IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

PAUL POSPISIL, **Plaintiff,** **v.** **NEVRO CORP., a Delaware corporation; and** **GLOBUS MEDICAL, INC., a Delaware corporation,** **Defendants.**	**Case No.:** 3:26-cv-00980 **COMPLAINT FOR DAMAGES WITH DEMAND FOR JURY TRIAL**

1. Plaintiff Paul Pospisil, by and through undersigned counsel, brings this Complaint with Jury Demand against Defendants Nevro Corp. ("Nevro") and Globus Medical, Inc. ("Globus") (collectively, "Defendants"), and alleges as follows:

I. NATURE OF THE ACTION

2. Plaintiff brings this action under the Ohio Products Liability Act ("OPLA"), Ohio Rev. Code §§ 2307.71–2307.80, and Ohio common law, for injuries sustained as a direct and proximate result of Defendants' defective Nevro spinal cord stimulator ("SCS") system and Defendants' negligent conduct.

3. Nevro's SCS systems, including the Senza HFX iQ (the "Nevro SCS Product" or “SCS Device”), are Class III medical devices approved by the U.S. Food and Drug Administration ("FDA") under Premarket Approval Application No. P130022.[1]

4. The Nevro SCS Products are chronically and dangerously defective. Specifically, the electrical leads integral to these devices have an unacceptably high rate of failure, including but limited to lead fracture, insulation breach, and lead migration — resulting in permanent neurological injury, including nerve damage, to implanted patients.[2]

5. Making matters worse, Nevro deployed sales representatives to actively participate in the programming and reprogramming of implanted devices in a manner that exceeded the permissible scope of sales representatives under FDA regulations and Ohio law, thereby constituting the unauthorized practice of medicine. These representatives also made false and misleading representations to induce patients to undergo implantation and to discourage patients from seeking removal when complications arose, thereby prolonging patients’ exposure to the defective devices and worsening permanent nerve damage.

6. Furthermore, Nevro deviated from its FDA-approved manufacturing processes and Current Good Manufacturing Practice ("cGMP") regulations in the manufacture of its SCS products, rendering the implanted devices defective in manufacture. Nevro also failed to warn patients and physicians of the true risks of lead failure and permanent nerve damage.

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[1] U.S. Food and Drug Administration, PMA P130022 Approval Record, Nevro Corp. Senza SCS System (approved May 8, 2015), available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p130022.

[2] ASRA, Complications of Spinal Cord Stimulator Implantation (Aug. 2019), available at https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation.

7. On April 3, 2025, Globus Medical, Inc. completed its acquisition of Nevro Corp., with Nevro surviving as a wholly-owned subsidiary of Globus. Globus is liable as Nevro's successor and parent for the conduct described herein.

8. Plaintiff's state-law claims are not preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a), because each claim is premised on state-law duties that genuinely parallel, and do not exceed, the specific federal requirements imposed on Defendants by the FDA's PMA approval of P130022 and implementing regulations.

II. PARTIES

9. Plaintiff Paul Pospisil ("Plaintiff") is and was at all relevant times a resident and citizen of Sandusky, Erie County, Ohio. Plaintiff was implanted with a Nevro SCS system designed, manufactured, and distributed by Defendant Nevro Corp.

10. Defendant Nevro Corp. ("Nevro") is a corporation organized under the laws of the State of Delaware, with its principal place of business and global headquarters previously located at 1800 Bridge Parkway, Redwood City, California 94065.

11. Nevro designed, manufactured, marketed, sold, and distributed the SCS products at issue, and conducted business throughout the United States, including within the Northern District of Ohio, by marketing, selling, and distributing its SCS devices to physicians, hospitals, and patients, and by deploying sales and clinical representatives in this District.

12. Upon information and belief, Defendant Globus Medical, Inc. ("Globus") is a corporation organized under the laws of the State of Delaware, with its principal place of business at 2560 General Armistead Avenue, Audubon, Pennsylvania 19403.

13. On April 3, 2025, Globus completed its acquisition of Nevro through a merger, with Nevro surviving as a wholly-owned subsidiary of Globus.[3] Globus is liable as the corporate parent, successor-in-interest, and alter ego of Nevro for the conduct described herein.

14. At all relevant times, Nevro and Globus (hereinafter collectively "Defendants") were acting as agents, partners, joint venturers, or co-conspirators of one another, and each Defendant, in performing the acts and omissions alleged herein, was acting within the scope of such agency, partnership, joint venture, or conspiracy, and with the knowledge, permission, and consent of the other Defendants.

III. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over Plaintiff's claims pursuant to 28 U.S.C. § 1332. Plaintiff is a citizen of Ohio. Defendant Nevro Corp. is a Delaware corporation with its principal place of business in California. Defendant Globus Medical, Inc. is a Delaware corporation with its principal place of business in Pennsylvania. The amount in controversy exceeds $75,000, exclusive of interests and costs.

16. This Court has personal jurisdiction over Defendants pursuant to Ohio Rev. Code § 2307.382 and principles of general and specific personal jurisdiction. Defendants regularly conduct, transact, and solicit business in Ohio, have marketed and sold their SCS devices to physicians, hospitals, and patients throughout Ohio, have

[10] Nevro Corp., SEC Form 8-K, Completion of Acquisition (Apr. 3, 2025), available at https://www.sec.gov/Archives/edgar/data/1444380/000119312525071904/d912761d8k.htm.

deployed clinical and sales representatives in Ohio, and derive substantial revenue from those activities. Plaintiff's claims arise directly from Defendants' activities in Ohio.

17. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this District, including Plaintiff's implantation, post-implantation encounters with Nevro representatives, and resulting injuries.

IV. FACTUAL ALLEGATIONS

A. Overview of Class III Regulatory Requirements

18. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III medical 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. Due to the level of risk associated with Class III devices, these devices require PMA application under § 515 of the Federal Food, Drug, and Cosmetic Act ("FDCA") before they can be sold in the United States. The Senza HFX iQ Device is a Class III device.

19. In the PMA application, the applicant is required to supply information to the FDA. The information required includes device description, clinical safety trials, methods of its product testing, design of the device, specific manufacturing controls, outcome evaluation, and proposed labeling. The FDA does not conduct independent testing on a medical device in a PMA application. The FDA reviews the document provided to them by the PMA applicant and relies on the veracity of the company. The PMA applicant is solely responsible for submitting all truthful and necessary documentation to the FDA.

20. Once an application for PMA is approved, the holder (here, Defendants) must comply with any and all post-approval requirements established by statute, the FDA, and federal regulations.

21. In particular, federal regulations require a PMA holder such as Defendants to comply with the following requirements:

a. Adverse Events. Review, evaluate, and report to the FDA adverse events associated with the medical device:
   i. Report individual adverse events within 30 days after becoming aware of an adverse event or aware of a reportable death, serious injury or malfunction, 21 C.F.R. § 803.l0(c)(1); and
   ii. Report individual adverse events no later than five workdays after becoming aware of a "reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health," 21C.F.R. § 803.10(c)(2)(i).
b. Quality System. Establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured and that meets the requirement of this part. 21 C.F.R. § 820.5;
c. Management Responsibility. Management with executive responsibility shall establish its policy and objectives for, and commitment to quality. 21 C.F.R. § 820.20;
d. Qualified Personnel. Have sufficient personnel with the necessary educational background, training, and experience to assure that all activities required by this part are correctly performed. 21 C.F.R. § 820.25;
e. Corrective and Preventative Action (CAPA). Establish and maintain procedures for implementing corrective and preventive action and document all CAPA activities. 21 C.F.R. § 820.100;
f. Complaint Files. Maintain complaint files, processed in a uniform and timely manner, oral complaints must be documents and must be evaluated to determine whether the complaint represents a reportable event under Medical Device Reporting. 21 C.F.R. § 820.198; and
g. Statistical Techniques. Establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics. 21 C.F.R.§ 820.250.

B. <u>Overview of Spinal Cord Stimulation Devices</u>

22. SCS devices are Class III implantable neuromodulation systems designed to deliver electrical impulses to the spinal cord's dorsal columns to modulate chronic

intractable pain. An SCS system typically consists of an implantable pulse generator ("IPG"), one or more electrical leads placed in the epidural space, extensions connecting the leads to the IPG, and external patient and clinician controllers for programming and adjusting stimulation parameters.

23. SCS devices are classified as Class III medical devices by the FDA, meaning they present the highest risk to patients and require Premarket Approval ("PMA") demonstrating safety and effectiveness before commercialization.[4] Any proposed changes to a PMA-approved device's design, labeling, intended use, or manufacturing process must be submitted to the FDA as a PMA supplement.[5]

24. SCS devices are prescription devices within the meaning of 21 C.F.R. § 801.109 and may only be used by or upon the order of a licensed healthcare practitioner.

