

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF FLORIDA, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF MARYLAND, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF NEW JERSEY, THE STATE OF NEW YORK, THE STATE OF OKLAHOMA, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, AND THE DISTRICT OF COLUMBIA, *ex rel.* SWFC LLC,

Plaintiffs,

v.

STIMWAVE TECHNOLOGIES, INC., STIMWAVE LLC, AND LAURA TYLER PERRYMAN,

Defendants.

18 Civ. 4599 (GBD)

THE UNITED STATES OF AMERICA

Plaintiff-Intervenor,

v.

STIMWAVE TECHNOLOGIES, INC., et al.

Defendants.

STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL

WHEREAS, this Stipulation and Order of Settlement and Dismissal (“Stipulation”) is entered into by and among plaintiff the United States of America (the “United States” or “Government”), by its attorney, Damian Williams, United States Attorney for the Southern District of New York; the relator SWFC LLC (“Relator”), by its authorized representatives; and defendants Stimwave Technologies Incorporated and Stimwave LLC (collectively “Stimwave” or

“Defendants,” and together with the Government and Relator, the “Parties”), by their authorized representatives;

WHEREAS, Stimwave is a medical device company that manufactures and distributes implantable neurostimulation devices, including the StimQ PNS System (the “PNS system”), that are intended to treat intractable, chronic pain;

WHEREAS, the PNS system was designed to use electrical stimulation to block pain signals from reaching the brain and is powered wirelessly, without an implanted battery;

WHEREAS, the PNS system, cleared by the FDA in 2017 (the “PNS 510(k) Clearance”), included the following primary components: an implantable electrode array or “Lead” (the “Lead”) that stimulated the nerve; a separate implantable receiver component, referred to as the “Pink Stylet”; and an externally worn transmitter (including an antenna and battery, which was collectively called the “Wearable Antenna Assembly” or “Battery”) to power the device;

WHEREAS, the Pink Stylet had a distinctive pink handle, had a conductive copper core, and was connected to the Lead during the implant procedure. The purpose of the Pink Stylet was to transmit energy through its copper core, from the Battery to the Lead and to improve the efficiency of energy transfer, through its copper core, from the Battery to the Lead;

WHEREAS, Stimwave sold the PNS system to medical providers for over approximately \$16,000;

WHEREAS, medical care providers were reimbursed by insurers, such as Medicare, between \$4,000 and \$6,000 for implanting the Lead and between \$16,000 and \$18,000 for implanting the Pink Stylet;

WHEREAS, on or about May 23, 2018, Relator filed a complaint under the *qui tam* provisions of the False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, in the United States District

Court for the Southern District of New York (the “Court”) against Stimwave and Laura Tyler Perryman (“Laura Perryman”), the former CEO of Stimwave, alleging, *inter alia*, that Stimwave, at the direction of former management, violated the FCA by causing the submission of false claims to Medicare in connection with the implantation of an inert component of the PNS system that was added to the PNS kit by former management (the “Relator Complaint”);

WHEREAS, the Government alleges that Stimwave, at the direction of former management, including a former officer (“Former Officer-1”), designed, created, and manufactured a component referred to as the “White Stylet,” an inert, non-functioning component of the PNS system that served no medical purpose, and instructed medical providers to surgically implant the White Stylet into patients, so that medical providers could seek reimbursement payments from Medicare, which caused the submission of false claims to Medicare from 2018 up to and including 2020 (the “Covered Period”). The conduct described in this Paragraph is the “Covered Conduct” for purposes of this Stipulation;

WHEREAS, as described in the NPA, after being notified of the investigation by the United States Attorney’s Office for the Southern District of New York (the “Office”) into the Covered Conduct, new management took significant steps to remediate that misconduct, including an exhaustive Health Hazard Evaluation (“HHE”) and the initiation of a voluntary public recall, which was implemented in coordination with the FDA. The HHE and voluntary recall showed that use of the White Stylet could potentially result in the PNS System not providing the full range of stimulation available to alleviate pain, as when the Lead and Pink Stylet were used. In conducting the HHE, the Company found that this risk was mitigated as a result of intraoperative testing of the device conducted at the time of implant. Aside from this mitigated risk, the Company found no actual medically-related patient harm in connection with the implant of the White Stylet,

beyond the risks associated with implanting any plastic medical device into a patient, and other than the fact that implantation of the White Stylet was medically unnecessary. The HHE was provided to this Office and to the FDA as part of the voluntary recall. FDA extensively reviewed and supported the action plan for the recall conducted by the Company.

