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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) **COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA**
THE UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. STIMWAVE LLC, STIMWAVE TECHNOLOGIES, INC. and LAURA PERRYMAN, Defendants.	**JURY TRIAL DEMANDED**

The United States of America, by its attorney, Damian Williams, United States Attorney for the Southern District of New York, alleges for its complaint-in-intervention as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by the United States of America (the "United States" or the "Government") against Stimwave LLC, Stimwave Technologies, Inc. (collectively with Stimwave LLC, "Stimwave"), and Laura Perryman ("Perryman," and collectively with Stimwave, "Defendants"), under the False Claims Act (the "FCA"), 31 U.S.C. §§ 3729-3733, to recover treble damages sustained by, and civil penalties owed to, the Government resulting from the submission of false and fraudulent claims for reimbursement to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* ("Medicare"). In particular, Stimwave caused medical providers to submit false claims for reimbursement to Medicare by representing that they were implanting medically functioning receivers into patients, when in fact, the providers were implanting inert, non-functional components that lacked any receiver functionality.

2. Perryman is the former CEO and founder of Stimwave, a Florida-based medical device company that manufactured and provided implantable neurostimulation products. As the founder and CEO of Stimwave, Perryman oversaw the design of the StimQ PNS System (the "PNS System"), a neurostimulator medical device that treated chronic pain by producing electrical currents to target peripheral nerves outside the spinal cord.

3. Stimwave, at the direction of Perryman, 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, so that medical providers could seek unlawful reimbursement payments from insurance providers,

including federal healthcare payors such as Medicare. This scheme caused the submission of false claims to Medicare from 2018 up to and including 2020 (the "Relevant Period").

4. When Stimwave brought the PNS System to market in or about 2017, the PNS System included an implantable electrode array, a separate implantable receiver, referred to as the "Pink Stylet," and a battery to be worn over the skin in the general area of implantation. The Pink Stylet was developed to aid in the transmission of energy from the external battery to the implanted electrode array.

5. 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—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 a receiver (such as the Pink Stylet), CPT Code 64590, provided for reimbursement at a rate of between approximately $16,000 and $18,000.

6. CPT Code 64590 is permitted to be used for reimbursement of the"[i]nsertion or replacement of peripheral or gastric neurostimulator pulse generator or *receiver*, direct or inductive coupling." *See, e.g.*, "Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence," *available at* https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53359 (last visited March 8 2023) (emphasis added).

7. 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 could function without the use of the Pink Stylet, but only if an external battery was placed at or near the neurostimulator.

8. However, if doctors did not implant the Pink Stylet, they could not claim reimbursement for implanting a receiver under CPT Code 64590. In such a circumstance, implanting the PNS System without the Pink Stylet was not economically viable for doctors because the cost of purchasing the PNS System (approximately $16,000) would exceed the reimbursement they could receive from insurers (approximately $4,000 under CPT Code 64555). Because of this disparity, Perryman feared some medical providers would not purchase the device.

9. 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 Perryman's direction—designed, manufactured, and created the "White Stylet," a completely inert, non-functioning component disguised as a receiver. Stimwave and Perryman falsely represented to medical providers that the White Stylet, like the Pink Stylet, contained copper and functioned as a receiver to transmit energy from the external battery to the electrode array. Additionally, Perryman directed Stimwave employees to lie to doctors and falsely state that the White Stylet was a receiver and therefore purportedly provided some functionality.

10. The White Stylet was similar in length to the Pink Stylet, but was made entirely of plastic, and therefore could be cut by a medical provider to the desired length to fit into smaller anatomical spaces. Stimwave and Perryman told doctors that they should use the White Stylet if it was not feasible to implant the Pink Stylet due to its length. But the White Stylet provided no receiver functionality whatsoever.

11. Based on Stimwave's and Perryman's false representations, doctors incorrectly believed that the White Stylet was a functioning receiver, implanted it into patients, and sought reimbursement from Medicare using CPT Code 64590 for the implantation procedure. Accordingly, Stimwave and Perryman caused medical providers to submit false claims to Medicare by billing CPT Code 64590, which is to be used for implanting a receiver and should not have been used for implanting the wholly non-functional White Stylet.

JURISDICTION AND VENUE

12. This Court has jurisdiction over claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345.

13. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because Defendants transact business in this district, including by selling medical devices, including the PNS System, to doctors and medical practices in this District and by causing medical providers to seek reimbursement from Medicare for implanting Stimwave devices in residents of this District.

