

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of California (“the State”), QOL Medical, LLC (“QOL”), and Frederick E. Cooper (“Cooper” and, together with QOL, “Defendants”), collectively, “the Parties.”

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. QOL is a privately held Delaware limited liability company with a principal place of business in Florida. QOL is a pharmaceutical manufacturer that sells therapies for patients with rare diseases, including its principal product, Sucraid (sacrosidase). Sucraid is the only FDA-approved therapy for the rare genetic condition, Congenital Sucrase-Isomaltase Deficiency (“CSID”).

B. Cooper, an individual residing in Nashville, Tennessee, has served as QOL’s Chief Executive Officer since 2010; he holds a substantial indirect ownership stake in QOL.

C. CSID is a rare genetic disorder that prevents the body from breaking down sucrose and sugars from other starches. CSID patients have difficulty digesting sucrose and sugars from other starches because of mutations in the gene for the sucrase-isomaltase enzyme, which results in reduced enzymatic activity in their digestive tracts. The undigested sugars cause gastrointestinal symptoms such as diarrhea, abdominal pain, bloating, and gas. CSID symptoms usually appear early in life, but some research indicates it may also first manifest in adolescence or adulthood. CSID can be difficult to diagnose.

D. On June 26, 2020, Relators John Does 1 through 4 (the “Relators”) filed a *qui tam* action in the United States District Court for the District of Massachusetts, captioned *United States*

of America., ex rel. John Doe 1, et al. v. QOL Medical, LLC, et al., Civil Action No. 1:20-cv-11243-AK (D. Mass.). On July 22, 2024, Relators filed a Second Amended Complaint which added 28 States as plaintiffs. This *qui tam* action will be referred to as the “Civil Action.” The Civil Action alleges, *inter alia*, that Defendants paid illegal remuneration to induce the purchase of Sucraid, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (“AKS”), the federal False Claims Act (“FCA”), and 28 state law False Claims Act corollary statutes. The United States partially intervened in the Civil Action on January 22, 2024.

E. The AKS prohibits pharmaceutical companies from knowingly and willfully paying remuneration to induce a person to purchase or order, or arrange for the purchasing or ordering, of any drug reimbursed by a federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). Compliance with the AKS is a material condition of payment for the Medicaid Program.

F. The State contends that Defendants caused the submission of claims for payment to be submitted to the State’s Medicaid Program (42 U.S.C. Chapter 7 Subchapter XIX), including “managed care entities” as defined by 42 U.S.C. § 1396u-2.

G. Defendants admit, acknowledge, and accept responsibility for the following facts:

- (1) QOL, with Cooper’s approval, marketed Sucraid to health care providers specializing in gastroenterology and to patients, including adult patients, who were experiencing gastrointestinal symptoms. One message QOL used was that adults experiencing symptoms of irritable bowel syndrome could instead have undiagnosed CSID.
- (2) Beginning in 2018, QOL, with Cooper’s approval, distributed free Carbon-13 (“C13”) breath test kits to health care providers and asked providers to give the kits to patients with common gastrointestinal symptoms. Defendants claimed that the C13 test could “rule in or rule out” CSID.
- (3) The C13 test, like many other laboratory-developed tests, is not FDA-approved. The C13 test also does not specifically diagnose CSID. Rather, the C13 test is designed to assess sucrase activity. Although low or absent sucrase activity is a feature of CSID, it is also a feature of other conditions.

And conditions other than CSID can cause a patient to test “positive” for low sucrase activity on a C13 test.

