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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

J.B. MOUNTEER,

Plaintiff,

v.

NEVRO CORPORATION, GLOBUS MEDICAL, INC., UNITED STATES FOOD & DRUG ADMINISTRATION,

Defendants.

Case No. 3:26-cv-2514

COMPLAINT FOR DAMAGES AND DECLARATORY AND INJUNCTIVE RELIEF

JURY TRIAL DEMANDED

Plaintiff **J.B. MOUNTEER** ("Plaintiff") by and through undersigned counsel, and for their Complaint against Defendants **NEVRO CORPORATION, GLOBUS MEDICAL, INC.,** and the **UNITED STATES FOOD AND DRUG ADMINISTRATION** seeking damages as well as declaratory and injunctive relief (the "Action") as follows:

INTRODUCTION

This is a product liability and administrative law action involving injuries sustained by Plaintiff following the implantation and failure of a spinal cord stimulator (SCS) system designed, manufactured, and marketed by Defendant Nevro Corporation The devices were implanted in Plaintiff's body as a purported treatment for chronic pain, but they failed to perform as promised and instead caused serious harm.

The original Nevro SCS device received Food and Drug Administration (FDA) approval under the PMA process in 2015. Since that time, however, the device has been fundamentally altered through hundreds of PMA supplements, modifying its battery chemistry, firmware, waveform control, leads, and user interface, without the benefit of a new PMA or any renewed clinical safety validation.

These cumulative changes, approved outside public view, transformed the device's mechanism of action, performance characteristics, and risk profile. Nevro failed to disclose these material changes to patients, physicians, or regulators. As a result, Plaintiff was implanted with a device that was materially different from what had been tested and originally approved by the FDA. Plaintiff suffered painful neurologic symptoms, worsening pain symptoms, and potentially permanent injuries.

Plaintiff brings this Action under California, Pennsylvania, and Utah law, and the federal Administrative Procedure Act ("APA"), asserting both traditional product liability and statutory claims. Plaintiff seeks compensatory damages for their injuries and equitable relief requiring the FDA to fulfill its statutory duties and restore integrity to the PMA process.

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PARTIES

I. PLAINTIFFS

1. **Plaintiff** J.B. Mounteer is a resident and citizen of the State of Utah. At the time this Complaint is filed, Plaintiff resides in Emery County, UT. The devices at issue were implanted in Plaintiff in Utah. Plaintiff has received medical treatment related to the device in Utah. Plaintiff J.B. Mounteer had their Nevro SCS permanent device implanted in September 23, 2022.

II. DEFENDANTS

2. **Defendant** Nevro Corporation (hereinafter "Nevro"), now is, and at all times relevant to this action was, a Delaware Corporation which now claims on the California Secretary of State's website that its principal place of business and headquarters are in the State of Pennsylvania. At the time that Nevro sold its SCS system to Plaintiff, its headquarters were located at 1800 Bridge Parkway, Redwood City, California and Nevro, however, still maintains on its website promoting its HFX SCS system that it is headquartered in Redwood City, California.

3. **Defendant** Globus Medical, Inc. (hereinafter "Globus") is a Delaware corporation which has its principal place of business in the State of Pennsylvania. On February 6, 2025, Globus and Nevro entered into an agreement whereby Globus acquired Nevro, making Nevro a wholly owned subsidiary of Globus. The terms of the merger agreement include the assumption by Globus of, *inter alia*, Nevro's liabilities for warranty claims.

4. **Defendant** the United States Food and Drug Administration is an agency of the United States government within the Department of Health and Human Services responsible for regulating medical devices under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., and its implementing regulations. The FDA is named solely in its official capacity for purposes of claims brought under the Administrative Procedures Act ("APA"), 5 U.S.C. § 701-706.

JURISDICTION AND VENUE

5. *Subject Matter Jurisdiction.* This Court has subject matter jurisdiction over Plaintiff's claims against the FDA pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 702. This Court has supplemental jurisdiction over related state-law claims pursuant to 28 U.S.C. § 1367 and diversity

jurisdiction under 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000 and the parties are citizens of different states.

6. This Court also has federal question jurisdiction over Plaintiff's claims brought under the Administrative Procedure Act, 5 U.S.C. § 701 et seq., pursuant to 28 U.S.C. § 1331, as those claims arise under the laws of the United States.

7. *Personal Jurisdiction.* Nevro and Globus Medical, Inc. have conducted business and derived substantial revenue from within California and have sufficient minimum contacts and have purposefully availed themselves of the California Market so as to render the exercise of jurisdiction over it by the California courts consistent with the traditional notions of fair play and substantial justice. This Court has personal jurisdiction over Defendant as Defendant conducted such business within the State including acts which caused or contributed to Plaintiff's injuries.

8. *Venue.* Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. §1965 (a) because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacts business affairs and conducts activity that gave rise to the claim of relief in this District. Venue is also appropriate with respect to the FDA under 28 U.S.C. § 1391(e)(1) because a substantial part of the events giving rise to the APA claims occurred in this District.

9. At all relevant times, Nevro negligently and recklessly conveyed false and misleading information concerning the SCS implants and concealed the risks of serious adverse events associated with the SCS implants from Plaintiff, Plaintiff's healthcare providers, the FDA and the public. But for Nevro's actions, Plaintiff would not have suffered the severe injuries and harms that have resulted from the implantation of the SCS implant into Plaintiff 's body.

FACTUAL ALLEGATIONS

III. APPLICABLE LAW AND CHOICE OF LAW CONSIDERATIONS

10. This Action arises under both federal and state law. Plaintiff brings federal claims against the United States Food and Drug Administration under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, and state-law claims against Nevro for personal injuries sustained

as a result of its defective spinal cord stimulator system, which was designed, regulated, and marketed from within this District.