PARTIES

14. Plaintiff is the United States of America suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS"), and its component agency, the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare Program.

15. Defendants Stimwave LLC and Stimwave Technologies, Inc. filed for protection under chapter 11 of title 11 of the United States Code in the United States Bankruptcy Court for the District of Delaware on June 15, 2022, and sold substantially all of their assets to a third party through an auction pursuant to 11 U.S.C. § 363. Prior to selling most of its assets through

the bankruptcy proceeding, Stimwave was a medical device manufacturer headquartered at 1310 Park Central Blvd. S., Pompano Beach, FL 33064.

16. Defendant Laura Perryman is a Florida resident and, with others, founded Stimwave in or about 2010. Perryman served as CEO of Stimwave from in or about 2010 through in or about November 2019, when she was terminated by Stimwave.

FACTS

A. The Medicare Program

17. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services. Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A. Medicare is administered by CMS, a federal agency under HHS. Individuals who receive benefits under Medicare are referred to as "Medicare beneficiaries."

18. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule for physician services as well as a variety of "medical and other services." *See* 42 U.S.C. §§ 1395j to 1395w-6. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and by contributions from the Federal Treasury. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. The vast majority of health care providers who participate in Medicare elect to enter into Medicare Participation Agreements, which allow the beneficiaries' claims to be assigned directly to the medical provider. Pursuant to Medicare Participation Agreements, service providers and practitioners, such as physicians, bill the Medicare Program directly, and Medicare Part B payments are typically made directly to these service providers, rather than to the patient/beneficiary.

B. CPT Codes

19. In order to receive reimbursement payments from Medicare for covered medical services, a provider must submit claims for payment containing Current Procedural Terminology ("CPT") Codes, which are a set of standardized medical codes developed and maintained by the American Medical Association. CPT Codes are used to describe and report medical, surgical, and diagnostic procedures and services to public and private health insurance programs for medical billing purposes. The claims are required to reflect, among other things: (a) the diagnosis code that accurately identifies the medical diagnosis or the patient's condition; (b) the date the service was rendered; (c) the name of the patient who received the services; and (d) the name of the provider. Claims for reimbursement for Medicare Part B services are submitted on CMS Form 1500 or via the 837 electronic process.

20. Government healthcare payors use CPT Codes to determine both coverage, *i.e.*, if they will pay for the billed medical procedures and services, and reimbursement, *i.e.*, how much they will pay for the billed medical procedures and services.

21. Each procedure or service or item furnished to a patient has a specific CPT Code. Further, each CPT Code receives a certain level of reimbursement, which may vary depending on what other Codes are simultaneously submitted. The amount of money a physician is paid by Medicare for a service rendered to a patient depends on which CPT Codes are submitted as part of the corresponding claim.

22. In the Medicare Program Integrity Manual, CMS lists as an example of Medicare fraud the incorrect reporting of procedures to maximize payments and billing for services not furnished. *See* Medicare Program Integrity Manual, Section 4.2.1, Rev. 827, 09-21-18.

23. As is relevant here, medical practitioners sought reimbursement 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 what they believed to be a receiver. 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 a receiver, CPT Code 64590, provided for reimbursement at a rate of between approximately $16,000 and $18,000. CPT 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 inductive coupling."

C. False Claims Act

24. The FCA establishes liability to the United States for any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," § 3729(a)(1)(B). "Knowingly" is defined to include actual knowledge, reckless disregard, and deliberate indifference. *Id.* § 3729(b). No proof of specific intent to defraud is required. *Id.*

D. Defendants' Fraudulent Conduct

From 2018 to 2020, Stimwave and Perryman knowingly caused medical providers to submit false claims to Medicare for reimbursement using CPT Code 64590 for implantation of a "receiver," when Defendants knew that the providers were actually implanting an inert dummy component with no receiver functionality. As a result of Stimwave's and Perryman's fraudulent scheme, the Government paid reimbursements to medical providers to which they were not entitled.

1. The PNS System

25. The PNS System is an implantable neurostimulation device that is intended to treat intractable, chronic pain. The PNS System, which was cleared by the FDA in 2017 (the "PNS 510(k) Clearance"), was designed to use electrical stimulation to target peripheral nerves outside the spinal cord and block pain signals from reaching the brain, and is powered wirelessly, without an implanted battery.

