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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

HOOVER JOHNSON, JR. Plaintiff, v. BOSTON SCIENTIFIC CORPORATION; and BOSTON SCIENTIFIC NEUROMODULATION CORPORATION; Defendants.	Case No. 2:26-cv-5211 **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**

COMPLAINT - ACTION FOR DAMAGES

Plaintiff Hoover Johnson Jr. ("Plaintiff") by and through undersigned counsel, brings this Complaint against Defendants Boston Scientific Corporation ("BSC"), Boston Scientific Neuromodulation Corporation ("BSNC"), and alleges as follows:

I. INTRODUCTION

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

2. The SCS devices at issue received Food and Drug Administration ("FDA") approval in 2001 under PMA P010032, originally granted to Advanced Neuromodulation Systems, later acquired by St. Jude Medical. Since that time, however, the devices have been fundamentally altered through dozens of PMA supplements, modifying its battery chemistry, firmware, waveform control, leads, and user interface, without the benefit of a new PMA or any renewed clinical safety validation.

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

4. Plaintiff brings this Action under California, and Georgia law, asserting both traditional product liability and statutory claims. Plaintiff seeks compensatory damages for their injuries and equitable relief requiring the FDA to fulfill its statutory

duties and restore integrity to the PMA process.

II. PARTIES, JURISDICTION, AND VENUE

5. **Plaintiff Hoover Johnson Jr.** is a resident and citizen of the State of South Carolina. At the time this Complaint is filed, Plaintiff resides in South Carolina. The devices at issue were implanted in Plaintiff in Georgia. Plaintiff has received medical treatment related to the device in Georgia. Plaintiff had their Boston Scientific SCS permanent device implanted in August 2015. Plaintiff had device removed.

6. Defendant Boston Scientific Corporation ("Boston Scientific") is a corporation organized under the laws of the State of Delaware with its principal place of business located in Marlborough, Massachusetts. Boston Scientific is registered and interacts with the Food and Drug Administration through its offices located at 25155 Rye Canyon Loop, Valencia, CA 91355. Boston Scientific conducts business nationwide and within this District, including the design, manufacture, regulatory submission, and distribution of Class III neuromodulation devices, such as its spinal cord stimulator systems marketed under the trade names Spectra WaveWriter, Precision Spectra, and other similar devices.

7. Defendant Boston Scientific Neuromodulation Corporation ("Boston Scientific Neuromodulation"), is formed under the laws of Delaware, with its stated principal place of business located in Marlborough, Massachusetts. Boston Scientific Neuromodulation conducts business nationwide and within this District, including the design, manufacture, regulatory submission, and distribution of Class III neuromodulation devices, such as its spinal cord stimulator systems marketed under the trade names Spectra WaveWriter, Precision Spectra, and other similar devices. However, its registered agents and listed authorized employees and functional principal place of business is actually 2710 Gateway Oaks Drive, Sacramento, California. In addition, Defendant Boston Scientific Neuromodulation is registered with the FDA as the Specification Developer for the WaveWriter Precision Spectra, the device at issue in this complaint, and other similar devices through its facilities located at 25155 Rye

Canyon Loop, Valencia, CA 91355. As the Specification Developer for the device at issue in this case, Boston Scientific Neuromodulation was responsible for the development and design of the device at issue, including crucial functions such as design validation, gap analysis, and coordination of Corrective and Preventive Actions ("CAPAs") required by the Food, Drug & Cosmetic Act.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(1)–(2) because Defendants effectively reside in this District and a substantial part of the events or omissions giving rise to the claims occurred here.

9. Additionally, Defendant Boston Scientific maintains substantial regulatory and operational facilities in Valencia, California, from which it directs design, testing, regulatory compliance, and post-market surveillance activities for the devices at issue in this case. These activities provide a further basis for venue in this District and establish that a substantial part of the events and omissions giving rise to Plaintiff's claims occurred here.

10. This Court has subject matter jurisdiction over Plaintiff's claims against the Boston Scientific pursuant to 28 U.S.C. § 1332 as the amount in controversy exceeds $75,000 and the parties are citizens of different states.