WHEREAS, contemporaneous with the filing of this Stipulation, the Government is filing a Notice of Election to Partially Intervene and a Complaint-In-Intervention in the above-referenced *qui tam* action (“Government Complaint”), in which it is asserting claims against Stimwave, among others, under the FCA and common law for the Covered Conduct;

WHEREAS, contemporaneous with the filing of this Stipulation, the Criminal Division of the United States Attorney’s Office for the Southern District of New York is also entering into a Non-Prosecution Agreement (the “Non-Prosecution Agreement”) with Stimwave concerning the conduct described in the Covered Conduct;

WHEREAS, pursuant to the Non-Prosecution Agreement, Stimwave has agreed to pay a total penalty of \$10,000,000, consisting of \$1,400,000 as money subject to forfeiture, and \$8,600,000 that can be satisfied by payment of the Settlement Amount as defined in Paragraph 3 of this Stipulation;

WHEREAS, on June 15, 2022, Stimwave filed for protection under chapter 11 of title 11 of the United State Code (“Bankruptcy Code”) in the United States Bankruptcy Court for the District of Delaware (the “Bankruptcy Court”) in the case captioned, *In re Stimwave Technologies Incorporated, et al.*, Case No. 22-10541 (Bankr. D. Del. 2022);

WHEREAS, upon the closing of the Section 363 Sale, (i) certain Stimwave assets and operations will be purchased by the buyer (the “Buyer”) pursuant to that Section 363 Sale, and (ii) Stimwave will proceed to wind down and liquidate its estate in Bankruptcy Court.

WHEREAS on September 30, 2022, the Bankruptcy Court entered an order approving the sale of certain Stimwave assets to a third-party through an auction pursuant to 11 U.S.C. § 363 (the “Section 363 Sale” or “Sale”). The Sale is expected to close on October 31, 2022 (the “Closing”).

WHEREAS, the filing of the Government Complaint is excepted from the automatic stay under section 362(b)(4) of the Bankruptcy Code;

WHEREAS, Stimwave filed a motion with the Bankruptcy Court under Bankruptcy Rule 9019 for court approval of this Stipulation on or about October 7, 2022 (the “9019 Motion”);

WHEREAS, the Bankruptcy Court granted Stimwave’s 9019 Motion on October 26, 2022;

WHEREAS, the Parties have, through this Stipulation, reached a mutually agreeable resolution addressing the claims asserted against Stimwave in the Government Complaint and the Relator Complaint, for the Covered Conduct;

NOW, THEREFORE, upon the Parties’ agreement IT IS HEREBY ORDERED that:

TERMS AND CONDITIONS

1. The Parties agree that this Court has subject matter jurisdiction over this action and consent to this Court’s exercise of personal jurisdiction over each of them.
2. Stimwave admits, acknowledges and accepts responsibility for the following conduct (the “Admitted Conduct”):
 - a. During the Covered Period Stimwave marketed and sold to medical providers the PNS system—a neurostimulator medical device that treats chronic pain by producing electrical currents to target peripheral nerves outside the spinal cord.
 - b. The PNS system, as covered by the PNS 510(k) Clearance, contained the following primary components: the Lead, the Pink Stylet, and the Battery.
 - c. The Pink Stylet was part of the FDA-cleared PNS Kit and was referenced in the device labeling and Instructions for Use (“IFU”). The Pink Stylet had

a distinctive pink handle, had a conductive copper core, and was connected to the Lead during the implant procedure. The purpose of the Pink Stylet was to transmit energy through its copper core, from the Battery to the Lead, and to improve the efficiency of energy transfer, through its copper core, from the Battery to the Lead.