26. When Stimwave brought the PNS System to market in or about 2017, as covered by the PNS 510(k) Clearance, 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 (together, the "PNS Kit"). The Pink Stylet has a pink handle, contains a copper core, and is connected to the Lead during the implant procedure. The purpose of the Pink Stylet is to transmit energy (and improve the efficiency of energy transfer) through its copper core, from the Battery to the Lead. The PNS System could, in certain scenarios, function without any stylet at all, because the Lead was also capable of receiving power directly from the external wearable Battery provided the Battery could be placed close enough to the Lead.

27. 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 doctors implanted the Pink Stylet, they used CPT Code 64590 when seeking reimbursement for the implantation from Medicare.

28. The Pink Stylet was part of the FDA-cleared PNS Kit and was referenced in the device labeling and Instructions for Use ("IFU"). However, Stimwave did not submit the White Stylet to the FDA for clearance.

29. Stimwave sold the PNS Kits to medical providers for over approximately $16,000. Stimwave intended that these providers would then be reimbursed by insurers, such as Medicare, between $4,000 and $6,000 for implanting the Lead (using CPT Code 64555) and between $16,000 and $18,000 for implanting the Pink Stylet (using CPT Code 64590). Given the cost of the PNS Kits, without the ability to implant the Pink Stylet and bill CPT Code 64590, the device would not have been cost-effective for doctors to purchase.

30. In or about 2017, soon after the PNS System was released, physicians informed Stimwave that they were having trouble implanting the Pink Stylet (which was approximately 23 centimeters) in certain patients because the Pink Stylet was too long to fit comfortably into anatomically small locations (such as near elbows). Perryman knew that the Pink Stylet could not be cut or trimmed to shorten it without interfering with the functionality of the PNS System. The PNS System could 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, however, 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 the 510(k) Clearance.

2. Perryman Personally Approved the Design, Creation and Manufacture of the White Stylet in Order to Keep the Price of the PNS System Economically Viable for Medical Providers and Maintain Sales

31. Rather than lower the price of the PNS System so that its cost to medical providers could be covered by reimbursement under CPT Code 64555 for 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, Perryman directed that Stimwave design, create, and manufacture a dummy "receiver" stylet—the White Stylet—that had no receiver functionality or purpose but could be cut to a smaller size, so that medical providers would continue to purchase the PNS System and use it in smaller anatomical spaces (and, therefore, bill for implantation of the White Stylet using CPT Code 64590).

32. From late 2017 through 2019, Perryman was personally involved in the design and 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, show that Perryman approved the specification and design of the White Stylet as an entirely plastic product that contained no copper, and thus had no ability to act as a receiver.

33. Starting in or about the spring of 2018, Stimwave, at Perryman's direction, 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 that would make it functional as a receiver.

3. Stimwave, Under Perryman, Circumvented Its Own Standard Operating Procedures in Developing the White Stylet

34. 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. But in creating and designing the White Stylet, Stimwave, under Perryman's leadership and at her direction, circumvented its own SOPs.

35. Specifically, between 2017 and 2019, Stimwave's document control SOP required

design change documents, like drawings relating to the design and revision of the White Stylet, to be subject to controls defined in Stimwave's SOP concerning "engineering change requests." The engineering change request 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 also supposed to include additional verification, validation, training, and/or FDA or international regulatory notification or approval.

36. The Stimwave personnel involved in the design and creation of the White Stylet, including Perryman, were aware of Stimwave's own document control and engineering change request SOPs and their requirements. Nevertheless, Stimwave, with Perryman's knowledge, failed to conduct the evaluation of the White Stylet that its own protocols required, before manufacturing the component and including it in PNS Kits sold to medical providers and implanted in patients.

4. Perryman and Stimwave Falsely Told Doctors and Sales Representatives That the White Stylet Was Functional and Reimbursable Under CPT Code 64590

37. During the Relevant Period, Perryman oversaw training of Stimwave's sales representatives and the marketing of the PNS System to doctors, as part of Defendants' scheme to cause doctors to implant the White Stylet and falsely bill Medicare for that procedure. In or about 2018 and 2019, Stimwave, at Perryman's direction, conducted trainings of its sales representatives to provide them with product information to be conveyed to medical providers implanting the PNS System. 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 Perryman, 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.

38. Stimwave told medical providers that unlike the Pink Stylet, 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, while still supposedly remaining functional as a receiver. Perryman herself also told doctors that the White Stylet contained copper and retained receiver functionality. But in actuality, regardless of its length, the White Stylet had no receiver functionality and, therefore, no medical efficacy at all.