11. This Court has personal jurisdiction over Defendants because it purposefully directs regulatory, clinical support, post-market surveillance, and commercialization activities relating to the device at issue from facilities located within California and has sufficient minimum contacts with California such that the exercise of jurisdiction comports with traditional notions of fair play and substantial justice.

Applicable Law and Choice of Law Considerations

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

13. California applies a functional choice-of-law analysis that considers the

place where the injury occurred, the place where the conduct causing the injury occurred, the domicile and residence of the parties, and the center of the relationship. *See McCann v. Foster Wheeler*, 225 P.3d 516 (2010); Restatement (Second) of Conflict of Laws § 6.

14. Because this action involves conduct undertaken by a California based corporation and safety-related activities directed from this District, California has a significant interest in regulating corporate conduct occurring within its borders and in ensuring that manufacturers provide complete risk information to physicians and patients.

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

III. FACTUAL ALLEGATIONS REGARDING BOSTON SCIENTIFIC SCS DEVICES AND REGULATORY HISTORY

A. Overview of Spinal Cord Stimulation Devices and Their Intended Use

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

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

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

19. Due to these inherent risks, SCS devices are classified by the FDA as Class III medical devices. The federal regulatory framework is referenced solely to describe the type of safety information ordinarily available to manufacturers of

implantable medical devices and relied upon by physicians when making treatment decisions, and not as an independent basis for liability.

B. Boston Scientific's Device Portfolio and Regulatory Approval History

20. Boston Scientific's spinal cord stimulator product line originates from PMA P030017, initially approved by the FDA in 2004 for its Precision Spinal Cord Stimulator System.

21. Since the original approval of P030017, Boston Scientific has introduced numerous subsequent models and upgrades under PMA supplements, including the Precision Plus, Precision Spectra, and Spectra WaveWriter systems.

22. These newer generations of devices incorporated significant modifications, including multiwaveform stimulation (simultaneous tonic, burst, and sub-perception modes), posture-adaptive programming, expanded electrode arrays, Bluetooth-enabled programming, and major revisions to battery architecture and lead designs.

23. Boston Scientific marketed its Spectra WaveWriter system and successor models while omitting material risk information known to the manufacturer that would have been important to physicians and patients when deciding whether implantation was appropriate.

24. The defects alleged herein concern the PMA-approved spinal cord stimulation system and its component parts implanted in Plaintiff.

C. Material Changes to Device Architecture and Functionality

25. Over time, Boston Scientific introduced substantial modifications to the originally approved Precision SCS system, including:

- The addition of simultaneous multiwaveform stimulation, including tonic, burst, and sub-perception programming (PMA Supplement P030017/S015, approved November 14, 2012);
- The redesign of the implantable pulse generator battery system and addition of Bluetooth-enabled wireless communication capabilities

(PMA Supplement P030017/S032, approved August 9, 2016);

- The integration of posture-adaptive stimulation algorithms (PMA Supplement P030017/S032);
- The expansion of lead configurations and multi-source current delivery systems (PMA Supplements P030017/S015 and S032).

26. These modifications affected the device's performance characteristics and created risk information material to physician treatment decision-making that a reasonably prudent manufacturer would communicate to healthcare providers and patients.

27. After implementing design and performance changes, a reasonably prudent manufacturer would evaluate resulting safety information and communicate material risk information necessary for physicians to make informed treatment decisions.

D. Regulatory Manipulation and Abuse of the PMA Supplement Process

28. Boston Scientific possessed safety information concerning performance limitations and complications associated with the device but did not adequately communicate that information to physicians and patients.

29. The omission of this information deprived treating physicians of material risk information necessary to evaluate whether implantation was appropriate.

30. As a direct consequence, physicians recommended implantation without complete safety information relevant to the treatment decision.

