U.S. Department of Justice

United States Attorney
Southern District of New York

The Silvio J. Mollo Building
One Saint Andrew's Plaza
New York, New York 10007

October 29, 2022

Rebecca C. Martin, Esq.
Rachel E. Page, Esq.
Jones Day
250 Vesey Street
New York, New York 10281

Re: In re Stimwave Tech. Inc., et al., Non-Prosecution Agreement

Dear Meses. Martin and Page:

Subject to the terms, conditions, and understandings set forth herein, the Office of the United States Attorney for the Southern District of New York ("this Office") will not criminally prosecute Stimwave Technologies Incorporated, a Delaware corporation and Stimwave LLC, a Nevada limited liability company (collectively "Stimwave" or the "Company"), a medical technology company, for its participation—at the direction of former management—in a conspiracy to commit health care fraud and wire fraud in connection with Stimwave's design and manufacture of an inert, non-functioning component of a medical device that served no medical purpose, but which was intended to be surgically implanted into patients by doctors, so that medical providers could seek unlawful reimbursement payments from insurance providers, including federal healthcare payors, from at least in or about 2017, up to and including 2020.

The criminal conduct of Stimwave (the "Conduct") is described more fully in the Statement of Facts, attached hereto as Exhibit A, which Stimwave acknowledges and accepts as accurate and which is incorporated by reference herein. This Agreement does not provide any protection against prosecution for any crimes except as set forth above. This Agreement applies only to Stimwave, and does not apply to any other entities or any individuals. Pursuant to a resolution of the Subcommittee of the Executive Committee of the Board of Directors of Stimwave, Aure Bruneau, Stimwave's Chief Executive Officer ("CEO") is authorized to enter into this agreement on behalf of Stimwave and bind Stimwave to the obligations set forth herein.

This Office enters into this Agreement based on the individual facts and circumstances presented by this case and the Company, including:

a. The Company did not receive voluntary disclosure credit because prior management did not voluntarily and timely disclose the Conduct described in the Statement of Facts. However, the Company did receive a reduction of its fine amount because after receiving a Civil Investigative Demand from the Government, the Company replaced prior senior management, fully cooperated with the Government's investigation, and implemented timely and appropriate remedial actions.

b. The Company received full credit for its cooperation with the Government.

Among the factors this Office considered in this regard include: (i) Stimwave voluntarily cooperated with this Office, including Stimwave's production of over 140,000 documents; (ii) Stimwave conducted a thorough internal investigation; (iii) Stimwave collected, organized and analyzed documentation relating to the topics at issue in the Government's investigation, including the involvement of specific individuals in wrongdoing; (iv) Stimwave made significant efforts to make witnesses available to the Government and, where appropriate, provided separate counsel to those witnesses to facilitate the Government's investigation; (v) Stimwave made regular factual presentations to this Office, providing facts learned during witness interviews; (vi) Stimwave provided to this Office all relevant facts known to it, including information about individuals involved in the Conduct described in the attached Statement of Facts and other conduct disclosed to this Office prior to the Agreement; (vii) as reflected in this Agreement, Stimwave is willing to continue to cooperate with this Office, and the Federal Bureau of Investigation ("FBI"), the U.S. Food and Drug Administration, Office of the Inspector General ("FDA-OIG"), and any other law enforcement agency, to the extent permitted by applicable law; and (viii) Stimwave disclosed conduct outside the scope of the Government's original inquiry.

c. The Company received a further reduction in its fine amount based on an ability-to-pay discount, because Stimwave has been operating at a net loss for years, and on June 15, 2022, Stimwave filed for bankruptcy under Chapter 11 of the Bankruptcy Code, pursuant to which it is selling substantially all of its assets to a third-party (the "Buyer") through an auction and sale process approved by the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court") in *In re Stimwave Tech. Inc., et al.*, Case No. 22-10541 (KBO) (Del. Bankr.), pursuant to 11 U.S.C. § 363 (the "Sale").

d. The Company has no prior criminal history and has not previously been the subject of a Government investigation.

e. The misconduct at the Company began with Stimwave's former senior leaders. Despite the presence of some internal controls at that time, Stimwave's then-CEO did not create a culture of compliance, and management at the time ignored compliance controls and instead prioritized sales revenue. To the extent there were compliance measures in place, no attempt was made by management to put procedures into place to incentivize corporate compliance. Stimwave was wholly captive to the edicts and dictates of the then-CEO.

f. Under current management, the Company voluntarily implemented various significant remedial measures, including, among other things: (i) the Company replaced the entire senior management of Stimwave; (ii) the Company appointed new, experienced executive professionals in the health care industry, under whom the cooperation efforts began, and have continued; (iii) the Company engaged an electronic vendor to undertake extensive restoration of email and the Company's electronic document management and storage system; (iv) the Company began conducting an extensive internal investigation into the conduct of former management on a range of topics, and began a series of extensive disclosures to this Office; and (v) the Company built a Company-wide compliance program comporting with relevant guidance from the Office of the Inspector General for the United States Department of Health and Human Services.

g. The Company enhanced, and has committed to continuing to enhance, its compliance program and internal controls, including by, as discussed in this Agreement, taking steps to retain its Chief Compliance Officer even after the closing of the Sale ("Closing of the Sale").

h. The misconduct at the Company occurred under prior management, and as discussed above, the Company took effective measures to remove prior management from control of the Company, and install a new, independent Chief Executive Officer.

i. The nature and seriousness of the offense conduct, including: the loss amount to Government and private insurers; conduct in multiple U.S. jurisdictions; the deliberate creation of an inert component for a medical device, which component had no functionality and was created for the purpose of implantation by physicians into patients; the continuation of unlawful conduct for more than two years; and the involvement of certain high level former executives.

