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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

[UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No: **COMPLAINT** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

DOCUMENT TO BE KEPT UNDER SEAL

DO NOT ENTER INTO PACER

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

UNITED STATES, *ex rel.* Dustin Poole and Thomas Stillings, Plaintiff, v. Master Equity Texas Limited Partnership d/b/a Emerging Solutions, and Michael Bingham, individually, Defendants.	Case No: 3-20CV2824-E **COMPLAINT** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

Plaintiff-Relators Dustin Poole and Thomas Stillings ("Relators"), through their attorneys, on behalf of the United States of America (the "Government"), for their Complaint against Master Equity Texas Limited Partnership, d/b/a Emerging Solutions ("Emerging Solutions" or "Defendant") and Michael Bingham, individually, (collectively, "Defendants") allege, based on personal knowledge, relevant documents, and related information and belief, as follows:

I. INTRODUCTION

1. Emerging Solutions uses a fraudulently altered FDA approval document and false billing guidance to trick physicians into prescribing a several-thousand-dollar acupuncture device that Medicare categorically does not pay for. Defendants defraud the Government by submitting and/or causing the submission of false claims to Medicare for this non-reimbursable device using billing codes for unrelated goods and services, in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*

2. Defendants defraud Medicare by pawning off an electro-acupuncture device as an electrical nerve stimulator, when those types of devices are extremely different. Acupuncture involves the use of tiny needles to stimulate certain points on the body in an effort to relieve pain or other conditions. An electro-acupuncture device delivers electrical impulses through those

small needles. Electro-acupuncture is often performed by non-physician practitioners in private offices. In contrast, electrical nerve stimulators (also known as neurostimulators) and attached electrodes are surgically implanted a patient's nervous system by medical professionals in hospitals or ambulatory surgery centers.

3. Pursuant to National Coverage Determinations, which are mandatory guidelines for Medicare payment, the Government pays for implantation of electrical nerve stimulators. Conversely, until January 2020, Medicare refused to pay for acupuncture at all, and since then it only pays under specific conditions not applicable here.

4. The medical device involved in this lawsuit—Drug Relief—is manufactured by DyAnsys Corporation. It is designed and approved by the FDA only to treat patients addicted to opioid medications. It is a small, non-invasive device affixed with tape behind a patient's ear and connected to wires with tiny needles that poke at certain points on the ear. The device sends impulses to the needles, which may provide some patients with some relief from some opioid withdrawal symptoms. FDA approval does not mean that Medicare pays for the device; it merely allows DyAnsys to market and sell the device in the United States.

5. In fact, Medicare categorically does not pay for the device or associated treatments, because it is an acupuncture device.

6. Defendant Emerging Solutions and its CEO Defendant Michael Bingham market and sell Drug Relief nationwide as distributors for DyAnsys. But because Drug Relief is not eligible for Medicare (or most commercial insurance) reimbursement, the $2,200 device, sold in boxes of ten for $22,000, is difficult to sell. To increase sales, and to get around Medicare's complete exclusion of Drug Relief from reimbursement, Defendants first trick physicians into prescribing the device by lying about its approved indications. Defendants tell physicians that

the device is FDA-approved for pain relief. It is not. To deceive physicians, Defendants fraudulently edited the FDA's Drug Relief approval letter, adding in a fake alternate device name ("Primary Relief") and a false approved indication for pain relief.

7. Next, Defendants lure physicians with the promise of thousands of dollars in reimbursement from both Medicare and commercial payers. But because Drug Relief is not reimbursable by Medicare at all, Defendants bill or instruct physicians and other providers to submit false claims for Drug Relief using a billing code that pays thousands of dollars for "implantable neurostimulators." Drug Relief is not an implantable neurostimulator, and representing that it is is false.

8. Defendants also bill and advise physicians to bill for the device using a code for implanting neurostimulator electrodes. That representation is also false because Drug Relief has no electrodes, let alone electrodes connected to a neurostimulator, and Drug Relief's small needles are not implanted.

9. Defendants know they are billing and/or causing others to bill under these false billing codes for a device categorically excluded from Medicare reimbursement.

10. These false representations are material to the Government. In addition to decades-old policies denying reimbursement for acupuncture and thus devices like Drug Relief, the Government has sued providers under the FCA for billing for similar devices under these same false billing codes. The Government has also recently issued clear, unequivocal guidance reminding providers that these devices are not reimbursable. Defendants have nevertheless persisted in their fraud, despite knowing about these lawsuits and knowing about this guidance.

11. In short, Emerging Solutions and Michael Bingham have engaged in a brazen fraud that has caused Medicare to unwittingly pay for devices that it unequivocally would not

have paid for absent Defendants' fraud. Worse, Emerging Solutions may have created false hope for patients seeking relief from chronic pain by peddling a device that has not been approved to alleviate that pain.

12. This action, under the False Claims Act, seeks to redress the financial harm to the Government and to stop the Defendants' outrageous, deceitful actions.

II. PARTIES

A. Plaintiff-Relators

13. Plaintiff-Relator Dustin Poole is a healthcare industry salesperson. He is employed by a company which is a subcontractor of a subcontractor for Emerging Solutions.