- d. In order for the PNS system to accomplish its goal of reducing pain, doctors were instructed to implant the Lead near a nerve, through an initial incision. Then, through a second incision and pocket, doctors implanted the Pink Stylet and connected it to the Lead. When physicians implanted the Pink Stylet, they used reimbursement code (known as a CPT Code) 64590, when seeking reimbursement from Medicare.¹
- e. Stimwave sold the PNS system to doctors for over approximately \$16,000 with the understanding that medical insurance providers, including Medicare, would reimburse medical practitioners for implanting the PNS system into patients through two separate CPT codes—one for implantation of the electrode array, and a second for implantation of the Pink Stylet.
- f. The billing code for implanting the electrode array, CPT code 64555, provided for reimbursement at a rate of between approximately \$4,000 and \$6,000, while the billing code for implanting the Pink Stylet, CPT code 64590, provided for reimbursement at a rate of between approximately \$16,000 and \$18,000.
- g. In or about 2017, Stimwave learned that doctors who had implanted the PNS system complained that the Pink Stylet, which was approximately 23 centimeters long, could not be implanted to fit comfortably into a patient's smaller anatomical spaces (such as near elbows). In such small anatomical spaces, the PNS system would function without the use of the Pink Stylet, but only if an external battery was placed at or near the neurostimulator. This potential utilization of the PNS system was not included or in any manner referenced in Stimwave's PNS 510(k) Clearance to market the PNS system or in the PNS IFU related to such PNS 510(k) Clearance.
- h. If doctors did not implant the Pink Stylet, they could not claim reimbursement for implanting it, and thus could not seek reimbursement under CPT code 64590. In such a circumstance, implanting the PNS system without the Pink Stylet was not economically viable for medical providers because they could not bill for the additional procedure, and Stimwave's former management had concerns that some medical

¹ Reimbursement code 64590 is permitted to be used for reimbursement of “[i]nsertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or indirect coupling.” *See, e.g.,* <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53359>.

providers would cease purchasing the device.

- i. But rather than lower the price of the PNS system so that its cost to medical providers could be covered by reimbursement for the implantation of the Lead, or recommending that medical providers not implant the PNS system or its receiver component in cases where the Pink Stylet could not fit comfortably, Former Officer-1 directed that Stimwave create a “receiver” stylet – referred to as the “White Stylet.”
- j. Subsequently, Stimwave—at the direction of Former Officer-1—designed, manufactured, and created the White Stylet component, which was disguised as a receiver and was falsely represented to contain copper and function as a receiver (such that it could transmit energy from the external battery), like the Pink Stylet. However, the White Stylet was actually without function.
- k. The White Stylet was similar in length to the Pink Stylet, but was made entirely of plastic and therefore could be cut by the doctor to the desired length. It provided no receiver functionality and had no medical purpose. At no point did Stimwave seek to update their FDA clearance or the approved IFU to reference the White Stylet.
- l. Stimwave created the White Stylet and misrepresented it as a receiver at the direction of former management so that medical practitioners could implant a second component in situations where the longer, functional, Pink Stylet would not fit or otherwise would be uncomfortable, and could thereby seek reimbursement from health insurers, including Medicare, for the procedure under CPT code 64590.
- m. Former Officer-1 told doctors that the White Stylet contained copper and, therefore, retained functionality, when in fact it was made of plastic and was not functional. Furthermore, former management instructed Stimwave sales representatives to inform medical providers that they could still use CPT code 64590 for reimbursement of insertion of the White Stylet. This information was provided by sales representatives to doctors. However, while CPT code 64590 may have been appropriate for implantation of a functioning receiver such as the Pink Stylet, under no circumstance would it have covered the implantation of a component with no receiver (or no other) medical functionality, such as the White Stylet.

3. Stimwave LLC shall pay to the Government within fourteen (14) business days of the Effective Date (defined below in Paragraph 28) the sum of \$8,600,000 (the “Settlement Amount”) in accordance with instructions to be provided by the Financial Litigation Unit of the

United States Attorney's Office for the Southern District of New York. Of the Settlement Amount, \$8,600,000 constitutes restitution to the United States.