Accordingly, after considering (a) through (i) above, this Office believes that the appropriate resolution of this case is a non-prosecution agreement with the Company, a total monetary penalty with an aggregate discount of 33% off of the bottom of the U.S. Sentencing Guidelines fine range, and the various other terms and conditions set forth in this Agreement.

It is understood that Stimwave shall: (a) truthfully and completely disclose all information with respect to the activities of Stimwave, its officers and employees, and others concerning all such matters about which this Office inquires, which information can be used for any purpose, except as limited by this Agreement or by applicable laws or regulations; (b) cooperate fully with this Office, the FBI, FDA-OIG, and any other law enforcement agency so designated by this Office, except as limited by applicable laws or regulations; (c) consent to the production to this Office of any document, record, or other tangible evidence, except as limited by applicable laws or regulations; and (d) commit no violations of the federal criminal law of the United States. Unless otherwise specified below, Stimwave's obligations pursuant to this paragraph shall continue for a period of three years from the date this Agreement is executed (the "NPA Period").

Notwithstanding the NPA Period, Stimwave shall also continue to cooperate with this Office in any and all matters relating to the 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 NPA Period, including: (a) 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 Conduct; (b) undertake the preservation and retention of all documents, data, and records related to the 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; (c) assist this Office or any designated federal law enforcement agency in any investigation, prosecution, or civil proceeding arising out of or related to the 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; (d) 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 Conduct; (e) 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 (f) 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 Conduct about which this Office or any designated federal law enforcement agency inquires.

Stimwave's cooperation pursuant to this Agreement 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 this Office a log of any information or cooperation that is not provided in response to this 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.

It is further understood that Stimwave shall continue its ongoing efforts to implement and maintain an adequate compliance program designed to prevent and detect violations of federal law and other applicable U.S. state laws throughout its operations (the "Stimwave Business"), including those of its affiliates, agents, and majority owned or controlled joint ventures, and those of its contractors and subcontractors, in each case, to the extent utilized by Stimwave in the conduct of the Stimwave Business. In addition, during the NPA Period, Stimwave shall make all reasonable efforts to retain the individual currently functioning as Chief Compliance Officer (the "Current CCO"), or retain a similarly credentialed individual, who will have the responsibility for overseeing Stimwave's compliance obligations. Such efforts shall include, but not be limited to, offering the Current CCO, or a similarly credentialed individual, a three-year contract in an amount that is not less than the Current CCO's current compensation amount. The Chief Compliance Officer shall also, at his or her option, retain the right to hire a deputy Chief Compliance Officer, to assist with or perform additional compliance functions.

It is further understood that Stimwave shall comply fully with existing reporting and other obligations as set forth in FDA's quality system regulation (21 C.F.R. Part 820). In addition, subject to applicable laws and regulations, Stimwave shall cooperate fully with any requests by the FDA to inspect Stimwave's premises or medical devices, or for information from Stimwave regarding its medical devices, including the design, production, or functionality of Stimwave's medical devices.

Stimwave, having truthfully admitted to the Conduct set forth in the Statement of Facts attached hereto as Exhibit A, agrees that 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 Conduct or suggests that the Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by Stimwave, its attorneys, agents, officers, or employees, shall constitute a violation of this Agreement, thereby authorizing the Government to pursue any of the remedies set forth in this Agreement, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify Stimwave that it has determined that Stimwave has 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 (4) business days. If Stimwave's Executive Subcommittee, Chief Executive Officer, Chief Legal Officer, and Chief Compliance Officer or their equivalent learns 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: (i) any statement constitutes a Contradictory Statement; (ii) any Contradictory Statement will be imputed to Stimwave for the purpose of this Agreement; or (iii) Stimwave adequately repudiated a Contradictory Statement to cure a violation of this Agreement, 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 Conduct.

As a result of the Conduct described in this Agreement and in the attached Statement of Facts, Stimwave agrees to pay a monetary penalty in the amount of $10,000,000 (the "Total Payment") to this Office. The Total Payment is based upon profits of approximately $8.6 million as a result of the offense conduct, and reflects a discount of 33% off of the bottom of the U.S. Sentencing Guidelines fine range, which includes a 25% discount for early cooperation, and an 8% discount based on ability to pay. Payment shall be made pursuant to payment instructions provided by the Government to Stimwave management. Such payment instructions shall be provided by the Government to Stimwave no later than October 28, 2022.