E. Post-Market Failures, Adverse Events, and Concealment of Risks

31. Publicly available MAUDE (Manufacturer and User Facility Device Experience) database entries, peer-reviewed studies, and post-market surveillance data demonstrate that Boston Scientific's SCS systems are associated with serious complications, including:

- Device migration and loss of therapeutic coverage;
- Lead fractures requiring surgical revision;

- Battery depletion and communication failures;
- Stimulation-induced autonomic dysfunction, including urinary incontinence and orthostatic hypotension;
- Persistent ineffective pain relief despite extensive reprogramming.

32. Despite knowledge of these adverse outcomes, Boston Scientific did not communicate updated risk information to physicians and patients that a reasonably prudent medical device manufacturer would disclose for informed medical decision-making.

33. Peer-reviewed literature has increasingly associated SCS therapy, particularly multiwaveform stimulation platforms like Spectra WaveWriter, with autonomic side effects that required communication of risk information to physicians and patients.

34. Plaintiff's injuries are consistent with risks that treating physicians consider material when evaluating whether implantation of a spinal cord stimulation system is appropriate and when determining whether alternative treatment options should be recommended.

IV. REGULATORY FRAMEWORK AND DUTIES

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

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

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

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

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

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

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

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

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

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

45. Plaintiff's state-law claims arise under the substantive law determined by the Court's choice-of-law analysis, including California law, and Georgia law and, to the extent applicable, the law of any jurisdiction whose consumer protection or product liability law governs specific issues in this action. Federal requirements are referenced solely to define parallel safety duties and not as independent causes of action.

V. PLAINTIFF-SPECIFIC ALLEGATIONS

46. On or about June 1, 2022, Plaintiff was surgically implanted with a Boston Scientific permanent spinal cord stimulator system (SCS).

47. Plaintiff was told by Boston Scientific's sales representative that the permanent device would relieve most of Plaintiff's pain. In reality, the device provided minimal pain relief, numbness or loss of control of extremities in the arms and legs, burns from the unit itself, erectile dysfunction, heart issues and depression, despite being initially programmed by a Boston Scientific sales representative.

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

49. Boston Scientific's conduct with regard to Plaintiff represented a consistent pattern and practice.

50. Immediately after the permanent implant surgery, a Boston Scientific representative programmed and made therapeutic adjustments to the SCS system without meaningful physician supervision. Plaintiff's device was reprogrammed at least five times throughout the time it was implanted.

51. Throughout the time that Plaintiff were implanted with a SCS system manufactured by Boston Scientific or its predecessors, they were required to undergo additional procedures.

52. All leads used in the SCS systems implanted in Plaintiff were manufactured and sold by Boston Scientific or its predecessors.

53. Plaintiff had SCS device surgically removed from their body.

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

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

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

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

VI. DEFENDANTS' MISREPRESENTATIONS, OMISSIONS, AND REGULATORY VIOLATIONS

A. Failure to Disclose Material Risks

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

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

60. Boston Scientific represented to Plaintiff, his healthcare providers, and the medical community that its spinal cord stimulation systems were safe, effective, and appropriate for long-term implantation.

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

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

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

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

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

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

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

B. Violations of Current Good Manufacturing Practices (cGMPs)

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

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

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

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

VII. CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Applicable State Product Liability Law)

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

73. At all times relevant to this action, Boston Scientific and Boston Scientific Neuromodulation (collectively, "Boston Scientific") were engaged in the business of designing, manufacturing, testing, labeling, distributing, and selling medical devices, including the spinal cord stimulator systems implanted in Plaintiff.

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

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

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

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

78. Under all applicable state law, Boston Scientific is strictly liable for injuries caused by a manufacturing defect that rendered the device unreasonably dangerous at the time it left its control.

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

and other damages.

COUNT II – FAILURE TO WARN

(Failure to Warn Under Applicable State Law)

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

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

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

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

84. Boston Scientific failed to update its Instructions for Use (IFU), patient education materials, and physician-facing labeling to disclose: the risk of painful stimulation spikes or loss of therapy during wireless charging; the instability of firmware updates and potential for loss of device communication; the increased rate of lead migration and therapy failure reported post-market; the cumulative nature of the device's evolution, and that its current form bore little resemblance to the device described in PMA P010032 or its Summary of Safety and Effectiveness Data.

