil claims against OC Genetic and Carralejo arising from the following alleged conduct, by which OC Genetic and Carralejo caused laboratory RDx Bioscience, Inc. (RDx) to submit false or fraudulent claims to Medicare:

i. During the period of August 1, 2020 to September 30, 2021, OC Genetic and Carralejo conspired with Ralston Health Group Inc. (Ralston) and Dr. Dan Eidman (Dr. Eidman) to knowingly and willfully pay to Dr. Eidman thousands of dollars in monthly kickbacks, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, that were disguised as consulting and/or medical director fees but actually were offered to induce Dr. Eidman to order laboratory testing, including medically unnecessary testing, from RDx Bioscience, Inc. (RDx), a clinical laboratory in Kenilworth, New Jersey, and NEXT Bio-Research Services, LLC d/b/a NEXT

Molecular Analytics (Next Molecular), a clinical laboratory in Chester, Virginia. OC Genetic and Carralejo introduced Dr. Eidman to Ralston, arranged for RDx and Next Molecular to pay commissions to Ralston based on Dr. Eidman's referrals, and knew of Ralston's financial arrangement with Dr. Eidman, furthering the scheme by which Ralston kicked back a portion of its commissions to Dr. Eidman to induce him to refer Medicare beneficiaries to RDx and Next Molecular for laboratory testing services.

ii. During the period of October 1, 2021 to October 31, 2022, OC Genetic and Carralejo conspired with BeauMed Consultants LLC (BeauMed) and Dr. Regina Pondexter Hunter (Dr. Hunter) to knowingly and willfully pay to Dr. Hunter thousands of dollars in monthly kickbacks, in violation of the AKS, that were disguised as consulting fees but actually were offered to induce Dr. Hunter to order laboratory testing, including medically unnecessary testing, from RDx. OC Genetic and Carralejo, in coordination with BeauMed, provided commission numbers to Dr. Hunter or her staff, so that Dr. Hunter could prepare false consulting invoices to disguise both the reason that BeauMed was paying Dr. Hunter (to induce referrals, not for consulting work) and the calculation of such payments (based on reimbursements from her referrals, not hourly pay for consulting work). On the same day that Carralejo received a subpoena from the Department of Justice regarding a "False Claims Act investigation [that] concerns allegations that [OC Genetic] and/or [its] agents offered, paid, solicited, and/or received remuneration in violation of the [AKS]," and the same day that Carralejo learned that BeauMed had received a similar subpoena, Carralejo deleted text message evidence of his role and participation in the scheme to pay kickbacks to Dr. Hunter.

The conduct set forth in this Paragraph C is referred to below as the "Covered Conduct."

D. This Agreement is neither an admission of liability by OC Genetic and Carralejo, nor a concession by the United States that its claims are not well founded. OC Genetic and Carralejo do not admit the United States' allegations in Paragraph C.

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. Under the terms and conditions specified herein, OC Genetic and Carralejo shall pay to the United States a total of Four Hundred Thousand Dollars (\$400,000.00) (Settlement Amount), of which One Hundred Ninety Thousand Dollars (\$190,000.00) is restitution, no later than thirty (30) calendar days after the Effective Date by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, subject to Paragraph 9 (concerning default) below, and conditioned upon OC Genetic's and Carralejo's full payment of the Settlement Amount to the United States, the United States releases OC Genetic and Carralejo 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 release 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 or enforcement right, 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 other than Carralejo;
- g. Any liability of corporate entities other than OC Genetic;
- h. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- i. Any liability for failure to deliver goods or services due; and
- j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. OC Genetic and Carralejo waive and shall not assert any defenses OC Genetic and/or Carralejo 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.

5. OC Genetic and Carralejo 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 OC Genetic and/or Carralejo have asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers,

agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

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) or any state payer, related to the Covered Conduct; and OC Genetic and Carralejo 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.

7. OC Genetic and Carralejo 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 OC Genetic and/or Carralejo in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (3) OC Genetic's and/or Carralejo'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
- (5) the payment(s) OC Genetic and Carralejo make to the United States pursuant to this Agreement,