The Total Payment shall be comprised of a forfeiture of $1,400,000 and a payment of $8,600,000 pursuant to a False Claims Act settlement concerning the Conduct (the "Civil Settlement"), as described further below. Stimwave agrees to pay to the United States the sum of $1,400,000 (the "Forfeiture Amount") within three (3) days of the Closing of the Sale. Stimwave agrees that the Forfeiture Amount represents a substitute *res* for proceeds it obtained as a result of the unlawful conduct covered by this agreement. Stimwave consents to the administrative or civil forfeiture of the Forfeiture Amount, and agrees that such funds are forfeitable pursuant to 18 U.S.C. §§ 981(a)(1)(C) and 982(a)(7) as proceeds traceable to the violation of 18 U.S.C. §§ 1343 and 1347. The Forfeiture Amount shall be wired to the United States Marshals Service consistent with wiring instructions to be provided by the Government to Stimwave and deposited in the Seized Asset Deposit Fund. Additionally, Stimwave further agrees to pay to the United States the sum of $8,600,000 pursuant to the Civil Settlement (the "Civil Payment"). The Civil Payment shall be wired to the United States Treasury consistent with wiring instructions to be provided by the Government to Stimwave.

Stimwave acknowledges that this Total Payment is a final payment and no portion of the payment will be refunded or returned under any circumstance. Stimwave agrees that it shall not file any petitions for remission, restoration, or otherwise contest the civil or administrative forfeiture of the Forfeiture Amount, and will not assist anyone else in doing so, and agrees that it shall not file any other assertion of ownership or request for return relating to the Total Payment amount or the calculation thereof, or file any other action or motion, or make any request or claim whatsoever, seeking to collaterally attack the payment or calculation of the Total Payment. Stimwave agrees that it shall not assist any others in filing any such claims, petitions, actions, or motions. Stimwave further agrees that no portion of the Total Payment that Stimwave has agreed to pay to this Office under the terms of this Agreement will serve as a basis for Stimwave

to claim, assert, or apply for, either directly or indirectly, any tax deduction, any tax credit, or any other offset against any U.S. federal, state, or local tax or taxable income.

Stimwave releases any and all claims it may have to the Forfeiture Amount, agrees that the forfeiture of such funds may be accomplished either administratively or judicially at this Office's election, and waives the requirements of any applicable laws, rules or regulations governing the forfeiture of assets, including service and notice of the forfeiture. If this Office seeks to forfeit the Forfeiture Amount administratively, Stimwave consents to the entry of a declaration of forfeiture and knowingly and voluntarily waives the 60-day deadline requirement for notice in the administrative forfeiture proceedings pursuant to 19 U.S.C. § 1607 and 18 U.S.C. § 983.

Stimwave further agrees to waive all challenges in any manner (including direct appeal, *habeas corpus*, or any other means) to any forfeiture of the Forfeiture Amount carried out in accordance with this Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. Stimwave agrees to take any and all steps as requested by the United States to pass clear title to the Forfeiture Amount to the United States. This consent to forfeiture may be incorporated into an Order of Forfeiture.

Stimwave agrees that, in the event this Office determines, in its sole discretion, that Stimwave has violated any provision of this Agreement or has failed to completely perform or fulfill each of the Stimwave's obligations under this Agreement, an extension or extensions of the NPA Period may be imposed by this Office, in its sole discretion, for up to a total additional time period of one year, without prejudice to this Office's right to proceed as provided in the breach provisions of this Agreement below. Any extension of the Agreement extends all terms of this Agreement for an equivalent period.

It is understood that, should this Office in its sole discretion determine that: (a) Stimwave committed any violation of federal criminal law of the United States during the NPA Period; (b) Stimwave or any of its representatives have deliberately given false, incomplete, or misleading testimony or information; or (c) Stimwave has otherwise violated any provision of this Agreement, then: (i) Stimwave shall thereafter be subject to prosecution for any federal offense of which this Office has knowledge, including perjury, false statements, and obstruction of justice; (ii) all statements made by Stimwave's representatives to this Office or other designated law enforcement agents, including but not limited to the appended Statement of Facts, and any testimony given by Stimwave's representatives before a grand jury or other tribunal whether prior to or subsequent to the signing of this Agreement, and any leads therefrom, shall be admissible in evidence in any criminal proceeding brought against Stimwave and relied upon as evidence to support any penalty imposed on Stimwave; and (iii) Stimwave shall assert no claim under the United States Constitution, any statute, Rule 410 of the Federal Rules of Evidence, or any other federal rule that such statements or any leads therefrom should be suppressed. In addition, any such prosecution that is not time-barred by the applicable statute of limitations on the date of the execution of this Agreement may be commenced against Stimwave, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the commencement of such prosecution. It is the intent of this Agreement to waive all defenses based on the statute of limitations with respect to any prosecution that is not time-barred on the date when this Agreement is signed. It is the intent of this Agreement to waive all rights in the foregoing respects.

On September 30, 2022, the Bankruptcy Court entered a sale order (the "Sale Order") binding the Buyer, as of the Closing of the Sale, to the terms set forth in Exhibit B of this Agreement (the "Assumed Terms"). 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.

