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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

LINDA GUTHRIE v. BOSTON SCIENTIFIC CORPORATION; UNITED STATES FOOD AND DRUG ADMINISTRATION	Case No. 2:25-cv-11508 **COMPLAINT – ACTION SEEKING NATIONWIDE RELIEF**

COMPLAINT – ACTION SEEKING NATIONWIDE RELIEF

Plaintiff, by and through undersigned counsel, brings this Complaint against Defendants Boston Scientific Corporation and the United States Food and Drug Administration and alleges as follows:

I. PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Linda Guthrie ("Plaintiff") is and was at all relevant times a resident of California. Plaintiff was implanted with a spinal cord stimulator ("SCS") system designed, manufactured, and distributed by Defendant Boston Scientific Corporation.

2. 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 WaveWriter Alpha and other similar devices.

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

4. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(1)–(2) because Defendant Boston Scientific resides in this District and a substantial part of the events or omissions giving rise to the claims occurred here. Venue is also appropriate with respect to the FDA under 28 U.S.C. § 1391(e)(1) because a substantial part of the events giving rise to the APA claims occurred in this District.

5. This Court has subject matter jurisdiction over Plaintiff's claims against the FDA pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 702. This Court has supplemental jurisdiction over related state-law claims pursuant to 28 U.S.C. § 1367 and diversity jurisdiction under 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000 and the parties are citizens of different states.

6. This Court has personal jurisdiction over Boston Scientific because it maintains its principal place of business in this District and regularly conducts

and solicits business, and derives substantial revenue from the sale of spinal cord stimulators and related services within this District.

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

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

7. 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.

8. 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.

9. 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.

10. Due to these inherent risks, SCS devices are classified by the FDA as Class III medical devices, requiring Premarket Approval ("PMA") or PMA supplement review for any design or functional changes affecting the safety and effectiveness of the device.

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

11. The Federal Food, Drug & Cosmetic Act ("FDCA") sets forth the requirements for Premarket Approval, which is necessary for the commercialization of a high-risk Class III device such as the device at issue in this case.

12. Among the aforesaid requirements is the requirement to provide the FDA with adequate clinical data to support a finding of sufficient safety and efficacy of the subject device.

13. The The FDCA's implementing regulations require that an applicant for premarket approval of a device submit, with respect to the device proposed to be marketed:

> results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications [...]

14. Boston Scientific's spinal cord stimulator product line originates from and is, for all intents and purposes, predicated on PMA P030017, initially approved by the FDA in 2004 for its Precision Spinal Cord Stimulator System. PMA P030017 was awarded despite the applicant's failure to supply the data required by 21 CFR §814.20.

15. Instead, the referenced PMA was granted following submission of clinical data from "available peer reviewed published literature for similar implantable spinal cord stimulation (SCS) systems."

16. Thus, the defining parameter for the grant of premarket approval of a medical device has never been met with respect to the device at issue in this case.

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

18. 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.

19. Boston Scientific aggressively marketed its WaveWriter Alpha system and other upgraded models as offering superior pain relief through innovative stimulation patterns, despite the absence of independent premarket clinical testing validating the long-term safety and effectiveness of these substantial modifications.

C. Material Changes to Device Architecture and Functionality

20. 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;
- The redesign of the implantable pulse generator battery system and the addition of Bluetooth-enabled wireless communication capabilities;
- The integration of posture-adaptive stimulation algorithms;
- The expansion of lead configurations and multi-source current delivery systems.

21. These substantial modifications materially altered the device's safety and effectiveness profile compared to the originally approved Precision system, triggering regulatory obligations that Boston Scientific failed to fulfill.

22. Under 21 C.F.R. § 814.39(a), such significant changes require submission of a new PMA or substantial clinical data demonstrating continued safety and effectiveness. Boston Scientific failed to pursue a new PMA review for these cumulative design changes and instead improperly utilized the PMA supplement pathway.

23. Exemplifying the significant changes Boston Scientific has improperly made to its SCS systems over the years, it currently advertises three distinct systems on its website – the Precision Montage, Specra WaveWriter, and the WaveWriter Alpha systems. Boston Scientific advertises these systems as distinct from each other. Despite advertising three distinct systems, it has only ever received one PMA approval.

D. Regulatory Manipulation and Abuse of the PMA Supplement Process

24. Boston Scientific submitted successive PMA supplements treating major modifications as discrete "minor" changes to avoid the heightened scrutiny, public transparency, and rigorous independent clinical evaluation required for new PMA applications.

25. This regulatory strategy deprived physicians, patients, and the FDA of complete information necessary to evaluate the true risks associated with the modified devices, particularly in the areas of neurological safety, device longevity, stimulation safety, and autonomic complications.

26. As a direct consequence of these omissions and regulatory manipulations, the WaveWriter Alpha and other successor systems entered the market and were widely implanted without sufficient scientific validation of their safety and effectiveness.

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

27. 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.

28. Despite knowledge of these adverse outcomes, Boston Scientific failed to timely update device labeling, issue field safety notices, or seek revised PMA approvals as required under federal regulations.

29. Peer-reviewed literature has increasingly associated SCS therapy, particularly multiwaveform stimulation platforms like the WaveWriter Alpha, with unexpected autonomic side effects. *See*, e.g., Steven Smeijers et al., Spinal Cord Stimulation and Urinary Dysfunction, 23 Pain Med. 1204, 1204–1216 (2022).

