

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 (“HHS-OIG”) of the Department of Health and Human Services, Exagen Inc. (“Exagen”), and Omni Healthcare, Inc. (the “Relator”) (hereafter collectively referred to as the “Parties”), through their authorized representatives.

RECITALS

A. Exagen is a Delaware corporation with its principal place of business in Vista, CA. Exagen is a life sciences company that makes proprietary diagnostic tests for the treatment of autoimmune conditions.

B. On June 7, 2021, Relator filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned *United States, et al., ex rel. Omni Healthcare, Inc. v. Exagen, Inc.*, 21-cv-10950, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relator subsequently amended his Complaint on August 29, 2022, to add defendants John Does 1-10. Relator alleged that Exagen provided illegal financial inducements to physicians in the form of specimen processing fees in exchange for patient referrals for laboratory testing.

C. The United States contends that Exagen 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”).

D. Exagen admits, acknowledges, and accepts responsibility for the following facts. Numerous physicians and physician groups ordered Exagen’s laboratory tests to assist in the diagnosis of autoimmune conditions (collectively, “the referring physicians”). From June 25, 2014 through June 21, 2021, Exagen paid certain of the referring physicians to complete blood

draws for patients pursuant to specimen processing agreements that Exagen had executed with the referring physicians. Exagen also billed Medicare for tests that it performed after receiving orders from the referring physicians to whom it paid the specimen processing fees. On June 25, 2014, HHS-OIG released a Special Fraud Alert: Laboratory Payments to Referring Physicians (“SFA”), which indicated that these arrangements could present a substantial risk of fraud and abuse under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2). Exagen terminated the physician referral arrangements by June 21, 2021, and it no longer has any such agreements with referring physicians. This conduct is referred to as the “Covered Conduct.” The physician referral arrangements included as part of the Covered Conduct are referenced in Schedule A, attached hereto in redacted form.

E. With the exception of the Covered Conduct, Exagen expressly denies the allegations of the Relator as set forth in the Civil Action.

F. The United States contends that it has certain civil claims against Exagen arising from the Covered Conduct during the period from June 25, 2014, through June 21, 2021.

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 expenses, attorneys’ fees, and costs.

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

TERMS AND CONDITIONS

1. Exagen shall pay to the United States \$653,143 (the “Settlement Amount”), of which \$653,143 is restitution, and interest on the Settlement Amount at a rate of 3.625% per annum from May 26, 2023, no later than 15 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the District of Massachusetts.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$104,505 to Relator by electronic funds transfer (the “Relator’s Share”).

3. Exagen shall pay Relator \$85,000 for expenses, and attorneys’ fees and costs pursuant to 31 U.S.C. 3730(d)(1). Such payment shall be made no later than 15 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided to Exagen by Relator’s counsel.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, the United States releases Exagen, together with its predecessors, and its current and former divisions, parents, subsidiaries, successors, and assigns (the “Exagen Releasees”) from any civil or administrative monetary claim the United States has for the Covered Conduct under the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 6 below, and upon the United States’ receipt of the Settlement Amount, Relator, for itself and its heirs, successors, attorneys, agents, and assigns, releases the Exagen Releasees from any and all liability, claims, allegations, demands, actions and causes of action whatsoever in law or equity, that Relator has or could have asserted against Exagen for the Covered Conduct, including but not limited to any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. Notwithstanding the releases given in Paragraphs 4 and 5 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; and
- f. Any liability of individuals;

7. Relator and its 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 Relator's Share, Relator and its 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 Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, and from any claims to a share of the proceeds from the Covered Conduct under the False Claims Act, 31 U.S.C. §§.

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

9. Exagen fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Exagen 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 or the United States' investigation or prosecution thereof.

10. Exagen fully and finally releases Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Exagen has asserted, could have asserted, or may assert in the future against Relator, related to the Covered Conduct and 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 Exagen 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. Exagen 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 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Exagen, 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 investigation(s) of the matters covered by this Agreement;
- (3) Exagen's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in

connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement; and
- (5) the payment Exagen makes to the United States pursuant to this Agreement and any payments that Exagen may make to Relator, including costs and attorneys' 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 shall be separately determined and accounted for by Exagen, and Exagen 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 Exagen or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

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

13. Exagen agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Exagen 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. Exagen 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. Exagen 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 payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action as follows:

- a. dismissal shall be with prejudice as to the United States and Relator for the Covered Conduct; and
- b. dismissal shall be without prejudice to the United States as to all other claims against Exagen in the Civil Action.

17. 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.