In the event that: (a) the Bankruptcy Court reverses or rescinds the Sale Order, in which the Assumed Terms and the Total Payment are incorporated; or (b) the Closing of the Sale does not occur for any reason; this Agreement shall be null and void, with no force or effect.

It is further understood that this Agreement does not bind any other federal, state, or local prosecuting authorities other than this Office. If requested by Stimwave, this Office will, however, bring the cooperation of Stimwave to the attention of such other prosecuting offices or regulatory agencies.

It is understood that the Bankruptcy Court entered a sealing order (the "Sealing Order") sealing the Civil Settlement and other filings (the "Sealed Filings"). Stimwave agrees not to seek any order or cause any person or entity to seek any order that would lift the seal or otherwise cause the disclosure of the Sealed Filings, without the written consent of the Government. It is further understood that only upon the expiration of the sealing order, or other Bankruptcy Court order lifting the Sealing Order, this Agreement and the Statement of Facts appended hereto may become public documents, which then may be provided to any person by this Office or Stimwave.

This Agreement supersedes all prior understandings, promises and/or conditions between this Office and Stimwave. No additional promises, agreements, and conditions have been entered into other than those set forth in this Agreement and none will be entered into unless in writing and signed by both parties.

The parties understand that this Agreement reflects the special facts of this case and is not intended as precedent for other cases.

Very truly yours,

DAMIAN WILLIAMS
United States Attorney

By: _____
Jacob M. Bergman
Monica P. Folch
Louis A. Pellegrino
Assistant United States Attorneys
(212) 637- 2776/6559/2617

APPROVED:

_____ /JB
Daniel Gitner
Chief, Criminal Division

AGREED AND CONSENTED TO:

Stimwave Technologies Incorporated

By: _____ 10.29.22

Aure Bruneau — DATE
Chief Executive Officer
Authorized Signatory by Resolution
of the Subcommittee of the Executive Committee of the Board of Directors

Stimwave LLC

By: _____ 10.29.22

Aure Bruneau — DATE
Manager
Authorized Signatory by Resolution
of the sole corporate member

APPROVED:

_____ _____

Rebecca C. Martin, Esq. — DATE
Rachel E. Page, Esq.
Attorneys for Stimwave

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Stimwave LLC

By: _____ _____

Aure Bruneau — DATE
Manager
Authorized Signatory by Resolution
of the sole corporate member

APPROVED:

Rebecca C. Martin — October 29, 2022

Rebecca C. Martin, Esq. — DATE
Rachel E. Page, Esq.
Attorneys for Stimwave

EXHIBIT A

SECTION I

STATEMENT OF FACTS

Overview of the Scheme

1. From at least in or about 2017, up to and including 2020, Stimwave Technologies Incorporated and Stimwave LLC ("Stimwave" or the "Company"), at the direction of a former officer ("Former Officer-1"), and with the assistance of other former members of the Company, engaged in a scheme in which Stimwave designed, created, and manufactured an inert, non-functioning component of a medical device that served no medical purpose, but that was intended to be surgically implanted into patients by doctors, so that medical providers could seek unlawful reimbursement payments from insurance providers, including federal healthcare payors, such as Medicare.

2. During the relevant period, Stimwave marketed and sold to medical providers the StimQ PNS System (the "PNS system") – a neurostimulator medical device that treats chronic pain by producing electrical currents to target peripheral nerves outside the spinal cord. The PNS system 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. The Pink Stylet contained copper that functioned like an antenna to transmit energy from an external transmitter (battery) to the electrode array under circumstances where, because of the location of the implant, an external transmitter (battery) could not be placed directly on or next to the electrode array.

3. 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 reimbursement codes, known as CPT codes[1] – one for implantation of the electrode array, and a second for implantation of the Pink Stylet. 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.

4. 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

[1] Current Procedural Terminology, or "CPT," codes offer doctors and health care professionals a uniform language for coding medical services and procedures to streamline reporting to entities such as Medicare and private insurance companies. Among other things, CPT codes are used for administrative management purposes such as claims processing, and for developing guidelines for medical care review.

utilization of the PNS system was not included or in any manner referenced in the Company's PNS 510(k) clearance[2] or in the Company's PNS Instructions for Use. Additionally, 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 providers would cease purchasing the device. In order to ensure that medical providers who sought to implant the PNS system in smaller anatomical spaces in patients would continue to purchase the device, and to increase sales of the PNS system, Stimwave—at the direction of Former Officer-1—designed, manufactured, and created a component disguised as a receiver that was falsely represented to contain copper and function as a receiver to transmit energy from the external battery, like the Pink Stylet, but which was actually without function. This component, referred to as the "White Stylet," was similar in length, however, 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.

5. Stimwave created the White Stylet 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 claim reimbursement from health insurers, including Medicare, for the procedure under CPT code 64590. Moreover, 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, even though CPT code 64590 could not be used for implantation of a non-functioning receiver such as the White Stylet. This information was provided by sales representatives to doctors.