30. Plaintiff's injuries occurred as a direct and foreseeable result of Defendant Boston Scientific's conduct and the FDA's arbitrary and capricious regulatory approvals as set forth herein.

III. REGULATORY FRAMEWORK AND DUTIES

31. 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.

32. 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.

33. 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.

34. Once a PMA is granted, any proposed changes to the device's design, labeling, intended use, or manufacturing process must be submitted to the FDA as a PMA supplement. *See* 21 C.F.R. § 814.39(a).

35. The MDA distinguishes between different types of PMA supplements based on the nature and significance of the change. A "panel-track supplement" is required for changes that affect the safety or effectiveness of the device, such as new indications for use, major design modifications, or significant changes in component materials. *See* 21 C.F.R. § 814.39(c).

36. For any change that could affect safety or effectiveness, the FDA must receive and approve the PMA supplement before the manufacturer implements the change. *Id.* The burden of proof remains with the manufacturer to demonstrate that the modified device continues to be safe and effective.

37. Manufacturers are also required to comply with post-market surveillance and reporting obligations, including:

- Timely submission of adverse event reports under 21 C.F.R. § 803.50;
- Maintenance of complaint files under 21 C.F.R. § 820.198;
- Evaluation of nonconforming products under 21 C.F.R. § 820.90;
- Implementation of corrective and preventive actions under 21 C.F.R. § 820.100.

38. These regulatory obligations are non-discretionary and enforceable under both federal and state law. A manufacturer's failure to comply with these requirements renders its device adulterated or misbranded under 21 U.S.C. §§ 351 and 352.

39. Additionally, under the APA, 5 U.S.C. §§ 701–706, FDA actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law are subject to judicial review.

40. The FDA's passive acceptance or failure to meaningfully review Boston Scientific's original PMA and the supplements thereto—particularly where those supplements concealed the scope and safety implications of the changes—constitutes agency action unlawfully withheld and final agency action subject to review under 5 U.S.C. §§ 706(1), 706(2)(A)–(D).

41. Plaintiff does not seek to enforce the FDCA directly. Rather, Plaintiff asserts state-law tort claims based on duties that parallel and incorporate federal requirements, as recognized in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and as preserved under 21 U.S.C. § 360k(a).

42. These state-law claims are not preempted by the MDA because they are premised on conduct that violates both federal law and equivalent duties imposed by California law. Plaintiff also seeks judicial review under the APA for final agency action by the FDA that facilitated or failed to correct the wrongful acts of Defendant Boston Scientific.

IV. ALLEGATIONS AGAINST THE FDA UNDER THE ADMINISTRATIVE PROCEDURE ACT

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

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

45. Under the APA, 5 U.S.C. §§ 701–706, federal courts are authorized to review final agency actions, including agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. See 5 U.S.C. §§ 706(1), 706(2)(A)–(D); *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

46. The FDA's passive acceptance and approval of Boston Scientific's original PMA P030017 and numerous PMA supplements submitted by Boston Scientific Corporation for spinal cord stimulator devices under PMA P030017, including the WaveWriter Alpha system implanted in Plaintiff, constituted final agency action within the meaning of the APA.

47. In 2004, the FDA failed to require Boston Scientific to submit the clinical data required by 21 CFR §814.20 in support of PMA P030017.

48. Instead, the FDA granted PMA P030017 despite Boston Scientific's failure to provide the required data, and its reliance on literature for similar implantable spinal cord stimulation systems.

49. The FDA also failed to require Boston Scientific to submit new Premarket Approval applications for substantial modifications to the original Precision SCS System, including:

- The addition of simultaneous multiwaveform stimulation (tonic, burst, sub-perception);
- The redesign of the IPG battery architecture and the addition of Bluetooth-enabled wireless communication features;
- The integration of posture-adaptive stimulation algorithms;
- The expansion of lead configurations and multi-source current delivery systems.

50. By approving substantial cumulative changes via successive PMA supplements without requiring full panel-track review or independent clinical validation, the FDA unlawfully allowed Boston Scientific to materially alter the design, intended use, and safety profile of its spinal cord stimulator systems outside the bounds of statutory and regulatory requirements. *See* 21 U.S.C. § 360e(d); 21 C.F.R. § 814.39(a).

51. The FDA's acceptance and approval of Boston Scientific's original PMA P030017 and PMA supplements submitted by Boston Scientific constitutes "final agency action"[1] under 5 U.S.C. § 551(13) and 5 U.S.C. § 704. A "final agency action" is one that (1) marks the consummation of the agency's decision-making process and (2) determines rights or obligations or from which legal consequences flow. *See Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). The FDA's approval of Boston Scientific's PMA P030017 and subsequent supplements were final steps in the regulatory process, authorizing the commercial marketing of spinal cord stimualtors, and subsequently, materially modified spinal cord stimulator systems. This approval carried immediate and direct legal consequences, allowing Boston Scientific to market and distribute there devices nationwide under federal premarket authorization. Plaintiff's Administrative Procedure Act claims challenge these final agency actions, not discretionary enforcement decisions or ongoing regulatory processes, and thus fall squarely within the scope of judicial review authorized by 5 U.S.C. §§ 702 and 706.

