SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among (a) 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 (b) Chad Shelton, M.D. (Dr. Shelton), Michael Boedefeld, M.D. (Dr. Boedefeld), and Pro Pain, LLC (Pro Pain), through their authorized representatives. Collectively, all of the above will be referred to as the Parties.

RECITALS

A. Drs. Shelton and Boedefeld own and operate Pro Pain, a pain management medical practice with offices in Fenton, St. Peters, and Wentzville, Missouri. Drs. Shelton and Boedefeld are physicians licensed to practice in the state of Missouri.

B. The United States contends that Dr. Shelton, Dr. Boedefeld, and Pro Pain caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395111 (Medicare).

C. The United States contends that it has certain civil claims against Dr. Shelton, Dr. Boedefeld, and Pro Pain arising from the following alleged conduct, referred to below as the Covered Conduct:

i. From February 1, 2017 to September 30, 2018, Dr. Shelton, Dr. Boedefeld, and Pro Pain knowingly and willfully solicited and/or received \$77,165 in remuneration from Beachwood Services LLC (Beachwood) in return for ordering clinical laboratory services (as defined in 42 U.S.C. § 1395nn(h)(6)(A)) from Landmark Diagnostics LLC (Landmark), a clinical laboratory in Houston, Texas, and Sprint Diagnostics LLC (Sprint), a clinical laboratory in Santa Ana, California, in violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b). Beachwood, a purported management services organization (MSO), paid thousands of dollars to Pro Pain that were disguised as investment returns but were actually based on, and offered in return for, Dr. Shelton's and Dr. Boedefeld's referrals to Landmark and Sprint for urine toxicology testing.

ii. From July 1, 2018 to October 31, 2020, Dr. Shelton, Dr. Boedefeld, and Pro Pain knowingly and willfully solicited and/or received \$54,955 in remuneration from Alari Group LLC (Alari) in return for ordering clinical laboratory services from Genesis Reference Laboratories LLC (Genesis), a clinical laboratory in Orlando, Florida, American Institute of Toxicology Inc. d/b/a HealthTrackRx (AIT), a clinical laboratory in Denton, Texas, and InHealth Diagnostic LLC d/b/a RealLab (InHealth), a clinical laboratory in Dallas, Texas, in violation of the AKS. Alari, a purported MSO, paid thousands of dollars to Pro Pain that were disguised as investment returns but were actually based on, and offered in return for, Dr. Shelton's and Dr. Boedefeld's referrals to Genesis, AIT, and InHealth for urine toxicology testing.

D. This Settlement Agreement is neither an admission of liability by Dr. Shelton, Dr.Boedefeld, or Pro Pain, nor a concession by the United States that its claims are not well founded.

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

TERMS AND CONDITIONS

1. Dr. Shelton, Dr. Boedefeld, and Pro Pain shall pay to the United States a total of Three Hundred Ninety-Six Thousand Three Hundred Sixty Dollars (\$396,360.00) (Settlement Amount), of which One Hundred Thirty-Two Thousand One Hundred Twenty Dollars (\$132,120.00) is restitution, under the terms and conditions specified herein, within thirty (30) calendar days of the Effective Date by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, subject to Paragraph 9 (concerning default) below, and conditioned upon the full payment of the Settlement Amount to the United States by Dr. Shelton, Dr. Boedefeld, and Pro Pain, the United States releases Dr. Shelton, Dr. Boedefeld, and Pro Pain 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. 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;
- 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 other than Drs. Shelton and Boedefeld;
- g. Any liability of corporate entities other than Pro Pain;
- Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

- i. Any liability for failure to deliver goods or services due; and
- j. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Dr. Shelton, Dr. Boedefeld, and Pro Pain waive and shall not assert any defenses they 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.

5. Dr. Shelton, Dr. Boedefeld, and Pro Pain fully and finally release 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain have 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.

6. 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

7. Dr. Shelton, Dr. Boedefeld, and Pro Pain agree to the following:

a. <u>Unallowable Costs Defined</u>: 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dr. Shelton, Dr. Boedefeld, and Pro Pain in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;
- (3) Dr. Shelton, Dr. Boedefeld, and Pro Pain'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 Dr. Shelton, Dr. Boedefeld, and Pro Pain 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. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by Dr. Shelton, Dr. Boedefeld, and Pro Pain, and Dr. Shelton, Dr. Boedefeld, and Pro Pain 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain, or any of Pro Pain's subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

Treatment of Unallowable Costs Previously Submitted for Payment: Dr. c. Shelton, Dr. Boedefeld, and Pro Pain further agree that within ninety (90) days of the Effective Date of this Agreement they 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain, or any of Pro Pain's subsidiaries or affiliates, and shall request, and agrees, 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. Dr. Shelton, Dr. Boedefeld, and Pro Pain agree that the United States, at a minimum, shall be entitled to recoup from Dr. Shelton, Dr. Boedefeld, and Pro Pain 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain, or any of Pro Pain's subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dr. Shelton, Dr. Boedefeld, and Pro Pain, or any of Pro Pain's 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain's books

