

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of North Carolina (“the State”) and Advanced Bionics Corporation (“AB”), collectively, “the Parties.”

II. PREAMBLE

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

A. At all relevant times, AB, a California corporation with its principal place of business in Valencia, California, provided various healthcare goods and services, including manufacturing and selling cochlear implant systems in the United States, specifically AB’s cochlear implant systems using Neptune and Naida sound processors.

B. On July 30, 2019, David Nyberg (the “Relator”) filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania captioned *United States of America et al., ex rel. Nyberg v. Advanced Bionics Corp., et al.*, Civil Action No. 2:19-cv-3439. This *qui tam* action will be referred to as the “Civil Action.”

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

D. The State contends that AB 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.

E. The State contends that it has certain civil and administrative causes of action against AB for engaging in the following conduct (the “Covered Conduct”): Beginning in January

2011 and continuing through December 2019, as a result of the conduct alleged in this paragraph, AB knowingly submitted, or caused to be submitted, false or fraudulent claims to the State's Medicaid Program for AB's cochlear implant systems using Neptune and Naida sound processors.

In connection with AB's submission of Premarket Approval Applications ("PMAs") to the U.S. Food & Drug Administration ("FDA") for its Neptune and Naida sound processor components of its cochlear implant systems, AB represented that these processors satisfied an internationally recognized standard for radio frequency ("RF") emissions. These RF standards attempt to limit the extent to which devices like cochlear implant systems interfere with other devices that use the RF spectrum, including but not limited to telephones, alarm and security systems, televisions, and radios, which interference the FDA recognizes can occur with cochlear implant systems. However, the State alleges that AB did not comply with the emissions standard it purported to satisfy. Specifically, AB did not adequately disclose to the FDA that it failed to test the Neptune and Naida sound processors using "worst case" configurations and that it shielded certain emissions-generating system components during emissions testing, methods that the State alleges were improper under the standard. AB's actions were designed to induce the FDA's decision to approve the PMAs for Neptune and Naida sound processors, which permitted federal healthcare programs to reimburse for AB's cochlear implant systems. The State alleges that claims to the State's Medicaid Program for AB's Neptune and Naida cochlear implant systems were false, regardless of whether or not there were safety issues with the Neptune and Naida systems due to the RF emissions testing methods referenced above.

F. AB denies the allegations in Preamble E.

G. This Agreement is neither an admission of facts or liability by AB nor a concession by the State that its allegations are not well founded.

H. 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. AB 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 \$12,600,000.00 plus accrued interest (the “Settlement Amount”). 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) AB shall pay to the United States the sum of \$11,361,420.00 plus accrued interest, pursuant to the terms of the Federal Settlement Agreement.

(b) The total Medicaid recovery for the Covered Conduct is \$2,627,208.99, consisting of \$1,238,580.00 for the states pursuant to this Agreement, and \$1,388,628.99 for the United States pursuant to the Federal Settlement Agreement. AB shall pay to the Medicaid Participating States the sum of \$1,238,580.00, of which \$619,290.00 is restitution, plus accrued interest of 1.5% per annum commencing on March 2, 2022, 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 AB. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph III. 1. (d) below.

(c) AB shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which AB and the State Team have agreed, or in a form otherwise agreed to by AB and an individual State. The State shall constitute being a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to AB's attorneys within 60 days of receiving this Agreement. If the State does not execute and deliver this Agreement within 60 days of receiving this Agreement, AB's offer to resolve this matter with the State shall become null and void absent written agreement between counsel for AB and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by AB in settlement for the Covered Conduct for the State is \$138,146.99 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 \$60,035.23 plus applicable interest (the "State Amount"), of which \$30,017.62 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 AB absent written agreement between counsel for AB 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 AB in State or Federal Courts for the Covered Conduct, including any supplemental state law claims asserted in the Civil Action. The State further agrees to dismiss without prejudice all other claims against the Defendant Released Entities (as defined below) 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 the amount of \$9,905.81 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 AB set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release AB, together with its current and former direct and indirect parent corporations and limited liability companies ("Parents"); its and their affiliates, direct and indirect subsidiaries, brother or sister corporations, and divisions; and its and their current and former corporate owners; and the predecessors, affiliates, successors, transferees and assigns of any of them (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. The payment of the amounts required hereunder fully discharge the Defendant Released Entities from any obligation to pay Medicaid restitution, Medicaid damages, and/or any Medicaid civil fine or penalty 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 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.

5. AB 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 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 AB 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 AB 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. AB 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. AB 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, AB agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. AB 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 AB 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) reflect the result of negotiations between 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.

STATE OF NORTH CAROLINA

By:  Dated: 1/11/2023

F. Edward Kirby, Jr.
Name

Director
Title

NCDOJ Medicaid Investigations Division
Organization

By:  Dated: 01/12/23 | 8:32 AM PST

Dave Richard
Name

Deputy Secretary, NC Medicaid
Title

NC Department of Health & Human Services, Division of Health Benefits
Organization

ADVANCED BIONICS CORPORATION

By: 5B2A14GB06054FC... Dated: 02/17/2023

DAWN SORENSEN
Vice President, Global Legal Affairs
Advanced Bionics Corporation

By:  Dated: 02/21/2023

MATTHEW O'CONNOR
Counsel to Advanced Bionics Corporation

(May need multiple blocks)