52. The FDA's actions and omissions materially contributed to the injuries suffered by Plaintiff by enabling the marketing and widespread implantation of devices whose risks had not been fully evaluated or disclosed, depriving physicians and patients of critical safety information.

Evidence of Agency Capture: ANA Reclassification Petition and FDA Override

53. In 2001, Advanced Neuromodulation Systems (ANS) submitted a petition to the FDA requesting that implantable spinal cord stimulators be reclassified from Class III to Class II devices. *See* FDA Docket No. 02P-0321.

[1] Under the Administrative Procedure Act, "agency action" includes "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act," and final agency action is judicially reviewable when it consummates the decision-making process and determines rights or obligations or produces legal consequences. *See* 5 U.S.C. § 551(13); 5 U.S.C. § 704; *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997).

54. An FDA advisory panel, after reviewing the available scientific evidence, recommended granting the reclassification request, concluding that SCS devices did not warrant Class III treatment based on their risk profiles and clinical experience.

55. Despite the advisory panel's recommendation, FDA headquarters overruled the panel. They unilaterally decided to maintain Class III classification for SCS devices, yet without imposing meaningful PMA enforcement obligations or new clinical evidence requirements thereafter.

56. This historical regulatory decision is evidence of agency capture and arbitrary administrative conduct. The FDA simultaneously acknowledged that SCS devices did not merit full Class III regulatory burdens, yet failed to require proper PMA oversight for subsequent generations of increasingly complex and modified SCS systems.

57. The FDA's passive and deferential treatment of Boston Scientific's PMA supplements following the override of its advisory panel further illustrates systemic regulatory failure and arbitrary decision-making in violation of the APA.

58. Plaintiff was injured as a direct and foreseeable result of the FDA's arbitrary and unlawful regulatory actions. Had the FDA properly enforced PMA standards and statutory requirements, the WaveWriter Alpha device implanted in Plaintiff would not have entered or remained on the market in the materially altered form that caused Plaintiff's injuries.

59. Plaintiff seeks judicial review of these final agency actions under the APA, including declaratory and injunctive relief as necessary to vindicate statutory rights, remedy the injury caused by the agency's conduct, and prevent ongoing harm to Plaintiff and the public.

V. PLAINTIFF-SPECIFIC ALLEGATIONS

60. Plaintiff Linda Guthrie is a resident of Ione, California. On September 13, 2023, Plaintiff underwent implantation of a Boston Scientific spinal cord stimulator system.

61. The implanted system included a WaveWriter Alpha implantable pulse generator, along with Boston Scientific leads and anchoring components.

62. Plaintiff's spinal cord stimulator was implanted for the treatment of chronic pain, following a trial procedure that was represented as predictive of long-term efficacy.

63. Prior to deciding to have the WaveWriter Alpha system implanted, Plaintiff met multiple times with Boston Scientific sales representative Holly (last name unknown).

64. Boston Scientific's sales representative Holly (last name unknown) represented to Plaintiff that the permanent WaveWriter Alpha system would be "much better" and provide more significant pain management results than the trial stimulator.

65. Several weeks after the permanent SCS system was implanted, Plaintiff stopped experiencing pain relief from the stimulator. Her doctor advised her to meet with Holly from Boston Scientific, who told her to put the system on different frequencies. Through the following months, Plaintiff spoke with Holly who reprogrammed the system and worked with Plaintiff to find an appropriate frequency for the stimulator system.

66. On December 20, 2023, Plaintiff required a revision surgery due to migrated Boston Scientific leads.

67. On January 24, 2024, Plaintiff required another surgery due to migrated Boston Scientific leads.

68. Throughout the years after being implanted with the WaveWriter Alpha system, Plaintiff had her system reprogrammed by Boston Scientific

representatives multiple times, even when it was later determined by physicians that her leads had migrated and were not positioned appropriately to provide proper pain reducing stimulation.

69. Plaintiff is currently still implanted with the Boston Scientific WaveWriter Alpha system, although she has turned the system off because it completely stopped providing her any pain relief.

70. Plaintiff and her providers were not informed that the WaveWriter Alpha system or its predicate products had not undergone independent clinical validation, or that the product was initially approved based on literature on other similar devices.

71. Plaintiff and her providers were not informed that the WaveWriter Alpha system, including its multiwaveform stimulation capabilities and revised battery architecture, had not undergone independent clinical validation via a new PMA application, and instead reached the market through piecemeal PMA supplement filings.

72. Plaintiff relied on Boston Scientific's representations, through both direct promotional materials, direct spoken representations by the Boston Scientific sales representatives, and the statements of her healthcare providers, in deciding to proceed with the initial implantation of the WaveWriter Alpha system.

73. Specifically, Plaintiff relied on Boston Scientific's representations, among others, that the WaveWriter system was uniquely suited to provide her with long-term pain relief and was safe for long-term implantation.

74. The representations relied upon by Plaintiff are still being made by Boston Scientific about the WaveWriter Alpha to this day.

75. Plaintiff's interactions with Boston Scientific's representatives were so substantial that Plaintiff alleges that they directly sold her the WaveWriter Alpha system.

