

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 Exceltox Laboratories LLC (“Exceltox”) (collectively, the “Parties”), through their authorized representatives.

RECITALS

- A. Exceltox is a diagnostic laboratory located in Irvine, California.
- B. The United States contends that Exceltox submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”).
- C. The United States contends the following (1) that, from September 2015 to November 2015, Exceltox contracted with MD Global for independent contractor marketing services; (2) MD Global, in turn, contracted with Seth Rehfuss and Good Samaritans of America; (3) Rehfuss and Good Samaritans of America provided independent contractor services to MD Global and Rehfuss’ and Good Samaritans of America’s efforts persuaded groups of senior citizens in senior housing complexes to submit to genetic tests to Exeltox without sufficient involvement of a health care professional, despite 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) (Docket No. 54).
- D. The United States contends that it has certain civil claims against Exceltox arising from Exceltox 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 and

Good Samaritans of America during the period from September 1, 2015 through November 30, 2015. That conduct is referred to below as the “Covered Conduct.”

E. This Settlement Agreement is neither an admission of liability by Exceltox 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. Exceltox shall pay to the United States Three-Hundred Fifty-Seven Thousand, Five-Hundred Eighty-Four Dollars (\$357,584) (“Settlement Amount”), of which \$204,333 is restitution, and interest on the Settlement Amount at a rate of 0.75% from August 24, 2020 (“Interest”), with payments as follows:

- a. Within 7 days of the Effective Date of this Agreement, Exceltox shall pay \$30,000; and
- b. Exceltox shall pay the remaining \$327,584 plus interest over 17 months at a rate of \$19,269.65 per month; and
- c. Exceltox shall make the payments described in sub-paragraphs (a) and (b) above by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of New Jersey. The Settlement Amount plus interest described above are referred to as the “Settlement Proceeds”; and

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Exceltox’s full payment of the Settlement Amount, the United States releases Exceltox, together with its current or former parent corporations; direct and indirect subsidiaries;

brother or sister corporations; divisions; corporate successors and assigns; 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 Exceltox fails to pay any amount as provided in Paragraph 1 within 10 business days of the date on which such payment is due, Exceltox shall be in default of their payment obligations (“Default”). In the event of such Default, OIG-HHS may exclude Exceltox from participating in all Federal health care programs until Exceltox 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 Exceltox. Exceltox 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 Exceltox wishes to apply for reinstatement, Exceltox must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Exceltox 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 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;
- g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

5. Exceltox waives and shall not assert any defenses Exceltox 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. Exceltox 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 Exceltox 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 Exceltox 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. Exceltox 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. §§ 1395-1395lll-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Exceltox, 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) Exceltox'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 Exceltox 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 Exceltox, and Exceltox 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 Exceltox or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

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

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

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. Exceltox 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.

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. 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.

14. 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.

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 Exceltox's successors, transferees, heirs, and assigns.

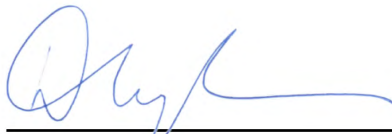
19. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

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

[Signatures Appear On Next Page]


THE UNITED STATES OF AMERICA

DATED: 12/15/2020

BY: 

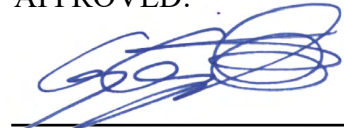
DANIEL W. MEYLER
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

APPROVED:



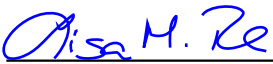
LEE M. CORTES, JR.
Chief, Health Care Fraud Unit
United States Attorney's Office
District of New Jersey

APPROVED:



CRAIG CARPENITO
UNITED STATES ATTORNEY
District of New Jersey

DATED: 12/16/2020

BY: 

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

EXCELTOX

DATED: _____

BY: _____
CASEY CRAWFORD
Managing Partner

APPROVED AS TO FORM:

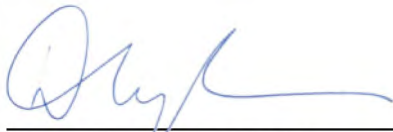
DATED: _____

BY: _____

JOSEPH R. LAMAGNA
DAVID S. SCHUMACHER
Hooper, Lundy & Bookman, PC
Counsel for Exceltox Laboratories, LLC


THE UNITED STATES OF AMERICA

DATED: 12/15/2020

BY: 

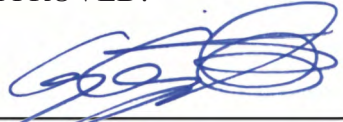
DANIEL W. MEYLER
Assistant United States Attorney
United States Attorney's Office
District of New Jersey

APPROVED:



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

APPROVED:



CRAIG CARPENITO
UNITED STATES ATTORNEY
District of New Jersey

DATED: _____

BY: _____
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

EXCELTOX

DATED: 12/16/2020

BY: 

CASEY CRAWFORD
Managing Partner

APPROVED AS TO FORM:

DATED: 12/28/2020

BY:



JOSEPH R. LAMAGNA
DAVID S. SCHUMACHER
Hooper, Lundy & Bookman, PC
Counsel for Exceltox Laboratories, LLC