14. Plaintiff-Relator Thomas Stillings works at the same company as Plaintiff-Relator Poole.

B. Defendants

15. Emerging Solutions is the name under which a Texas-based corporation called "Master Equity Texas Limited Partnership" does business. It is located in Dallas, Texas; its registered agent, according to the Texas Franchise Tax Account lookup available through the Texas Office of the Comptroller, is Michael Bingham. On information and belief, Emerging Solutions sells Drug Relief pursuant to a contract with the device's manufacturer, DyAnsys, Inc.

16. Michael Bingham is Emerging Solutions' CEO and registered agent in Texas.

III. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

18. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because Defendants

have minimum contacts with the United States. Moreover, Defendants can be found in and transact business in the Northern District of Texas.

19. Venue is proper in the Northern District of Texas pursuant to 28 U.S.C. § 1391(b), 28 U.S.C. § 1395(a), and 31 U.S.C. § 3732(a) because the Defendants can be found in, and transact and have transacted business in, this district. At all times relevant to this Complaint, Defendants regularly conducted, and continue to conduct, substantial business within this district, and maintain employees and offices in this district. Much of the alleged misconduct occurred in this district.

IV. BACKGROUND

A. Medical Background

20. Millions of Americans suffer from chronic pain. There are many treatments for chronic pain, with differing efficacy levels, wildly different side effects, and dramatically different costs. While pharmaceuticals, including opioids, are one option, nerve stimulation is another option that many physicians prescribe or administer to their patients. Yet another option is acupuncture, or the use of needles to alter energy flows within the body, which can be administered by physicians or non-physician practitioners.

21. To understand why Defendants' practices violate the False Claims Act, it is necessary to understand the difference between four broad categories of pulse-emitting devices used to treat or evaluate potential treatments for chronic pain—electrical nerve stimulators ("ENS"), peripheral nerve stimulators ("PENS"), transcutaneous nerve stimulators ("TENS"), and electro-acupuncture devices.

i. Electrical Nerve Stimulators

22. Neurostimulation has many approved uses, from pain relief to bladder and bowel control. For present purposes, there are two types of relevant ENS used to treat chronic pain—

central nervous system stimulators and implanted peripheral nerve stimulators. The central nervous system includes the brain and spinal cord, while the peripheral nervous system includes all of the nerves that branch out to other parts of the body, including muscles and organs. The devices use electrical impulses to stimulate nerves to reduce pain. Both types of devices require surgical incisions and surgical implantation, and both types of devices stay in or on the body for a long time (*i.e.*, months or years).

23. According to Medicare's definition, implanted peripheral nerve stimulators induce stimulation "by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room."

24. Similarly, a central nervous system stimulator involves implantation of electrodes into the spine or brain.

ii. Transcutaneous and Peripheral Nerve Stimulators

25. Prior to implantation of an ENS, and in particular an implanted peripheral nerve stimulator, patients may be evaluated using a TENS or a PENS.

26. According to Medicare, TENS therapy involves "attachment of a transcutaneous nerve stimulator to the *surface* of the skin over the peripheral nerve to be stimulated." TENS are generally used on a trial basis by physicians or physical therapists to evaluate the effectiveness of electrical stimulation in modulating pain. If TENS treatment provides some incomplete pain relief, full implantation with a percutaneous (*i.e.*, through the skin) electrical nerve stimulator may be considered. However, TENS treatment may be used as a primary treatment if it significantly alleviates pain.

27. PENS, by contrast, stimulate peripheral nerves through needle electrodes *inserted* (but not implanted) through the skin. PENS needles are inserted close to the nerves expressing

pain in an attempt to alleviate that pain. If the patient experiences relief, he or she may be eligible for an implanted ENS device. For Medicare purposes, PENS is a purely diagnostic procedure used to evaluate whether the patient would benefit from implanted electrodes. PENS is not a primary treatment for pain relief.

iii. Electro-Acupuncture Devices

28. According to Medicare, "[a]cupunture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques." In contrast to PENS, which determines needle placement based on proximity to pain, acupuncture determines needle or non-needle treatment location based on theories of energy flow throughout the body. Acupuncture does not involve implantation of any device, and the needles do not remain embedded in nerves for nearly as long as ENS devices. Physicians or non-physician practitioners may perform acupuncture treatments.

29. Electro-acupuncture is a form of acupuncture that delivers mild electrical pulses through tiny needles inserted at certain acupuncture points. One form of electro-acupuncture is "auricular peripheral nerve stimulation." "Auricular" means "relating to the ear," and "auricular peripheral nerve stimulation" refers to peripheral nerve stimulation of the ear. According to Medicare, "[e]lectro-acupuncture devices … are applied behind the ear using an adhesive and/or with needles inserted into the patient's ear (similar to acupuncture)." Electro-acupuncture devices are not ENS, TENS, or PENS.

B. DyAnsys's Drug Relief, an electro-acupuncture device

30. Emerging Solutions markets, sells, and bills on behalf of physician practices for DyAnsys's Drug Relief device. Drug Relief is classified by the FDA as a Percutaneous Nerve Stimulator for Opioid Withdrawal under 21 C.F.R. § 882.5896. The device's *only* indicated use is to aid in the reduction of opioid withdrawal symptoms.