6. This misconduct occurred under the direction of Stimwave's former management. not its current management. Upon learning of the misconduct, current management took quick and significant steps to address the matter, including by publicly issuing a recall for all PNS Kits[3], *see* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=183123, and conducting an analysis of the potential harm caused by the White Stylet and providing that analysis to the government, including the FDA. Moreover, Stimwave's current management has fully cooperated with the Government in its civil and criminal investigation.

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[2] A 510(k) is a premarket submission made to the U.S. Food and Drug Administration to demonstrate that the device to be marketed is as safe and effective (on the basis that it is substantially equivalent) to a legally marketed device (Section 513(i)(1)(A) of the FD&C Act). *See* https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k.

[3] When a medical practitioner received a PNS system it came in what Stimwave described as a "kit" (referred to here as the "PNS Kit"), which was essentially a package containing all of the PNS system components, including the Pink Stylet and, during the relevant time period, the White Stylet.

A. Relevant Parties and Corporate Structure

7. Stimwave was founded in 2010 by Former Officer-1 (and others), and is a medical device company that manufactures and distributes implantable neurostimulation devices designed to treat intractable, chronic pain. Until Former Officer-1's departure from Stimwave on or about November 25, 2019, Former Officer-1 managed and operated the company.

8. The Food and Drug Administration ("FDA") cleared Stimwave to market the PNS system at issue to medical providers in August 2017. 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. The PNS system can be used for peripheral nerve stimulation, which entails targeting pain of peripheral nerve origin below the neck. Commercialization of the currently-marketed PNS system began in and about 2018, and, to date, over 5,000 patients have received permanent PNS system implants.

9. In October 2019, this Office sent Stimwave a Civil Investigative Demand ("CID") regarding the PNS system. The next month, Stimwave placed Former Officer-1 on leave and took steps to terminate Former Officer-1's employment. Following Former Officer-1's departure and the departure of employees and executives associated with Former Officer-1, the Company's new management began cooperating with this Office. After conducting an internal investigation, Stimwave discovered and disclosed the conduct described herein.

10. At present, Stimwave has approximately 135 employees worldwide and is being led by a new CEO, who was not affiliated with the Company during the time period of the conduct set forth herein. On June 15, 2022, Stimwave filed for bankruptcy under Chapter 11 of the Bankruptcy Code, pursuant to which it is seeking to sell substantially all of its assets to a third-party through an auction pursuant to 11 U.S.C. § 363. In 2021, the year prior to filing for bankruptcy, Stimwave operated at a net loss of $14,000,000. In 2020, Stimwave operated at a net loss of over $18,000,000.

B. 2017 Clearance of the PNS

11. The PNS Kit covered by the August 2017 FDA clearance included the following primary components:

- An implantable electrode array or "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.

12. 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. At no point did former management of Stimwave seek to update their FDA clearance or IFUs related to such FDA clearance to reference the White Stylet.

13. 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 CPT code 64590 when seeking reimbursement from Medicare for that procedure.[4]

C. Former Management's Introduction of the White Stylet

14. As described above, Stimwave sold the PNS Kits to medical providers for over $16,000. These providers would then be reimbursed by insurers between $4,000 and $6,000 for implanting the Lead and between $16,000 and $18,000 for implanting the Pink Stylet. Given the cost of the PNS Kits, without the ability to implant a receiver and bill CPT code 64590, the device would not have been cost-effective for doctors to purchase.

15. As described above, doctors who had implanted the PNS system complained that the Pink Stylet, because of its length, could not be implanted to fit comfortably into a patient's smaller anatomical spaces. 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 electrode array (by utilizing CPT code 64555, which provided for reimbursement at a rate of between $4,000 and $6,000), 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 – the White Stylet – that had no medical purpose, but could be cut by the doctor, so that medical providers would continue to purchase and use the PNS system in smaller anatomical spaces and continue to bill for the implantation of the stylet using the reimbursement CPT code 64590.

16. From late 2017 through 2019, various members of Stimwave's former management, including Former Officer-1 and three other officers ("Former Officer-2," "Former Officer-3," and "Former Officer-4") were involved in the design and/or internal corporate approvals relating to the White Stylet and its introduction into PNS Kits. Documentation and audit trail history data maintained in Stimwave's internal document control system, known as MasterControl, detail the involvement of Former Officer-1, Former Officer-2, Former Officer-3, and Former Officer-4 in the design, documentation, and approval processes of the White Stylet as an entirely plastic product that contained no copper, and thus had no ability to act as a receiver. During the relevant period, Former Officer-1 continued to encourage doctors to bill for

[4] 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.

the implantation of the White Stylet using the reimbursement code for receiver implantation, even though Former Officer-1 knew that the White Stylet had no receiver functionality.[5] Among other things, Former Officer-1 and other former officers of the Company told sales representatives and doctors that the White Stylet contained copper and, therefore, functioned as a receiver and instructed the sales force to encourage doctors to bill CPT code 64590 when implanting the White Stylet.