25. In September 2020, following a Public Citizen report, the FDA issued a letter to healthcare providers advising that over the preceding four years it had received 107,728 adverse event reports regarding SCS devices, including 30,321 reports of unsatisfactory pain relief and 428 patient deaths. o[6] These figures include reports involving Nevro's SCS devices.

26. Post-market published data confirm that SCS devices, including the Nevro SCS Products, are associated with serious complications at high rates. Lead migration and fracture rates have been reported at between 13.2% and 22.6% of implanted patients in published literature, often requiring surgical revision.[7] A 2025 study confirms that up

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[4] *See generally* 21 U.S.C. § 360e; 21 C.F.R. Part 814.

[5] *See generally* 21 C.F.R. § 814.39(a).

[6] MedTech Dive, FDA Flags 428 Spinal Cord Stimulator Patient Deaths, Urges More Tests Before Implanting (Sept. 4, 2020), available at https://www.medtechdive.com/news/fda-flags-428-spinal-cord-stimulator-patient-deaths-urges-more-tests-befor/584714/ (last visited on April 23, 2026).

[7] ASRA, Complications of Spinal Cord Stimulator Implantation (Aug. 2019) available at https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation). *See also* Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery. 2006;58(3):481–496. https://doi.org/10.1227/01.NEU.0000192162.99567.96. *See also M*ekhail NA, Mathews M, Nageeb F,

to 40% of SCS patients experience complications from hardware failure (including lead migration and breakage), biological complications (infection, epidural hematoma), or other causes.[8] SCS explant rates have been reported at up to 38%, with most occurring within the first and second year of implantation.[9]

C. Nevro's SCS Products and Regulatory History

27. All Nevro SCS products are regulated as Class III medical devices under product code LGW ("Stimulator, Spinal-Cord, Totally Implanted for Pain Relief"), subject to the PMA pathway under 21 U.S.C. § 360e and 21 C.F.R. Part 814.

28. All Nevro SCS products — the Senza, Senza II, Senza Omnia, and HFX iQ — operate under a single PMA number: P130022. Every successive product generation and indication expansion was handled through PMA supplements.[10]

29. FDA approved PMA P130022 for the original Senza SCS System on May 8, 2015.[11] The original PMA was based on the SENZA-RCT (NCT01609972), a pivotal clinical trial funded by Nevro Corp. Critically, the original PMA record for P130022 does not indicate an independent advisory committee was convened prior to approval.[12]

Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. Pain Pract. 2011;11(2):148–153. https://doi.org/10.1111/j.1533-2500.2010.00407.x.

[8] Vanessa Choi Yin Wong et al., *Risk Factors for Spinal Cord Stimulator Explant After Implantation for Neuropathic Pain: A Systematic Review*, Neuromodulation (Mar. 6, 2026), https://doi.org/10.1016/j.neurom.2026.02.001, available at https://www.sciencedirect.com/science/article/pii/S1094715926000280.

[9] Amruta Pai et al., *Spinal Cord Stimulation Explantation and Chronic Pain*, 2025 J. *Pain Res.* (PMC), PMCID: PMC11929510, at *Conclusion* (Mar. 17, 2025), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11929510/.

[17] *See generally* U.S. Food and Drug Administration, Summary of Safety and Effectiveness Data (SSED), PMA P130022, Nevro Senza SCS System (2015), available at https://www.accessdata.fda.gov/cdrh_docs/pdf13/p130022b.pdf.

[18] *See* U.S. Food and Drug Administration, Summary of Safety and Effectiveness Data (SSED), PMA P130022, Nevro Senza SCS System (2015), available at https://www.accessdata.fda.gov/cdrh_docs/pdf13/p130022b.pdf.

[12] *Id*.

30. Nevro's subsequent SCS systems received approval through PMA supplements: the Senza II was approved via Supplement S013 in January 2018[13]; the Senza Omnia was approved via Supplement S023 in July 2019[14]; and the HFX iQ was approved via Supplement S044 in October 2022.[15] The complete PMA supplement history for P130022 is publicly available.[16]

31. As a condition of PMA approval, Nevro was required to maintain ongoing post-approval obligations under 21 C.F.R. § 814.84, including submission of annual post-approval study reports, timely Medical Device Reports ("MDRs") for serious injuries (within 30 days) and events requiring remedial action (within 5 days), and submission of PMA supplements for any changes to the device's design or manufacturing process.[17] Any failure to meet these obligations constitutes a violation of PMA conditions and potentially a misbranding or adulteration violation under 21 U.S.C. §§ 331 and 351.[18]

32. MAUDE adverse event reports for Nevro's SCS devices document instances of device malfunction, lead failure, and patient injury.[19]

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[13] Premarket Approval (PMA), P130022/S013, FDA (Jan. 2018) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130022S013 (last visited April 20, 2026).

[14] Premarket Approval (PMA), P130022/S023 (FDA July 18, 2019) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130022S023 (last visited April 20, 2026).

[15] Premarket Approval (PMA), P130022/S044 (FDA Oct. 12, 2022) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130022S044 (last visited April 20, 2026).

[16] U.S. Food and Drug Administration, Complete PMA Supplement History for P130022, available at https://fda.report/PMA/P130022.

[17] *See* 21 C.F.R. §§ 814.82, 814.84, 803.50, 803.53 (2025).

[18] *See* 21 U.S.C. §§ 331(a)–(b), 351 (2025); 21 C.F.R. § 814.82(c) (2025).

[19] *See* U.S. Food and Drug Administration, MAUDE Adverse Event Search – Product Code LGW (Nevro Corp.), available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. (last visited April 20, 2026). *See e.g.*, U.S. Food and Drug Administration, MAUDE MDR Report No. 18791332 (Nevro Corp. Senza), available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=18791332&pc=LGW. *See also e.g.*, U.S. Food and Drug Administration, MAUDE MDR Report No. 23606092 (Nevro Corp. Spinal Cord Stimulator, Malfunction), available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=23606092&pc=LGW. *See also e.g.*, U.S. Food and Drug Administration, MAUDE MDR Report No. 17605365 (Nevro Corp. Spinal Cord Stimulator), available at

D. Known Lead Failure Risks and Resulting Permanent Nerve Damage

33. The electrical components of the Nevro SCS Products have an unacceptably high rate of failure, including lead fracture, insulation breach, and migration from the implantation site. These lead failures are not incidental side effects of an otherwise effective therapy; they are evidence of fundamental defects in the design and manufacture of Nevro's leads.

34. When SCS components fail, whether by fracturing, breaching insulation, or migrating, the electrical current delivered to the spinal cord is no longer directed to the therapeutic target. Uncontrolled electrical stimulation can cause burning pain, electrical shocking sensations, nerve irritation, and ultimately permanent nerve damage if the device is not promptly removed.

35. Published peer-reviewed literature reporting real-world SCS outcomes, including Nevro devices, documents post-market lead migration rates ranging from 13.2% to 22.6%, far exceeding the rates disclosed in Nevro's manufacturer-funded clinical trial.[20]

36. The permanence of nerve damage resulting from delayed device removal is a foreseeable and known consequence of lead failure. When a failing or migrated lead continues to deliver uncontrolled stimulation, nerve injury progresses over time. The longer a failing device remains implanted, the greater the potential for permanent

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=17605365&pc=LGW.

[20] ASRA, Complications of Spinal Cord Stimulator Implantation (Aug. 2019) (reporting post-market lead migration rates of 13.2%–22.6% in published literature), available at https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation). *See also* Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery. 2006;58(3):481–496. https://doi.org/10.1227/01.NEU.0000192162.99567.96. *See also M*ekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. Pain Pract. 2011;11(2):148–153. https://doi.org/10.1111/j.1533-2500.2010.00407.x.

neurological harm. Prompt recognition and removal are therefore essential to preventing permanent injury.

37. Representations by Nevro's sales representatives that discouraged or delayed removal, as described herein, directly and foreseeably worsened the permanence and severity of Plaintiff's nerve injuries.

E. Nevro's Deviations from FDA-Approved Manufacturing Processes and cGMP Regulations

38. Manufacturers of PMA-approved Class III medical devices are required to comply with the FDA's Quality System Regulation ("QSR"), also known as Current Good Manufacturing Practices ("cGMP"), codified at 21 C.F.R. Part 820. These regulations impose non-discretionary, binding legal obligations on Nevro.