31. The FDA approved DyAnsys's Drug Relief device pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, which allows device manufacturers to market and sell a device that is "substantially equivalent" to a product already cleared for sale in the United States. The already-cleared product is referred to as a "predicate device."

32. The predicate device for Drug Relief was the NSS-2 BRIDGE, approved by the FDA on March 17, 2017 as a percutaneous nerve stimulator (sometimes referred to as a "percutaneous nerve field stimulator"). The manufacturer's summary of the NSS-2 BRIDGE notes that the device "is nearly identical to the Electronic Auricular Device (EAD) previously cleared [by the FDA] for a different intended use (i.e., in the practice of acupuncture)."

33. Much like the NSS-2 BRIDGE, which is "nearly identical" to that device manufacturer's auricular acupuncture device, Drug Relief is nearly identical to DyAnsys's own auricular acupuncture device, the ANSiStim-PP. In its request for 510(k) approval, DyAnsys noted that "All the hardware components, form factors, material for sterilization and patient contacting materials of the Drug Relief are similar to the 510(K) cleared device ANSiStim-PP."

34. The only material differences between ANSiStim-PP and Drug Relief are that the latter operates at a higher frequency, has one extra wire, and has small needles that prick the skin of the ear (as opposed to clipping to the ear).

35. As Drug Relief's approval makes clear, it is not implanted, but rather affixed behind the ear with adhesive. A photograph from Emerging Solutions' guidance to doctors on placement of the device clearly shows it is affixed to the patient's head with an adhesive:

36. The image shows that three wires connect to small needles that prick the skin and are kept in place by additional adhesive, while the fourth wire (a ground wire) attaches with adhesive to the outside of the skin around the cheek or neck. As the FDA approval documents and Emerging Solutions' guidance make clear, neither the device nor the wires are implanted. Indeed, the FDA's classification of percutaneous nerve stimulators expressly state that these devices are not implanted.

37. Drug Relief is not an ENS or TENS, and therefore may not be used as a primary treatment. Although it is FDA-classified as a percutaneous nerve stimulator, in fact, it is not a PENS, but rather an electro-acupuncture device.

V. APPLICABLE LAW

A. The False Claims Act

38. The FCA prohibits knowingly presenting or causing to be presented to the federal Government a false or fraudulent claim for payment or approval and knowingly making or using or causing to be made or used a false or fraudulent record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)-(B).

39. Any person who violates the FCA is liable for a civil penalty for each violation, plus three times the amount of the damages sustained by the United States. *Id.* § 3729(a)(1).

40. For purposes of the FCA, a person "knows" a claim or statement is false if that person: "(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1). The FCA does not require proof that a defendant specifically intended to commit fraud. *Id.*

41. The FCA allows a Relator with information about an FCA violation to bring a *qui tam* action on behalf of the United States and to share in any recovery. The FCA requires that the Relator file the *qui tam* complaint under seal. The seal lasts for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit. The Government may seek extensions of the seal to further its investigation.

B. The Medicare Program

42. Medicare provides national health coverage for Americans aged 65 and older, or those with certain health conditions. *See* 42 U.S.C. §§ 1395 *et seq.* The government funds Medicare through the Medicare Trust Funds, paid for through workers' and employers' payroll deductions and other government funds. The United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS, direct and manage the Medicare program.

43. Medicare has four parts: Part A, which provides hospital insurance; Part B, which provides medical insurance; Part C, which provides funding for Medicare Advantage plans; and Part D, which provides prescription drug benefits. Parts B and C are relevant to this action because they cover the goods and services at issue here.

44. Medicare Administrative Contractors ("MACs") act as agents for the government in reviewing and paying claims submitted by health care providers. 42 U.S.C. § 1395kk-1; 42

C.F.R. §§ 421.3, 421.100. MACs process and pay Medicare claims within a specific jurisdiction on behalf of CMS. Novitas Solutions, Inc. is the MAC for Texas (including this district), along with Colorado, New Mexico, Oklahoma, Arkansas, Louisiana, Mississippi, Delaware, the District of Columbia, Maryland, New Jersey, and Pennsylvania.

45. Physicians and other providers submit claims for Medicare payment through MACs using Form CMS 1500.

i. National and Local Coverage Determinations establish whether Medicare will pay for certain goods or services, and Medicare providers agree to abide by those determinations

46. Medicare does not reimburse physicians for every procedure they perform. In fact, Medicare is prohibited by statute from paying for items or services that "are not reasonable and necessary" for the diagnosis or treatment of illness or injury, for the prevention of illness, or for the palliation or management of terminal illness. 42 U.S.C. § 1395y(a). National Coverage Determinations, or NCDs, issued by the Secretary of Health and Human Services, are binding determinations of whether certain goods or services are "reasonable and necessary." *See* 42 U.S.C. § 1395ff(f) (defining NCDs); 42 C.F.R. § 405.1060 (same); *see also* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(I) (making NCDs "binding" on the Medicare contractors adjudicating eligibility for Medicare reimbursement).