11. Plaintiff's injuries occurred in Utah. Plaintiff's product liability and personal injury claims arise under applicable state law, including California, Pennsylvania, and Utah law and any other law determined by the Court's choice-of-law analysis. Federal law is referenced solely to identify parallel safety duties applicable to the device.

12. However, significant aspects of the design, manufacture, regulatory strategy, and labeling of the device occurred within the State of California and the State of Pennsylvania. Nevro, up until it was acquired by Globus, was headquartered in Redwood City, California, and despite formal change to its headquarters address with the California Secretary of State, continues to maintain to the public, on its website promoting its HFX SCS device, that its headquarters are in Redwood City, California. *See,* https://www.nevrohfx.com/about/about-us/ visited on March 20, 2026 ("Nevro is a medical device company headquartered in Redwood City, California that has the goal of helping more people living with chronic pain achieve lasting relief.") Defendant Globus is headquartered in Montgomery County, Pennsylvania, and the same address for Globus' headquarters is now Nevro's headquarters address as listed with the California Secretary of State.

13. Utah law may govern Plaintiff's personal injury claim, however, to the extent this action concerns Nevro's regulatory decisions, FDA submissions, and corporate conduct occurring in California and Pennsylvania, Plaintiff also invokes California and Pennsylvania law in the alternative for claims that arise from Nevro's forum-based behavior.

14. California applies a functional choice-of-law analysis that considers the place where the injury occurred, the place where the conduct causing the injury occurred, the domicile and residence of the parties, and the center of the relationship. *See McCann v. Foster Wheeler*, 225 P.3d 516 (2010); Restatement (Second) of Conflict of Laws § 6.

15. Because this action involves conduct undertaken by a California headquartered corporation during the majority of the time period involved and safety-related activities directed from this District, California has a significant interest in regulating corporate conduct occurring

within its borders and in ensuring that manufacturers provide complete risk information to physicians and patients.

16. Plaintiff does not seek a determination of governing law at the pleading stage and alleges claims under all applicable state laws to be determined by the Court.

IV. REGULATORY BACKGROUND AND PMA HISTORY

A. OVERVIEW OF SPINAL CORD STIMULATION DEVICES AND THEIR INTENDED USE

17. SCS devices are Class III implantable neuromodulation systems designed to deliver electrical impulses to the spinal cord to mask or modulate chronic intractable pain. SCS systems typically consist of an implantable pulse generator (IPG), one or more electrical leads, and external patient controllers for adjusting therapeutic levels.

18. The underlying therapeutic premise of SCS devices is that electrical stimulation of the dorsal columns can "override" or "mask" the transmission of pain signals to the brain, thereby providing relief for chronic pain conditions that are otherwise resistant to conventional treatments.

19. SCS devices have long been associated with complex risks, including but not limited to device migration, lead breakage, battery failure, infection, stimulation-induced neurological deficits, exacerbation of pain, and autonomic dysfunction.

20. Due to these inherent risks, SCS devices are classified by the FDA as Class III medical devices. The federal regulatory framework is referenced solely to describe the type of safety information ordinarily available to manufacturers of implantable medical devices and relied upon by physicians when making treatment decisions, and not as an independent basis for liability.

B. NEVRO'S SCS PRODUCTS

21. Defendant Nevro designs, manufactures, markets, and distributes the Nevro HFX Senza Omnia SCS, an implantable device indicated for the treatment of limited varieties of chronic and intractable pain.

22. Defendant's SCS product includes an Implanted Pulse Generator (IPG) and percutaneous lead wires. The IPG is a rechargeable implantable device with 16 output channels.

Each of the 16 outputs can be programmed as a cathode or an anode. The IPG is powered by a 3.6 V nominal Li-Ion rechargeable battery (single cell). It is capable of stimulating the spinal cord nerves through the electrodes of the leads connected to any combination of the output terminals, using a single current source.

23. The IPG component of the SCS is implanted in the patient subcutaneously, and the lead wires are implanted and secured along predetermined locations along the patient's spinal cord.

24. Once implanted and operational, the SCS delivers electrical impulses to the patient's spinal cord, with the purpose of modulating the electrical pain signals which manifest in subjective patient pain.

25. The implantation parameters for the SCS and the magnitude of electrical stimulation delivered by it often results in repeated electrical insult to one or more branches of the vagus nerve and other nerve tissues.

26. The different branches of the vagus nerve, respectively, modulate such processes as esophageal motility, cardiac rhythm, equilibrium, bowel function, and many others.

27. The overstimulation caused by the design of the Nevro SCS can lead to dysmotility, syncope, arrhythmias and incontinence.

28. Moreover, the magnitude and duration of insult to the vagus nerve caused by the Nevro SCS can give way to a process called nociception, whereby the parasympathetic nervous system perpetuates the manifestations of the aforementioned overstimulation, rendering the complications functionally permanent.

29. Defendant is aware of these risks and has failed to adequately warn patients or medical providers, including those of Plaintiff.

30. Other manufacturers of SCS devices include warnings on their devices of these potential adverse events.

31. In the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress instituted a process for product review and clearance, using different pathways and processes to permit drugs and medical devices to be sold to U.S.

consumers. Three classes of medical devices are regulated by the FDCA, Class I, Class II and Class III, with greater degrees of scrutiny and regulation imposed on the manufacturer as the levels go from I to III.

32. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

33. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

34. Under a Class III PMA, manufacturers have substantial and ongoing duties because of the degree of risk associated with products carrying the classification. Failing to fulfill the duties and comply with the associated requirements can result in the PMA being withdrawn.