39. Upon information and belief, Nevro violated cGMP requirements including, but not limited to:

- 21 C.F.R. § 820.30 (Design Controls): Nevro failed to establish and maintain adequate design controls sufficient to ensure the leads of its SCS products conformed to design specifications and performance standards established by the FDA-approved PMA, including specifications governing lead structural integrity, insulation integrity, and electrical performance.
- 21 C.F.R. § 820.70 (Production and Process Controls): Nevro failed to establish and maintain adequate process controls to ensure the consistent production of leads conforming to approved specifications, including failure to identify and control manufacturing variables contributing to lead fracture and insulation failure.
- 21 C.F.R. § 820.75 (Process Validation): Nevro failed to adequately validate its manufacturing processes for leads to ensure consistent product conformance, including failure to validate processes capable of producing leads that maintain their structural integrity under physiological conditions.
- 21 C.F.R. § 820.100 (Corrective and Preventive Action — CAPA): Nevro failed to implement adequate corrective and preventive action in response to known patterns of lead failure identified in post-market MAUDE data and field reports, including failure to analyze the root causes of lead fractures and insulation breaches and to implement effective corrections.

40. Nevro's lead products were manufactured at multiple manufacturing sites, including facilities in Redwood City, California; Costa Rica (Cirtec); and other locations.[21] Each manufacturing site was subject to FDA inspection and to Nevro's obligation to submit PMA supplements for manufacturing site changes.[22] Manufacturing site changes, process changes, and supplier changes each required submission and approval of appropriate PMA supplements before implementation. Nevro was required to maintain identical product quality across all sites.

41. The pattern of lead and device failures in Nevro's SCS products, as documented in MAUDE reports and reflected in Plaintiff's injuries, is consistent with deviations from Nevro's FDA-approved manufacturing specifications and cGMP requirements. When an SCS lead fractures, breaches its insulation, or migrates in a manner inconsistent with the device's approved design specifications, the device has deviated from Nevro's approved design specifications, formula, and performance standards.[23]

42. These cGMP violations caused Nevro's defective SCS devices to reach the market and be implanted in Plaintiff. They constitute the parallel state-law duties imposed by Ohio Rev. Code § 2307.74, which likewise prohibits the marketing of products that deviate from the manufacturer's design specifications.[24] These claims

[21] Nevro Corp., 10-K Annual Report (2023), available at https://www.annualreports.com/Company/nevro-corp (last visited April 20, 2026).
[22] *See e.g.,* Nevro Corp., Press Release: FDA Approval of Costa Rica Manufacturing Operations (Oct. 4, 2022).
[23] U.S. Food & Drug Admin., Summary of Safety & Effectiveness Data (SSED) for P130022/S039 tbl.6 (Aug. 16, 2021), https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022S039B.pdf (listing lead migration, insulation breaches, and device malfunction as potential risks inconsistent with approved device performance). *See also* Ohio Rev. Code § 2307.74.
[31] Ohio Rev. Code § 2307.74.

impose the same duty as, rather than a different duty from, the applicable federal requirements.

F. Nevro's Sales Representatives and the Unauthorized Practice of Medicine

43. At all relevant times, Nevro employed and deployed clinical and sales representatives to assist with and actively participate in the selection, implantation, programming, and post-operative management of its SCS devices in Ohio and throughout the United States at both the trial and permanent device stages.

44. Nevro's sales representatives, including the representative(s) who interacted with Plaintiff, were not licensed physicians or healthcare providers. Nevertheless, in the course and scope of their employment with Nevro, these representatives routinely:

- Participated in and directed the programming of Plaintiff's SCS devices, including selection of stimulation parameters, waveforms, amplitude, and frequency settings, during implantation surgery and post-operative care.
- Made real-time clinical decisions about device settings based on their own assessment of patient responses, substituting their judgment for that of Plaintiff's licensed treating physician.
- Advised Plaintiff and Plaintiff's physicians about medical treatment decisions concerning the SCS devices, including recommendations to continue implantation therapy and undergo reprogramming.
- Directly reprogrammed Plaintiff's SCS devices on post-operative occasions, including on occasions when Plaintiff's treating physician was not present.
- Made representations directly to Plaintiff — acting as medical advisors — about the expected therapeutic outcomes of the devices and the anticipated results of devices reprogramming, in a manner intended to and having the effect of influencing Plaintiff's treatment decisions.

45. Ohio law defines the practice of medicine to include, among other things, prescribing, advising, recommending, administering, or dispensing, for compensation of any kind, direct or indirect, an appliance or treatment of whatever nature for the cure or relief of a bodily injury, infirmity, or disease. Ohio Rev. Code § 4731.34(A)(3)(b).[25]

[25] Ohio Rev. Code § 4731.34(A)(3)(b)

46. These activities constituted the practice of medicine within the meaning of Ohio Rev. Code § 4731.34, performed without a license in violation of Ohio Rev. Code § 4731.41. No person may practice medicine in Ohio without a valid license or certificate from the Ohio State Medical Board. Ohio Rev. Code § 4731.41(A).[26]

47. Nevro's sales representatives also made materially false and misleading statements to Plaintiff concerning:

a. the effectiveness of the SCS devices in providing long-term pain relief;

b. the safety profile of the devices, including the risks of lead failure and nerve damage;

c. the significance of complications Plaintiff was experiencing, which representatives falsely characterized as minor, adjustable issues rather than as symptoms of device failure; and

d. the likely outcome of continued reprogramming, which representatives falsely represented would resolve Plaintiff's complications.

48. These misrepresentations were made to induce Plaintiff to (a) agree to the initial implantation of the SCS devices, and (b) delay or forgo removal of the devices after complications arose.

49. Nevro's representatives were authorized and directed by Nevro to engage in this conduct as part of Nevro's device sales and clinical support model.[27] Nevro's compensation structure for its sales and clinical representatives created incentives for representatives to prioritize device sales and continued implantation over the medical welfare of patients.

[26] Ohio Rev. Code § 4731.41(A)
[27] *See* Nevro Corp., Form 10-K (2023)

G. Nevro's Corporate Scheme and Institutional Responsibility

50. The clinical and sales representatives supporting Nevro's SCS devices were employees and/or agents of Nevro and acting within the scope of that relationship while interacting with patients and respective devices as described herein.

51. The conduct of Nevro's sales and clinical representatives described herein was not incidental or isolated. It was the product of a deliberate corporate structure and policy by which Nevro institutionalized the participation of its sales and clinical representatives in the practice of medicine, despite knowing this conduct was unauthorized under state law.

52. Similarly, the widespread and systemic use of false and misleading statements by Nevro's clinical and sales representatives was not isolated or incidental. Rather, it was the product of a deliberate corporate structure and policy by which Nevro incentivized and institutionalized the practice of its representatives' use of false and misleading statements to encourage implantation of its devices, minimize patient concerns, and discourage removal of defective devices.

53. Nevro knew, or in the exercise of reasonable care should have known, that its representatives were:

a. programming and reprogramming SCS devices in ways that constituted the practice of medicine;

b. making medical recommendations and representations to patients outside the representatives' permissible scope; and

c. misleading patients about device performance and complications.

54. Nevro failed to take reasonable steps to prevent, stop, or correct this conduct. Specifically, Nevro:

a. failed to establish and enforce adequate policies limiting the scope of its representatives' participation in device programming to permissible technical support activities;

b. failed to train its representatives on the legal limits of their permissible conduct;

c. failed to supervise its representatives to ensure compliance with applicable law and company policy; and

d. retained representatives whom it knew or should have known were engaging in impermissible conduct.

55. As a direct and proximate result of Nevro's institutional conduct, Plaintiff was induced to undergo SCS implantation, was misled about device performance, and was dissuaded from seeking timely removal of the devices after complications arose, thereby sustaining injuries that would not have occurred or would have been less severe but for Defendants' conduct.

H. Plaintiff's Individual Allegations

56. Plaintiff Paul Pospisil is a resident of Sandusky, Erie County, and a citizen of the State of Ohio.

57. On or about July 3, 2024, Plaintiff was when permanently implanted with a Nevro SCS Device, specifically the Senza HFX iQ, Model No. NIPG 3000, Serial No. 1053906, along with associated Nevro leads and components (collectively, the "Device"), at The University of Toledo Medical Center in Toledo Ohio.

58. On or about January 8, 2025, to address a different area of the spine, Plaintiff was permanently implanted with a Nevro SCS Device, specifically the specifically the Senza HFX iQ], Model No. NIPG 3000 Serial No. 1062435, along with associated Nevro leads and components (collectively, the "Device"), at The University of Toledo Medical Center in Toledo Ohio.

59. Prior to and during both implantation processes, Plaintiff interacted with Nevro sales and clinical representatives, including a "Krissy" and "Paige" ("the Representative(s)"). The Representative(s) actively participated in both the selection and implantation processes, including attending the implant procedure, directing or

participating in the intraoperative programming of the Devices, and communicating directly with Plaintiff and Plaintiff's treating physician about the Devices and its expected benefits.

