

## STATE SETTLEMENT AGREEMENT

### I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of California (the “State”) and Medical Device Business Services, Inc., collectively, the “Parties.”

### II. PREAMBLE

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

A. Therakos, Inc. (“Therakos”) was a Florida corporation that manufactured and marketed a medical-device system and a related pharmaceutical product for performing extracorporeal photopheresis using the UVAR XTS® and Cellex® systems.

B. Therakos was acquired by a third party, TGG Medical Solutions, Inc. (the “Gores Group”), in December 2012, and subsequently acquired by Mallinckrodt plc.

C. Prior to December 2012, Therakos was owned by Ortho-Clinical Diagnostics (“OCD”), at the time a subsidiary of Johnson & Johnson, which divested OCD after the Covered Conduct described below.

D. Medical Device Business Services, Inc. (“MDBS”) is an Indiana corporation that provided medical-device services to affiliates of OCD and Therakos (MDBS, OCD, and Therakos, collectively, defined as “Defendants”).

E. On December 14, 2016, Relators Michael Johnson and Frank J. Strobl (collectively the “Relators”) filed an amended qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned *United States ex rel. Johnson, et al. v. Therakos, Inc., Ortho-Clinical Diagnostics, Inc., Johnson & Johnson, The Gores Group, and Mallinckrodt plc*, Case No. 12-cv-1454 (JHS) (E.D. Pa.), pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C.

§ 3730(b), and the false claims and/or anti-fraud statutes of several states and the District of Columbia (the “Civil Action”).

F. MDBS has entered into a separate civil settlement agreement (the “Federal Settlement Agreement”) with the “United States” (“United States”) as that term is defined in the Federal Settlement Agreement.

G. The State contends that MDBS caused 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.

H. The State contends it has certain civil and administrative causes of action against Defendants for causing the submission of false claims to the State’s Medicaid Program arising from the marketing, promotion, sale, and reimbursement of extracorporeal photopheresis, including for uses not approved by the Food and Drug Administration, in particular for use to treat pediatric patients, during the period January 1, 2006 through December 31, 2012. This alleged conduct is referred to herein as the “Covered Conduct.”

I. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by Defendants, nor a concession by the State that its allegations are not well founded. Defendants expressly deny the allegations of the State set forth herein and in the Civil Action and deny that they engaged in any wrongful conduct in connection with the Covered Conduct.

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. MDBS agrees 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 \$10,000,000.00, plus accrued interest (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt due and owing to the United States and the Medicaid Participating States on the "Effective Date of this Agreement," as that term is defined in the Federal Settlement Agreement, 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) MDBS shall pay to the United States the sum of \$6,277,225.75 plus accrued interest pursuant to the terms of the Federal Settlement Agreement.

(b) The Total Medicaid recovery for the Covered Conduct is \$8,343,286.09 consisting of \$3,722,774.25 for the states pursuant to this Agreement and \$4,620,511.84 for the United States pursuant to the Federal Settlement Agreement. MDBS shall pay to the Medicaid Participating States the sum of \$3,722,774.25, plus accrued interest on that amount at the rate of 0.75 percent per annum from the Effective Date and continuing until and including the day payment is made under this Agreement, subject to the non-participating state deduction provision of sub-paragraph (d) below (the "Medicaid Participating State Settlement Amount"), no later than fourteen (14) 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 settlement team (the "State Team"), which written instructions shall be delivered to counsel for MDBS. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III.1.(d). After making the Medicaid Participating State Settlement Amount payment to the New York State Attorney General's National Global Settlement Account, MDBS shall have no continuing obligations with respect to payment of the State Amount (defined below).

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

(d) The total portion of the amount paid by MDBS in settlement for the Covered Conduct for the State is \$131,137.48, 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 \$73,062.16 plus applicable interest (the "State Amount"), of which \$36,531.08 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 MDBS absent written agreement

between counsel for MDBS and the State Team to extend the time period for executing this Agreement.

2. 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 the MDBS Released Entities as defined in Paragraph 3 below in State or Federal Courts for the Covered Conduct. The Parties shall promptly sign and file a Stipulation of Dismissal in the Civil Action pursuant to Rule 41(a)(1). The Stipulation will provide for the dismissal with prejudice as to the State for the Covered Conduct and dismissal without prejudice as to the State for all other claims. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relators' share, agrees to pay the Relators the amount of \$17,534.92 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letters with the Relators in the Civil Action.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of MDBS set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State, on behalf of itself, and its agencies, departments, political subdivisions (to the extent authorized by law), and personnel including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities, agrees to release Defendants, and their current and former direct and indirect parent corporations; current and former direct and indirect subsidiaries; current and former brother or sister corporations, divisions, and affiliates; and the predecessors, successors, transferees, heirs, and assigns of any of them (collectively, the "MDBS Released Entities"), from any civil or administrative monetary cause of action that the State, its agencies, departments, political subdivisions (to the extent authorized by law), and personnel including, but not limited to, officials, employees, and agents, whether current



or former in their official and individual capacities have or may have for any claims submitted or caused to be submitted to the State's Medicaid Program for the Covered Conduct. The payment of the Medicaid Participating State Settlement Amount fully discharges the MDBS Released Entities from any obligation to pay Medicaid restitution, Medicaid damages, and/or Medicaid civil fines or Medicaid civil penalties to the State 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 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 MDBS 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) 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, including mandatory or permissive 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.

5. MDBS waives and shall not assert any defenses it 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 MDBS 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 and costs, and expenses of every kind and however denominated) which the MDBS 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 MDBS 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 MDBS agrees 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. MDBS 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. MDBS 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, MDBS agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. MDBS 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 MDBS 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. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

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.

State of California

By:



Dated: 01/13/2021

RANDAL L. GLASER  
Deputy Attorney General  
Division of Medi-Cal Fraud and Elder Abuse  
Office of the Attorney General  
California Department of Justice



**MEDICAL DEVICE BUSINESS SERVICES, INC.**


By:

  
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Tina French  
Assistant Secretary  
Medical Device Business Services, Inc.

Dated:

2/11/2021

By:

  
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MARK A. JENSEN, ESQ.  
BRANDT LEIBE, ESQ.  
King & Spalding LLP  
1700 Pennsylvania Avenue, NW  
Washington, DC 20006

Dated:

02/19/2021

Counsel for Medical Device Business Services, Inc.