47. The Secretary has not issued nationally binding NCDs for every medical procedure. To fill in the gaps, MACs have authority to issue local coverage determinations ("LCDs") for their jurisdictions. 42 U.S.C. § 1395ff(f)(2)(B); § 1395m-1(g). LCDs are MAC "determinations … respecting whether or not a particular item or service is covered" within the MAC's service area.

48. Participants in the Medicare system contractually agree to comply with NCDs and LCDs. To bill Medicare for items and services, institutional providers, clinics, group practices,

physicians and non-physician practitioners, and DME suppliers must enroll in the Medicare program. To do so, they enter into a participation agreement with Medicare using CMS Forms 855A, 855B, 855I, or 855S, depending upon what type of vendor or provider they are. Each of those forms contains a certification that the vendor or provider is required to sign stating, in substantially similar language, that

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [the signatory or the signatory's organization]. … I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions … and on the provider's compliance with all applicable conditions of participation in Medicare.
>
> …
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

49. In order to enable participation in the Medicare program, every billing provider has executed one of the CMS forms identified in paragraph 48 above.

50. For claims to Medicare and TRICARE, providers also must certify on Form CMS 1500 that:

> 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim . . . complies with all applicable Medicare and/or Medicaid laws, regulations, and programs instructions for payment . . . ; [and] 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision . . . ."

51. Accordingly, each participant in the Medicare program expressly agrees by contract to abide by all Medicare laws and regulations, including those enabling the Secretary to issue binding NCDs and MACs to issue LCDs, and confirms by certification that all submitted claims comply with those laws.

C. Medicare Payment Rules for Electrical Nerve Stimulators and General Non-Payment of Acupuncture

i. Pursuant to National Coverage Determinations, Medicare pays for electrical nerve stimulators

52. Medicare pays for ENS, but the NCDs governing ENS reimbursement have requirements that exclude the DyAnsys Drug Relief device. An NCD for electrical nerve stimulators, NCD 160.7, limits reimbursement for the two categories of ENS described above, namely central nervous system stimulators and implanted peripheral nerve stimulators. This NCD has been in effect since August 7, 1995.

53. NCD 160.7 makes it clear that ENS requires "surgery" for "implantation" of the device.

54. Another NCD, NCD 160.7.1, in effect since June 19, 2006, makes clear that ENS procedures performed in a physician's office, by a physical therapist or outpatient clinic, are not reimbursable.

55. NCD 160.7.1 also describes the conditions under which Medicare will pay for TENS and PENS. As mentioned above, TENS may be eligible for reimbursement if therapy results in significant pain reduction, while PENS is purely diagnostic.

56. Neither NCD 160.7 nor 160.7.1 allows reimbursement for electro-acupuncture devices affixed behind the ear in an outpatient setting.

ii. Pursuant to a National Coverage Determination, Medicare does not pay for acupuncture except for one express limited condition

57. Prior to January 21, 2020, the Medicare NCD for Acupuncture, NCD 30.3, determined that "acupuncture is not considered reasonable and necessary." Medicare's website also noted that NCD 30.3 "is a longstanding national coverage determination." The NCD was in effect for decades, and Medicare's position with respect to the reasonableness and necessity of

acupuncture, or rather the lack thereof, was widely known within the medical community.

58. As of January 21, 2020, NCD 30.3 was updated to make acupuncture a covered service only for chronic low back pain, and only under certain limited criteria. Pursuant to that NCD, all other indications for acupuncture are not reasonable and necessary and not reimbursable by Medicare.

59. The Secretary's statement is unambiguous: "Medicare reimbursement for acupuncture, as an anesthetic, or as an analgesic or for other therapeutic purposes, may not be made unless the specific indication is excepted. All indications for acupuncture outside of NCD section 30.3.3 remain non-covered."

iii. Pursuant to a Local Coverage Determination, Medicare does not pay for auricular peripheral nerve stimulators

60. Novitas Solutions, Inc. has issued Local Coverage Determination A55240 titled "Billing and Coding: Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)." This LCD was first issued on June 14, 2018, and republished on November 21, 2019 and again on January 21, 2020.

61. According to that coverage determination, Medicare will not pay for auricular peripheral nerve stimulation because it is a form of acupuncture. The LCD is unambiguous: "The service for auricular peripheral nerve stimulation … will be denied as non-covered. This service is not a covered Medicare benefit because acupuncture for auricular stimulation does not meet the definition of reasonable and necessary…."

62. The LCD expressly identifies the NSS-2 Bridge device (the predicate device through which DyAnsys received 510(k) approval) and the ANSiStim device (which Drug Relief is "nearly identical" to) as non-covered acupuncture devices. The LCD is not limited to those devices, however, providing that "[w]hile the information given in this article is directed to

Neurostim system/NSS, P-Stim, ANSiStim, E-Pulse, and NSS-2 Bridge, other current or future devices when used for the procedure auricular nerve stimulation or electro-acupuncture, would also be considered a non-covered service."

iv. Only electrical nerve stimulation may be billed using codes L8679 and 64555

63. When submitting claims to Medicare using CMS 1500, providers must include a five-digit alphanumeric code, known as Current Procedural Terminology, or CPT code, that identifies the good or service for which the provider seeks reimbursement. CMS pays for a good or service based on reimbursement amounts assigned to each CPT code, and subject to certain adjustments, including, among others, place of service (*e.g.*, hospital or office) and geographic location.