60. Prior to implantation, the Representative(s) represented to Plaintiff that the Devices would provide reliable, long-term pain relief; that the Devices was safe for long-term implantation; and that any initial adjustments or reprogramming would optimize therapeutic outcomes. The Representative(s) failed to advise Plaintiff of the known risk of lead failure, the risk of permanent nerve damage resulting from device failure, and the risk that complications would not be resolvable through reprogramming alone.

61. Plaintiff reasonably relied on the Representative(s)' representations in consenting to the trial implantation of a Nevro SCS device. Had Plaintiff been fully and accurately informed of the risks of lead failure and permanent nerve damage, Plaintiff would not have consented to the implantation or would have elected an alternative treatment.

62. Following the trial period, the Representative(s) made representations that the permanent devices would work like the trial.

63. Plaintiff reasonably relied on the Representative(s)' representations in consenting to the permanent implantation of the Devices. Had Plaintiff been fully and accurately informed of the risks of lead failure and permanent nerve damage, Plaintiff would not have consented to the implantation or would have elected an alternative treatment.

64. Plaintiff initially experienced some pain relief following implantation. Beginning on or about July 24, 2024 and January 29, 2025, respectively, Plaintiff began

to experience burning pain, sporadic electrical shocking sensations, loss of pain relief, numbness, and weakness in his lower extremities.

65. On multiple occasions following the onset of complications, Plaintiff was contacted by or met with the Representative(s), who: (a) attributed Plaintiff's symptoms to sub-optimal device settings rather than device failure; (b) represented that reprogramming would resolve Plaintiff's complications; and (c) reprogrammed the Devices, in some instances without Plaintiff's treating physician present.

66. Plaintiff reasonably relied on the Representative(s)' representations and delayed seeking removal of the Devices. As a direct result of this delay, Plaintiff sustained worsening neurological injury. The longer the Devices — which was causing uncontrolled, injurious electrical stimulation due to lead failure — remained implanted, the more severe and permanent Plaintiff's nerve damage became.

67. Plaintiff has not had the Devices removed yet due to ongoing medical and personal circumstances.

68. As a direct and proximate result of the defective Devices and Defendants' conduct, Plaintiff has sustained and continues to sustain the following injuries and damages: neuropathic pain, motor weakness, emotional distress, loss of enjoyment of life, and past and future medical expenses.

69. Plaintiff discovered the probable causal connection between the Devices, Defendants' conduct, and Plaintiff's injuries on or about August 23, 2024 and February 28, 2025, respectively.

70. Plaintiff did not discover the defects and unreasonably dangerous condition of Defendants' Products, including but not limited to the defective leads, inadequate safety features, and the risks associated with their use — including but not limited to lead fracture, insulation breach, lead migration, and resulting nerve damage — and could

not have discovered the defects and unreasonably dangerous condition of Defendants' Products and the risks associated with their use until recently, due to each Defendant's failure to warn, suppression of material information about the risks of the Products, and the active concealment by Defendants' sales representatives of any defect or fault on Defendants' part. Plaintiff further did not know, and could not have known with reasonable diligence, that Defendants' conduct was the cause of Plaintiff's injuries. Any knowledge Plaintiff had about the general risks of spinal cord stimulator implantation is distinct from the knowledge of Defendants' culpable conduct and the basis of a cause of action, the latter having been gained within the applicable statute of limitation and repose periods.

71. Each Defendant had a duty to disclose that their respective Products were unreasonably dangerous, including disclosing the true rates of lead failure, the known risk of lead fracture and migration causing permanent nerve damage, the limitations of reprogramming as a remedy for hardware failure, and that the use of Defendants' SCS Devices carried with it the serious risk of developing the injuries of which Plaintiff complains herein. Defendants breached that duty.

72. Neither Plaintiff nor the general public had knowledge of, nor any reasonable means of discovering, the harmful conditions in each Defendants' SCS Devices or the true risks associated with their use at the time Plaintiff received and used each Defendants' SCS Devices.

73. None of the Defendants notified, informed, or disclosed to Plaintiff or the general public that each Defendant's respective SCS Devices were unreasonably dangerous, including failing to disclose the true rates of lead failure and migration, the inadequacy of post-implant reprogramming to address hardware defects, the risk of progressive and permanent nerve damage resulting from a retained defective device,

and that the use of Defendants' SCS Devices carried with it the serious risk of developing the injuries of which Plaintiff complains herein.

74. Because each Defendant failed in its duty to notify Plaintiff and the general public that their SCS Devices were unreasonably dangerous, and because Defendants' sales representatives actively concealed from Plaintiff the existence of any defect or fault on Defendants' part — including by attributing Plaintiff's symptoms to causes other than device failure and by representing that reprogramming would resolve Plaintiff's complaints — Defendants should be estopped from asserting defenses based on statutes of limitation or repose, including but not limited to any theories of equitable tolling or contra non valentem.

75. Further, the relationship between Plaintiff's injuries and Defendants' conduct — including the defective leads, the failure of Defendants to disclose known post-market complication data, and the active concealment of device defects by Defendants' sales representatives — was inherently difficult to discover, in part due to Defendants' knowing suppression of material safety and risk information, and Plaintiff had no actual or constructive knowledge of the causal relationship between Plaintiff's injuries and the use of Defendants' SCS Devices.

76. Some of Plaintiff's injuries are latent in nature, developing progressively over time following implantation of defective devices, such that while symptoms became apparent upon onset, Plaintiff did not know and could not reasonably have known that those symptoms were caused by a defect in Defendants' SCS Devices rather than by other conditions or the natural course of Plaintiff's underlying diagnosis.

77. Plaintiff is a lay individual who was, until recently, unaware that exposure to Defendants' SCS Devices and the defects therein — including defective leads prone to fracture, migration, and insulation breach — could cause or contribute to the permanent

nerve damage and other injuries of which Plaintiff complains, and who reasonably relied on representations by Defendants' sales representatives that the devices were functioning properly and that Plaintiff's symptoms had causes unrelated to any device defect.

78. Plaintiff was unaware of any publicly available information sufficient to put Plaintiff on notice of a causal association between exposure to Defendants' SCS Devices and the injuries suffered, particularly given Defendants' active concealment of post-market complication data and the affirmative misrepresentations of Defendants' sales representatives that no defect existed.

V. CAUSES OF ACTION

COUNT I: MANUFACTURING DEFECT

Ohio Rev. Code § 2307.74

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

80. At all times relevant to this action, Defendants were the manufacturer and/or distributors that designed, produced, created, made, constructed, and/or assembled the SCS devices that was placed into the stream of commerce.

81. The SCS devices were expected to, and did, reach the ultimate user, including Plaintiff, without substantial change in condition.

82. Under Ohio Rev. Code § 2307.74, a product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards.

83. The Devices implanted in Plaintiff — including the Nevro SCS leads — was defective in manufacture within the meaning of Ohio Rev. Code § 2307.74. The Devices deviated materially from Nevro's FDA-approved design specifications, formula, and performance standards for the leads, including specifications governing structural integrity, insulation integrity, and electrical performance. As manufactured and as implanted in Plaintiff, the Devices failed to maintain its structural integrity and electrical insulation, resulting in lead migration causing uncontrolled electrical stimulation and pain.

84. Defendants violated non-discretionary federal manufacturing and quality system regulations in the production of the Devices, specifically:

- 21 C.F.R. § 820.30: Failure to implement adequate design controls to ensure products conform to approved design specifications;
- 21 C.F.R. § 820.70: Failure to establish adequate production and process controls to ensure product conformity;
- 21 C.F.R. § 820.75: Failure to validate manufacturing processes capable of consistently producing leads conforming to approved specifications;
- 21 C.F.R. § 820.100: Failure to implement corrective and preventive action in response to known patterns of lead failure; and

85. Because of Defendant's failures to implement adequate design controls to ensure products conform to approved design specifications; establish adequate production and process controls to ensure product conformity; validate manufacturing processes capable of consistently producing leads conforming to approved specifications; implement corrective and preventive action in response to known patterns of lead failure; and take adequate corrective action, the SCS Device implanted in Plaintiff deviated in a material way from the design specifications, formula, or

performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards and thus violated state law requirements that parallel federal requirements.

86. These defects existed at the time the Devices left Defendants' control and were not detectable by Plaintiff or Plaintiff's treating physicians through reasonable inspection prior to implantation.

87. Defendants' SCS Devices were defective in that at the time it left control of Defendants, the foreseeable risks associated with its design exceeded the benefits associated with that design, including but not limited to lead migration, burning and pain.