17. Starting in or about the spring of 2018, Former Officer-1 and various members of Stimwave former management added the White Stylet to Stimwave's PNS Kits. The White Stylet had similar external physical characteristics to the Pink Stylet because it was made of the same plastic outer material, but it did not contain a conductive copper core. In addition, Stimwave informed medical providers that the White Stylet could be "cut-to-fit" by the implanting medical provider so that it could be made significantly smaller than the Pink Stylet. (The 23-centimeter Pink Stylet could not be cut without interfering with the overall functionality of the PNS system.) However, training medical providers to cut the White Stylet was a pointless exercise, because regardless of its length, the White Stylet had no receiver functionality and no medical efficacy. Because the White Stylet was not in fact a receiver and had no real functionality, it could not be billed under CPT code 64590, which provided reimbursement only for implantation of a "receiver" or a "generator."

i. Former Management Circumvented Stimwave's Standard Operating Procedures in Developing the White Stylet

18. During the period when the White Stylet was included as a component part of PNS Kits, Stimwave maintained standard operating procedures ("SOPs") relating to document and design controls, including procedures for the identification, documentation, validation, verification, review, and approval of design changes before their implementation. In the case of the White Stylet, in the course of the design and creation process, former Stimwave management circumvented these SOPs.

19. Specifically, between 2017 and 2019, Stimwave's document control SOP required design change documents, such as the creation of and revisions to the White Stylet drawing, to be subject to controls defined in Stimwave's SOP concerning "engineering change requests." This SOP required a thorough evaluation of the impact of a design change, with special attention to any potential risks introduced by the change. Such an evaluation was supposed to include additional verification, validation, training, and/or FDA or international regulatory notification or approval.

20. Nonetheless, former Stimwave management did not conduct such an evaluation of the White Stylet before manufacturing the component and including it in PNS Kits sold to medical providers and implanted in patients – even though the former Stimwave personnel

[5] The PNS system still functioned without the White Stylet, because the Lead was also capable of receiving power from the external wearable Battery, provided the Battery was placed close enough to the Lead.

involved in the design and creation of the White Stylet were aware of the document control and engineering change request SOPs.

ii. Former Management's Training of Sales Force Regarding the White Stylet and Use of Reimbursement Code 64590

21. In and about 2018 and 2019, former Stimwave management conducted trainings of its sales force to provide sales representatives with product information to be conveyed to the medical providers implanting the PNS system. That training included instructions to describe the White Stylet as a functioning receiver component when, in fact, it had no functionality. Specifically, Stimwave's former management instructed sales representatives that the White Stylet contained copper and could therefore function as a receiver, when in fact several members of management, including Former Officer-1, knew that was false. Stimwave sales representatives were also instructed to encourage medical providers to implant the White Stylet if the medical provider determined that the Pink Stylet was too long for a particular patient, and to further inform medical providers that they could still use CPT code 64590 for reimbursement in that situation. Stimwave sales representatives did, in fact, encourage medical providers to implant the White Stylet and to use CPT code 64590 when submitting claims for reimbursement for implantation of the White Stylet. 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.

22. Moreover, Former Officer-1 received communications from Stimwave personnel in which they stated that they intended to tell doctors that they needed to implant a stylet (either Pink or White) in all permanent PNS procedures and that doctors should bill 64590 for that procedure, even when the White Stylet was implanted. Specifically, in the summer of 2019, a Company employee shared with Former Officer-1 a document outlining various "Action Items," which included telling doctors that the "Stylet is **ABSOLUTELY ALWAYS** necessary during **ALL PNS** [permanent implants]," that the doctor should bill 64590 for implanting the Pink or White Stylet, and that the White Stylet may be appropriate for implantation near the elbow.

23. Former Officer-1 also directly provided doctors with materials mispresenting the functionality of the White Stylet, and stating that providers could use billing code 64590 when seeking reimbursement from Medicare for implanting the PNS. For example, in November 2019, Former Officer-1 emailed a doctor a slide deck which described the White Stylet as an "Adjustable Polarity" and "Advanced Programing" "receiver," even though Former Officer-1 knew that the White Stylet was made entirely of plastic and non-functioning. The presentation also encouraged doctors to use CPT code 64590 when seeking reimbursement for implanting the stylet component of the PNS system.

SECTION II

STIMWAVE'S COOPERATION AND REMEDIATION

24. Since November 2019, shortly after receiving the CID from this Office, the Company has engaged in significant cooperation and remediation efforts. Moreover, the entire senior management of Stimwave has been replaced. However, it is also the case that the Company, while led by Former Officer-1, did not self-report the misconduct to any authority prior to receiving the CID. Moreover, the compliance systems in place at the time of the misconduct were easily ignored by former Stimwave management. Despite the presence of some internal controls at that time, such as the SOPs required for changes to design mentioned above, Stimwave was driven by Former Officer-1. Former Officer-1 did not create a culture of compliance, and management ignored compliance controls and instead prioritized sales revenue. Moreover, Former Officer-1 installed Former Officer-4, an individual who had no prior experience in compliance, as both the regulatory director and the Chief Compliance Officer.

25. By January 2020, within two months of Former Officer-1's departure, the Company started appointing new, experienced executive professionals in the health care industry, under whom the cooperation efforts have continued. The Company engaged an electronic vendor to undertake extensive restoration of email and the Company's electronic document management and storage system.