64. There are two billing codes relevant to this Complaint.

65. CPT Code L8679 represents an "implantable neurostimulator, pulse generator, any type." This code is associated only with electrical nerve stimulators, and not TENS, PENS, or electro-acupuncture devices.

66. CPT Code 64555 represents "Implantation of peripheral nerve neurostimulator electrodes, accessed through the skin." This code is used with implanted electrodes, generally with ENS, but never with TENS, PENS, or electro-acupuncture devices.

67. There are several billing codes associated with TENS, but they are not relevant to this Complaint. There are no billing codes specifically for PENS or electro-acupuncture because they are non-covered.

68. A January 29, 2020 CMS release makes it clear that electro-acupuncture devices, like DyAnsys's Drug Relief, are not neurostimulators and are not reimbursable under Code L8679. The release, MLN Matters Number SE20001, states

> "Electro-acupuncture devices, including but not limited to P-STIM® devices, are applied behind the ear using an adhesive and/or with needles inserted into the patient's ear (similar to acupuncture). Providers are inappropriately coding electro-acupuncture devices as neurostimulators (HCPCS L8679 – implantable neurostimulator, pulse generator, any type)… electro-acupuncture devices are non-invasive (that is, do not require surgical implantation and/or an incision), and have an external battery sources. Electro-acupuncture devices and implantable neurostimulators are two separate devices, and coding electro-acupuncture devices as implantable neurostimulators is incorrect."

69. The release makes clear that an implanted neurostimulator properly coded with L8679 should also be accompanied by a surgical code—*i.e.*, a code indicating that an incision or implantation occurred, often CPT Code 64555.

70. Although the CMS release is dated January 29, 2020, it is merely a clarification of pre-existing standards. The Government routinely denies reimbursement for auricular acupuncture devices, and has enforced this standard through the FCA by bringing suit against defendants who have billed for these devices under code L8679.

71. Similarly, in LCD A55240, referenced at paragraphs 60-62, Novitas Solutions, Inc. wrote that "CPT code 64555[] does not describe the procedure of auricular acupuncture stimulation…" The MAC instructed providers submitting claims for auricular peripheral nerve stimulation to use "Not Otherwise Classified" ("NOC") CPT code 64999 for "unlisted procedure, nervous system." However, as mentioned at paragraph 61, Medicare will not pay for auricular peripheral nerve stimulation even if billed with NOC CPT code 64999.

VI. ALLEGATIONS

72. Defendants submit and/or cause the submission of false claims to the Government. Emerging Solutions uses an FDA document altered by Michael Bingham to trick physicians into believing that Drug Relief is FDA-approved for pain relief, when it is not. It falsely advises physicians that they can bill Medicare for thousands of dollars for Drug Relief using CPT codes L8679 and 64555, and sometimes bills on those physicians' behalf. It has

submitted or caused the submission of numerous false claims, a few representative examples of which are included below. Bingham has similarly caused the submission of numerous false claims to the Government.

73. These false claims and records are material to the Government's decision to pay the claims. The Government does not pay for electro-acupuncture devices like Drug Relief; if these claims had truthfully described the services provided, the Government would not have paid them.

74. When Bingham altered official FDA documents and when Emerging Solutions disseminated false billing advice, both Defendants knew that their actions were fraudulent and knew that they were submitting and/or causing the submission of false claims.

75. Defendants' conduct thus violates the False Claims Act.

A. Defendants submit and/or cause the submission of false claims to the Government and made and used false records material those claims

i. Defendants knowingly use falsified FDA approval documents to mislead doctors and cause them to prescribe the Drug Relief device

76. Relators are sub-sub-distributors of DyAnsys's Drug Relief device pursuant to an agreement with a sub-distributor of Emerging Solutions. However, Relators have had direct interactions with Emerging Solutions, principally through two of Emerging Solutions' employees, Tina Archuletta, Regional Director, and Katherine Matangos, also a Regional Director.

77. Relators initially agreed to market and sell Drug Relief based on Emerging Solutions' false representations that the device was FDA approved for pain relief, that patients experienced dramatic ongoing reductions in pain after using the device, and that the device was eligible for thousands of dollars in Medicare reimbursement.

78. However, in late May or early June 2020, Relators noticed that on the FDA's

website the FDA's approval letter did not indicate that Drug Relief was approved for pain relief; instead, the official letter on the FDA's website indicated that the device was approved solely for opioid withdrawal symptoms. On June 2, 2020, Relator Stillings asked Ms. Archuleta at Emerging Solutions by text message about the discrepancy between the FDA's approval and Emerging Solutions' claim that the device was also approved for pain relief.

79. In response, Ms. Archuleta texted Relator Stillings shortly thereafter that she had "Just email[ed] you the FDA letter that indicates pln [pain] relief".

