

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 United States Department of Health and Human Services (“HHS”), the Office of Inspector General of the Department of Health and Human Services (“OIG-HHS”) (collectively, the “United States”), Caris Life Sciences, Inc. and Relators [REDACTED] and Samuel Caughron (“Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Caris Life Sciences, Inc. (“Caris”) is a medical diagnostic laboratory, headquartered in Dallas, Texas, which has developed a series of predictive genetic marker tests. Caris represents that these tests assist physicians, principally oncologists, in determining appropriate treatment options for cancer patients. Caris’s tests have the proprietary names of Caris Molecular Intelligence (formerly known as Caris Target Now) and the ADAPT Biotargeting System, which are utilized primarily for cancer patients.

B. On [REDACTED] Relator [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). Relator alleged certain civil claims against Caris arising from its violations of 42 C.F.R. § 414.510 (colloquially known as the “Date of Service”, “DOS Rule” or “14-Day Rule”). On May 22, 2018, Relator Samuel Caughron filed an action in the United States District Court for the Eastern District

of New York, captioned *United States ex rel. Samuel Caughron v. CDX Holdings Inc. f/k/a Caris Life Sciences, Inc.*, Civil Action No. 18-CV-0352, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b). Relator alleged certain civil claims against Caris arising from its violations of the DOS Rule (both actions are collectively referred to as the “Civil Actions” and Relator [REDACTED] and Relator Samuel Caughron are collectively referred to as the “Relators”).

C. The United States contends that Caris 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. The United States contends that it has certain civil claims against Caris arising from its failure to comply with the DOS Rule, 42 C.F.R. § 414.510. Specifically, the United States contends as follows: (1) During the period from January 1, 2007 through December 31, 2017, Caris sought direct reimbursement from CMS for claims on behalf of Medicare beneficiaries, when tests were ordered and submitted for testing within 14 days after an in-patient discharge; (2) During the period from January 1, 2007 through December 31, 2017, Caris sought direct reimbursement from CMS for claims on behalf of Medicare beneficiaries, when Caris failed to discourage providers who ordered testing within 14 days after an in-patient or outpatient discharge from canceling the order and placing a new order for testing after the 14 day time period had elapsed; (3) During the period from January 1, 2007 through December 31, 2017, Caris sought direct reimbursement from CMS for tests ordered within 14 days of a beneficiary’s out-patient procedure; and (4) The United States contends that in so doing, Caris violated the DOS Rule and knowingly submitted false claims. The conduct set forth in this Paragraph is referred to below as the “Covered Conduct.”

E. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

F. This Agreement is the result of a compromise of disputed issues of law and fact and is neither an admission of liability by Caris nor a concession by the United States that its claims are not well founded.

G. 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. Caris shall pay to the United States \$2,886,675.00 ("Settlement Amount"), of which \$1,630,837.43 is restitution, no later than 5 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 Eastern District of New York. In addition, Caris shall pay to Relator [REDACTED] \$150,000.00 and to Relator Samuel Caughron \$30,000.00 as their reasonable attorney fees, no later than 5 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by each of their counsel.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$505,168.12 to Relators by electronic funds transfer ("Relator's Share").

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States releases

Caris together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors 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.

4. Upon the receipt of the amounts in Paragraph 1 above, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Caris together with its current and former officers, directors, parents, affiliates, divisions, and subsidiaries, their predecessors and successors, and their respective current and former officers, directors, employees, agents, servants and attorneys, and assigns of any of them from any civil monetary claim the Relators have on behalf of themselves and the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and all claims set forth in the Civil Actions, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

5. Notwithstanding the releases given in Paragraph 3 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;
- g. Express or implied warranty of claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relators and their 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 Relators' receipt of the Relators' Share, Relators and their 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 filing of the Civil Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

7. Caris waives and shall not assert any defenses Caris 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. Caris 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 Caris 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.

9. Caris fully and finally releases the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Caris has asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct and the Relators' investigation and prosecution thereof.

10. 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 Caris 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.

11. Caris 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 Caris, 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) Caris'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 Caris makes to the United States pursuant to this Agreement and any payments that Caris 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 Caris, and Caris 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 Caris or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment:

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

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

13. 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.

14. Caris 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.

15. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file Notices of Dismissal of the Civil Actions pursuant to Rule 41(a)(1) in the forms attached as Exhibit 1.

16. Except as provided in Paragraph 1 of this Agreement with regard to Caris's liability to counsel for Relators for attorney fees, each Party shall bear its own legal and other

costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17. 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.

18. 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 Eastern District of New York. 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.

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

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

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

22. This Agreement is binding on Caris's successors, transferees, heirs, and assigns.

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


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

25. 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: 5/21 2022

BREON PEACE
UNITED STATES ATTORNEY
Eastern District of New York
271 Cadman Plaza East
Brooklyn, New York 11201


BY: DEBORAH B. ZWANY
Assistant U.S. Attorney
(718) 254-6010

DATED: _____

BY: LISA RE
Digitally signed by LISA RE
Date: 2022.03.11 13:29:55 -05'00'
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

CARIS LIFE SCIENCES, INC.- DEFENDANT

DATED: 5/4/22

BY:

[REDACTED]

Russell O. Farr
SVP – General Counsel

DATED: 5/3/22

BY:

[REDACTED]

John P. McDonald
Locke Lord LLP
2200 Ross Avenue
Suite 2800
Dallas, TX 75201

RELATOR

DATED: 03/16/2022

BY:

DATED: _____

BY: _____

Erika A. Kelton
Peter P. Budetti
John W. Tremblay
Phillips & Cohen LLP
Counsel for _____
2000 Massachusetts Ave NW
Washington, D.C. 20036

[REDACTED] - RELATOR

DATED: _____

BY: [REDACTED] _____


DATED: March 15, 2022

BY: *[Signature]* [REDACTED] _____

Erika A. Kelton
Peter P. Budetti
John W. Tremblay
Phillips & Cohen LLP
Counsel for [REDACTED]
2000 Massachusetts Ave NW
Washington, D.C. 20036

SAMUEL CAUGHRON - RELATOR

DATED: 3/16/22

BY: 
Samuel Caughron M.D.