35. State law, via common law and statutory enactments, provide financial remedies for personal injuries arising from violations of parallel federal regulations applicable to Class III devices. 21 U.S.C. § 360(k)(a).

36. Nevro received Pre-Market Approval from the FDA for the Senza spinal cord stimulator in May 2015.

37. The Senza Omnia was brought to market via a PMA Supplement, Supplement S039 on July 16, 2021

C. NEVRO'S SALES AND MARKETING PRACTICES

38. At all relevant times, Nevro engaged in aggressive and deceptive sales practices in order to market its SCS devices to clinicians engaged in the practice of spinal surgery and treatment of chronic pain syndromes.

39. These sales practices involved direct contact between Nevro sales representatives and patients, including Plaintiff.

40. As a prerequisite to reimbursement for the cost of SCS devices, including the Nevro device at issue here, public and private insurance providers maintain strict requirements to assure that the placement is medically necessary, including:

i. The implantation of the stimulator is used only as a late resort or (if not last resort) for patients with chronic intractable pain.

ii. With respect to the first condition, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory or are judged to be unsuitable or contraindicated for the given patient.

iii. Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation (such screening must include psychological, as well as physical evaluation).

iv. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy the third condition) must be available.

v. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation. Such relief must exhibit either 50% or greater reduction of the patient's pain or 50% or greater reduction of the patient's reliance on analgesic pain medications.[1]

41. In order to assure the placement of a permanent stimulator implant following the trial stimulation and procure reimbursement for an SCS device, Nevro's sales representatives are trained to make false and/or misleading statements to patients and/or healthcare providers during the trial stimulation period.

42. The aforesaid false and misleading statements are intended to induce patients and healthcare providers to move forward with implantation of the permanent SCS device.

D. REGULATORY FRAMEWORK AND FEDERAL DUTIES

43. Spinal cord stimulator (SCS) systems are regulated as Class III medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq.

[1] See, e.g. CMS NCD Manual, chapter 1, part 2, § 160.7(B)(2), Electrical Nerve Stimulators.

44. Class III devices are those that present the highest risk to patients and are subject to the most rigorous form of regulatory oversight, including the requirement to obtain Premarket Approval from the FDA prior to marketing. *See* 21 U.S.C. § 360e.

45. To obtain PMA, a manufacturer must submit detailed information demonstrating the safety and effectiveness of the device, including clinical trial data, descriptions of manufacturing methods, proposed labeling, and a risk-benefit analysis. *See* 21 C.F.R. § 814.20.

46. Manufacturers of implantable medical devices possess safety and performance information after a device enters the market that is important to physicians evaluating treatment options.

47. The federal regulatory framework is referenced solely as evidence of the safety information and risk data available to Defendants and not as an independent basis for liability.

48. Plaintiff's claims arise exclusively under traditional state tort law duties requiring manufacturers to provide reasonably safe products and adequate warnings to physicians and patients.

49. Medical device manufacturers maintain internal complaint handling, monitoring, and corrective action processes designed to evaluate safety information arising after a device enters the market.

50. The referenced safety requirements identify categories of safety information available to Defendants regarding device performance and risk.

51. The claim against the FDA seeks only to compel completion of a discrete, nondiscretionary administrative processing duty after receipt of mandatory safety submissions and does not request the Court to evaluate, modify, or invalidate any approval decision, scientific judgment, or enforcement determination.

52. Plaintiff asserts traditional state law claims that parallel duties requiring reasonably safe products and adequate warnings to physicians and patients.

53. Plaintiff's state-law claims arise under the substantive law determined by the Court's choice-of-law analysis, including California, Pennsylvania, and Utah law and, to the extent

applicable, the law of any jurisdiction whose consumer protection or product liability law governs specific issues in this action. Federal requirements are referenced solely to define parallel safety duties and not as independent causes of action.

V. ALLEGATIONS AGAINST THE FDA UNDER THE ADMINISTRATIVE PROCEDURE ACT

54. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint as though fully set forth herein.

55. Defendant United States Food and Drug Administration is an agency of the United States government charged with ensuring that medical devices marketed in the United States are safe and effective for their intended use, pursuant to the FDCA, 21 U.S.C. § 301 *et seq*., and the MDA, 21 U.S.C. § 360c et seq.

56. Under the APA, 5 U.S.C. §706(1), federal courts may compel agency action unlawfully withheld or unreasonably delayed.

57. Plaintiff seeks relief limited to unreasonable delay in processing mandatory safety submissions and does not request the Court to direct any particular regulatory outcome.

58. Safety information required to be submitted to the agency was provided through mandatory reporting mechanisms applicable to Class III medical devices.

59. After receipt of those submissions, the agency did not complete the required administrative processing step within a reasonable time, independent of any scientific or regulatory evaluation of the content of those submissions.

60. This claim seeks only to require completion of that processing duty and does not request review of the agency's scientific or policy determinations.

61. Plaintiff does not allege the FDA caused their injuries and seeks only prospective relief requiring completion of a nondiscretionary administrative processing duty.

62. The administrative processing sought in this action concerns the agency's handling of submitted safety information and does not require the Court to determine any particular regulatory outcome.

VI. PLAINTIFF-SPECIFIC FACTUAL ALLEGATIONS

63. On or about August 8, 2022, Plaintiff was surgically implanted with a Nevro trial spinal cord stimulator system (SCS).

64. On or about September 23, 2022, Plaintiff was surgically implanted with a Nevro permanent spinal cord stimulator system (SCS).