76. During the time in which the SCS system was implanted in Plaintiff, Boston Scientific representatives, believed to be unlicensed in the State of California, actively participated in programming and waveform selection. These actions involved real-time interpretation of patient responses and materially influenced the configuration and function of the implanted system. These actions were essentially medical treatment and had a significant impact on the way the SCS system affected Plaintiff's body.

77. Plaintiff did not learn of the likely connection between her injuries and the defective nature of Boston Scientific's WaveWriter Alpha system until reviewing publicly available FDA documents, adverse event disclosures, and litigation-related findings that contradicted prior assurances of safety and regulatory compliance. Further, she did not and could not have known that any of Boston Scientific's representations were false until she ultimately concluded that the reprograming attempts by Boston Scientific representatives were futile, and further concluded that the WaveWriter Alpha system had failed her. This occurred in approximately April 2024.

78. Plaintiff's injuries, including physical pain, emotional distress, surgical trauma, loss of enjoyment of life, and the permanent implantation of defective hardware, were directly and proximately caused by the acts and omissions of Boston Scientific, as well as the FDA's unlawful and arbitrary grant of PMA P030017 without the required and mandatory clinical data, and subsequent failure to require a new PMA for the substantially modified WaveWriter Alpha device.

VI. DEFENDANTS' MISREPRESENTATIONS, OMISSIONS, AND REGULATORY VIOLATIONS

A. Failure to Disclose Material Risks and Regulatory Evasion

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

80. At all relevant times, Defendant Boston Scientific Corporation engaged in a course of conduct designed to conceal material risks associated with its spinal cord stimulator systems, misrepresent the safety and efficacy of its devices, and improperly utilize the PMA supplement process to introduce significant, unvalidated design changes without triggering mandatory premarket review.

81. Boston Scientific represented to Plaintiff, her healthcare providers, and the medical community that its WaveWriter Alpha system and related devices were safe, effective, supported by clinical data, and appropriately cleared for long-term implantation.

82. These representations were false, misleading, and incomplete. Boston Scientific knew, or should have known through post-market surveillance and regulatory obligations, that the WaveWriter Alpha system:

- Posed an increased risk of device migration, stimulation failure, and neurological injury;
- Was marketed with stimulation modalities not adequately tested in clinical trials;
- Carried a known risk of autonomic dysfunction, including incontinence, hypotension, and cardiac arrhythmia;
- Had materially different performance characteristics from the external trial device.

83. Boston Scientific actively concealed this information by:

- Failing to report adverse events under 21 C.F.R. § 803.50;
- Withholding labeling updates and field safety communications under 21 C.F.R. § 814.39(d);
- Submitting fragmented PMA supplements to avoid full panel-track review required by 21 C.F.R. § 814.39(a).

84. These actions violated non-discretionary regulatory obligations and rendered the device unsafe for its intended use, depriving physicians and patients of information required for informed medical decision-making.

B. Violations of Current Good Manufacturing Practices (cGMPs)

85. In addition to the above, Boston Scientific violated multiple cGMP requirements codified at 21 C.F.R. Part 820 — including those governing design control, process validation, complaint handling, and corrective and preventive action (CAPA).

86. Specifically, Boston Scientific:

- Failed to maintain adequate design validation under 21 C.F.R. § 820.30(g), particularly in light of the software and waveform changes introduced with the WaveWriter Alpha system;
- Failed to validate and monitor manufacturing processes as required under 21 C.F.R. § 820.75, leading to inconsistencies in lead bonding and IPG housing integrity;
- Failed to investigate and correct known device performance issues through its CAPA system, in violation of 21 C.F.R. § 820.100;
- Failed to evaluate post-market complaints systematically and incorporate them into product redesign and labeling revisions, in violation of 21 C.F.R. § 820.198.

87. These cGMP violations are not discretionary; they are binding legal obligations imposed by the FDA to ensure the safety and effectiveness of devices. They establish minimum standards for medical device manufacturers and are incorporated by reference into California tort law as parallel duties.

88. The Ninth Circuit has expressly recognized that manufacturers of FDA-regulated medical devices may be held liable under state law where they violate non-discretionary FDA regulations, including those arising under cGMPs. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233–34 (9th Cir. 2013) (*en banc*).

89. Boston Scientific's repeated and willful violations of cGMP requirements caused or substantially contributed to the defects and injuries at issue in this case, and support Plaintiff's claims under California law for strict liability, negligence per se, failure to warn, and fraudulent omission.

90. These claims are not preempted under Riegel or Buckman because they are premised on state-law duties that genuinely parallel federal requirements and do not exist solely by virtue of the FDCA.

VII. CAUSES OF ACTION

COUNT I – MANUFACTURING DEFECT

Against Defendant Boston Scientific

(Cal. Civ. Code § 1714.45; 21 U.S.C. § 360k(a); 21 C.F.R. §§ 820.30, 820.70, 820.75, 820.100)

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

92. At all relevant times, Defendant Boston Scientific Corporation was engaged in the design, manufacture, labeling, marketing, and distribution of spinal cord stimulator systems throughout the United States, including the WaveWriter Alpha system implanted in Plaintiff.

93. California law recognizes strict liability for manufacturing defects in medical devices. See *Soule v. General Motors Corp.*, 8 Cal. 4th 548, 560 (1994).