26. Also in January 2020, the Company began conducting an extensive internal investigation into the conduct of former management on a range of topics, and began a series of extensive disclosures to this Office. Among other things, the Company disclosed the nature and timing of the conduct of former management in a timely manner, including, among other things, conduct relating to the White Stylet. Moreover, the Company fully produced information regarding each employee involved in this conduct.

27. In the course of its cooperation, Stimwave produced over 140,000 documents; directed the Government to third parties possessing relevant documents no longer in the Company's control; and collected, analyzed, and organized documentation relating to the topics covered in its disclosures, such as records from its MasterControl system demonstrating involvement of specific individuals in wrongdoing and circumvention of change control processes. Stimwave also helped make witnesses available to the Government and, where appropriate, provided separate counsel to those witnesses to facilitate the Office's investigation. The Company provided this Office with substantial and extensive information concerning the topics at issue in the investigation, including relevant facts related to the conduct described in this Statement of Facts, saving investigative resources and disclosing matters that may not otherwise have been discovered in the course of the Government's investigation.

28. Under the direction and oversight of new management, in early 2020, Stimwave built a Company-wide compliance program comporting with relevant guidance from the Office of the Inspector General for the United States Department of Health and Human Services. The Company's compliance program includes written policies and procedures; the designation of a compliance officer and compliance committee; the delivery of training and educational materials (including, but not limited to, training all employees on the Code of Business Conduct and

Ethics, and training all employee on fraud and abuse); development of effective lines of communication (*e.g.*, a hotline that allows for anonymous reporting of potential misconduct); internal monitoring and auditing; enforcement of standards through disciplinary guidelines; and responding to and correcting identified problems, including through termination of personnel or vendors where appropriate. Through this work, the Company has emphasized a culture of compliance and, in particular, has addressed issues involved in this investigation.

29. With respect to misconduct related to the White Stylet, new management took significant steps to assess and disclose that misconduct to this Office and FDA, and to remediate that misconduct. The remediation included an exhaustive Health Hazard Evaluation ("HHE")[6] 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, meaning that upon implantation (and during a trial period after implantation) the Battery and Lead were tested to ensure they were working as intended. Because the White Stylet was inert and served no purpose, it did not interfere with the functioning of the Lead. 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.

[6] A Health Hazard Evaluation is the process that the FDA follows to determine the risks associated with problems with medical devices and the action a manufacturer should take to resolve such issues. Further, the Health Hazard Evaluation is a tool for classifying a voluntary recall by a manufacturer. This evaluation guides the FDA in determining the risk to the public from the defective product and the appropriate actions for the manufacturer and the FDA to take to protect public health. *See* https://www.fda.gov/about-fda/cdrh-transparency/health-hazard-evaluations-hhes-and-health-risk-assessments-hras.

EXHIBIT B

- **Preamble**
  - The terms set forth herein (the "Assumed Terms") will be or have been incorporated into a Sale Order in *In re Stimwave Tech. Inc., et al.*, Case No. 22-10541 (KBO) (Del. Bankr.) entered in connection with the sale of the assets of Stimwave pursuant to Section 363 of the Bankruptcy Code (the "Sale") and shall be effective as of the closing of the Sale.

- **Stimwave Admissions**

  1. Stimwave Technologies Incorporated and Stimwave, LLC ("Stimwave") have acknowledged and accepted as accurate the criminal conduct described more fully in the Statement of Facts (the "Conduct"), which is attached as Exhibit A and is incorporated by reference herein.

- **Cooperation Obligations**

  2. It is understood that NewCo, with respect to the activities of Stimwave: (a) shall truthfully and completely disclose all information with respect to the activities of Stimwave, its officers and employees, and others concerning all matters relating to Stimwave about which the Office inquires, which information can be used for any purpose, except as limited by the Non-Prosecution Agreement between the Office and Stimwave (the "Non-Prosecution Agreement") or by applicable laws or regulations; (b) shall cooperate fully with the Office, the Federal Bureau of Investigation ("FBI"), the U.S. Food and Drug Administration, Office of the Inspector General ("FDA-OIG"), and any other law enforcement agency so designated by the Office, except as limited by applicable laws or regulations; (c) shall consent to the production to the Office of any document, record, or other tangible evidence, except as limited by applicable laws or regulations; and (d) shall commit no violations of the federal criminal law of the United States. Unless otherwise specified below, NewCo's obligations pursuant to this paragraph shall begin on the closing date of the Sale and continue for a period of three years from the date on which Stimwave has signed a Non-Prosecution Agreement with the Office (the "Applicable Period").

  3. Notwithstanding the Applicable Period, NewCo shall also continue to cooperate with the Office in any and all matters relating to the 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 Applicable Period including: (a) cooperate fully with the Office, the FBI, FDA, OIG, and any other federal law enforcement agency designated by the Office regarding all matters related to the Conduct; (b) undertake the preservation and retention of all documents, data, and records related to the Conduct, including by storing such documents, records, and data in an external storage facility if necessary for

preservation and retention; (c) assist the Office or any designated federal law enforcement agency in any investigation, prosecution, or civil proceeding arising out of or related to the Conduct by providing logistical and technical support for any meeting, interview, federal grand jury proceeding, or any federal trial or other federal court proceeding; (d) use 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 Conduct; (e) provide testimony of a competent witness as needed to enable the Office and any designated federal law enforcement agency to use the information and evidence obtained pursuant to Stimwave's cooperation with the Office; and (f) provide the 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 Conduct about which the Office or any designated federal law enforcement agency inquires.