65. Plaintiff was told by Nevro's sales representative that the permanent device would relieve most of Plaintiff's pain. In reality, the device caused worsening pain, avascular necrosis of both femoral heads, shocking sensations, and weakness in extremities, despite being both initially programmed by a Nevro sales representative as well as being reprogrammed after the initial programming.

66. Plaintiff was met by a Nevro sales representative on multiple occasions. These visits occurred outside of the presence of their doctor. During these visits, Plaintiff voiced complaints about the unit's negative side effects and the sales representative reprogrammed the device.

67. Plaintiff underwent final surgical intervention to remove the SCS system due to mechanical and therapeutic failure of the device. Plaintiff continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

68. Based on the representations made by the sales representatives, before, during and after the SCS trial period, Plaintiff elected to be permanently implanted with the Nevro SCS system.

69. Immediately after the permanent implant surgery, Nevro representatives programmed and made therapeutic adjustments to the SCS system without meaningful physician supervision. This continued to occur on multiple occasions after Plaintiff was implanted with the SCS system.

70. Throughout the time that Plaintiff was implanted with a SCS system manufactured by Nevro, they were required to undergo additional procedure.

71. All leads used in the SCS systems implanted in Plaintiff were manufactured and sold by Nevro.

72. As a direct and proximate result of the defective and misrepresented nature of the device, Plaintiff suffered physical injury, worsening pain, emotional distress, and economic damages including medical expenses and loss of quality of life.

73. Plaintiff discovered the probable causal relationship between their injuries and Nevro's conduct only after experiencing continued device-related complications, removal of the device, and finally being informed about the underlying facts of the SCS that contradicted Nevro's representations.

74. Until Plaintiff learned the underlying facts of the safety and efficacy of Nevro's SCS devices, they continued to believe that their conditions and the efficacy of the devices were an aberration limited to themselves and not caused by a pattern and practice of Nevro.

75. During all times relevant to this Complaint Nevro fraudulently concealed from Plaintiff the truth regarding the safety and efficacy of the SCS devices, and Plaintiff could not have, with reasonable due diligence, determined such truth. In fact, to this day, Nevro continues to insist that its SCS devices are safe and efficacious.

VII. DEFENDANTS' MISREPRESENTATIONS, OMISSIONS, AND REGULATORY VIOLATIONS

A. FAILURE TO DISCLOSE MATERIAL RISKS

76. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint as though fully set forth herein.

77. At all relevant times, Defendants engaged in a course of conduct that withheld material safety information from physicians and patients and failed to meet safety practices expected of a reasonably prudent medical device manufacturer after a device enters the market.

78. Nevro represented to Plaintiff, their healthcare providers, and the medical community that its spinal cord stimulation systems were safe, effective, and appropriate for long-term implantation.

79. These representations were false, misleading, and incomplete. Nevro knew, or should have known through post-market surveillance and regulatory obligations, that the spinal cord stimulation system:

80. Posed an increased risk of device migration, stimulation failure, and neurological injury;

81. Was marketed with stimulation modalities whose known risks were not disclosed to physicians and patients;

82. Carried a known risk of autonomic dysfunction, including incontinence, hypotension, and cardiac arrhythmia;

83. Had materially different performance characteristics from the external trial device.

84. Had material risk information been provided, Plaintiff's treating physicians would have considered additional treatment options and risk factors when determining whether implantation was appropriate.

85. Without material risk information, treating physicians lacked information necessary to determine whether implantation was appropriate for Plaintiff.

B. VIOLATIONS OF CURRENT GOOD MANUFACTURING PRACTICES (cGMPs)

86. A reasonably prudent manufacturer of implantable neuromodulation devices evaluates performance problems and communicates material risk information revealed during post-market experience.

87. The safety practices referenced in this Complaint reflect the type of information ordinarily available to manufacturers and relied upon by physicians when making treatment decisions.

88. Defendants failed to exercise reasonable care in evaluating and communicating material safety information, allowing undisclosed risks to affect treatment recommendations made to Plaintiff.

89. Plaintiff's claims arise from Defendants' failure to provide reasonably safe products and adequate safety information to physicians and patients under traditional state law duties.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

90. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

91. At all times relevant to this action, Nevro was engaged in the business of designing, manufacturing, testing, labeling, distributing, and selling medical devices, including the spinal cord stimulator systems implanted in Plaintiff.

92. The devices implanted in Plaintiff were not reasonably safe for their intended use due to a manufacturing defect. The products, as manufactured and sold, deviated from Nevro's own FDA-approved specifications and did not conform to the design and performance standards described in PMA P010032 and its associated supplements.

93. Specifically, as detailed in preceding allegations, the SCS systems implanted in Plaintiffs failed to conform with federal Quality System Regulations, including 21 C.F.R. §§ 820.30(g) (design validation), 820.75 (process validation), 820.100 (corrective and preventive action), and 820.198 (complaint handling). These violations resulted in systemic defects in firmware execution, wireless programming reliability, and battery charging performance.

94. These deviations were not theoretical. Plaintiff's implanted device failed during normal and foreseeable use, producing painful sensations, stimulation loss, and other adverse effects that led to surgical removal and permanent injury.

95. Plaintiff's injuries were not caused by a known or inherent risk of the device when properly manufactured, but rather by a departure from its intended and approved construction. The product failed to perform as represented, and it would not have failed but for Nevro's failure to comply with FDA-mandated specifications and manufacturing protocols.

96. Under California, Pennsylvaia, and Utah law, Nevro is strictly liable for injuries caused by a manufacturing defect that rendered the device unreasonably dangerous at the time it left its control.

97. As a direct and proximate result of the manufacturing defect in the device, the Plaintiff suffered physical injury, pain, medical expenses, loss of enjoyment of life, and other damages.