94. The spinal cord stimulator system implanted in Plaintiff was not reasonably safe as manufactured. It deviated materially from its intended design specifications and from applicable federal requirements governing Class III medical devices.

95. Defendant Boston Scientific violated non-discretionary federal manufacturing and quality system regulations, including but not limited to:

- 21 C.F.R. § 820.30: failure to implement adequate design controls;

- 21 C.F.R. § 820.70: failure to establish process controls ensuring conformity to design specifications;
- 21 C.F.R. § 820.75: failure to validate manufacturing processes capable of consistently producing conforming devices;
- 21 C.F.R. § 820.100: failure to implement corrective and preventive action in response to known device defects.

96. The WaveWriter Alpha system implanted in Plaintiff was manufactured with latent defects affecting performance, stability, and safety, including but not limited to:

- Inadequate lead anchoring, resulting in migration and therapeutic failure;
- Battery instability contributing to irregular stimulation output and early depletion;
- Defects impacting the physical stability of the battery in the bodies of patients;
- Faulty firmware or programming inconsistencies affecting waveform delivery.

97. These defects were not detectable by Plaintiff or her physicians through reasonable inspection prior to implantation and were not reasonably foreseeable based on the information available to Plaintiff or her treating physicians at the time.

98. As a direct and proximate result of the manufacturing defects described herein, Plaintiff suffered the injuries, damages, and losses set forth above, including physical pain and suffering, emotional distress, medical expenses, lost income, and diminished enjoyment of life.

99. Plaintiff's manufacturing defect claim arises under state-law duties that parallel federal manufacturing obligations imposed on Boston Scientific. These claims are not expressly or impliedly preempted under 21 U.S.C. § 360k(a),

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), or *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, attorneys' fees where permitted, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT II – FAILURE TO WARN

Against Defendant Boston Scientific

(Cal. Civ. Code § 1714.8; 21 C.F.R. §§ 803.50, 814.39, 820.198)

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

101. At all relevant times, Defendant Boston Scientific Corporation was engaged in the design, manufacture, labeling, marketing, and distribution of spinal cord stimulator systems throughout the United States, including the WaveWriter Alpha system implanted in Plaintiff.

102. Under California law, a manufacturer is liable for failing to provide adequate warnings about known or reasonably knowable risks associated with the ordinary use of its product.

103. Boston Scientific had a duty to warn Plaintiff, her healthcare providers, and the medical community of the material risks associated with its spinal cord stimulator systems, including but not limited to:

- The risk of lead migration and device failure requiring surgical revision;
- The risk of autonomic dysfunction, including arrhythmias, urinary incontinence, and hypotension;
- The risk that the trial device would not reliably predict the performance of the permanently implanted device;

- The risk of device-related pain exacerbation and loss of therapeutic efficacy over time.

104. Boston Scientific breached its duty to warn by:

- Failing to update product labeling and Instructions for Use (IFU) to reflect emerging adverse event trends;
- Failing to disseminate "Dear Doctor" letters or field advisories warning of known failure modes;
- Failing to adequately train sales representatives and clinicians regarding the safety limitations of multiwaveform stimulation;
- Actively promoting the WaveWriter Alpha system as superior and safe without disclosing material limitations and risks.

105. These failures were compounded by violations of federal law, including:

- 21 C.F.R. § 803.50: failure to timely report adverse events;
- 21 C.F.R. § 814.39: failure to submit PMA supplements for significant changes;
- 21 C.F.R. § 820.198: failure to investigate and address post-market complaints.

106. Plaintiff and her physicians justifiably relied on Defendant's representations and omissions.

107. Had appropriate warnings been provided, Plaintiff would not have consented to implantation.

108. As a direct and proximate result, Plaintiff suffered injuries including physical pain, emotional distress, surgical revision, and economic loss.

109. These claims are not preempted because they are based on parallel state-law duties that mirror federal requirements.

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, attorneys' fees where permitted, costs of suit, interest, and all such further relief as the Court deems just and proper.

COUNT III – NEGLIGENCE PER SE AND BREACH OF FEDERAL REGULATORY DUTIES

Against Defendant Boston Scientific

(Cal. Civ. Code § 1714(a); *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013); 21 C.F.R. §§ 820.30(g), 820.75, 820.100, 820.198)

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

111. At all relevant times, Defendant Boston Scientific Corporation owed duties to Plaintiff, her healthcare providers, and the public to comply with federal medical device regulations and to manufacture, monitor, and report on its spinal cord stimulator systems in accordance with Current Good Manufacturing Practices ("cGMPs") set forth in 21 C.F.R. Part 820.

112. These cGMP requirements are not discretionary. They impose binding legal obligations to implement and maintain design controls, process validation, complaint handling systems, and corrective and preventive actions for Class III medical devices.

113. Defendant breached these duties by failing to:

- Implement effective design validation under 21 C.F.R. § 820.30(g);
- Validate and monitor production processes under 21 C.F.R. § 820.75;

- Respond adequately to known product failures through its Corrective and Preventive Action (CAPA) system in violation of 21 C.F.R. § 820.100;
- Investigate and act upon post-market complaints in accordance with 21 C.F.R. § 820.198.

114. These regulatory breaches materially contributed to the manufacture, release, and continued distribution of unsafe, unvalidated, and defectively designed spinal cord stimulator systems that failed during normal use, including the WaveWriter Alpha system implanted in Plaintiff.