4. NewCo's cooperation pursuant to Paragraphs 2 and 3 is subject to applicable laws and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, NewCo 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 NewCo bears the burden of establishing the validity of any such assertion.

- **Compliance Obligations**

5. NewCo shall continue Stimwave's ongoing efforts to implement and maintain an adequate compliance program designed to prevent and detect violations of federal law and other applicable U.S. state laws throughout its operation of the business operated by Stimwave prior to the Sale and purchased in the Sale by NewCo (the "Purchased Business"), including those of NewCo's affiliates, agents, and majority owned or controlled joint ventures, and those of its contractors and subcontractors, in each case, to the extent utilized by NewCo in the conduct of the Purchased Business. In addition, during the Applicable Period, NewCo shall make all reasonable efforts to retain the individual currently functioning as Chief Compliance Officer (the "Current CCO"), or retain a similarly credentialed individual, who will have the responsibility for overseeing Stimwave's compliance obligations. Such efforts shall include, but not be limited to, offering or assuming a three-year contract with the Current CCO, or a similarly credentialed individual, at an amount that is not less than Current CCO's compensation amount as of the execution date of the Non-Prosecution Agreement. The Chief Compliance Officer shall also, at his or her option, retain the right to hire a deputy Chief Compliance Officer, to assist with or perform additional compliance functions.

6. NewCo's Board shall have a compliance committee that meets at least quarterly to consider compliance issues, and the Chief Compliance Officer, and any deputy Chief Compliance Officer, shall be *ex officio* members of the compliance committee. NewCo will also assign responsibility to one or more New Co. Board members for the implementation and oversight of NewCo's compliance codes, policies, and procedures. The compliance committee shall have the authority to report directly to independent monitoring bodies, including internal audit, NewCo's full Board, or any other appropriate committee of NewCo's Board, and shall have an adequate level of autonomy from management as well as sufficient resources and authority to maintain such autonomy.

7. NewCo shall comply fully with existing reporting and other obligations as set forth in FDA's quality system regulation (21 C.F.R. Part 820). In addition, subject to applicable law and regulations, NewCo shall cooperate fully with any requests by the FDA to inspect NewCo's premises or medical devices, or for information from NewCo regarding its medical devices, including the design, production, or functionality of NewCo medical devices.

- **Non-Disparagement Obligations**

8. NewCo, 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 Conduct or suggests that the Conduct is not wrongful (a "Contradictory Statement"). Any Contradictory Statement by NewCo, its attorneys, agents, officers, or employees, shall constitute a violation of these Assumed Terms, thereby authorizing the Government to pursue any of the remedies set forth in Paragraph 9 of these Assumed Terms, or seek other appropriate relief from the Court. Before pursuing any remedy, the Government shall notify NewCo that it has determined that NewCo has made a Contradictory Statement. Upon receiving notice from the Government, NewCo may cure the violation by repudiating the Contradictory Statement in a press release or other public statement within four business days. If NewCo's Board or similar governing body and senior executive management, including, but not limited to, the Chief Executive Officer, Chief Legal Officer, and Chief Compliance Officer or their equivalents learns of a potential Contradictory Statement by its attorneys, agents, officers, or employees, NewCo must notify the Government of the statement within 72 hours. The decision as to whether: (i) any statement constitutes a Contradictory Statement; (ii) any Contradictory Statement will be imputed to NewCo for the purpose of these Assumed Terms; or (iii) NewCo adequately repudiated a Contradictory Statement to cure a violation of these Assumed Terms, shall be within the sole discretion of the Government. Consistent with this provision, NewCo 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 Conduct.

- **Breach Provisions**

9. NewCo agrees that, in the event the Office determines, in its sole discretion, that NewCo has violated any provision of the Assumed Terms or has failed to completely perform or fulfill each of NewCo's obligations under the Assumed Terms, an extension of the Applicable Period may be imposed by the Office, in its sole discretion, for up to a total additional time period of one year, without prejudice to the Office's right to proceed with any other legal remedies. Any extension of the Applicable Period extends all provisions of the Assumed Terms for an equivalent period.

- **Ratification**

10. In the event that (i) the Assumed Terms are not incorporated into a Sale Order in *In re Stimwave Tech. Inc., et al.*, Case No. 22-10541 (KBO) (Del. Bankr.), (ii) the Bankruptcy Court declines to enter a Sale Order incorporating the Assumed Terms, or (iii) the closing of the Sale does not occur for any reason, the Non-Prosecution Agreement shall be null and void, with no force or effect.

- **Monetary**

11. Within three days of the closing of the sale, NewCo will pay $10,000,000 to Stimwave which Stimwave will use to pay Stimwave's monetary obligation to the Government.