

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) RDx Bioscience Inc. (RDx); and (c) Eric Leykin (Leykin), through their authorized representatives. Collectively, all of the above will be referred to as the Parties.

RECITALS

A. Eric Leykin, of Brooklyn, New York, was the Chief Executive Officer of RDx, a clinical laboratory in Kenilworth, New Jersey that provided laboratory testing for patients referred by physicians and other healthcare providers. RDx is no longer operating.

B. The United States contends that RDx and Leykin submitted and/or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (Medicare), and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (Medicaid).

C. The United States contends that it has certain civil claims against RDx and Leykin arising from the following conduct:

i. During the period of January 1, 2018 to December 31, 2022, RDx and Leykin knowingly and willfully paid commissions based on the volume and value of Medicare and Medicaid referrals to independent contractor marketers BeauMed Consultants LLC (BeauMed), Corum Group LLC (Corum), Nocher Enterprises Inc., OC Genetic Consultants Inc. (OC Genetic), Ralston Health Group Inc. (Ralston), Seaworthy Recovery Services Inc. (Seaworthy) (collectively, RDx Marketers) to arrange for and/or recommend that healthcare

providers (HCPs) order RDx's laboratory tests, in violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b).

ii. RDx and Leykin knew that the RDx Marketers were paying and/or arranging for the payment to HCPs of the kickbacks specified in Recital C(ii)(a)–(e) below to induce those HCPs to refer patients to RDx for laboratory testing, in violation of the AKS, and that those HCPs subsequently referred Medicare and Medicaid patients to RDx for laboratory testing. Nevertheless, RDx and Leykin submitted and/or caused the submission of claims to Medicare and Medicaid for laboratory testing ordered by those HCPs. Specifically:

a. During the period of August 1, 2018 to January 31, 2022, RDx marketer Corum used purported management services organizations (MSOs) Alari Group LLC and Avior Group LLC to knowingly and willfully pay thousands of dollars in kickbacks to healthcare providers Shamim Badiyan, M.D., Paul Bierig, M.D., Imran Chishti, M.D., Stanley Librach, M.D., Vijesh Patel, M.D., and Carmen Wong, M.D. (all collectively, Paid Corum HCPs) that were disguised as investment returns but were actually offered to induce the Paid Corum HCPs to order RDx laboratory tests.

b. During the period of September 1, 2017 to September 30, 2022, RDx marketers BeauMed and Ralston, with the knowledge and assistance of RDx marketer OC Genetic, knowingly and willfully paid thousands of dollars in kickbacks to Daniel Eidman, M.D. that were disguised as consulting and/or medical director fees but were actually offered to induce Dr. Eidman to order, among other things, RDx laboratory tests.

c. During the period of July 1, 2018 to October 31, 2022, RDx marketer BeauMed, with the knowledge and assistance of RDx marketer OC Genetic, knowingly and willfully paid thousands of dollars in kickbacks to Regina Pondexter Hunter, M.D. that were

disguised as consulting fees but were actually offered to induce Dr. Hunter to order, among other things, RDx laboratory testing.

d. During the period of September 1, 2019 to March 31, 2023, RDx marketer Ralston knowingly and willfully paid thousands of dollars in kickbacks to Moustafa Moustafa, M.D. that were disguised as consulting and/or medical director fees but were actually offered to induce Dr. Moustafa to order, among other things, RDx laboratory testing.

e. During the period of July 1, 2019 to October 31, 2020, RDx marketer Seaworthy knowingly and willfully paid thousands of dollars in kickbacks to one or more principals of Beaches Recovery Services LLC and Tides Edge Recovery Services LLC (Paid Seaworthy HCPs) to induce those substance abuse recovery centers to refer patients to RDx for laboratory testing.

iii. During the period of December 1, 2018 to August 1, 2022, RDx and Leykin knowingly and willfully paid remuneration in the form of specimen collection payments to one or more members of the office staff, including at least one family member, of the Paid Corum HCPs, Paid Seaworthy HCPs, Dr. Eidman, Dr. Hunter, and Dr. Moustafa (collectively, Paid HCPs) to induce the Paid HCPs to order RDx laboratory testing, in violation of the AKS.

iv. During the period of September 1, 2017 to March 31, 2023, RDx and Leykin knowingly submitted and/or caused to be submitted claims to Medicare and Medicaid for tests ordered by the Paid HCPs that were: (a) not reasonable and necessary; (b) not covered as blanket orders of the most extensive urine drug testing (UDT) using Current Procedural Terminology (CPT) code G0483; and/or (c) not covered as duplicative claims for UDT ordered on the same date of service, for the same patient, testing for the same drug(s) using both presumptive and definitive testing methods.