115. Plaintiff and her physicians were members of the class of individuals the cGMP regulations were intended to protect — users of Class III implanted medical devices.

116. The harms suffered by Plaintiff, including physical pain, device failure, revision surgery, and ongoing neurological complications, are of the precise type that the cGMP regulations are intended to prevent.

117. Under California law, a manufacturer's failure to use reasonable care — including compliance with federal regulatory duties — constitutes actionable negligence.

118. The Ninth Circuit has expressly recognized that violations of non-discretionary FDA requirements — including post-market surveillance and manufacturing controls — may give rise to parallel state-law claims. See *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233–34 (9th Cir. 2013) (en banc).

119. Defendant's violations of mandatory federal regulations constitute negligence per se under California law.

120. As a direct and proximate result of these regulatory violations, Plaintiff suffered physical injuries, emotional distress, medical costs, diminished enjoyment of life, and other compensable harms.

121. These claims arise under state-law duties that genuinely parallel federal obligations imposed by the FDCA and are not expressly or impliedly preempted under *Riegel*, *Buckman*, or 21 U.S.C. § 360k(a).

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, attorneys' fees where permitted, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT IV – BREACH OF EXPRESS WARRANTY

Against Defendant Boston Scientific

(Cal. Com. Code § 2313(1)(a))

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

123. At all relevant times, Defendant Boston Scientific Corporation expressly warranted, through its labeling, advertising, marketing materials, website representations, sales representatives, and field support personnel, that its spinal cord stimulator systems, including the WaveWriter Alpha system, were safe, effective, durable, and fit for the treatment of chronic pain conditions.

124. These express warranties included, but were not limited to, assurances that:

- The therapeutic benefits achieved during trial stimulation would reliably predict the performance of the permanently implanted device;
- The WaveWriter Alpha system's multiwaveform stimulation technology provided superior pain relief without significant risk of adverse side effects;
- The device was durable and appropriately designed for long-term implantation and therapeutic use without significant risks of lead migration, neurological injury, battery failure, rapidly declining efficacy, or stimulation-induced autonomic dysfunction;

- The system had been adequately tested for safety and effectiveness consistent with FDA requirements.

125. Such express warranties were made to Plaintiff's healthcare providers and directly to Plaintiff through Boston Scientific's promotional materials and field representatives, namely Holly (last name unknown).

126. Plaintiff and her healthcare providers reasonably relied on these express warranties in choosing to proceed with implantation of the WaveWriter Alpha system and in making ongoing treatment decisions.

127. Contrary to these express warranties, the WaveWriter Alpha system implanted in Plaintiff was defective, unreasonably dangerous, and incapable of delivering the promised therapeutic benefits. Instead, it caused Plaintiff to suffer injuries including persistent lead migration, ineffective pain relief, nerve damage, device failure, stimulation-related complications, and ultimately, significant physical and emotional harm.

128. Defendant's conduct described herein breached its express warranties under California law. *See* Cal. Com. Code § 2313(1)(a).

129. Under California, a manufacturer may be liable for breach of warranty if a product fails to perform as expressly warranted and causes harm.

130. Defendant's breaches of express warranty were a direct and proximate cause of Plaintiff's injuries, including physical pain, mental anguish, loss of enjoyment of life, additional medical expenses, and financial loss.

131. Plaintiff's claims for breach of express warranty are based on independent state-law duties and contractual obligations and are not expressly or impliedly preempted under federal law.

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, consequential and incidental damages, punitive damages where permitted, attorneys' fees where allowed, costs

of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT V – BREACH OF IMPLIED WARRANTIES

Against Defendant Boston Scientific

(Cal. Com. Code § 2314-2315

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

133. Boston Scientific knew of the use that the WaveWriter Alpha system was intended for and impliedly warranted to Plaintiff and her healthcare providers that the system was of merchantable quality and safe for the use for which it was intended.

134. Plaintiff and her healthcare providers reasonably relied on these express warranties in choosing to proceed with implantation of the WaveWriter Alpha system and in making ongoing treatment decisions.

135. Contrary to these implied warranties, the WaveWriter Alpha system was not of merchantable quality or safe for it intended use.

136. Defendant's breaches of express warranty were a direct and proximate cause of Plaintiff's injuries, including physical pain, mental anguish, loss of enjoyment of life, additional medical expenses, and financial loss.

137. Plaintiff's claims for breach of express warranty are based on independent state-law duties and contractual obligations and are not expressly or impliedly preempted under federal law.

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, consequential and incidental damages, punitive damages where permitted, attorneys' fees where allowed, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT VI – FRAUDULENT MISREPRESENTATION

Against Defendant Boston Scientific

(Cal. Civ. Code § 1710;

Restatement (Second) of Torts § 531)

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

139. At all relevant times, Defendant Boston Scientific Corporation, acting individually and through its agents, employees, and representatives, made material misrepresentations and omissions of fact regarding the safety, efficacy, and regulatory compliance of its spinal cord stimulator systems, including the WaveWriter Alpha system implanted in Plaintiff.