COUNT II: FAILURE TO WARN

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

98. Plaintiff incorporates by reference allegations set forth above as though fully set forth herein.

99. At all times relevant, Nevro had a duty to provide adequate warnings and instructions regarding the known or reasonably foreseeable risks associated with its spinal cord stimulator systems.

100. Under California, Pennsylvania, and Utah law, a product is defective if it is unreasonably dangerous due to the absence of adequate warnings or instructions. This duty extends to risks known or knowable in light of the scientific, clinical, or regulatory knowledge available at the time the product was marketed and distributed.

101. The spinal cord stimulator devices implanted in Plaintiff were materially altered from the system originally approved under PMA P010032. The systems they received included firmware-driven stimulation control, Bluetooth-enabled programming interfaces, and high-density waveform functionality that were never clinically validated in human trials or publicly disclosed at the time of approval.

102. Nevro failed to update its Instructions for Use (IFU), patient education materials, and physician-facing labeling to disclose: the risk of painful stimulation spikes or loss of therapy during wireless charging; the instability of firmware updates and potential for loss of device communication; the increased rate of lead migration and therapy failure reported post-market; the

cumulative nature of the device's evolution, and that its current form bore little resemblance to the device described in PMA P010032 or its Summary of Safety and Effectiveness Data.

103. The failure to warn was compounded by Nevro's internal knowledge of these risks, including MAUDE reports, post-market complaint data, and prior design and validation issues. Despite this knowledge, Nevro continued to represent the device as "safe and effective" and failed to initiate field safety notifications, device labeling changes, or provider education consistent with 21 C.F.R. § 814.39(d) or 21 C.F.R. § 820.198.

104. Plaintiff and their healthcare providers reasonably relied on Nevro's representations and omissions in deciding to proceed with implantation of the SCS devices. Had they been adequately warned of the known risks, the device would not have been implanted, or alternative treatments would have been pursued.

105. Plaintiff's injuries were caused in whole or in part by Nevro's failure to warn of known or knowable dangers associated with the use of its product. These failures rendered the device unreasonably dangerous for its intended use and constitute a defect under California, Pennsylvania, and Utah law.

106. As a direct and proximate result of Nevro's failure to warn, Plaintiff suffered physical injury, pain, medical costs, surgical intervention, emotional distress, and other damages.

COUNT III: NEGLIGENCE PER SE – FEDERAL REGULATORY VIOLATIONS

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

107. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

108. Under California, Pennsylvania, and Utah law, a person injured by the violation of a statute or regulation intended to protect the class of persons to which that person belongs may recover damages under a theory of negligence per se.

109. Nevro was subject to, and violated, multiple non-discretionary federal duties that were enacted for the protection of public health and safety. These duties are embodied in the Food, Drug, and Cosmetic Act (FDCA), the Medical Device Amendments of 1976, and FDA regulations promulgated thereunder, including:

i. **21 C.F.R. § 814.39(a)** – requiring new PMAs for changes that may affect device safety or effectiveness;

ii. **21 C.F.R. § 803.50** – mandating adverse event reporting;

iii. **21 C.F.R. § 820.30(g)** – requiring design validation under expected use conditions;

iv. **21 C.F.R. § 820.75** – requiring process validation to ensure consistent device output;

v. **21 C.F.R. § 820.198** – requiring investigation of complaints;

vi. **21 C.F.R. § 820.100** – mandating corrective and preventive action (CAPA) when product failures are identified;

vii. **21 C.F.R. § 814.39(d)** – requiring labeling updates in response to known risks.

110. The device implanted in Plaintiff materially deviated from the system approved in PMA P010032. It incorporated design and firmware changes that altered its safety profile, yet Nevro failed to file a new PMA or submit panel-track supplements, as required by 21 C.F.R. § 814.39(a). Nevro instead submitted piecemeal supplements and exploited expedited review programs to bypass clinical safety validation.

111. Nevro also failed to report adverse events linked to stimulation shutoff, therapy loss, and electrical shocks under 21 C.F.R. § 803.50. These adverse effects were known to Nevro prior to Plaintiff's implantation and were consistent with reports subsequently leading to Class I recalls in 2023.

112. Nevro violated design and manufacturing regulations by failing to validate the performance of its firmware-dependent stimulation control, Bluetooth-based programming, and battery recharging systems. It also failed to initiate CAPA processes in response to known problems,

and did not investigate or disclose known product complaints in accordance with 21 C.F.R. §§ 820.100 and 820.198.

113. Each of these violations constitutes a breach of federal laws that were designed to protect a class of persons, of which Plaintiff is a member, against a particular type of harm.

114. Plaintiff is a member of the class of persons these statutes and regulations are intended to protect: patients receiving high-risk Class III medical implants under the FDA's PMA regulatory framework. Plaintiff's injuries are of the type these laws are intended to prevent—namely, harm resulting from undisclosed and unremedied device malfunctions that occur due to failures in quality systems, post-market reporting, and product validation.

115. As a direct and proximate result of Nevro's violations of federal regulations and California, Pennsylvania, and Utah law, Plaintiff suffered compensable physical injury, pain, medical costs, loss of enjoyment of life, and other damages.

116. These regulatory violations were not merely technical infractions, but material breaches of duties specifically intended to prevent the type of harm suffered by Plaintiff—namely, therapy loss, neurological injury, and delayed surgical intervention due to systemic firmware and charging failures.

COUNT IV: BREACH OF EXPRESS WARRANTY

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

117. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

118. Under California law, an express warranty is created when a seller makes any affirmation of fact or promise to the buyer that relates to the goods and services and becomes part of the basis of the bargain. Pennsylvania and Utah law are in accord.