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

D. RDx and Leykin have entered into, or will be entering into, a separate settlement agreement described below in Paragraph 1(b) (Medicaid State Settlement Agreement) with the State of New Jersey in settlement of the conduct released in that separate Medicaid State Settlement Agreement.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. RDx and Leykin shall pay to the United States and the State of New Jersey the sum of Thirteen Million Two Hundred Fifty Thousand Dollars (\$13,250,000.00) (Total Settlement Amount) as follows:

a. RDx and Leykin shall pay to the United States the sum of Ten Million Three Hundred Fifteen Thousand Twenty-Three Dollars (\$10,315,023.00) (Federal Settlement Amount), of which Five Million One Hundred Three Thousand Six Hundred Forty-Seven Dollars (\$5,103,647.00) is restitution, no later than fourteen (14) 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. RDx and Leykin shall be jointly and severally liable for the Federal Settlement Amount, but Leykin shall pay to the United States at least Five Hundred Thousand Dollars (\$500,000.00) of the Federal Settlement Amount from Leykin's personal bank account.

b. RDx and Leykin shall pay to the State of New Jersey the sum of Two Million Nine Hundred Thirty-Four Thousand Nine Hundred Seventy-Seven Dollars (\$2,934,977.00) (State Settlement Amount), pursuant to written instructions from the State of New Jersey and under the terms and conditions of the separate agreement that RDx and Leykin have entered into, or will enter into, with the State of New Jersey.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, subject to Paragraph 9 (concerning default) below, and conditioned upon RDx's and Leykin's full payment of the Federal Settlement Amount to the United States and the State Settlement Amount to the State of New Jersey, the United States releases RDx and Leykin 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 Leykin;
- g. Any liability of corporate entities other than RDx;
- 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. RDx and Leykin waive and shall not assert any defenses RDx and/or Leykin 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. RDx and Leykin 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 RDx and/or Leykin 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 RDx and Leykin 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. RDx and Leykin 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 RDx and/or Leykin 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) RDx's and/or Leykin'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 RDx and Leykin 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 RDx and Leykin, and RDx and Leykin 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 RDx, Leykin, or any of RDx's subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: RDx and Leykin further agree that within ninety (90) days of the Effective Date of this Agreement RDx

and Leykin 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 RDx, Leykin, or any of RDx'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. RDx and Leykin agree that the United States, at a minimum, shall be entitled to recoup from RDx and Leykin 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 RDx, Leykin, or any of RDx's subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on RDx, Leykin, or any of RDx'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 RDx's and Leykin's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. RDx and Leykin agree to cooperate fully, truthfully, completely, and forthrightly with the United States' investigation(s) of, and/or legal proceeding(s) against, individuals and entities not released in this Agreement. Upon request by the United States and reasonable notice, Leykin shall be available for interviews by the United States and shall fully, truthfully, completely,

and forthrightly answer questions; and Leykin 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. RDx and Leykin agree to encourage, and not impair, the cooperation of RDx's directors, officers, and employees, and to use its best efforts to make available, and encourage, the cooperation of RDx's former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. RDx and Leykin 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, RDx's current or former independent contractor marketers, or HCPs who ordered testing from RDx.

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

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

b. If RDx and/or Leykin fail to pay the Federal Settlement Amount as provided in Paragraph 1 above, the United States will provide a written Notice of Default, and RDx and Leykin 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 RDx and Leykin or to such other representative as RDx and Leykin shall designate in

advance in writing. If RDx and/or Leykin 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 Federal 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), RDx and Leykin 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 RDx and/or Leykin 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 RDx and/or Leykin 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 RDx and Leykin 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, RDx and Leykin 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, RDx and Leykin 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 RDx and/or Leykin 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. RDx and Leykin 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 RDx and/or Leykin from participating in all Federal healthcare programs (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to RDx and Leykin. RDx and Leykin waive any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agree 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, RDx and/or Leykin wish to apply for reinstatement, RDx and/or Leykin must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001–.3005. RDx and/or Leykin 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. RDx and Leykin 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 RDx's and Leykin'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: 1/10/2024

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

DATED: 1/10/2024

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

DATED: 1/9/2024

BY: **SUSAN**
GILLIN
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

 Digitally signed by SUSAN
GILLIN
Date: 2024.01.09 19:49:57
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RDX BIOSCIENCE INC.

DATED: _____

BY: _____
ERIC LEYKIN
Chief Executive Officer
RDx Bioscience Inc.

DATED: 1/8/24

BY: 
ROBERT A. DEL GIORNO *as to form*
JOHN MARTIN
Garfunkel Wild, P.C.
Counsel for RDx Bioscience Inc.

ERIC LEYKIN

DATED: _____

BY: _____
ERIC LEYKIN

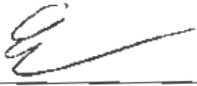
DATED: 1/8/24

BY: 
ROBERT A. DEL GIORNO *as to form*
JOHN MARTIN
Garfunkel Wild, P.C.
Counsel for Eric Leykin

RDX BIOSCIENCE INC.

DATED: 12/29/2023

BY: _____


ERIC LEYKIN
Chief Executive Officer
RDx Bioscience Inc.

DATED: _____

BY: _____

ROBERT A. DEL GIORNO
JOHN MARTIN
Garfunkel Wild, P.C.
Counsel for RDx Bioscience Inc.

ERIC LEYKIN

DATED: 12/29/2023

BY: _____


ERIC LEYKIN

DATED: _____

BY: _____

ROBERT A. DEL GIORNO
JOHN MARTIN
Garfunkel Wild, P.C.
Counsel for Eric Leykin