88. The SCS Devices were in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.

89. At all times herein mentioned, the SCS Devices were in a defective condition and unsafe, and Defendants knew, or had reason to know, that they were defective and unsafe, especially when used as instructed by Defendants and their agents and in the form and manner provided by Defendants and their agents.

90. Had Defendants complied with the Current Good Manufacturing Practices, 21 CFR 820 regulations and parallel state requirements under the Ohio Products Liability Act, the defect in Plaintiff's devices would not have occurred and/or would have been timely discovered so as to prevent Plaintiff from receiving a defective, malfunctioning SCS Devices.

91. As a direct and proximate result of Defendants' manufacturing defects and violations of state law, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

92. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT II: DESIGN DEFECT

Ohio Rev. Code § 2307.75

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

94. At all times relevant to this action, Defendants were the manufacturers and/or distributors that designed, produced, created, made, constructed, and/or assembled the SCS Devices that was placed into the stream of commerce.

95. The SCS Devices were expected to, and did, reach the ultimate users, including Plaintiff, without substantial change in condition.

96. Under Ohio Rev. Code § 2307.75, a product is defective in design if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design exceeded the benefits associated with that design.

97. The Nevro SCS devices were defective in design within the meaning of Ohio Rev. Code § 2307.75 because the foreseeable risks of the lead design exceeded the benefits of that design. These risks, which include but are not limited to lead migration and uncontrolled electrical stimulation causing pain and discomfort, weighed against the availability of alternative lead designs offering superior fixation and structural integrity, exceed the benefits.

98. A practical and technically feasible alternative design was available at the time the leads left Defendants' control that would have prevented the harm without substantially impairing the usefulness or intended purpose of the product.

99. Specifically, alternative lead designs providing superior mechanical fixation, improved insulation integrity, and better lead anchoring mechanisms were available and were used in surgical/paddle leads offered in other SCS Devices. These alternative designs would have reduced the risk of lead migration, fracture, uncontrolled electrical exposure, burns and nerve damage without substantially impairing the therapeutic utility of the SCS devices.

100. Additionally, and independently, Defendants made material changes to the design of their SCS leads following original PMA approval without submitting the required PMA supplements under 21 C.F.R. § 814.39(a), or through PMA supplements that failed to comply with applicable regulations. These unauthorized design changes altered the leads' structural and performance characteristics in ways that were not evaluated by the FDA and were not disclosed to Plaintiff or Plaintiff's treating physicians. Defendants' failure to submit required PMA supplements for these design changes violated both federal regulations and the parallel state-law duty not to market an SCS product containing unapproved and undisclosed design modifications.

101. Plaintiff's design defect claim is premised on the parallel state-law duty under Ohio Rev. Code § 2307.75 not to market products with designs whose foreseeable risks exceed benefits.

102. These defects existed at the time the Devices left Defendants' control and were not detectable or otherwise known by Plaintiff or Plaintiff's treating physicians through reasonable inspection prior to implantation or other due diligence.

103. The SCS Devices were in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users and, in particular, Plaintiff.

104. The intended or actual utility of the SCS Devices were not of such benefit to justify the risks described herein.

105. At all times herein mentioned, the SCS Devices were in a defective condition and unsafe, and Defendants knew, or had reason to know, that it was defective and unsafe, especially when used as instructed by Defendants and their agents and in the form and manner provided by Defendants and their agents.

106. As a direct and proximate result of Defendants' design defects and violations of state law, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

107. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT III: FAILURE TO WARN

Ohio Rev. Code § 2307.76

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

109. At all times relevant to this action, Defendants were the manufacturers and/or distributors that designed, produced, created, made, constructed, and/or assembled the SCS Devices that were placed into the stream of commerce.

110. The SCS Devices were expected to, and did, reach the ultimate users, including Plaintiff, without substantial change in condition.

111. Under Ohio Rev. Code § 2307.76, a product is defective at the time of marketing due to inadequate warning if the manufacturer knew, or in the exercise of ordinary care should have known, of the risk or hazard about which it failed to warn, and failed to provide that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type Plaintiff seeks to recover for and in light of the likely seriousness of the harm.

112. Under Ohio Rev. Code § 2307.76, a product is defective due to inadequate post-marketing warning or instruction if the manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages and the manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which Plaintiff seeks to recover compensatory damages and in light of the likely seriousness of that harm.

113. Defendants knew at the time Plaintiff's SCS Devices were marketed, or in the exercise of ordinary care should have known, through post-market surveillance, MAUDE reports, clinical data, and field reports, of the following risks associated with their SCS leads: (a) the high risk of lead fracture, insulation breach, and migration under physiological conditions; (b) the risk of permanent nerve damage resulting from continued exposure to uncontrolled electrical stimulation from failing leads; (c) the risk that complications would not be resolvable through device reprogramming alone; and

(d) the risk that delay in device removal following lead failure would result in increasingly severe and ultimately permanent neurological injury.

114. Defendants breached their duty to warn Plaintiff and Plaintiff's treating physicians by:

- Failing to update the IFU and device labeling to adequately disclose the known post-market rates of lead failure and the risk of permanent nerve damage resulting therefrom, in violation of 21 C.F.R. § 814.39(d);
- Failing to timely submit Medical Device Reports to the FDA for serious injuries and device failures consistent with those experienced by Plaintiff, in violation of 21 C.F.R. § 803.50;
- Failing to investigate, evaluate, and act upon post-market complaints regarding lead failure, in violation of 21 C.F.R. § 820.198;
- Actively conveying, through Defendants' sales and clinical representatives, information to Plaintiff that contradicted, downplayed, and undermined the approved labeling's risk disclosures, including by misrepresenting the significance of Plaintiff's complications and the efficacy of reprogramming as a remedy; and
- Failing to warn Plaintiff, Plaintiff's physicians, and the public that device reprogramming could not cure lead failure and that delay in removal following lead failure would worsen nerve injury.

115. The risks Defendants failed to warn of were not open and obvious risks nor were they a matter of common knowledge.

116. Plaintiff and Plaintiff's treating physicians justifiably relied on Defendants' representations and omissions. Had adequate warnings been provided, Plaintiff would not have consented to implantation of the Devices, and would have sought prompt

removal upon the onset of complications, thereby preventing or mitigating permanent nerve damage.

117. Any warnings provided to Plaintiff's physician or other legally authorized person were inadequate given the direct interaction between Plaintiff and Defendants' agents, particularly in light of those agents' representations which contracted, downplayed or otherwise refuted the warnings or instructions provided by Defendants. Plaintiff reasonably relied upon the representations of those agents.

118. Plaintiff's failure-to-warn claim is premised on parallel state-law duties under Ohio Rev. Code § 2307.76 that mirror Defendants' federal obligations under 21 C.F.R. §§ 803.50, 814.39(d), and 820.198.

119. As a direct and proximate result of Defendants' design defects and violations of state law, Plaintiff suffered the injuries and damages described herein, including pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

120. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT IV: FAILURE TO CONFORM TO REPRESENTATIONS

Ohio Rev. Code § 2307.77

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

122. At all relevant times, Defendants were the designers, manufacturers, marketers, sellers, and distributors of the Nevro SCS Products, including the Devices implanted in

Plaintiff, and are "manufacturers" as defined under the Ohio Products Liability Act ("OPLA"), Ohio Rev. Code § 2307.71(K).

123. Ohio Rev. Code § 2307.77 provides that a product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A "representation" within the meaning of § 2307.77 includes any express statement of fact concerning the character, quality, or safety of a product made by the manufacturer in connection with the marketing or sale of the product.

124. Defendants made material express representations of fact concerning the character, quality, and safety of the Nevro SCS Products in connection with their marketing, sale, and distribution of those products, including representations disseminated through their patient-directed website, printed promotional materials, and through their sales and clinical representatives.

125. These representations included, but were not limited to: (a) that the HFX/Senza SCS system has been a "safe and effective approach to managing chronic pain" for over ten years; (b) that the safety of HFX has been "thoroughly studied and proven"; (c) that HFX is "proven safe and effective"; (d) that the system is "clinically proven to deliver superior long-term pain relief"; (e) that "nearly 80% of people with chronic pain have found relief with HFX"; (f) that HFX "works by quieting pain signals at the source, providing continuous relief day and night"; and (g) that "97% of people using HFX to manage their pain report feeling better."[28]

126. In addition to corporate-level representations, Nevro's sales and clinical representatives who interacted with Plaintiff made express representations directly to Plaintiff concerning the character, quality, and safety of the Devices, including

[28] Nevro Corp. (Nevro HFX), Important Safety Information, nevrohfx.com/resources/safety-information/ (last visited Apr. 22, 2026).*See also* How HFX works, https://www.nevrohfx.com/why-hfx/how-hfx-works/ (last visited April 23, 2026).

representations that: (a) the Devices would provide reliable, long-term pain relief; (b) the Devices were safe for long-term implantation; (c) any initial complications could be resolved through reprogramming; and (d) the Devices' performance would be equivalent to or better than the trial experience. These representations were made prior to and during the implantation process and in the post-operative period.