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 OC Genetic and Carralejo, and OC Genetic and Carralejo 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 OC Genetic, Carralejo, or any of OC Genetic's subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: OC Genetic and Carralejo further agree that within ninety (90) days of the Effective Date of this Agreement OC Genetic and Carralejo 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 OC Genetic, Carralejo, or any of OC Genetic's 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. OC Genetic and Carralejo agree that the United States, at a minimum, shall be entitled to recoup from OC Genetic and Carralejo 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 OC Genetic, Carralejo, or any of OC Genetic's subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on OC Genetic, Carralejo, or any of OC Genetic's 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 OC Genetic's and Carralejo's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. OC Genetic and Carralejo agree to cooperate fully, truthfully, completely, and forthrightly with the United States' investigation(s) of, and/or legal proceeding(s) against, individuals and entities referenced in the Covered Conduct and/or in OC Genetic's subpoena response(s). Upon request by the United States and reasonable notice, Carralejo shall be available for interviews by the United States and shall fully, truthfully, completely, and forthrightly answer questions; and Carralejo shall testify under oath fully, truthfully, completely, and forthrightly at any and all trials of cases or other court proceedings, including depositions, at which his testimony may be deemed relevant by the United States. OC Genetic and Carralejo agree to encourage, and not impair, the cooperation of OC Genetic's directors, officers, and employees, and to use its best efforts to make available, and encourage, the cooperation of OC Genetic's former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. OC Genetic and Carralejo agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control relating to the Covered Conduct,

the individuals or entities referenced in the Covered Conduct, and/or the individuals and entities referenced in OC Genetic's subpoena response(s). For avoidance of doubt, this Agreement does not require OC Genetic or Carralejo to waive any protection they have under the work product doctrine or the attorney-client privilege.

9. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims against OC Genetic and Carralejo arising from the Covered Conduct pursuant to the terms and conditions in this Agreement.

a. OC Genetic and Carralejo shall be in default of this Agreement (Default) if OC Genetic and/or Carralejo fail to pay the Settlement Amount as provided in Paragraph 1 above or if OC Genetic and/or Carralejo fail to comply materially with any other term or condition of this Agreement, including Paragraph 8 above (concerning cooperation).

b. If OC Genetic and/or Carralejo fail to pay the Settlement Amount as provided in Paragraph 1 above, the United States will provide a written Notice of Default, and OC Genetic and Carralejo shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to OC Genetic and Carralejo or to such other representative as OC Genetic and Carralejo shall designate in advance in writing. If OC Genetic and Carralejo fail to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (Uncured Default), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of twelve percent (12%) per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

c. In the event of Uncured Default, or a failure to comply materially with Paragraph 8 above (concerning cooperation), OC Genetic and Carralejo agree that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement, and bring any civil and/or administrative claim, action, or proceeding against OC Genetic and/or Carralejo for the claims that would otherwise be covered by the releases provided in Paragraph 2 above, with any recovery reduced by the amount of any payments previously made by OC Genetic and Carralejo to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to OC Genetic and Carralejo and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, OC Genetic and Carralejo agree immediately to pay the United States the greater of (i) a ten percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, OC Genetic and Carralejo waive and agree not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the United States against OC Genetic and Carralejo within one hundred twenty (120) days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. OC Genetic and Carralejo agree not to contest any offset, recoupment, and /or collection action

undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

d. In the event of Uncured Default, or a failure to comply materially with Paragraph 8 above (concerning cooperation), OIG-HHS may exclude OC Genetic and/or Carralejo from participating in all Federal healthcare programs (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to OC Genetic and Carralejo. OC Genetic and Carralejo waive any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, OC Genetic and/or Carralejo wish to apply for reinstatement, OC Genetic and/or Carralejo must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001–.3005. OC Genetic and Carralejo will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

10. 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 11 (waiver for beneficiaries Paragraph), below.

11. OC Genetic and Carralejo agree that they waive and shall not seek payment for any of the healthcare billings covered by this Agreement from any healthcare beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

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

13. The Parties and signatories to this Agreement represent that they freely and voluntarily enter into this Agreement without any degree of duress or compulsion.

14. This Agreement is governed by the laws of the United States. The exclusive 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.

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

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

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

18. This Agreement is binding on OC Genetic's and Carralejo's successors, transferees, heirs, and assigns.

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

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

[SIGNATURE PAGE(S) FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 3/8/2024

BY: 
CHRISTOPHER TERRANOVA
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 3/8/2024


BY: 
KRUTI DHARIA
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

DATED: 3/7/2024

BY: 
SUSAN GILLIN
Digitally signed by SUSAN GILLIN
Date: 2024.03.07 19:06:05 -05'00'
SUSAN E. GILLIN
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

OC GENETIC CONSULTANTS INC.

DATED: 2/29/24

BY: 
GEORGE CARRALEJO
Owner and Chief Executive Officer
OC Genetic Consultants Inc.

DATED: 3/5/24

BY: Pamela Johnston
PAMELA JOHNSTON
RYAN LOWRY
Foley & Lardner LLP
Counsel for OC Genetic Consultants Inc.

GEORGE CARRALEJO

DATED: 2/29/24

BY: 
GEORGE CARRALEJO

DATED: 3/5/24

BY: Pamela Johnston
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