140. Defendant communicated directly with Plaintiff through sales reprentative Holly (last name unknown).

141. Defendant represented to Plaintiff, her healthcare providers, and the general public, through marketing materials, sales presentations, Instructions for Use (IFU), direct to patient communications, and other communications, that:

- The WaveWriter Alpha system was supported by clinical data as required for Premarket Approval;
- The WaveWriter Alpha system was safe and effective for the long-term management of chronic pain;
- The benefits achieved during trial stimulation reliably predicted the success of the permanently implanted device;
- The device's multiwaveform stimulation capabilities reduced the risk of therapy failure and side effects compared to older systems;
- The device had been adequately validated and reviewed consistent with FDA requirements for significant design and functionality changes.

142. These material representations were false. Defendant knew or should have known, through reasonable investigation, post-market surveillance, and adverse event reporting, that:

- The WaveWriter Alpha system was not supported by clinical data;
- The WaveWriter Alpha system was associated with a materially increased risk of lead migration, therapy abandonment, stimulation-induced autonomic dysfunction, and device-related complications;
- The permanent device materially differed in performance and risk profile from the external trial device;
- Boston Scientific had not submitted adequate clinical evidence to substantiate the safety and effectiveness of its multiwaveform and posture-adaptive programming technologies;
- Boston Scientific's devices were being improperly marketed under serial PMA supplements rather than undergoing new PMA review as required by law.

143. Defendant made these material misrepresentations and omissions intentionally, willfully, recklessly, and with the intent to induce healthcare providers to recommend, and patients to consent to, implantation of its devices.

144. Plaintiff's healthcare providers justifiably relied on Boston Scientific's representations in recommending the WaveWriter Alpha system, and Plaintiff justifiably relied on the same representations in consenting to implantation and subsequent medical decisions.

145. Boston Scientific's field representatives directly interacted with Plaintiff and Plaintiff's care team and participated in programming the device. Their conduct reinforced the impression that the system was safe and effective and that post-implantation adjustments would resolve complications. These

communications omitted material facts and conveyed false assurances, including before the implantation and for years after the implantation.

146. Plaintiff had no reasonable means of independently discovering the falsity of Defendant's statements at the time of implantation, as Boston Scientific had superior knowledge of the device's design changes, clinical performance, and regulatory history, and actively concealed adverse information from physicians, patients, and regulators.

147. Plaintiff also had no reasonable means of independently discovering the falsity of Defendant's statements following implantation, as Boston Scientific had superior knowledge of the device's design changes, clinical performance, and regulatory history, and actively concealed adverse information from physicians, patients, and regulators.

148. Defendant's misrepresentations, including those made by sales representative Holly (last name unknown), before the implantation procedure caused Plaintiff to consent to the implantation of the SCS system.

149. Defendant's misrepresentations, including those made by the sales representative Holly (last name unknown). during the years following the implantation procedure caused her to keep the SCS system in her body long after it had any efficacy, because Defendant's representatives assured her it would work with more adjustments and programming. These representations caused delayed treatment of lead migration, and led to greater harm to Plaintiff.

150. Plaintiff discovered the probable causal relationship between her injuries and Defendant's conduct only after experiencing continued device-related complications and reviewing public disclosures, adverse event reports, and litigation materials that contradicted Defendant's original representations.

151. As a direct and proximate result of Defendant's fraudulent misrepresentations and omissions, Plaintiff suffered significant injuries, including

physical pain, emotional distress, medical expenses, lost income, diminished quality of life, and other consequential damages.

152. Plaintiff's fraud claims arise under California common law, and are not based solely on FDCA violations, but rather Defendant's intentional misstatements and concealments made to induce reliance.

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, punitive damages where permitted, attorneys' fees where allowed, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT VII – NEGLIGENT MISREPRESENTATION

Against Boston Scientific

(Cal. Civ. Code § 1710(2))

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

154. At all relevant times, Defendant Boston Scientific Corporation, acting individually and through its agents, employees, and representatives, owed a duty to exercise reasonable care in communicating truthful, accurate, and complete information about its spinal cord stimulator systems, including the WaveWriter Alpha system.

155. Defendant supplied false information in its promotional materials, sales presentations, Instructions for Use (IFU), labeling, and direct communications to healthcare providers and patients regarding the safety, efficacy, design features, and regulatory status of the WaveWriter Alpha system.

156. Specifically, Defendant negligently misrepresented that:

- The WaveWriter Alpha system was supported by clinical data;
- The WaveWriter Alpha system was safe and effective for the long-term treatment of chronic pain;

- The system's multiwaveform stimulation would enhance therapeutic outcomes and reduce adverse effects compared to previous devices;
- The results achieved during trial stimulation were reliable predictors of permanent implant performance;
- The system had been appropriately validated through regulatory submissions consistent with FDA standards for safety and effectiveness.

157. Defendant made these representations without reasonable grounds for believing them to be true. A reasonable manufacturer exercising appropriate care would have known that:

- The WaveWriter Alpha system was not supported by clinical data;
- The permanent implant differed materially in performance from the external trial device;
- The modified stimulation technologies and battery architecture introduced new and significant risks not present in predicate devices;
- Clinical data validating the long-term safety and efficacy of the device modifications were lacking or insufficient;
- Adverse event trends, including stimulation-related autonomic dysfunction, required disclosure to regulators and treating physicians.