4. Stimwave shall continue to cooperate with this Office in any and all matters relating to the Covered Conduct until the date on which all civil or criminal examinations, investigations, prosecutions, or proceedings, including all appeals, are concluded, whether or not those examinations, investigations, or proceedings are commenced or concluded within the Stipulation Period, including: (1) cooperate fully with this Office, the FBI, FDA-OIG, and any other federal law enforcement agency designated by this Office regarding all matters related to the Covered Conduct; (2) undertake the preservation and retention of all documents, data, and records related to the Covered Conduct, including by storing such documents, records, and data in an external storage facility if necessary for preservation and retention or by transferring them to the Buyer following the Sale; (3) assist this Office or any designated federal law enforcement agency in any investigation, prosecution, or civil proceeding arising out of or related to the Covered Conduct by making its best efforts to provide logistical and technical support for any meeting, interview, federal grand jury proceeding, or any federal trial or other federal court proceeding; (4) make its best efforts promptly to secure the attendance and truthful statements or testimony of any officer, director, employee, agent, or consultant of Stimwave at any meeting or interview or before a federal grand jury or at any federal trial or other federal court proceeding regarding matters arising out of or related to the Covered Conduct; (5) make its best efforts to provide testimony of a competent witness as needed to enable this Office and any designated federal law enforcement agency to use the information and evidence obtained pursuant to Stimwave's cooperation with this Office; and (6) provide this Office, upon request, all information, documents, records, or other tangible evidence that can be obtained through reasonable efforts regarding matters arising out of

or related to the Covered Conduct about which this Office or any designated federal law enforcement agency inquires. Stimwave's cooperation pursuant to this paragraph is subject to applicable laws and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, Stimwave must provide to the Office a log of any information or cooperation that is not provided in response to the Office's requests based on an assertion of law, regulation, or privilege, and Stimwave bears the burden of establishing the validity of any such assertion.²

5. Subject to the exceptions in Paragraph 9 (concerning reserved claims) below and subject to Paragraph 10 (concerning default) below, and conditioned on Stimwave's full compliance with the terms of this Stipulation, including full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, the United States releases Stimwave, including its subsidiaries and corporate predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has for the Covered Conduct under the FCA, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812, and the common law theories of fraud, payment by mistake, and unjust enrichment. For avoidance of doubt, this Stipulation does not release any current or former officer, director, employee, or agent of Stimwave from liability of any kind, including but not limited to Laura Perryman.

6. Stimwave fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses

² It is understood that after the Closing of the Sale on or about October 31, 2022, certain Stimwave assets will transfer to the Buyer and certain Stimwave employees will be hired by the Buyer. Thereafter, Stimwave will retain certain assets and certain administrators to assist in the final disposition of Stimwave. It is understood that after the Closing of the Sale Stimwave intends to file a plan of liquidation or seek a Court order otherwise resolving the bankruptcy case.

of every kind and however denominated) that Stimwave has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, or agents related to the Covered Conduct or the United States' investigation, prosecution and settlement thereof.

7. Conditioned on Stimwave's full payment of the Settlement Amount to the United States pursuant to Paragraph 3 above, Relator, for itself and its predecessors, successors, owners, members, attorneys, agents, and assigns, releases Stimwave, including its subsidiaries and corporate predecessors, the Buyer, successors, transferees, and assigns, as well as all of Stimwave's and Buyer's current and former officers, directors, employees, attorneys, consultants and other agents, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Relator has against Stimwave; provided, however, that nothing in this Stipulation shall (a) release Laura Perryman from liability of any kind; and (b) preclude Relator from seeking to recover against Stimwave its reasonable expenses and attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d), and nothing shall preclude Stimwave from asserting defenses against expenses and attorneys' fees and costs sought by Relator.

8. In consideration of the execution of this Stipulation by Relator and the Relator's release as set forth in Paragraph 7 above, Stimwave, for itself and its subsidiaries, predecessors, and corporate successors and assigns, as well as all of its current and former officers, directors, employees, attorneys, and other agents, releases Relator and its successors, attorneys, agents, and assigns, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that Stimwave has against Relator related to or arising from the Relator Complaint; provided, however, for avoidance of doubt that nothing in this Stipulation shall release any claims

Stimwave may have against Relator, its predecessors, successors, owners, members, managers, attorneys, agents, and assigns, for conduct unrelated to the Relator Complaint.

