

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 GWRX Acquisition, LLC (collectively, the “Parties”), through their authorized representatives.

RECITALS

- A. GWRX Acquisition, LLC (“GWRX”) is a Delaware corporation with principal executive offices located in King of Prussia, PA.
- B. On February 23, 2017, GWRX executed an agreement to purchase the assets of Genetworx, LLC, a Virginia-based molecular laboratory (“the Laboratory”).
- C. The United States contends that the Laboratory submitted or caused to be submitted claims for payment for genetic testing to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III (“Medicare”).
- D. The United States contends that from July 7, 2014 to September 25, 2015, the Laboratory utilized the services of Seth Rehfuss as a sales representative and that Rehfuss persuaded groups of senior citizens in senior housing complexes to submit genetic test specimens to the Laboratory without sufficient involvement of a health care professional to constitute a valid physician order as required by applicable Medicare rules requiring proper orders from a treating physician. In January 2019, Rehfuss pleaded guilty to defrauding Medicare. *See United States v. Rehfuss*, 18-cr-00134 (AET) (D.E. 54).
- E. The United States contends that it has certain civil claims against GWRX arising from the Laboratory submitting claims for payment to Medicare for the genetic tests performed without a valid physician oversight and orders from samples that were obtained by Rehfuss

during the period July 7, 2014 to September 25, 2015. That conduct is referred to below as the “Covered Conduct.”

F. This Settlement Agreement is neither an admission of liability by GWRX nor a concession by the United States that its claims are not well founded. The Covered Conduct occurred prior to the asset purchase.

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. GWRX shall pay to the United States one million four-hundred twenty-two thousand dollars (\$1,422,000.00) (“Settlement Amount”), of which \$812,571 is restitution, and interest on the Settlement Amount at a rate of 1.625% from April 27, 2021 (“Interest”) no later than 7 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by Office of the United States Attorney for the District of New Jersey.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases GWRX, together with its current and former direct and indirect parent corporations and limited liability companies; its and their affiliates and subsidiaries; and the predecessors, successors, transferees, 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.

3. In the event that GWRX fails to pay any amount as provided in Paragraph 1 within 10 business days of the date on which such payment is due, GWRX shall be in default of their payment obligations (“Default”). In the event of such Default, OIG-HHS may institute a period of exclusion as to GWRX and any parent, affiliate, or subsidiary from participating in all Federal health care programs until GWRX pays the Settlement Amount and reasonable costs as set forth in Paragraph 1, above. OIG-HHS will provide written notice of any exclusion under this paragraph to GWRX. GWRX waives 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 GWRX wishes to apply for reinstatement, GWRX must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. GWRX will not be reinstated unless and until OIG-HHS approves such request for reinstatement.

4. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims and rights 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;

- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

5. GWRX waives and shall not assert any defenses GWRX 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.

6. GWRX fully and finally releases 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 GWRX has 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.

7. 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 GWRX 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.

8. GWRX 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-1 and 1396-1396w-5; and the regulations and official

program directives promulgated thereunder) incurred by or on behalf of GWRX, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) GWRX'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 GWRX makes 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) (the "Unallowable Costs").

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: GWRX 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 GWRX 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. GWRX agrees that the United States, at a minimum, shall be entitled to recoup from GWRX 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.

d. 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 GWRX or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on GWRX or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

e. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine GWRX's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph. GWRX agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, GWRX 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. GWRX 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.

9. 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.

10. GWRX 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.

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

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

13. 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.

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

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

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

17. This Agreement is binding on GWRX's successors, transferees, heirs, and assigns.

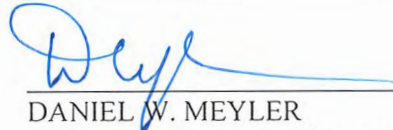
18. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. 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.


[Signatures Begin On Next Page]

THE UNITED STATES OF AMERICA

DATED: 6/30/21

BY: 
DANIEL W. MEYLER
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

APPROVED:

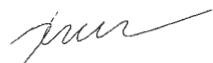

LEE M. CORTES, JR.
Chief, Health Care Fraud Unit
United States Attorney's Office
District of New Jersey

DATED: _____

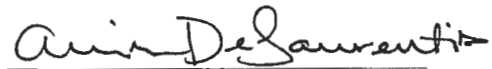
BY: **GREGORY
DEMSKE** Digitally signed by GREGORY
DEMSKE
Date: 2021.06.30 16:01:31 -04'00'
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

GWRX

DATED: 6/28/2021

BY: 
KEVIN MCCLURE
GWRX

DATED: 4/28/21

BY: 
THOMAS M. GALLAGHER
ALLISON E. DELAURENTIS
Troutman Pepper Hamilton Sanders LLP
Counsel for GWRX