39. Stimwave sales representatives and Perryman also encouraged medical providers to use CPT Code 64590 when submitting claims for reimbursement for implantation of the White Stylet, despite knowing that the White Stylet had no receiver functionality. However, using CPT Code 64590—which could only be used to obtain reimbursement for, as relevant here, the "[i]nsertion or replacement of" a "receiver"—constituted a false claim to Medicare, because the White Stylet was not a receiver and was simply a dummy component. While CPT Code 64590 may have been appropriate for implantation of a functioning receiver such as the Pink Stylet, under no circumstance did it cover the implantation of an inert component with no receiver or other medical functionality, like the White Stylet.

40. Moreover, Perryman received communications from Stimwave personnel indicating that they intended to instruct doctors to implant a stylet (either Pink or White) in all permanent PNS procedures, and to use CPT Code 64590 to bill for that procedure—even when the White Stylet was implanted. Specifically, in the summer of 2019, a Stimwave employee shared with Perryman a document outlining various "Action Items," including telling doctors that the "Stylet is **ABSOLUTELY ALWAYS** necessary during **ALL PNS** [permanent

implants]," that the doctor should use Code 64590 for implanting either the Pink or White Stylet, and that the White Stylet may be appropriate for implantation near the elbow. Therefore, Perryman was aware that Stimwave employees were encouraging doctors to use either the Pink or White Stylet in all scenarios, even those in which no stylet might have been needed (because the Battery could have been placed close to the Lead), and to bill for those implantations using CPT Code 64590.

41. Perryman also directly provided doctors with written materials mispresenting the functionality of the White Stylet and stating that providers could use CPT Code 64590 when seeking reimbursement from Medicare for implanting it. For example, in November 2019, Perryman emailed a doctor a slide deck which described the White Stylet as an "Adjustable Polarity" and "Advanced Programing" "receiver," even though Perryman knew that the White Stylet was made entirely of plastic and non-functioning. The slide deck also explicitly encouraged doctors to use CPT Code 64590 when seeking reimbursement for implanting the stylet component of the PNS System, without distinguishing been the Pink and White Stylets.

5. Defendants Caused Doctors to Submit False Claims to Medicare for Reimbursement Under CPT Code 64590 for Implantation of the White Stylet

42. As a result of the scheme described above, between 2018 and 2020, Stimwave caused doctors to submit hundreds of false claims to the Medicare program under CPT Code 64590 for implantation of the White Stylet, which had no receiver functionality or medical purpose whatsoever.

43. For instance, on June 11, 2019, Doctor A billed Medicare in connection with Patient Z using CPT Code 64590 for, upon information and belief, the implantation of the White Stylet. Medicare would not have reimbursed Doctor A for this service had it known that Doctor

A was, in fact, not implanting a receiver.

44. Similarly, on January 28, 2019, Doctor B billed Medicare in connection with Patient Y using CPT Code 64590 for, upon information and belief, the implantation of the White Stylet. Medicare would not have reimbursed Doctor B for this service had it known that Doctor B was, in fact, not implanting a receiver.

CLAIM FOR RELIEF

COUNT I

Violation of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

45. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

46. The United States seeks relief against Defendants under Section 3729(a)(1)(A) of the False Claims Act.

47. As a result of causing doctors to bill Medicare under CPT Code 64590 for implanting a wholly non-functional component into patients, Defendants knowingly caused false claims to be presented for reimbursement by Medicare, in violation of 31 U.S.C. § 3729(a)(1)(A).

48. By reason of these false or fraudulent claims that Defendants caused to be presented to Medicare, the United States has paid substantial Medicare reimbursements, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT II

Violation of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

49. The United States incorporates by reference each of the preceding paragraphs as if

fully set forth in this paragraph.

50. The United States seeks relief against Defendants under Section 3729(a)(1)(B) of the False Claims Act.

51. As a result of causing doctors to bill Medicare under CPT Code 64590 for implanting a wholly non-functional component into patients, Defendants knowingly caused false records or statements to be made that were material to getting false or fraudulent claims paid by Medicare in violation of 31 U.S.C. § 3729(a)(1)(B).

52. By reason of these false or fraudulent records or statements that Defendants caused to be made, the United States has paid substantial Medicare reimbursements, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the United States, requests that judgment be entered in its favor as follows:

(a) on the First and Second Claims for relief (violation of the FCA, 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B)), a judgment against Defendants for treble damages and civil penalties to the maximum amount allowed by law.

(b) An award of costs and such further relief as is proper.

Dated: New York, New York
March 8, 2023

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