119. Prior to the implantation of the spinal cord stimulator devices, Nevro made explicit representations in its promotional materials, device labeling, Instructions for Use (IFU), public statements, and directly to Plaintiff through its sales representatives that the device was safe,

effective, reliable, and had been adequately tested for use in human patients suffering from chronic pain.

120. Nevro expressly warranted that its SCS devices provided consistent pain relief, seamless therapy delivery, safe wireless programming, and a rechargeable platform with superior reliability and patient comfort. Nevro's provider materials represented that its SCS systems were "FDA-approved," "clinically validated," and "designed for long-term use with low complication rates." These claims were repeated in sales brochures, website copy, and Nevro's physician training materials. These claims were repeated directly to Plaintiff through Nevro's sales representatives prior to each of their implant decisions.

121. These affirmations and promises became part of the basis of the bargain between Nevro and Plaintiff, as well as Plaintiff's implanting physician. Plaintiff and their physician relied on these representations to proceed with the implantation of the spinal cord stimulator systems.

122. In fact, the SCS systems implanted in Plaintiff had never undergone clinical validation in its final marketed form. The FDA approved the system based on "sufficient similarity" to earlier devices, not on Nevro-sponsored clinical trial data specific to the device actually implanted. Nevro failed to disclose that its device had been significantly altered through nearly 250 PMA supplements, nor that these changes materially affected the device's safety and reliability.

123. The device failed to perform as promised. Plaintiff experienced therapy loss, painful electrical sensations, device communication failure, and required surgical revision and removal. The product was not safe, effective, or reliable as expressly warranted by Nevro, and Nevro failed to provide adequate warnings or updates contradicting its original claims.

124. Nevro's breach of its express warranties directly and proximately caused Plaintiff'sinjuries. Had the device performed as warranted, Plaintiff would not have suffered worsening pain, adverse neurological symptoms, or required surgical intervention.

125. As a result of this breach of express warranty, Plaintiff is entitled to recover all compensatory damages allowed under California, Pennsylvania, and Utah law, including medical expenses, pain and suffering, and other economic and noneconomic losses.

COUNT V: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

126. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

127. Under California law, a seller who is a merchant with respect to goods of that kind warrants that the goods shall be merchantable and fit for the ordinary purposes for which such goods are used. Pennsylvania and Utah law is in accord.

128. Nevro is a merchant engaged in the business of manufacturing, marketing, and selling spinal cord stimulator systems, including systems implanted in Plaintiff. These devices are used for the ordinary purpose of treating chronic pain through safe and effective neuromodulation therapy.

129. When Nevro marketed and sold its SCS systems implanted in Plaintiff, it impliedly warranted that the devices were of merchantable quality, conformed to FDA-approved specifications, and were reasonably safe for its intended medical purpose. Nevro also impliedly warranted that the devices were fit for the specific purpose of long-term implantation to treat Plaintiff's condition, as recommended by their physician.

130. The devices implanted in Plaintiff were not of merchantable quality, nor were they fit for their intended purpose. They failed to operate as expected due to known defects in firmware execution, wireless programming, battery recharging, and therapy delivery. Plaintiff experienced painful shocks, therapy failure, and ultimately underwent surgical removal due to the product's unreliability and malfunction.

131. These failures were not caused by misuse or physician error. They were the direct result of design-altering changes Nevro implemented without corresponding clinical testing or validation, and without disclosing these risks in labeling or provider materials. The devices failed

to conform to the minimum standards of merchantability and fitness for long-term neuromodulation therapy.

132. Nevro's breach of implied warranties was a proximate cause of Plaintiff's injuries, including physical pain, surgical intervention, economic loss, and emotional distress. Plaintiff would not have consented to the implantation had they or their physician known the device was unfit for its intended use.

COUNT VI: NEGLIGENCE

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

133. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

134. Nevro owed Plaintiff a duty of reasonable care in the design, development, manufacture, labeling, testing, marketing, sale, and post-market surveillance of the spinal cord stimulator systems that it placed into the stream of commerce.

135. Nevro breached its duty of care in one or more of the following ways:

136. By negligently failing to ensure that the devices were manufactured in accordance with FDA-approved specifications, including labeling, firmware, battery safety, and programming reliability standards;

137. By negligently introducing cumulative design changes through successive PMA supplements without proper validation, public clinical testing, or physician disclosure;

138. By negligently failing to investigate known risks associated with stimulation loss, painful shocks, and therapy failure, despite premarket complaints, post-market adverse event reports, and internal device testing;

139. By negligently failing to update its Instructions for Use, provider communications, or promotional materials in accordance with 21 C.F.R. § 814.39(d) and 21 C.F.R. § 820.198, despite known malfunctions;

140. By negligently failing to report adverse events related to its SCS systems in accordance with 21 C.F.R. Part 803;

141. By failing to initiate corrective and preventive actions under 21 C.F.R. § 820.100 after receiving adverse reports of stimulation instability, lead migration, or battery failure consistent with the experience of Plaintiff and other patients.

142. These negligent acts and omissions constitute breaches of both Nevro's duties under California, Pennsylvania, and Utah common law and its nondiscretionary regulatory obligations under the FDCA and FDA regulations, including 21 C.F.R. Part 803, 21 C.F.R. §§ 820.30(g), 820.75, 820.100, 820.198, and 814.39(a)–(d). These regulatory violations support a state-law claim for negligence and are not preempted under *Riegel v. Medtronic* or *Buckman v. Plaintiffs' Legal Committee*. Nevro's deviation from these standards was not isolated, but systemic, as evidenced by repeated internal and public reporting of identical failure modes across multiple product models.