- (4) QOL, with Cooper’s approval, entered into an arrangement with a laboratory known to the Parties (the “Laboratory”), whereby QOL paid the Laboratory to analyze patients’ C13 tests—at no cost to health care providers or patients—and provide (i) individual results to a patient’s health care provider and (ii) aggregate weekly results to QOL.
- (5) The test results that QOL received did not contain patient names, but did contain the name of the health care provider who ordered the test, along with the patient’s age, gender, symptoms, and test result (“Results Data”). QOL and its commercial team used the Results Data to find potential Sucraid patients and to follow up with health care providers for Sucraid marketing efforts. QOL did this with Cooper’s approval.
- (6) QOL was aware that, prior to its arrangement with QOL, the Laboratory charged the public approximately \$140 for C13 testing services. QOL also was aware that the Laboratory marketed the C13 test for conditions other than CSID, and QOL paid the Laboratory to stop such marketing.
- (7) QOL paid the Laboratory approximately \$105 to analyze each C13 test provided through its free testing program and report the aggregate weekly results to QOL.
- (8) QOL paid the Laboratory for over 75,000 C13 tests between 2018 and 2022. Approximately thirty percent of these tests were positive for low sucrase activity.
- (9) Between 2018 and 2022, QOL received Results Data and disseminated this information to its sales force with instructions to make sales calls for Sucraid to health care providers whose patients had positive C13 breath test results. Defendants tracked whether sales representatives converted “positive” breath tests into Sucraid prescriptions. QOL’s sales force followed up with health care providers to promote treatment with Sucraid. As QOL’s CEO, Cooper was aware of and approved the implementation and continuation of this marketing program. Some QOL sales representatives also made claims regarding the C13 test’s ability to definitively diagnose CSID that were not supported by published scientific literature. For example, at a 2019 national sales training, which Cooper attended and in slides that Cooper reviewed, QOL suggested that sales representatives tell health care providers, “If you have a positive breath test, the patient will not improve unless you treat with Sucraid.”
- (10) In January 2019, Cooper, after reviewing HHS-OIG guidance on the AKS and Beneficiary Inducement Civil Monetary Penalty (“CMP”) law, wrote in an email to three QOL executives that QOL was “going to have to provide

[the C13 test] without making it a marketing cornerstone” or using the word “free” in C13 test marketing materials, and likely was “going to have to stop sharing” C13 breath test results with its sales representatives. QOL then stopped using the word “free” in C13 test marketing materials, but later resumed. QOL did not stop providing C13 test Results Data to sales representatives, who then used that data to solicit Sucraid prescriptions from health care providers. QOL stopped sharing Results Data with its sales representatives in September 2022.

H. The State contends that it has certain civil and administrative causes of action against Defendants for engaging in the conduct described in paragraph G between May 1, 2018, and June 30, 2022 (the “Covered Conduct”). In particular, the State contends that, as a result of the Covered Conduct, Defendants caused the submission of false claims to Medicaid by paying remuneration: (1) to the Laboratory to induce the Laboratory to provide the Results Data which referred QOL employees to health care providers for the furnishing, or arranging for the furnishing, of Sucraid reimbursed by Medicaid; and (2) to beneficiaries in the form of covering the cost of the C13 breath testing services, to induce their purchase of Sucraid reimbursed by Medicaid.

I. Defendants have entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the United States of America (the “United States”).

J. The Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Defendants agree to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the sum of \$47,000,000.00 plus interest accruing at 4.25% from April 24, 2024, until the date of payment (the “Settlement Amount”). As stated in the Federal

Settlement Agreement, of the Settlement Amount, \$21,807,862 shall constitute restitution to the United States, and \$1,692,138 shall constitute restitution to the Medicaid Participating States. The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the “effective date” of the Federal Settlement Agreement, as defined therein and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) Defendants shall pay to the United States the sum of \$43,615,724.32 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$8,051,783.02 consisting of \$3,384,275.68 for the states pursuant to this Agreement and \$4,667,507.34 for the United States pursuant to the Federal Settlement Agreement. Defendants shall pay to the Medicaid Participating States the sum of \$3,384,275.68 plus accrued interest on that amount of 4.25% per annum commencing on April 24, 2024, and continuing to and including the day payment is made under this Agreement (the “Medicaid State Settlement Amount”), subject to the non-participating state deduction provision of sub-paragraph (d) below (the “Medicaid Participating State Settlement Amount”), no later than seven (7) business days after the expiration of the 60-day opt-in period for Medicaid Participating States described in sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid and immediately deposited by electronic funds transfer to the New York State Attorney General’s National Global Settlement Account pursuant to written instructions from the state negotiating team (the “State Team”), which written instructions shall be delivered to counsel for Defendants. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (d) below.