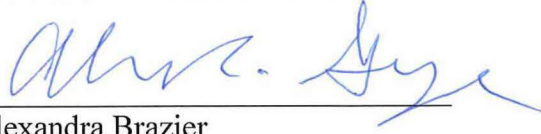
23. This Agreement is binding on Exagen's successors, transferees, heirs, and assigns.

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 and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA


DATED: 10/16/2023 BY: 

Alexandra Brazier
Abraham R. George
Assistant United States Attorneys
District of Massachusetts

EXAGEN INC. - DEFENDANT

DATED: 10/13/23

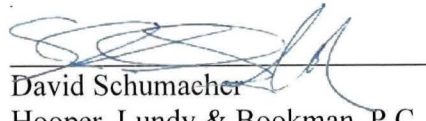
BY:



John Aballi
President & CEO
Exagen Inc.

DATED: 10/16/23

BY:

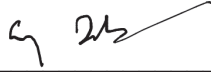


David Schumacher
Hooper, Lundy & Bookman, P.C.
Counsel for Exagen Inc.

OMNI HEALTHCARE, INC. - RELATOR

DATED: 10 / 13 / 2023

BY:



Craig Deligdish
Omni Healthcare, Inc.

DATED: 10 / 13 / 2023

BY:



Sean Estes
David Harrison
Svjetlana Tesic
Counsel for Omni Healthcare, Inc.

Schedule A

Exagen Referring Physicians Paid for Specimen Processing Post SFA			
Medical Office	Provider	Payment Start Date	Payment End Date
[REDACTED]	[REDACTED]	6/25/14	9/17/14
[REDACTED]	[REDACTED]	6/25/14	5/7/15
[REDACTED]	[REDACTED]	6/25/14	5/7/15
[REDACTED]	[REDACTED]	6/25/14	3/19/15
[REDACTED]	[REDACTED]	6/25/14	3/19/15
[REDACTED]	[REDACTED]	6/25/14	3/19/15
[REDACTED]	[REDACTED]	6/25/14	10/9/14
[REDACTED]	[REDACTED]	6/25/14	10/9/14
[REDACTED]	[REDACTED]	6/25/14	3/11/15
[REDACTED]	[REDACTED]	6/25/14	5/28/15
[REDACTED]	[REDACTED]	6/25/14	7/1/15
[REDACTED]	[REDACTED]	6/25/14	7/1/15
[REDACTED]	[REDACTED]	6/25/14	10/16/14
[REDACTED]	[REDACTED]	8/22/14	4/6/16
[REDACTED]	[REDACTED]	10/7/19	6/11/21
[REDACTED]	[REDACTED]	8/22/14	4/6/16
[REDACTED]	[REDACTED]	10/7/19	6/11/21
[REDACTED]	[REDACTED]	8/22/14	4/6/16
[REDACTED]	[REDACTED]	10/7/19	6/11/21
[REDACTED]	[REDACTED]	6/25/14	5/13/15
[REDACTED]	[REDACTED]	6/25/14	5/13/15

Exagen Referring Physicians Paid for Specimen Processing Post SFA

Medical Office	Provider	Payment Start Date	Payment End Date
		6/25/14	5/13/15
		6/25/14	7/29/15
		6/25/14	1/30/15
		6/25/14	1/30/15
		6/25/14	7/1/15
		6/25/14	7/23/14
		6/25/14	2/26/15
		6/25/14	7/17/14
		6/25/14	7/1/15
		6/25/14	7/29/15
		6/25/14	10/30/14
		6/25/14	7/1/15
		6/25/14	10/9/14
		6/25/14	7/1/15
		6/25/14	7/1/15
		6/25/14	5/7/15
		6/25/14	3/6/15
		6/25/14	7/1/15
		6/25/14	11/20/14
		6/25/14	11/7/14
		6/25/14	7/29/15
		6/25/14	7/1/15
		6/25/14	7/29/15

Exagen Referring Physicians Paid for Specimen Processing Post SFA

Medical Office	Provider	Payment Start Date	Payment End Date
	[REDACTED]	6/25/14	7/29/15
	[REDACTED]	6/25/14	7/1/15
	[REDACTED]	6/25/14	7/1/15
	[REDACTED]	6/25/14	7/1/15
	[REDACTED]	6/25/14	9/12/14
	[REDACTED]	6/25/14	7/16/15
	[REDACTED]	6/25/14	10/31/15
	[REDACTED]	6/25/14	7/16/15
	[REDACTED]	6/25/14	3/6/15
	[REDACTED]	6/25/14	7/1/15
	[REDACTED]	6/25/14	6/11/15