85. The failure to warn was compounded by Boston Scientific's internal knowledge of these risks, including MAUDE reports, post-market complaint data, and prior design and validation issues. Despite this knowledge, Boston Scientific continued to represent the device as "safe and effective" and failed to initiate field safety

notifications, device labeling changes, or provider education consistent with 21 C.F.R. § 814.39(d) or 21 C.F.R. § 820.198.

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

87. Plaintiff's injuries were caused in whole or in part by Boston Scientific's failure to warn of known or knowable dangers associated with the use of its product. These failures rendered the device unreasonably dangerous for its intended use and constitute a defect Under all applicable state law.

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

COUNT III – NEGLIGENCE PER SE – FEDERAL REGULATORY VIOLATIONS

(Under Applicable State Law)

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

90. Under all applicable state law, a person injured by the violation of a statute or regulation intended to protect the class of persons to which that person belongs may recover damages under a theory of negligence per se.

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

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

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

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

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

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

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

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

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

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

94. Boston Scientific violated design and manufacturing regulations by failing to validate the performance of its firmware-dependent stimulation control, Bluetooth-based programming, and battery recharging systems. It also failed to initiate CAPA processes in response to known problems, and did not investigate or disclose known product complaints in accordance with 21 C.F.R. §§ 820.100 and 820.198.

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

96. Plaintiff is a member of the class of persons these statutes and regulations

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

97. As a direct and proximate result of Boston Scientific's violations of federal regulations and All applicable state law, Plaintiff suffered compensable physical injury, pain, medical costs, loss of enjoyment of life, and other damages.

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

COUNT IV – BREACH OF EXPRESS WARRANTY

(Under Applicable State Law)

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

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

101. Prior to the implantation of the spinal cord stimulator devices, Boston Scientific made explicit representations in its promotional materials, device labeling, Instructions for Use (IFU), public statements, and directly to Plaintiff through its sales representatives that the device was safe, effective, reliable, and had been adequately tested for use in human patients suffering from chronic pain.

102. Boston Scientific expressly warranted that its SCS devices provided consistent pain relief, seamless therapy delivery, safe wireless programming, and a rechargeable platform with superior reliability and patient comfort. Boston Scientific's provider materials represented that its SCS systems were "FDA-approved," "clinically

validated," and "designed for long-term use with low complication rates." These claims were repeated in sales brochures, website copy, and Boston Scientific's physician training materials. These claims were repeated directly to Plaintiff through Boston Scientific's sales representatives prior to each of his implant decisions.

103. These affirmations and promises became part of the basis of the bargain between Boston Scientific and Plaintiff, as well as Plaintiff' implanting physicians. Plaintiff and their physicians relied on these representations to proceed with the implantation of the spinal cord stimulator systems.

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

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

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

107. As a result of this breach of express warranty, Plaintiff are entitled to recover all compensatory damages allowed Under all applicable state law, including medical expenses, pain and suffering, and other economic and noneconomic losses.

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

(Under Applicable State Law)

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

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

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

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

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

113. These failures were not caused by misuse or physician error. They were the direct result of design-altering changes Boston Scientific implemented without corresponding clinical testing or validation, and without disclosing these risks in labeling or provider materials. The devices failed to conform to the minimum standards of merchantability and fitness for long-term neuromodulation therapy.

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

COUNT VI – NEGLIGENCE

(Under Applicable State Law)

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

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

117. Boston Scientific breached its duty of care in one or more of the following ways:

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

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

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

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

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

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

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

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

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

127. As a direct and proximate result of Boston Scientific's negligence, Plaintiff suffered physical pain, emotional distress, financial harm, and other compensable damages Under all applicable state law.

COUNT VII – NEGLIGENT MISREPRESENTATION

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

129. At all times relevant, Boston Scientific, in the course of its business, made representations to healthcare providers, patients, and the general public regarding the

safety, effectiveness, regulatory status, and performance of its spinal cord stimulator systems.