80. The document that Ms. Archuleta emailed to Relator Stillings was not the official FDA 510(k) letter approving the DyAnsys Drug Relief device for sale in the United States, but rather an altered version of an that letter. The FDA's real approval letter, dated May 2, 2018, was for a device called "Drug Relief" with a "regulation name" of "Percutaneous nerve Stimulator for Opioid Withdrawal." The only indicated use for the device was "as an aid to reduce the symptoms of opioid withdrawal…"

81. The altered version of the document, by contrast, includes numerous changes throughout, including changes to the device's trade name, regulation name, and indicated uses, to make it appear that the device was broadly indicated not just for opioid withdrawal symptoms but also for pain relief more generally.

82. Based on a review of the metadata of the file that Ms. Archuleta sent, the altered document was created and last modified by Michael Bingham. According to the document's metadata, Mr. Bingham created the altered FDA approval letter on December 17, 2019.

83. The first image below shows a portion of the first page of the original FDA 510(k) approval letter, retrieved from the FDA's website on July 17, 2020, while the second image below shows a portion of Defendants' altered document changing the device name and

regulation name:

May 2, 2018

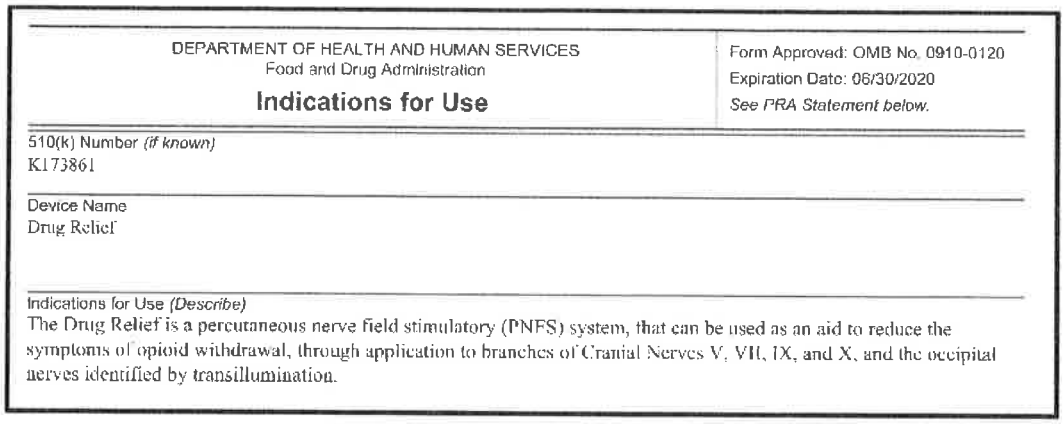
DyAnsys, Inc.
Srini Nageshwar
CEO
300 North Bayshore Boulevard
San Mateo, California 94401

Re: K173861
Trade/Device Name: Drug Relief
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous Nerve Stimulator For Opiod Withdrawal
Regulatory Class: Class II
Product Code: PZR
Dated: April 18, 2018
Received: April 20, 2018

DyAnsys, Inc.
Srini Nageshwar
CEO
300 North Bayshore Boulevard
San Mateo, California 94401

Re: K173861
Trade/Device Name: Drug Relief / Primary Relief V1
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous Nerve Stimulator for Opioids Withdrawal and percutaneous electrical nerve stimulator for Pain relief.
Regulatory Class: Class II
Product Code: PZR
Dated: April 18, 2018
Received: April 20, 2018

84. Defendant Bingham made other alterations to the document. For example, on the third page of the altered document Defendant Bingham changed the "Device Name" and the "Indications for Use" (the highlights in the excerpt below were, on information and belief, made by Defendants):



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

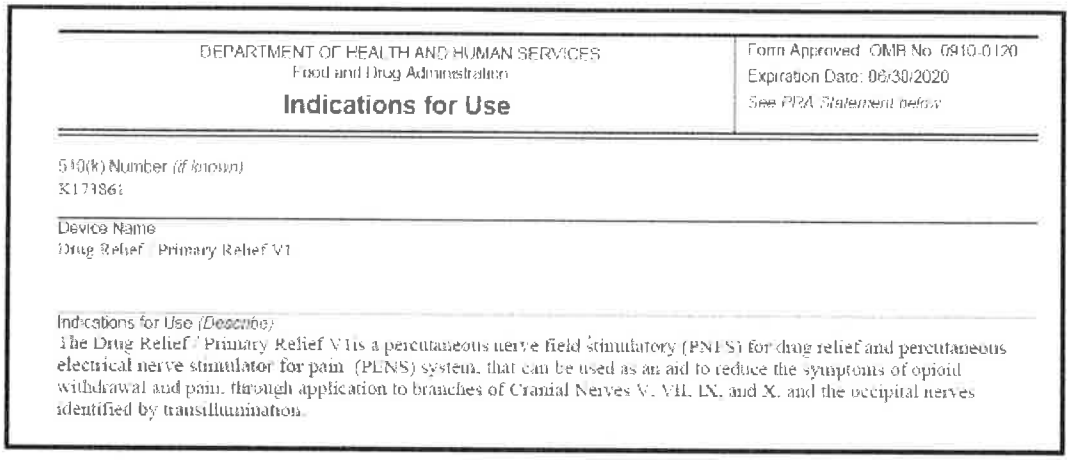
Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173861

Device Name
Drug Relief

Indications for Use *(Describe)*
The Drug Relief is a percutaneous nerve field stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173861

Device Name
Drug Relief / Primary Relief V1

Indications for Use *(Describe)*
The Drug Relief / Primary Relief V1 is a percutaneous nerve field stimulatory (PNFS) for drug relief and percutaneous electrical nerve stimulator for pain (PENS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal and pain, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.