(c) Defendants shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Defendants and the State Team have agreed, or in a form otherwise agreed to by Defendants and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Defendants' attorneys within 60 days of receiving this Agreement. Defendants' offer to resolve this matter with the State shall become null and void absent written agreement between counsel for Defendants and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Defendants in settlement for the Covered Conduct for the State is \$685,634.80, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$384,406.13 plus applicable interest (the "State Amount"), of which \$192,203.06 is restitution. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by Defendants absent written agreement between counsel for Defendants and the State Team to extend the time period for executing this Agreement.

2. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Defendants in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relator(s) the amount of \$57,660.92 plus applicable interest. This amount is to

be paid through the State Team and has been addressed via side letter with the Relator in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Defendants set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Defendants, its predecessors and current and former parents, divisions, subsidiaries, successors, and assigns (collectively, the “Defendant Released Entities”), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State’s Medicaid Program for the Covered Conduct.

4. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the State are specifically reserved and are not released:

- (a) any criminal, civil, or administrative liability arising under state revenue codes;
- (b) any criminal liability;
- (c) any civil or administrative liability that any person or entity, including the Defendant Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 3 above, including, but not limited to, any and all of the following claims: (i) claims involving unlawful or illegal conduct based on State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;
- (d) any liability to the State for any conduct other than the Covered Conduct;
- (e) any liability based upon obligations created by this Agreement;
- (f) except as explicitly stated in this Agreement, any administrative liability or right, including exclusion from the State’s Medicaid Program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals, except for liability released in paragraph 3 as to Cooper.

5. Defendants waive and shall not assert any defenses they may have to criminal prosecution or administrative action for the Covered Conduct, which defenses may be based in whole or in part on a contention, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, that this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. In consideration of the obligations of the State set forth in this Agreement, the Defendant Released Entities waive and discharge the State and any of its agencies, departments, and personnel (including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities) from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Defendant Released Entities have against the State and any of its agencies, departments, and personnel (as previously referenced) arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that Defendants must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid Program, or any other state program payor, for the Covered Conduct; and Defendants agree not to resubmit to the State's Medicaid Program or any other state

program payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

8. Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors.

9. QOL expressly warrants that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

10. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

11. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and the Parties do not release any liability as to any other person or entity.

13. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

14. In addition to all other payments and responsibilities under this Agreement, Defendants agree to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees; such expenses shall not exceed \$10,000.00. Defendants will pay this amount by separate check made payable to the National Association of

Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

15. This Agreement is governed by the laws of the State and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

16. The undersigned QOL signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

17. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. The facsimile, email or other electronically delivered signatures of the parties shall be deemed to constitute acceptable binding signatures for purposes of this Agreement, and facsimile or electronic copies shall be deemed to constitute duplicate originals.

18. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

19. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

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

21. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason. The recitals in Section I (Parties) and Section II (Preamble) are agreed

to by the Parties. The headings of this Agreement are not binding and are for reference only and do not limit, expand, or otherwise affect the contents or meaning of this Agreement.

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STATE OF CALIFORNIA

By:  _____ Dated: 12/12/24

Cheryl Shitabata
Name

Deputy Attorney General
Title

California Department of Justice
Organization

By: _____ Dated: _____

Name

Title

Organization

DEFENDANTS QOL MEDICAL, LLC AND FREDERICK E. COOPER

By: DocuSigned by:
Derick Cooper Dated: 1/7/2025
FREDERICK E. COOPER
On behalf of himself and QOL Medical, LLC
Chief Executive Officer, QOL Medical, LLC

By: Michael Packard Dated: 1/7/2025
WILLIAM A. BURCK
MICHAEL T. PACKARD
Counsel for Frederick E. Cooper and QOL Medical, LLC