9. Notwithstanding the releases given in Paragraph 5 above, or any other term of this Stipulation, the following claims of the Government are specifically reserved and are not released by this Stipulation:

- a. any liability arising under Title 26, United States Code (Internal Revenue Code);
- b. any criminal liability, except as set forth in the Non-Prosecution Agreement;
- c. except as explicitly stated in this Stipulation, any administrative liability or enforcement right, including but not limited to the mandatory or permissive exclusion from Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) or 42 U.S.C. § 1320a-7(b) (permissive exclusion);
- 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 Stipulation; and
- f. any liability of individuals, including but not limited to Laura Perryman.

10. Stimwave shall be in default of this Stipulation if Stimwave fails to make the required payment set forth in Paragraph 3 above on or before the due date for such payment, or if it fails to comply materially with any other term of this Stipulation that applies to it (“Default”). The Government will provide a written Notice of Default to Defendant of any Default in the manner set forth in Paragraph 27 below. Stimwave shall then have an opportunity to cure the 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 Stipulation up to the date of payment. If Stimwave fails to cure the Default within seven (7) calendar days of receiving the Notice of Default (“Uncured Default”), interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance). Stimwave also agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Stipulation, and reinstate the claims asserted against Stimwave in the Government Complaint, or bring any civil and/or administrative claim, action, or proceeding against Stimwave for the claims that would otherwise be covered by the releases provided in Paragraph 5 above, with any recovery reduced by the amount of any payments previously made by Stimwave to the United States under this Stipulation; (ii) take any action to enforce this Stipulation in a new action or by reinstating the Government Complaint; (iii) offset the remaining unpaid balance from any amounts due and owing to Stimwave 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 Stipulation, 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, Stimwave agrees 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 Stipulation pursuant to this paragraph, Stimwave waives and agrees 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 Stimwave within 120

days of written notification that this Stipulation has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on May 23, 2018. Stimwave agrees 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. For the avoidance of doubt, for purposes of this Paragraph 10, the Buyer shall not be considered an affiliated company.

11. Stimwave, having truthfully admitted to the Admitted Conduct set forth in Paragraph 2 hereof, agrees it shall not, through its attorneys, agents, officers, or employees, make any public statement, including but not limited to, any statement in a press release, social media forum, or website, that contradicts or is inconsistent with the Admitted Conduct or suggests that the Admitted Conduct is not wrongful (a “Contradictory Statement”). Any Contradictory Statement by Stimwave, its attorneys, agents, officers, or employees, shall constitute a violation of this Stipulation, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 10 hereof, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Stimwave that it has determined that Stimwave it made a Contradictory Statement. Upon receiving notice from the Government, Stimwave may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If Stimwave’s Executive Committee, Chief Executive Officer, Chief Legal Officer, or Chief Compliance Officer or their equivalent learn of a potential Contradictory Statement by its attorneys, agents, officers, or employees, Stimwave must notify the Government of the statement within 72 hours. The decision as to whether any statement constitutes a Contradictory Statement or will be imputed to Stimwave for the purpose of this Stipulation, or whether Stimwave adequately repudiated a Contradictory Statement to cure a violation of this

Stipulation, shall be within the sole discretion of the Government. Consistent with this provision, Stimwave may raise defenses and/or assert affirmative claims or defenses in any proceeding brought by private and/or public parties, so long as doing so would not contradict or be inconsistent with the Admitted Conduct.

12. Relator and its successors, attorneys, agents, and assigns shall not object to this Stipulation; Relator agrees and confirms that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

13. Stimwave agrees that it waives and shall not seek payment for any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

14. Stimwave waives and shall not assert any defenses Stimwave 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 Stipulation bars a remedy sought in such criminal prosecution or administrative action.

15. 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 Stimwave 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.

16. Stimwave 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-6; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Stimwave, including its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Stipulation and any related criminal disposition;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of matters covered by this Stipulation;
- (3) Stimwave'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 matters covered by this Stipulation (including attorneys' fees);
- (4) the negotiation and performance of this Stipulation and the Non-Prosecution Agreement;
- (5) any payment Stimwave makes to the United States pursuant to this Stipulation and any payment Stimwave may make to Relator, including expenses, 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 Stimwave, and Stimwave 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 Stimwave or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Stipulation, Stimwave 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 Stimwave 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. Stimwave agrees that the United States, at a minimum, shall be entitled to recoup from Stimwave 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, including the Department of Justice and/or the affected agencies, reserves its rights to disagree with any calculation submitted by Stimwave or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Stimwave or any of its subsidiaries' or affiliates' cost reports, cost statements, or information reports.

