

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 (“HHS”); and the Defense Health Agency (“DHA”), acting on behalf of the TRICARE program (collectively, the “United States”), and Guardant Health, Inc. (“Guardant”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Guardant is a precision oncology company based in Palo Alto, California, that provides blood testing and analytics services for health care providers, cancer patients, and clinical and biopharmaceutical customers.

B. On or about June 1, 2023, Guardant made a submission pursuant to HHS-OIG’s Self Disclosure Protocol (“Protocol”) concerning potential violations of the Anti-Kickback Statute (“AKS”) and/or the Physician Self-Referral Law (“Stark Law”) resulting from Guardant’s employment of certain individuals associated with a physician who referred patients for Guardant tests. After learning about the potential violations, Guardant initiated an internal investigation, ceased all further billing for tests referred by the physician, and, as set forth below, promptly took steps to remediate the issues identified. Guardant also cooperated with the United States’ investigation, including but not limited to, identifying individuals involved in or responsible for the issues; preserving, collecting, and disclosing documents requested by the United States; disclosing facts gathered during its independent investigation; and assisting in the determination and recovery of the losses caused to the United States. Guardant received credit under the United States Department of Justice’s guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual § 4-4.112.

C. The United States contends that Guardant submitted or caused to be submitted claims for payment to Part B of the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III (“Medicare”); and the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”).

D. The United States contends that it has certain civil claims against Guardant arising from the following conduct during the period from May 1, 2021 through May 13, 2023.

- i. In or around April 2021, an oncologist based in Austin, Texas (the “Physician”) contacted Guardant’s Human Resources Department to recommend a close friend of the Physician’s family member for a position as an Account Manager in Guardant’s Oncology Division. On April 30, 2021, the family friend accepted an offer for the Account Manager position. She was assigned to the South Texas region, and was responsible for the Physician’s account.
- ii. In October 2021, the Physician contacted Guardant again, this time seeking a position for his step-daughter (the “Family Member”) upon her graduation from college. He expressed that he was “excited to work” with Guardant while “potentially promoting [the Family Member’s] career at the same time.” The Family Member was considered for a position in Guardant’s Screening Division, but her application was rejected due to lack of experience for a Screening role and the absence of an open position in Guardant’s Oncology Division. However, in or around February 2022, two Guardant employees arranged for the family friend to be promoted from Account Manager to Account Executive, thereby creating an opening in the Oncology Division for employment of the Family Member. These employees knew of the relationship between the Family Member and the Physician, and that the Family Member was not qualified for the role.

- iii. In March 2022, Guardant offered the Family Member the role of Account Manager within the Oncology Division, which she accepted. In this role, the Family Member was responsible for the account of her step-father, the Physician.
- iv. The Physician ordered significantly more Guardant tests per quarter after Guardant hired the family friend and then the Family Member. Prior to April 2021, the Physician ordered *de minimis* Guardant tests. From approximately April 2021 to March 2022, the Physician ordered approximately 50 Guardant tests per quarter. Starting in approximately March 2022, the Physician's orders of Guardant tests rose to between 124 and 398 tests per quarter.
- v. As a direct result of the increase in business from the Physician, Guardant's South Texas sales team was recognized as one of the best performing regions in 2022.
- vi. Guardant submitted claims to and received payments from Medicare for designated health services, specifically clinical laboratory services, that had been referred to Guardant by the Physician during the relevant time period, and Guardant had a financial relationship with the Physician's immediate family member which did not satisfy the requirements of any applicable exception, in violation of 42 U.S.C. § 1395nn.
- vii. Guardant knowingly submitted or caused the submission of false claims for payment for Guardant tests ordered by the Physician during the relevant time period to Medicare Part B in violation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-31, and to TRICARE in violation of 32 C.F.R. § 199.9.
- viii. Shortly after receiving information regarding the Physician's referrals, Guardant stopped billing federal health care programs for Guardant tests ordered by the

Physician. On May 12, 2023, Guardant terminated the Family Member's employment.

The conduct described in Paragraph D, subparagraphs i-vii is referred to below as the "Covered Conduct."

E. This Settlement Agreement is neither an admission of liability by Guardant 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. Guardant shall pay to the United States nine hundred and thirteen thousand, nine hundred and thirty-two dollars and ninety-three cents (\$913,932.93) ("FCA Settlement Amount"), of which \$609,288.62 is restitution, plus interest accruing at a rate of 4.5% per annum from April 5, 2024, no later than 14 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Northern District of California.

2. Guardant shall pay to the DHA thirty-one thousand and eighty-two dollars (\$31,082.00) ("DHA Administrative Settlement Amount), plus interest accruing at a rate of 4.5% per annum from April 5, 2024, no later than 14 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Northern District of California.

3. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the FCA Settlement Amount, plus interest, due under Paragraph 1, the United States releases Guardant 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; the civil monetary provisions of the Stark Law at 42 U.S.C. §§ 1395nn(g)(3) and (g)(4); or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. In consideration of the obligations of Guardant in this Agreement, and upon the United States' receipt of full payment of the FCA Settlement Amount, plus interest, due under Paragraph 1, HHS-OIG shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Guardant under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6 (concerning reserved claims), below. HHS-OIG expressly reserves all rights to comply with any statutory obligations to exclude Guardant from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes HHS-OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

5. In consideration of the obligations of Guardant set forth in this Agreement, and upon the United States' receipt of full payment of the DHA Administrative Settlement Amount, plus interest, due under Paragraph 2, DHA shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against Guardant under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6 (concerning reserved claims), below. DHA expressly reserves authority to

exclude Guardant from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.

6. Notwithstanding the releases given in Paragraphs 3, 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 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. Guardant waives and shall not assert any defenses Guardant 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.

8. Guardant 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 Guardant 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.

9. 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 Guardant 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.

10. Guardant 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 Guardant, 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) Guardant'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 Guardant 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) (hereinafter referred to as Unallowable Costs).

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

c. Treatment of Unallowable Costs Previously Submitted for Payment: Guardant 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 Guardant 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. Guardant agrees that the United States, at a minimum, shall

be entitled to recoup from Guardant 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 Guardant or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Guardant 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 Guardant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

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

12. 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 13 (waiver for beneficiaries paragraph), below.

13. Guardant 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.

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

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

16. 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 Northern District of California. 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.

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

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

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

20. This Agreement is binding on Guardant's successors, transferees, heirs, and assigns.

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

22. 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.