127. The Nevro SCS Products, including the Devices implanted in Plaintiff, failed to conform to the express representations described herein. Specifically: (a) the Devices failed to provide the reliable, long-term pain relief represented by Defendants and their representatives; (b) the complication rate of lead migration experienced by Plaintiff and similarly situated patients far exceeded what was disclosed or suggested by Defendants' safety representations; and (c) reprogramming by Defendants' representatives did not and could not resolve the Devices' failures, contrary to Defendants' representations.

128. These failures to conform to Defendants' representations existed at the time the Devices left Defendants' control. The Devices, as manufactured, implanted, and performing in Plaintiff's body, did not possess the character, quality, or safety characteristics that Defendants represented it possessed.

129. Plaintiff reasonably relied upon Defendants' representations concerning the character, quality, and safety of the Devices in consenting to the trial and permanent implantation of the Devices, and in delaying removal of the Devices after complications arose. Had Plaintiff been accurately informed that the Devices did not conform to Defendants' representations, including but not limited to the fact that it was prone to defects and lead failure and that lead failure could cause permanent nerve damage, Plaintiff would not have consented to implantation or would have sought timely removal, thereby preventing or reducing the injuries Plaintiff sustained.

130. As a direct and proximate result of Defendants' product defect arising from the failure to conform to representations, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health, incidental, and related expenses.

131. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT V: CORPORATE NEGLIGENCE

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

133. Separate and apart from vicarious liability for the acts of their sales representatives, Defendants owed Plaintiff a direct, non-delegable corporate duty of care arising from Defendants' own institutional conduct. Defendants knew their sales and clinical representatives were engaged in the unauthorized practice of medicine and were making material misrepresentations to patients, and Defendants constructed and maintained the corporate structure and compensation scheme that enabled and incentivized this conduct.

134. Defendants breached their corporate duty of care by: (a) designing and implementing a business model that deployed sales and clinical representatives in the operating room and in post-operative care settings in a role that exceeded permissible technical support and constituted the practice of medicine; (b) establishing a compensation structure that financially incentivized representatives to maximize device

implantations and discourage device removal; (c) failing to establish adequate policies and procedures limiting representatives to permissible conduct; (d) failing to train, supervise, and discipline representatives to ensure compliance with applicable state medical practice laws; and (e) affirmatively directing and ratifying the representatives' unlawful conduct.

135. Defendants' corporate negligence was a direct and proximate cause of Plaintiff's injuries, including Plaintiff's initial implantation of the Devices based on misrepresentations, Plaintiff's delayed removal of the Devices based on continuing misrepresentations, and the resulting injuries.

136. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT VI: VICARIOUS LIABILITY

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

138. At all relevant times, Nevro's sales and clinical representatives, including the Representative(s) identified herein, were employees or agents of Nevro acting within the course and scope of their employment and/or agency relationship with Nevro in all respects relevant to this action.

139. The Representative(s)' conduct — including actively participating in device selection, actively participating in device programming, making medical representations to Plaintiff, and advising Plaintiff on treatment decisions regarding the Devices — was undertaken in furtherance of Nevro's business interests, within the

scope of the Representative(s)' assigned duties, and in the manner authorized, directed, or ratified by Nevro.

140. Under the respondeat superior doctrine, Defendants are vicariously liable for all of the Representative(s)' negligent and unlawful acts and omissions committed within the scope of their employment and agency, including: (a) the unauthorized practice of medicine; (b) making false and misleading representations to Plaintiff; and (c) advising Plaintiff to delay removal of the Devices, thereby causing and worsening Plaintiff's permanent nerve damage.

141. Globus Medical, Inc. is also vicariously liable for Nevro's conduct as Nevro's successor, parent, and the entity exercising ultimate ownership and control over Nevro and its operations.

142. As a direct and proximate result of Defendants' vicarious liability for the Representative(s)' conduct, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

143. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT VII: NEGLIGENCE PER SE

UNAUTHORIZED PRACTICE OF MEDICINE
Ohio Rev. Code §§ 4731.34 and 4731.41

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

145. Ohio Rev. Code § 4731.34(A)(3)(b) defines the practice of medicine to include prescribing, advising, recommending, administering, or dispensing for compensation of any kind, direct or indirect, an appliance or treatment of whatever nature for the cure or relief of a bodily injury, infirmity, or disease.[29] Ohio Rev. Code § 4731.41(A) prohibits any person from practicing medicine and surgery, or any of its branches, without the appropriate license or certificate from the Ohio State Medical Board.

146. These statutes are designed to protect patients from unqualified persons making medical treatment decisions, and Plaintiff is a member of the class of persons these statutes were designed to protect. The harms Plaintiff suffered, caused by the prolonged implantation of failing devices at the direction of unlicensed representatives, are precisely the type of harms these statutes were designed to prevent.

147. Nevro's sales and clinical representatives, acting within the scope of their employment with and as agents of Nevro, violated Ohio Rev. Code §§ 4731.34 and 4731.41 by engaging in the practice of medicine — specifically, by advising, recommending, and administering device treatment (including programming, reprogramming, and medical recommendations) for the relief of Plaintiff's pain and other medical conditions — without being licensed to practice medicine in the State of Ohio.

148. The Representative(s)' conduct of programming and reprogramming Plaintiff's implanted SCS devices, advising Plaintiff on treatment decisions, and making medical determinations about the appropriate device settings for Plaintiff's condition constituted the practice of medicine within the meaning of Ohio Rev. Code § 4731.34. This conduct was performed for compensation — as the representatives were

[38] Ohio Rev. Code § 4731.41(A).

compensated by Nevro based on, inter alia, continued use and deployment of Nevro's SCS devices.

149. Defendants' violation of Ohio Rev. Code §§ 4731.34 and 4731.41 constitutes negligence per se under Ohio law. Plaintiff need not separately prove that the conduct was unreasonable; the violation of these statutes establishes breach of duty as a matter of law.

150. Defendants' violations of Ohio Rev. Code §§ 4731.34 and 4731.41 were a direct and proximate cause of Plaintiff's injuries. Specifically, because Plaintiff relied on the representations of the Representative(s), who were masquerading as qualified clinical advisors, Plaintiff consented to implantation of the Devices and delayed their removal after complications arose, thereby sustaining permanent neurological injury.

151. This claim is based entirely on state law violations and is not preempted by the MDA or the FDCA.

152. As a direct and proximate result of Defendants' violation of these laws, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

153. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT VIII: NEGLIGENT SUPERVISION

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

155. Defendants owed a duty to Plaintiff to adequately supervise their sales and clinical representatives to ensure those representatives did not: (a) engage in the unauthorized practice of medicine; (b) make material misrepresentations to patients regarding the safety and efficacy of Defendants' SCS devices; or (c) advise patients to retain failing devices contrary to those patients' medical interests.

156. Defendants knew or, in the exercise of reasonable care, should have known that their representatives were engaging in the unauthorized practice of medicine, making material misrepresentations to patients, and inducing patients to delay device removal. This knowledge arose from, among other sources: (a) the nature of the representatives' assigned roles, which placed them in clinical settings with patients and physicians; (b) the compensation structure, which incentivized the conduct described herein; and (c) actual notice through complaints, adverse event reports, and publicly filed litigation.

157. Defendants breached their duty of supervision by failing to adequately monitor, review, and correct the conduct of their representatives; by failing to implement and enforce compliance protocols limiting representatives to permissible non-medical technical support activities; and by failing to take corrective action upon learning of instances of impermissible conduct.

158. Defendants' breach of their supervisory duty was a direct and proximate cause of Plaintiff's injuries, in that the absence of adequate supervision allowed the Representative(s)' unlawful conduct to continue unchecked, resulting in Plaintiff's implantation and delayed removal of defective devices and the permanent damage resulting therefrom.

159. As a direct and proximate result of Defendants' design defects and violations of state law, Plaintiff suffered the injuries and damages described herein, including

chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

160. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT IX: NEGLIGENT TRAINING

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

162. Defendants owed a duty to Plaintiff to adequately train their sales and clinical representatives on: (a) the legal scope of their permissible activities in clinical settings, including the prohibition on the unauthorized practice of medicine; (b) the accurate, truthful, and complete disclosure of the risks and limitations of the Nevro SCS Products to patients and physicians; and (c) the proper response to patient complaints, complications, and signs of device failure, including advising patients to seek timely medical evaluation and, where warranted, device removal.