- d. Nothing in this Stipulation shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Stimwave's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

17. This Stipulation 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 as otherwise provided herein.

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, nothing in this Stipulation shall preclude Relator from seeking to recover its expenses or attorneys' fees and costs from Stimwave, pursuant to 31 U.S.C. § 3730(d) or for Stimwave to assert any defenses to such expenses, fees and costs.

19. Any failure by the Government to insist upon the full or material performance of any of the provisions of this Stipulation shall not be deemed a waiver of any of the provisions hereof, and the Government, notwithstanding that failure, shall have the right thereafter to insist upon the full or material performance of any and all of the provisions of this Stipulation.

20. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York.

21. For purposes of construing this Stipulation, this Stipulation shall be deemed to have been drafted by all Parties to this Stipulation and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

22. This Stipulation constitutes the complete agreement between the Parties with respect to the subject matter hereof. This Stipulation may not be amended except by written consent of the Parties. No prior agreements, oral representations or statements shall be considered part of this Stipulation.

23. The undersigned counsel and other signatories represent and warrant that they are fully authorized to execute this Stipulation on behalf of the persons and the entities indicated below.

24. This Stipulation is binding on Stimwave's successors, transferees, and assigns; however it is not binding on the Buyer.

25. This Stipulation is binding on Relator's successors, owners, members, managers, transferees, and assigns.

26. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. E-mails that attach signatures in PDF form or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

27. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by hand, express courier, or e-mail transmission followed by postage-prepaid mail, and shall be addressed as follows:

TO THE UNITED STATES:

MÓNICA P. FOLCH
JACOB M. BERGMAN
Assistant United States Attorneys
United States Attorney's Office
Southern District of New York
86 Chambers Street, Third Floor
New York, New York 10007
Email: monica.folch@usdoj.gov
jacob.bergman@usdoj.gov

TO DEFENDANTS:

Rebecca C. Martin
Rachel Page
Jones Day
250 Vesey Street
New York, NY 10281
rcmartin@jonesday.com

TO RELATOR:

Stephen A. Weiss
Seeger Weiss LLP
55 Challenger Rd., 6th FL
Ridgefield Park, N.J. 07660
sweiss@seegerweiss.com

28. The effective date of this Stipulation is the date upon which the Stipulation is approved by the Court (the “Effective Date”).

Agreed to by:

THE UNITED STATES OF AMERICA

Dated: New York, New York

October 30 2022

DAMIAN WILLIAMS
United States Attorney for the
Southern District of New York

By:



MONICA P. FOLCH

JACOB M. BERGMAN

Assistant United States Attorneys

86 Chambers Street, Third Floor


New York, New York 10007

Tel.: (212) 637-6559

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Attorneys for the United States of America

RELATOR

Dated: 
November 2, 2022

RELATOR SWFC LLC

By: 
Member
Relator

Dated: New York, New York
November 1, 2022

SEEGER WEISS LLP

By: 
Stephen A. Weiss
Christopher L. Ayers
Seeger Weiss LLP
55 Challenger Rd., 6th FL
Ridgefield Park, N.J. 07660
sweiss@seegerweiss.com
cayers@seegerweiss.com
Attorneys for Relator

DEFENDANTS

Dated: _____, _____

STIMWAVE TECHNOLOGIES
INCORPORATED
STIMWAVE LLC

By: _____
Chief Legal Officer
Virginia V. Sullivan

Dated: New York New York
Oct 30, 2022

JONES DAY

By: 
Rebecca C. Martin
Rachel Page
250 Vesey Street
New York, NY 10281
remartin@jonesday.com

Attorneys for Defendants

SO ORDERED:

HON. GEORGE B. DANIELS
UNITED STATES DISTRICT JUDGE

DEFENDANTS

Dated: October 30, 2022

STIMWAVE TECHNOLOGIES
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STIMWAVE LLC

By: Virginia V. Sullivan
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_____, 2022

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SO ORDERED:

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UNITED STATES DISTRICT JUDGE

Dated: _____, 2023