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

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

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

133. Boston Scientific also made these misrepresentations directly to Plaintiff through its sales representatives, who misrepresented to Plaintiff that the permanent SCS systems would provide Plaintiff with long term pain relief, were safe and backed by clinical validation, would at least be functionally equivalent to the trial SCS system, and would alleviate Plaintiff's need to receive other treatment for his chronic pain.

134. Plaintiff's treating physician reasonably relied on Boston Scientific's misrepresentations when selecting the Boston Scientific system for implantation. Plaintiff, in turn, relied on the statements made by Boston Scientific in patient-directed materials and directly to Plaintiff by Boston Scientific sales representatives, including

assurance of FDA approval, therapy safety, and reliability, when consenting to implantation.

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

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

137. For avoidance of doubt, Plaintiff alleges misrepresentations were made to him and his healthcare providers, not the FDA.

COUNT VIII – FRAUDULENT CONCEALMENT

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

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

140. Boston Scientific was under a duty to disclose material facts relating to the performance and risks of the SCS system due to: exclusive access to adverse event reports and internal product complaint data; control over PMA supplement disclosures and labeling updates; direct and indirect representations to patients and physicians; statutory and regulatory duties under 21 C.F.R. §§ 803.50, 814.39, and 820.198 to disclose newly acquired safety information.

141. Boston Scientific actively concealed or failed to disclose that: the SCS systems had undergone extensive, untested design and firmware changes; the FDA had

approved the devices based only on similarity to legacy SCS systems—not on new clinical trial data; known issues with therapy interruption, device shutdown during charging, and unintended stimulation had been internally reported, but not publicly disclosed; and that these issues resulted in multiple FDA recalls, including Class I recalls in 2023 and Class II recalls in 2024, matching the adverse experiences of Plaintiff and other patients.

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

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

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

COUNT IX – VIOLATION OF CONSUMER PROTECTION LAWS

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

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

147. These acts include: falsely advertising the devices as safe, effective, and FDA-approved without disclosing that the approved form of the device was materially altered through over 230 PMA supplements; failing to disclose known malfunctions, including painful shocks, device shutdowns, and therapy loss; omitting material information regarding recalls, firmware instability, and clinical trial limitations; and misrepresenting the scope and meaning of FDA approval to patients and providers.

148. Plaintiff were foreseeable consumers of the device. Although Plaintiff relied in part on their physicians' advice, Boston Scientific engaged in direct-to-consumer advertising and disseminated patient-facing marketing materials that contained false or misleading information.

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

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

COUNT X – NEGLIGENCE PER SE – UNAUTHORIZED PRACTICE OF MEDICINE

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

152. All applicable state law prohibits the unauthorized practice of medicine by any individual or corporate entity not licensed in California, Georgia. These prohibitions reflect a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

153. Boston Scientific is not licensed to practice medicine in California, Georgia, or any other state. Nevertheless, Boston Scientific exercised functional control over the administration of Plaintiff's neuromodulation therapy by: actively participating in the implantation of its SCS system in Plaintiff's body, intra operatively

programing that SCS system, and programming the SCS system post-operatively; pushing firmware updates and stimulation programming changes remotely after implantation; designing and controlling preset therapy "profiles" that physicians could not override without manufacturer approval; and altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight.

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

155. Under all applicable state law, violation of a safety statute gives rise to negligence per se where the injured party is within the class the statute was intended to protect and the injury is of the type the statute was designed to prevent.

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

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

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

VIII. PRAYER FOR RELIEF

158. **WHEREFORE**, Plaintiff respectfully requests that this Court enter

judgment in his favor and against Defendant BSC and BSNC as to all counts and award the following relief:

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

b. Statutory damages and attorneys' fees and costs pursuant to any applicable consumer protection statutes;

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

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

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

f. The costs of this action; and

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

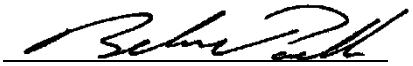
JURY TRIAL DEMAND

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

Dated: May 14, 2026

Respectfully submitted,

WISNER BAUM, LLP



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