143. Calfiornia law similarly imposes a duty on manufacturers to exercise ordinary care in the design, manufacture, labeling, and distribution of medical devices, including duties to investigate known hazards and warn of risks not adequately disclosed. Pennsylvania and Utah law is in accord.

144. Nevro's breach of its duties of care caused Plaintiff's injuries. As alleged above, Plaintiff suffered painful device malfunction and therapy failure resulting in surgical revision and eventual removal of the SCS system. These harms were foreseeable and preventable had Nevro exercised reasonable care.

145. As a direct and proximate result of Nevro's negligence, Plaintiff suffered physical pain, emotional distress, financial harm, and other compensable damages under California, Pennsylvania, and Utah law.

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COUNT VII: NEGLIGENT MISREPRESENTATION

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

146. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

147. At all times relevant, Nevro, in the course of its business, made representations to healthcare providers, patients, and the general public regarding the safety, effectiveness, regulatory status, and performance of its spinal cord stimulator systems.

148. Nevro represented, through promotional materials, Instructions for Use, patient education resources, and provider training, that its SCS devices: were safe and effective for the long-term treatment of chronic pain; were fully FDA-approved and compliant with all applicable regulations; had been validated through rigorous clinical trials or otherwise demonstrated safe through FDA-approved testing; and maintained reliability in therapy delivery, stimulation programming, and battery recharging.

149. These representations were false. As set forth in the preceding allegations, Nevro failed to disclose that: none of its SCS devices had ever been clinically validated in their marketed form; these devices had undergone significant design and firmware changes through more than 230 PMA supplements; These changes materially altered its performance and introduced new, untested risks; and multiple recalls and adverse events had already emerged related to therapy shutoff, stimulation spikes, battery failure, and wireless programming.

150. Nevro made these misrepresentations and omissions in a commercial context, intending physicians and patients to rely on them in making decisions regarding device selection, implantation, and long-term management.

151. Nevro also made these misrepresentations directly to Plaintiff through its sales representatives, who misrepresented to Plaintiff that the permanent SCS systems would provide Plaintiff with long term pain relief, were safe and backed by clinical validation, would at least be

functionally equivalent to the trial SCS system, and would alleviate Plaintiff's need to receive other treatment for their chronic pain.

152. Plaintiff's treating physician reasonably relied on Nevro's misrepresentations when selecting the Nevro system for implantation. Plaintiff, in turn, relied on the statements made by Nevro in patient-directed materials and directly to Plaintiff by Nevro sales representatives, including assurance of FDA approval, therapy safety, and reliability, when consenting to implantation.

153. Nevro failed to exercise reasonable care in obtaining or communicating accurate information about the device's clinical validation, safety risks, and actual approval history. A reasonable manufacturer in Nevro's position would have known, or should have known, that its cumulative modifications had introduced serious safety issues and altered the nature of the devices from its predicate.

154. As a direct and proximate result of Nevro's negligent misrepresentations and omissions, Plaintiff suffered foreseeable physical and economic harm, including the pain and cost of unnecessary and dangerous implantation and eventual revision surgery.

155. For avoidance of doubt, Plaintiff alleges misrepresentations were made to their and their healthcare providers, not the FDA.

COUNT VIII: FRAUDULENT CONCEALMENT

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

156. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

157. At all times relevant, Nevro had superior knowledge of critical facts concerning the safety, efficacy, and approval history of its spinal cord stimulator systems—information not available to Plaintiff, their treating physician, or the general public.

158. Nevro was under a duty to disclose material facts relating to the performance and risks of the SCS system due to: exclusive access to adverse event reports and internal product

complaint data; control over PMA supplement disclosures and labeling updates; direct and indirect representations to patients and physicians; statutory and regulatory duties under 21 C.F.R. §§ 803.50, 814.39, and 820.198 to disclose newly acquired safety information.

159. Nevro actively concealed or failed to disclose that: the SCS systems had undergone extensive, untested design and firmware changes; the FDA had approved the devices based only on similarity to legacy SCS systems—not on new clinical trial data; known issues with therapy interruption, device shutdown during charging, and unintended stimulation had been internally reported, but not publicly disclosed, matching the adverse experiences of Plaintiff and other patients.

160. Nevro's concealment of these material facts was intentional, or made with reckless disregard for the truth, and was undertaken to encourage widespread implantation and minimize safety concerns in order to preserve market share.

161. Plaintiff and their physician justifiably relied on Nevro's omission of material safety information when consenting to implantation of the SCS systems. Plaintiff was unaware—and had no way of knowing—that Nevro was concealing data and risks that materially affected the safety of these devices.

162. Nevro's fraudulent concealment directly and proximately caused the Plaintiff's injuries, including their exposure to harmful device malfunctions, surgical intervention, and resulting physical and emotional harm. Had the concealed risks been disclosed, Plaintiff would not have consented to implantation. The concealment of safety-related defects amounted to active fraud in the context of patient trust and medical device implantation. For the avoidance of doubt, Plaintiff is not alleging fraud on the FDA.

COUNT IX: VIOLATION OF CONSUMER PROTECTION LAWS

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

163. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

164. Nevro, through its consumer-oriented marketing, labeling, promotional efforts, and public communications, engaged in false, misleading, and deceptive acts and practices in connection with the promotion and sale of its spinal cord stimulator systems that were implanted in Plaintiff.

165. These acts include: falsely advertising the devices as safe, effective, and FDA-approved without disclosing that the approved form of the device was materially altered through hundreds of PMA supplements; failing to disclose known malfunctions, including painful shocks, device shutdowns, and therapy loss; omitting material information regarding recalls, firmware instability, and clinical trial limitations; and misrepresenting the scope and meaning of FDA approval to patients and providers.