85. While the 510(k) approval on the FDA's website refers exclusively to "Drug Relief" and use to "reduce the symptoms of opioid withdrawal," Defendants' altered document adds the name "Primary Relief V1" and adds pain reduction as an indication for use.

86. Notably, in the excerpt above at paragraph 84 and in other parts of the altered document, Defendants' altered document refers to the device as a PENS system, not an implantable neurostimulator.

87. Page 4 of both the real and altered documents describe the device as designed to provide "electrical stimulation at the auricular stimulation points … The electrical pulse from the device will be delivered to the branches of the Cranial Nerves on the ear through a set of wire assembly and Stimulation needles."

88. Page 5 of both the real and altered documents refer to the predicate device, which

allowed for 510(k) approval for "substantial equivalence", as the NSS-2 BRIDGE, which is a percutaneous nerve stimulator. As referenced at paragraph 33 above, the NSS-2 BRIDGE is "nearly identical" or "similar" to predicate electro-acupuncture devices.

89. Based on this document and conversations with Ms. Archuleta, Relators allege that Defendant Bingham altered this FDA approval document and Defendant Emerging Solutions distributed it in order to mislead physicians about the approved uses for the Drug Relief device and to cause physicians to prescribe the device for non-reimbursable services.

ii. Defendants knowingly bill and/or cause physicians to bill for Drug Relief using false billing codes that inaccurately describe the device and result in billing for services not performed

90. After suspecting that the FDA document was altered, Relators began to doubt whether the device was reimbursable at all, and eventually discovered the January 29, 2020 MLN Matters release referenced at paragraphs 68-69 above.

91. On July 6, 2020, Relator Stillings emailed Tina Archuleta with a copy of the MLN Matters release. Relator asked Ms. Archuleta "how our billing is being done."

92. Ms. Archuleta replied that same day "We begin addressing the CMS guideline changes back in February … When billing medicare or any medicare replacement plans we bill 64555 and L8679 [sic all]".

93. Any claim for reimbursement of the use of Drug Relief using code L8679 is a false claim, for two reasons. First, Code L8679 represents an "implantable neurostimulator, pulse generator, any type." This representation is false because Drug Relief is not such a device. As described above, and in Defendant's and DyAnsys's own literature on the device, the Drug Relief device is placed behind a patient's ear with tape and adhesive. The device is not implanted. Second, the request for payment is also false because the device is an electro-acupuncture device, which is categorically not reimbursable.

94. For these reasons, any claim for the Drug Relief device using code L8679 is a false claim that incorrectly represents the goods and services provided and requests payment for a non-reimbursable device.

95. Any claim for reimbursement for the affixing of the Drug Relief device using code 64555 is also false, for at least two reasons. First, CPT code 64555 is defined as "Implantation of peripheral nerve neurostimulator electrodes, accessed through the skin." This representation is false because the Drug Relief device is not a neurostimulator and this code cannot possibly apply to any services associated with the device. Second, this representation is false because the electrodes are not "implanted" and therefore the code does not apply.

96. For these reasons, any claim for the services associated with affixing the Drug Relief device to a patient using code 64555 is a false claim that bills for services not provided and requests payment for a service that is categorically not reimbursable.

97. On the July 6, 2020 email referenced at paragraph 92 above, Ms. Archuleta provided Relators with a document prepared by Emerging Solutions explaining why Emerging Solutions could bill for the device using Codes L8679 and 64555. The document's metadata indicates it was created by Lynn Fossum on March 11, 2020. On information and belief, Ms. Fossum is an employee of Emerging Solutions.

98. The document does not justify billing Drug Relief as an implantable neurostimulator. The document is at times incomprehensible, and at other times conclusory and circular. No reasonable person could rely on such a document to justify billing for Drug Relief as an implantable neurostimulator using codes L8679 and 64555.

iii. Sample False Claims

99. Emerging Solutions submitted claims and/or Defendants caused the submission of claims to Medicare for Drug Relief. Each of the representative sample claims below were for

patients treated by physicians that Emerging Solutions provided services to, including the false billing advice and services described above.

100. On June 9, 2019, a podiatrist in Grapevine, Texas affixed Drug Relief to a patient. That provider submitted a bill to that patient's Medicare HMO for Drug Relief using code L8679, which was a false description of the service provided. The HMO paid $5,315.79 for this false claim.

101. That same podiatrist submitted a claim to Medicare Part B for a Texas patient on August 9, 2019. The patient was diagnosed with chronic pain, neuropathy, and fibromyalgia—none of which are approved indications for Drug Relief. The provider or Emerging Solutions nevertheless submitted a claim to Medicare using code L8679, and received reimbursement of $6,542.50 on September 11, 2019.