163. Defendants breached their duty to train their representatives by: (a) failing to provide training on the applicable legal prohibitions on the unauthorized practice of medicine; (b) training representatives to minimize, dismiss, and counter patient concerns about device complications and to encourage continued device use regardless of patient symptoms; (c) training representatives to represent that reprogramming would resolve complications without disclosing that reprogramming cannot remediate lead failure; and (d) failing to train representatives on the known risk of permanent nerve damage arising from delayed removal of a failing device.

164. Defendants' breach of their duty to train their representatives was a direct and proximate cause of Plaintiff's injuries. Had the Representative(s) been adequately trained, they would not have engaged in the unauthorized practice of medicine with respect to Plaintiff, would not have made material misrepresentations about device performance and the significance of complications, and would not have discouraged Plaintiff from seeking timely removal of the failing Devices.

165. As a direct and proximate result of Defendants' negligent training, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

166. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT X: NEGLIGENT RETENTION

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

168. Defendants owed a duty to Plaintiff to not retain sales and clinical representatives whom they knew, or in the exercise of reasonable care should have known, were engaging in conduct that posed an unreasonable risk of harm to patients, including by engaging in the unauthorized practice of medicine and making material misrepresentations to induce device implantation and discourage removal.

169. Upon information and belief, Defendants knew or should have known that the Representative(s) who interacted with Plaintiff had, prior to their interactions with

Plaintiff, engaged in the same pattern of conduct with other patients and in other clinical settings — engaging in the unauthorized practice of medicine, making misleading representations, and improperly discouraging device removal. This knowledge arose from, inter alia, the systemic nature of the conduct (which reflected Defendants' institutional practices rather than individual deviation), prior patient complaints, and prior adverse event reports.

170. Despite this knowledge, Defendants retained the Representative(s) in their positions, and the Representative(s) continued to engage in this conduct with Plaintiff. Defendants' decision to retain the Representative(s) in these roles, despite knowledge of their propensity for the conduct described herein, was a direct and proximate cause of Plaintiff's injuries.

171. As a direct and proximate result of Defendants' negligent retention of its agents, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

172. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT XI: FRAUDULENT CONCEALMENT

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

174. At all relevant times, Defendants, as manufacturers and distributors of a Class III PMA-approved medical devices implanted in Plaintiff, had superior knowledge of

material facts concerning the safety and performance of their SCS products that were not known to Plaintiff or to Plaintiff's treating physicians and were not reasonably discoverable through inspection. This superior knowledge, combined with Defendants' partial affirmative representations concerning the safety and efficacy of the Devices, created an affirmative duty upon Defendants to disclose the concealed facts.[30]

175. Defendants and their agents knowingly concealed and/or with such utter disregard and recklessness as to whether it was true, material facts concerning the true nature and rate of the Devices' failures and associated risks, including: (a) that the Nevro SCS leads had an unacceptably high real-world rate of lead fracture, insulation breach, and migration, substantially exceeding the rates reported in Defendants' manufacturer-funded clinical trial and the rates suggested by Defendants' marketing representations; (b) that published post-market data documented real-world lead migration and failure rates between 13.2% and 22.6%, data that was known to Defendants through their post-approval surveillance obligations but was not disclosed to patients or prescribing physicians in Defendants' marketing or promotional materials; (c) that lead failure could cause and was causing, in implanted patients, permanent nerve damage and neurological injury; (d) that reprogramming by Defendants' sales representatives could not remediate lead fracture, insulation breach, lead migration or resulting injury; and (e) that continued implantation of a failing SCS device would cause progressive, permanent nerve injury.

176. Defendants and their agents additionally concealed, from Plaintiff and Plaintiff's treating physicians, material facts concerning the qualifications and conduct

[30] *See* 21 C.F.R. §§ 814.82 and 814.84; ASRA, Complications of Spinal Cord Stimulator Implantation (Aug. 2019), available at https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation.

of their sales and clinical representatives, including: (a) that these representatives were not licensed healthcare providers and were not authorized to perform the medical functions they were in fact performing; (b) that these representatives were operating outside the permissible scope of sales representative activity and were engaging in the unauthorized practice of medicine under Ohio law; and (c) that these representatives were trained and incentivized to encourage device implantation and discourage device removal, regardless of patient symptoms, in a manner that prioritized Defendants' financial interests over patient welfare.

177. These concealed facts were material to Plaintiff's decisions concerning: (a) whether to consent to the trial implantation of a Nevro SCS device; (b) whether to consent to the permanent implantation of the Devices; and (c) whether to seek timely removal of the Devices after complications arose. A reasonable person in Plaintiff's position would have considered these facts important or material in deciding whether to undergo implantation of and continued exposure to the Devices.

178. Defendants and their agents concealed these material facts with the intent to induce Plaintiff to consent to and maintain implantation of the Devices, thereby generating and preserving revenue from Device sales and continued implantation. Defendants' concealment was not inadvertent or negligent. Instead, it was the product of a deliberate corporate strategy to maximize device adoption and minimize removal rates by withholding adverse information from patients and their physicians.

179. Plaintiff justifiably relied upon what, unknown to Plaintiff, was Defendants' concealment of these material facts. Plaintiff had no independent means of discovering the true rate of lead failure, the progressive neurological risk of device retention following lead failure, or the actual scope and limitations of Defendants' representatives' authority and qualifications. Plaintiff's reliance was reasonable given

Defendants' superior knowledge, the medical setting of the interactions, and Defendants' affirmative representations concerning the Devices' safety and the representatives' clinical support role.

180. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff consented to implantation of the Devices, delayed seeking its removal following the onset of complications, and sustained injuries that would not have occurred, or would have been substantially less severe, but for Defendants' concealment. Had Defendants disclosed the material facts described herein, Plaintiff would not have consented to implantation or would have sought timely removal of the Devices.

181. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff suffered the injuries and damages described herein, including chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health, incidental, and related expenses.

182. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT XII: FRAUDULENT MISREPRESENTATION

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

184. Defendants made the following specific affirmative representations of material fact, each of which was false when made or became false in light of subsequently known facts that Defendants failed to correct: (a) Defendants' patient-directed website

represented that the HFX/Senza SCS system has been "proven safe and effective" and that its "safety . . . has been thoroughly studied and proven"; (b) Defendants' website represented that "nearly 80% of people with chronic pain have found relief with HFX," and that "97% of people using HFX to manage their pain report feeling better"; (c) Defendants' website represented that HFX is "clinically proven to deliver superior long-term pain relief"; (d) Defendants' sales and clinical representatives represented directly to Plaintiff that the Devices would provide reliable, long-term pain relief; (e) Defendants' representatives represented to Plaintiff that the Devices were safe for long-term implantation; (f) Defendants' representatives represented to Plaintiff, after complications arose, that the complications were attributable to sub-optimal device settings rather than device failure; and (g) Defendants' representatives represented to Plaintiff that reprogramming would resolve Plaintiff's complications.[31]

185. Each of these representations was false. Specifically: (a) the Devices were not "proven safe and effective" for Plaintiff, as it caused lead failure, uncontrolled electrical stimulation, and permanent nerve injury; (b) the real-world complication rates for Nevro SCS devices, including lead migration and failure rates of 13.2% to 22.6% documented in published peer-reviewed literature, materially undermined the safety representations made by Defendants in their marketing and by their representatives to Plaintiff; (c) the representations concerning long-term efficacy were made without adequate post-market data supporting the claimed outcomes at the rates represented; (d) the representatives' characterization of Plaintiff's complications as addressable through reprogramming was false because reprogramming cannot remediate lead fracture, insulation breach, or lead migration; and (e) the representatives' representation

[31] Nevro Corp. (Nevro HFX), Important Safety Information, nevrohfx.com/resources/safety-information/ (last visited Apr. 22, 2026). *See also* How HFX works, https://www.nevrohfx.com/why-hfx/how-hfx-works/ (last visited April 23, 2026).

that the Devices' performance would match the trial experience was false because the permanent devices delivered materially different performance.

186. Defendants made each of these representations knowing they were false or with such utter disregard and recklessness as to their truth or falsity that scienter may be inferred. Defendants' corporate-level representatives possessed actual knowledge of the real-world post-market failure rates of their SCS leads through MAUDE adverse event reporting, post-approval study data, and internal complaint-file data — none of which was accurately reflected in the safety representations made to patients and prescribers.

187. Defendants' sales representatives possessed or were imputed with actual knowledge that the representations they made to Plaintiff concerning the significance of Plaintiff's complications and the efficacy of reprogramming were false, given their direct role in Device programming and their access to device performance data.