and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Dr. Shelton, Dr. Boedefeld, and Pro Pain agree to cooperate fully, truthfully, completely, and forthrightly with the United States' investigation(s) of, and/or legal proceeding(s) against, individuals and entities not released in this Agreement. Upon request by the United States and reasonable notice, Drs. Shelton and Boedefeld shall be available for interviews by the United States and shall fully, truthfully, completely, and forthrightly answer questions. Upon request by the United States and reasonable notice, Drs. Shelton and Boedefeld shall testify under oath fully, truthfully, completely, and forthrightly at any and all trials of cases or other court proceedings, including depositions, at which their testimony may be deemed relevant by the United States. Drs. Shelton and Boedefeld agree to encourage, and not impair, the cooperation of Pro Pain's directors, officers, and employees, and to use their best efforts to make available, and encourage, the cooperation of Pro Pain's former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Dr. Shelton, Dr. Boedefeld, and Pro Pain further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control relating to Beachwood, Alari, Landmark, Sprint, Genesis, AIT, InHealth, any other MSO, or any agent of the foregoing entities.

9. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims against Dr. Shelton, Dr. Boedefeld, and Pro Pain arising from the Covered Conduct pursuant to the terms and conditions in this Agreement.

a. Dr. Shelton, Dr. Boedefeld, and Pro Pain shall be in default of this Agreement (Default) if they fail to pay the Settlement Amount as provided in Paragraph 1 above,

or if they fail to comply materially with any other term or condition of this Agreement, including Paragraph 8 above (concerning cooperation).

b. If Dr. Shelton, Dr. Boedefeld, and Pro Pain fail to pay the Settlement Amount as provided in Paragraph 1 above, the United States will provide a written Notice of Default, and Dr. Shelton, Dr. Boedefeld, and Pro Pain shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Dr. Shelton, Dr. Boedefeld, and Pro Pain, or to such other representative as Dr. Shelton, Dr. Boedefeld, and Pro Pain shall designate in advance in writing. If Dr. Shelton, Dr. Boedefeld, and Pro Pain fail to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (Uncured Default), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of twelve percent (12%) per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

c. In the event of Uncured Default, or a failure to comply materially with Paragraph 8 above (concerning cooperation), Dr. Shelton, Dr. Boedefeld, and Pro Pain agree that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Dr. Shelton, Dr. Boedefeld, and Pro Pain for the claims that would otherwise be covered by the releases provided in Paragraph 2 above, with any recovery reduced by the amount of any payments previously made by Dr. Shelton, Dr. Boedefeld, and Pro Pain to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to Dr. Shelton, Dr. Boedefeld, and Pro Pain, and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Dr. Shelton, Dr. Boedefeld, and Pro Pain agree immediately to pay the United States the greater of (i) a ten percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, Dr. Shelton, Dr. Boedefeld, and Pro Pain waive and agree not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the United States against Dr. Shelton, Dr. Boedefeld, and Pro Pain within one hundred twenty (120) days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. Dr. Shelton, Dr. Boedefeld, and Pro Pain agree not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

d. In the event of Uncured Default, or a failure to comply materially with Paragraph 8 above (concerning cooperation), OIG-HHS may exclude Dr. Shelton, Dr. Boedefeld, and Pro Pain from participating in all Federal healthcare programs (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Dr. Shelton, Dr. Boedefeld, and Pro Pain. Dr. Shelton, Dr. Boedefeld, and Pro Pain waive any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agree 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, Dr. Shelton, Dr. Boedefeld, and Pro Pain wish to apply for reinstatement, they must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001–.3005. Dr. Shelton, Dr. Boedefeld, and Pro Pain will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

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. Dr. Shelton, Dr. Boedefeld, and Pro Pain agree that they waive 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. The Parties and signatories to this Agreement represent that they freely and voluntarily enter into this Agreement without any degree of duress or compulsion.

14. 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 Eastern District of Texas. 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 Dr. Shelton, Dr. Boedefeld, and Pro Pain'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). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE PAGE(S) FOLLOW]

THE UNITED STATES OF AMERICA

DATED: <u>9/20/2023</u> BY: CHRISTOPHER TERRANOVA Senior Trial Counsel Commercial Litigation Branch **Civil Division** United States Department of Justice 9/20/2023 harva DATED: BY: **KRUTI DHARIA** Assistant United States Attorney United States Attorney's Office District of New Jersey LISA RE Digitally signed by LISA RE Date: 2023.09.20 07:57:20 -04'00' DATED: <u>9/20/2023</u> 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

CHAD SHELTON, M.D.

DATED: 9115/200

CHAD SHELTON, M.D.

BY:

BY:

BY:

BY:

BY:

DATED: 09/15/2023

BRIAN FLOOD ASHLEY TODD Husch Blackwell LLP Attorneys for Chad Shelton, M.D.

MICHAEL BOEDEFELD, M.D.

DATED: 9/15/2327 BY:

DATED: 09/15/2023

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MICHAEL BOEDEFELD, M.D.

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BRIAN FLOOD ASHLEY TODD Husch Blackwell LLP Attorneys for Michael Boedefeld, M.D.

PRO PAIN, LLC

DATED: 4/15/2023 BY:

CHAD SHELTON, M.D. Owner, Pro Pain, LLC

DATED: 9/15/2023

MICHAEL BOEDEFELD, M.D. Owner, Pro Pain, LLC

DATED: 09/15/2023

BRIAN FLOOD ASHLEY TODD Husch Blackwell LLP Attorneys for Pro Pain, LLC