102. On November 2, 2018, a different provider submitted a false claim for Drug Relief using code L8679 for a Medicare Part B beneficiary. Medicare approved a payment of $6,396.03, with the patient obligated to pay an additional $1,631.64.

103. These claims are merely representative samples of the many false claims that providers and/or Emerging Solutions have submitted and/or caused to be submitted for payment by Medicare.

104. Relators do not have in their possession requests for payment under CPT Code 64555, because those records are exclusively within the control of Defendant Emerging Solutions and/or providers that Defendant Emerging Solutions tricked into billing for Drug Relief using that code. Nevertheless, because Relators are aware that Defendant has submitted and/or caused the submission of false claims for Drug Relief using code L8679, and because Ms. Archuleta told Relator Stillings that Emerging Solutions also bills for Drug Relief using CPT

code 64555, Relators allege that Defendants have also submitted and/or caused the submission of false claims using Code 64555.

B. Defendants' conduct is material to the Government because the Government would not pay the claims if it knew that the claims were for electro-acupuncture devices and not implantable neurostimulators

105. Medicare would not pay claims for Drug Relief under code L8679, which is for implantable neurostimulators, if it had known that the service was not reimbursable under that code. As the CMS release referenced at paragraph 68 above makes clear, Drug Relief is not reimbursable under L8679. Furthermore, prior to that release, the Government pursued multiple cases under the False Claims Act against providers and other entities that submitted claims under code L8679 for devices similar to Drug Relief.

106. Similarly, Medicare would not pay claims under code 64555 for Drug Relief, because the service indicated by that code had not been performed. Because Drug Relief is not a neurostimulator, and because the electrodes are not implanted, providers do not "implant neurostimulator electrodes," as use of that code states.

C. Defendants acted knowingly

107. Defendants know that Drug Relief is not reimbursable under code L8679. Defendants have gone to great lengths to deceive physicians and cause them to prescribe Drug Relief for their patients, including altering and distributing an official FDA document.

108. Defendants also know that Emerging Solutions' billing guidance is wrong. Defendants knew Emerging Solutions was selling an electro-acupuncture device that was adhered to the skin but billing for it and advising physicians to bill for it using a code for an implantable neurostimulator. Defendants know Drug Relief was never reimbursable under code L8679 because it is not an implantable neurostimulator. Defendants similarly know that Drug Relief cannot be billed with Code 64555, because there are no implanted electrodes.

109. In fact, because it is an acupuncture device, Drug Relief was never reimbursable at all. Defendants know this.

110. And Defendants also know Emerging Solutions' billing guidance is wrong because, as referenced in paragraph 92, according to Tina Archuleta, Emerging Solutions has known about the MLN Matters release since at least February 2020. This guidance merely confirmed longstanding Medicare practice of which Defendants were well aware.

VII. CAUSES OF ACTION

Count I
Federal False Claims Act
31 U.S.C. § 3729(a)(1)(A) and (B)

111. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 110 above as though fully set forth herein.

112. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729 *et seq*.

113. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A). Emerging Solutions used knowingly falsified documents and knowingly false billing advice to induce doctors to prescribe Drug Relief, knowing that such guidance would cause doctors to prescribe the device. Emerging Solutions also submitted claims it knew to be false, because it knew that doctors prescribed the device based on false guidance. It also knew that the device was not reimbursable by Medicare. Michael Bingham caused the presentation of false claims when he created false documents that he knew would cause physicians to prescribe Drug Relief and lead to the submission of false claims by those physicians or Emerging Solutions.

114. By virtue of the acts described above, Defendants knowingly made or used, or

caused to be made or used, false records or statements to get the United States to pay or approve false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B). Emerging Solutions and Michael Bingham used knowingly falsified documents that caused to doctors to prescribe Drug Relief, which ultimately led the United States to pay the false claims.

115. Relators cannot now identify each of the false claims for payment that Defendants presented or caused to be presented, or the false records or statements Defendants made or used, or caused to be made or used, in support of such claims because Relators do not have access to records in Defendants' or third parties' possession.

116. The United States, unaware of the falsity of the records, statements, and claims that Defendants made or caused to be made, paid and continues to pay claims that would not be paid but for Defendant's illegal conduct.

117. Defendants have damaged, and continue to damage, the United States in a substantial amount to be determined at trial.

118. Additionally, the United States is entitled to the maximum penalty available under 31 U.S.C. §3729, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, for each and every violation alleged herein.

VIII. PRAYER

WHEREFORE, Relators pray for judgment against Defendants as follows:

119. That Defendants cease and desist from violating 31 U.S.C. §§ 3729 – 3733;

120. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus the maximum civil penalty permitted for each violation of the Federal False Claims Act;

121. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal False Claims Act;

122. That Relators be awarded all fees, costs, and expenses incurred in connection with this action, including attorneys' fees, costs, and expenses; and

123. That Relators recover such other relief as the Court deems just and proper.

IX. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: September 11, 2020

Respectfully Submitted,

By: Csilhan

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