188. Defendants made these representations with the intent to induce Plaintiff to: (a) consent to the trial implantation of a Nevro SCS device; (b) consent to the permanent implantation of the Devices; and (c) refrain from seeking removal of the Devices after complications arose, thereby preserving Defendants' revenue from continued device deployment.

189. Plaintiff justifiably relied upon Defendants' and their agents' representations in consenting to the implantation of the Devices and in delaying the removal of the Devices following the onset of complications. Plaintiff had no independent means of verifying the falsity of Defendants' representations at the time they were made. Plaintiff's reliance was reasonable in light of the medical setting, Defendants' superior knowledge as the device manufacturer, and the authority with which Defendants' representatives presented the representations.

190. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff consented to implantation of the Devices, delayed seeking its removal following the onset of complications, and sustained pain and discomfort that would not have occurred, or would have been substantially less severe, but for Plaintiff's reliance on Defendants' false representations.

191. At all relevant times, Defendants are and have been vicariously responsible for the actions and omissions of their agents, servants, contractors, and employees acting within the course and scope of their respective agencies and employment relationships, including the sales and clinical representatives who made the representations described herein.

192. As a direct and proximate result of Defendants' fraudulent misrepresentation, Plaintiff suffered the injuries and damages described herein, chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health, incidental, and related expenses.

193. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT XIII: NEGLIGENT MISREPRESENTATION

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

195. At all relevant times, Defendants were engaged in the business of designing, manufacturing, marketing, and distributing the Nevro SCS Products as Class III medical devices for the treatment of chronic intractable pain. In the course of that

business, and for pecuniary purposes, Defendants supplied information to Plaintiff and to Plaintiff's treating physicians intended to guide those persons in their medical treatment decisions, including the decision to implant and retain the Devices. Defendants had a pecuniary interest in the transactions in which they supplied this information, as Defendants' revenue was derived from device sales and implantations.

196. In the course of their business, Defendants and their agents supplied false information to Plaintiff for Plaintiff's guidance in the decision to undergo implantation and retain the Devices. This false information included: (a) Defendants' public representations that the HFX/Senza SCS system is "proven safe and effective" and that its safety "has been thoroughly studied and proven", when in fact real-world post-market data documented lead failure, lead migration, and device complication rates that materially exceeded the rates suggested by those representations; (b) representations by Defendants' sales and clinical representatives to Plaintiff, before implantation, that the Devices would provide reliable, long-term pain relief and was safe for long-term implantation, when Defendants lacked reasonable grounds for those representations given the known real-world performance data; and (c) representations by Defendants' representatives to Plaintiff, after complications arose, that the complications were attributable to sub-optimal programming rather than device failure and could be resolved through reprogramming, when the representatives lacked reasonable grounds for that conclusion and when known medical literature indicated that lead failure cannot be remediated through reprogramming.[32]

[32] ASRA, Complications of Spinal Cord Stimulator Implantation (Aug. 2019) (post-market lead migration rates of 13.2%-22.6%), available at https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation; Kumar K et al., Spinal cord stimulation in treatment of chronic benign pain, Neurosurgery 58(3):481-496 (2006), https://doi.org/10.1227/01.NEU.0000192162.99567.96; Mekhail NA et al., Retrospective review of 707 cases of spinal cord stimulation, Pain Pract. 11(2):148-153 (2011), https://doi.org/10.1111/j.1533-2500.2010.00407.x.

197. Defendants failed to exercise reasonable care or competence in obtaining or communicating the information supplied to Plaintiff. Specifically: (a) Defendants' corporate-level public representations concerning the safety and effectiveness of the Devices failed to accurately reflect or account for known post-market adverse event data, including MAUDE reports and published peer-reviewed literature documenting lead migration and failure rates of 13.2% to 22.6%; (b) Defendants' sales representatives lacked the medical qualifications and training necessary to make the clinical representations they made to Plaintiff concerning the significance of Plaintiff's complications and the adequacy of reprogramming; and (c) Defendants' training of their representatives failed to ensure that representatives communicated accurate and complete information to patients concerning the risks of lead failure and the limitations of reprogramming as a remedy.

198. At all relevant times, Defendants are and have been vicariously responsible for the actions and omissions of their agents, servants, contractors, and employees acting within the course and scope of their respective agencies and employment relationships, including the sales and clinical representatives who supplied the false information described herein.

199. Plaintiff justifiably relied upon the false information supplied by Defendants in consenting to the implantation of the Devices and in delaying the removal of the Devices following the onset of complications. Plaintiff had no reasonable basis for independently verifying the accuracy of Defendants' representations at the time they were made, and Plaintiff's reliance was reasonable given the medical setting, Defendants' superior knowledge as the device manufacturer, and the authority with which Defendants' representatives communicated.

200. Defendants lacked reasonable grounds for believing the truth of the representations they made. Even if Defendants' corporate-level safety representations were made without actual knowledge of their falsity, those representations were made without the reasonable care and competence required by Ohio law given the post-market surveillance data available to Defendants as a PMA-approved device manufacturer under 21 C.F.R. § 814.84.

201. As a direct and proximate result of Defendants' negligent misrepresentation, Plaintiff consented to implantation of the Devices, delayed seeking its removal following the onset of complications, and sustained pain and discomfort that would not have occurred, or would have been substantially less severe, but for Plaintiff's justifiable reliance on Defendants' false representations.

202. As a direct and proximate result of Defendants' negligent misrepresentation, Plaintiff suffered the injuries and damages described herein, chronic pain and discomfort, and other losses including mental anguish, diminished enjoyment of life, medical, health, incidental, and related expenses.

203. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

COUNT XIV PUNITIVE DAMAGES

Ohio Rev. Code § 2315.21

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

205. Ohio Rev. Code § 2315.21 authorizes the award of punitive or exemplary damages where the defendant acted with malice, engaged in aggravated or egregious fraud, or acted with conscious disregard for the rights and safety of others.

206. Defendants acted with actual malice and/or in conscious disregard of the rights and safety of Plaintiff and similarly situated patients by:

- Knowingly marketing and distributing SCS devices that deviated from FDA-approved manufacturing specifications and cGMP requirements, while concealing known lead failure risks from patients and physicians;
- Constructing and operating a corporate scheme by which sales and clinical representatives were deployed to engage in the unauthorized practice of medicine and to make material misrepresentations to patients for the purpose of maximizing device sales and preventing device removal, in knowing violation of Ohio law;
- Making material misrepresentations to Plaintiff about the performance of the Devices, the nature of Plaintiff's complications, and the efficacy of reprogramming as a remedy, while knowing these representations were false;
- Discouraging Plaintiff from seeking prompt removal of the failing Devices while knowing that continued implantation of the failing Devices would cause progressive and permanent nerve damage; and
- Retaining and continuing to deploy the Representative(s) after having actual or constructive knowledge of the Representative(s)' pattern of impermissible conduct.

207. Defendants' conduct reflects a systematic, willful, and conscious disregard for the rights and safety of Plaintiff and similarly situated patients, making an award of punitive damages appropriate to punish Defendants and deter similar conduct.

208. Plaintiff's claim for punitive damages is subject to the limitations set forth in Ohio Rev. Code § 2315.21(D) and will be pursued in accordance with the procedures set forth therein.

209. WHEREFORE, Plaintiff demands judgment against Defendants Nevro Corp. and Globus Medical, Inc. for compensatory damages, punitive damages where permitted, attorneys' fees where allowed by statute, costs of suit, pre- and post-judgment interest, and all such other and further relief as the Court deems just and proper.

VI. VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff Paul Pospisil respectfully requests that this Court enter judgment in Plaintiff's favor and against Defendants Nevro Corp. and Globus Medical, Inc., jointly and severally, and award the following relief:

1. Compensatory damages for Plaintiff's physical injuries, chronic pain and discomfort, emotional distress, loss of enjoyment of life, past and future medical expenses, lost earnings and earning capacity, and all other economic and non-economic losses in an amount to be determined at trial;

2. Punitive damages as permitted by Ohio Rev. Code § 2315.21 for Defendants' malicious, egregiously fraudulent, or consciously indifferent conduct;

3. Reasonable attorneys' fees and costs of suit as permitted by applicable statute or common law;

4. Pre-judgment and post-judgment interest at the maximum rates permitted by applicable law; and

5. Such other and further relief, whether at law or in equity, as the Court deems just and proper.

Respectfully submitted, this 24th day of April, 2026.

BULLOCK LEGAL GROUP, LLC

/s/ Carasusana B. Wall

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Counsel for Plaintiff

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted, this 24th day of April, 2026.

BULLOCK LEGAL GROUP, LLC

/s/ Carasusana B. Wall

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