DATED: 3/16/22

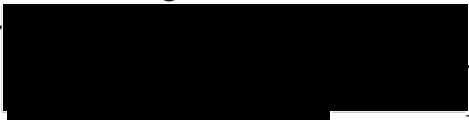
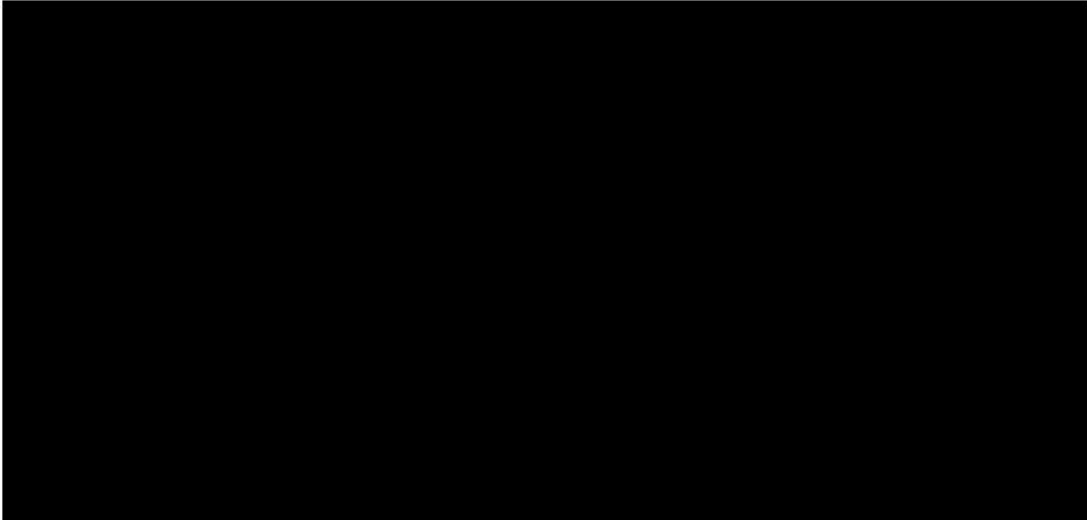
BY: 
Patrick S. Almonrode
Jason T. Brown
Brown, LLC
Counsel for Relator Samuel Caughron, M.D.
111 Town Square Place, Suite 400
Jersey City, New Jersey 07310

EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK



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NOTICE OF DISMISSAL AS TO DEFENDANT CARIS ONLY

Pursuant to Rule 41(a)(1)(A) of the Federal Rules of Civil Procedure and the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b)(1), and subject to the terms and conditions of the March 2022 Settlement Agreement (“Settlement Agreement”) between the United States, Relator Doe and Defendant Caris Life Sciences (“Caris”), the United States and Relator Doe hereby: (1) dismiss with prejudice all civil monetary claims on behalf of the United States against Caris for the Covered Conduct as defined in Recitals Paragraph D of the Settlement Agreement; (2) dismiss without prejudice to the United States and with prejudice to Relator Doe all other claims against Caris asserted on behalf of the United States by Relator Doe; and (3) dismiss with prejudice all claims on behalf of Relator Doe against Caris under 31 U.S.C. § 3730(d) for attorney’s fees, costs and expenses.

This Notice of Dismissal does not apply to or affect in any way any other claims alleged against any other defendants named in the above-captioned action.

Dated: Brooklyn, New York

_____, 2022

For the United States:

Respectfully submitted,

BREON PEACE
United States Attorney
Eastern District of New York
271 Cadman Plaza East
Brooklyn, New York 11201

By:

DEBORAH B. ZWANY
Assistant U.S. Attorney

For Relator Doe:

Erika A. Kelton
Peter P. Budetti
John W. Tremblay
Phillips & Cohen LLP
Counsel for [REDACTED]
2000 Massachusetts Ave NW
Washington, D.C. 20036

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA
ex rel. SAMUEL CAUGHORN, M.D.,

Plaintiffs,

Civil Action No.

18-CV-0352

-against-

(DeArcy Hall, J.)

(Levy, M.J.)

CDx Holdings, Inc. f/k/a Caris Life Science,

Defendant.

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NOTICE OF DISMISSAL

PLEASE TAKE NOTICE that pursuant to Rule 41(a)(1)(A)(i) of the Federal Rules of Civil Procedure, Relator hereby dismisses the above-captioned action with prejudice to Relator Caughorn and without prejudice to the United States. The United States concurs in this dismissal.

Dated: Jersey City, New Jersey
, 2022

Brown, LLC
Counsel for Relator Samuel Caughorn, M.D.
111 Town Square Place, Suite 400
Jersey City, New Jersey 07310

By: _____
Patrick S. Almonrode
Jason T. Brown
(877) 561-0000