166. Plaintiff was a foreseeable consumer of the device. Although Plaintiff relied in part on their physician's advice, Nevro engaged in direct-to-consumer advertising and disseminated patient-facing marketing materials that contained false or misleading information.

167. Plaintiff and their physician reasonably relied on Nevro's omissions and misrepresentations when consenting to device implantation. Had the material facts been disclosed, Plaintiff would not have proceeded with implantation.

168. As a result of Nevro's statutory violations, Plaintiff suffered personal injury and economic loss and is entitled to recover all damages, equitable relief, and attorneys' fees available under state consumer protection laws.

COUNT X: NEGLIGENCE PER SE – UNAUTHORIZED PRACTICE OF MEDICINE

(Against Defendant Nevro and Globus)

(Under Applicable State Law)

169. Plaintiff incorporates by reference all allegations set forth above as though fully set forth herein.

170. California, Pennsylvania, and Utah law prohibits the unauthorized practice of medicine by any individual or corporate entity not licensed in California, Pennsylvania, and Utah,

respectively. These prohibitions reflect a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

171. Nevro is not licensed to practice medicine in California, Pennsylvania, and Utah, or any other state. Nevertheless, Nevro exercised functional control over the administration of Plaintiff's neuromodulation therapy by: actively participating in the implantation of its SCS system in Plaintiff's body, intra operatively programing that SCS system, and programming the SCS system post-operatively; pushing firmware updates and stimulation programming changes remotely after implantation; designing and controlling preset therapy "profiles" that physicians could not override without manufacturer approval; and altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight.

172. These actions constitute the unauthorized practice of medicine, as they involved making decisions about the nature, extent, and delivery of Plaintiff's therapy during and after implantation, without informed consent or involvement by a licensed provider.

173. Under California, Pennsylvania, and Utah law, violation of a safety statute gives rise to negligence per se where the injured party is within the class the statute was intended to protect and the injury is of the type the statute was designed to prevent.

174. Plaintiff, as a patient undergoing neuromodulation therapy, is squarely within the protected class. Their injuries, caused by improper therapeutic manipulation without medical oversight, are the exact type the law is intended to prevent.

175. As a direct and proximate result of Nevro's unauthorized and unlicensed manipulation of Plaintiff's therapy, Plaintiff suffered harm, including painful stimulation, surgical revision, and other physical and emotional injuries. This harm was exacerbated by Plaintiff's loss of therapeutic control, wherein Nevro, through remote firmware updates, preset programming, and device-level automation, functionally practiced medicine by dictating post-implant treatment decisions that should have remained within the licensed provider-patient relationship.

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COUNT XI: ADMINISTRATIVE PROCEDURE ACT (APA) – DECLARATORY AND INJUNCTIVE RELIEF AGAINST THE FDA

(Against Defendant U.S. Food and Drug Administration)

(5 U.S.C. §§ 701–706; *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024))

176. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint as though fully set forth herein.

177. This claim is brought solely to compel agency action unlawfully withheld under 5 U.S.C. §706(1) and does not seek to impose liability on the FDA for Plaintiff's injuries.

178. This cause of action is brought against Defendant United States Food and Drug Administration solely in its official capacity under the Administrative Procedure Act, 5 U.S.C. §§ 701–706.

179. The APA authorizes a court to compel agency action unlawfully withheld under 5 U.S.C. §706(1).

180. Plaintiff seeks an order compelling the agency to perform the discrete administrative action required after receipt of mandatory safety submissions, without directing any particular substantive outcome.

181. Plaintiff does not seek review of any approval decision, scientific determination, or enforcement action.

182. Plaintiff does not seek damages or causation findings against the FDA.

183. The requested relief is limited to completion of the administrative processing duty described above and does not seek to control any scientific or enforcement decision.

184. Plaintiff requests a declaration as to unreasonable delay under 5 U.S.C. §706(1) and an order requiring completion of the administrative processing duty described above.

PRAYER FOR RELIEF

185. **WHEREFORE**, Plaintiff respectfully requests that this Court enter judgment in their favor and against Defendant Nevro and Globus as to all counts other than Count XI, and, with

respect to Count XI, against the United States Food and Drug Administration, and award the following relief:

i. Compensatory damages in an amount to be determined at trial for physical injury, pain and suffering, emotional distress, medical expenses, loss of enjoyment of life, and all other actual damages recoverable under applicable law;

ii. Statutory damages and attorney's fees and costs pursuant to any applicable consumer protection statutes;

iii. Punitive or exemplary damages, as allowed by law, based on Defendant Nevro's willful, malicious, and/or reckless disregard for the safety and rights of Plaintiff and the public;

iv. Declare that the FDA's failure to require a new PMA for Nevro's spinal cord stimulator systems referenced herein violated the APA and applicable statutory and regulatory duties;

v. Declare that the FDA's approval and ongoing allowance of materially altered devices under the PMA without new safety review is arbitrary, capricious, and contrary to law;

vi. Enter appropriate injunctive relief requiring the FDA to initiate enforcement proceedings or PMA reevaluation under 21 C.F.R. §§ 814.39 and 814.82;

vii. Award attorneys' fees and costs associated with this APA action under applicable law;

viii. Pre-judgment and post-judgment interest as provided by law;

ix. The costs of this action; and

x. Such other and further relief as the Court may deem just and proper.

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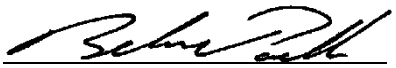
JURY TRIAL DEMAND

186. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: March 23, 2026

Respectfully submitted,

WISNER BAUM, LLP



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