158. Plaintiff's healthcare providers reasonably relied on Defendant's representations in recommending implantation of the WaveWriter Alpha system, and Plaintiff reasonably relied on the same representations in consenting to implantation.

159. Had Plaintiff and her healthcare providers been accurately and fully informed of the true risks and limitations associated with the device, they would not have elected to proceed with implantation or would have pursued alternative treatment options.

160. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff suffered physical injuries, emotional distress, additional medical expenses, financial losses, and diminished quality of life.

161. Plaintiff's negligent misrepresentation claims arise under state common law, including California Civil Code § 1710(2). These claims are not premised solely on FDCA enforcement and are not preempted under *Buckman* or *Riegel*.

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for compensatory damages, attorneys' fees where permitted, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT VIII – VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW

Against Defendant Boston Scientific

(Cal. Bus. & Prof. Code §§ 17200–17210; Cal. Civ. Code §§ 1750–1785)

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

163. At all relevant times, Defendant Boston Scientific Corporation was engaged in trade and commerce as defined by the California Unfair Competition Law ("UCL"), including the nationwide marketing, sale, and distribution of spinal cord stimulator systems such as the WaveWriter Alpha system.

164. The UCL prohibits unlawful, unfair, false, misleading, or deceptive acts and practices in the conduct of trade or commerce. Cal. Bus. & Prof. Code § 17200.

165. Defendant Boston Scientific engaged in unlawful and deceptive conduct, including but not limited to:

- Misrepresenting that the WaveWriter Alpha system was appropriately approved by the FDA through the Premarket Approval process, and was supported by the required clinical data;
- Misrepresenting the safety, reliability, and long-term performance of the WaveWriter Alpha system;
- Failing to disclose known risks of stimulation-induced autonomic dysfunction, device migration, and therapy failure;
- Marketing the external trial device as predictive of permanent implant outcomes despite internal knowledge to the contrary;
- Omitting material information regarding post-market failures, cGMP violations, and adverse events from its product labeling and promotional materials.

166. These acts and omissions were directed at Plaintiff, her healthcare providers, and the general public, and were likely to deceive reasonable consumers and physicians.

167. Boston Scientific's conduct further violated the California Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1770(a), including but not limited to:

- § 1770(a)(5): Representing that goods had characteristics or benefits which they did not have;
- § 1770(a)(7): Representing that goods were of a particular standard, quality, or grade when they were not;
- § 1770(a)(9): Advertising goods with the intent not to sell them as advertised;
- § 1770(a)(14): Representing that a transaction confers or involves rights or remedies it does not have.

168. Plaintiff and her healthcare providers reasonably relied on Boston Scientific's misrepresentations and omissions in consenting to the device's implantation and continuing therapy.

169. As a direct and proximate result, Plaintiff suffered injury in fact and economic damages, including unnecessary medical expenses, physical pain, emotional distress, and loss of quality of life.

170. Defendant's violations of the UCL and CLRA were willful and knowing. Plaintiff seeks actual damages, restitution, injunctive relief, and statutory damages under Cal. Civ. Code § 1780, as well as civil penalties under Cal. Bus. & Prof. Code § 17206.

WHEREFORE, Plaintiff demands judgment against Defendant Boston Scientific Corporation for actual damages, treble and statutory damages, restitution, attorneys' fees and costs, injunctive relief, and such further relief as this Court deems just and proper.

COUNT IX – NEGLIGENCE PER SE FOR PRACTICING MEDICINE WITHOUT A LICENSE

Against Defendant Boston Scientific

(Cal. Bus. & Prof. Code §§ 2052, 2400)

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

172. At all relevant times, Boston Scientific Corporation employed and deployed sales and clinical field representatives to assist in the surgical implantation and post-operative programming of its spinal cord stimulator systems, including the WaveWriter Alpha system implanted in Plaintiff.

173. These field representatives, none of whom were licensed healthcare professionals in the State of California, routinely and in Plaintiff's case:

- Entered surgical suites during spinal cord stimulator implantation procedures;
- Advised surgeons and operating room staff on intraoperative lead positioning and stimulation testing;
- Participated in real-time programming of the device based on patient response during surgery;
- Provided device setting recommendations to healthcare providers during post-operative care;
- Adjusted or instructed adjustment of device parameters that materially influenced treatment decisions;
- Directly advised patients, including Plaintiff, about the safety and efficacy of the SCS system, benefits of the system, and impacts of reprogramming the SCS system;
- Directly advised patients, including Plaintiff, to keep the SCS system in their body despite complications and lack of efficacy of the system;
- Provided medical advise to patients, including Plaintiff, regarding the SCS system, symptoms now alleged to be caused by the SCS system, and decisions related to the SCS system.

174. These activities constitute the unlicensed practice of medicine in violation of Cal. Bus. & Prof. Code §§ 2052 and 2400, which prohibit any person from diagnosing, treating, or recommending treatment for human ailments without a valid medical license.

175. California law recognize negligence per se where a defendant violates a statute designed to protect a particular class of persons, and the plaintiff suffers the type of harm the statute was intended to prevent.

176. The statute prohibiting unlicensed practice of medicine was enacted to protect patients from harm caused by unqualified individuals influencing or

substituting for licensed medical judgment. Plaintiff is within the class of persons this statute was intended to protect.

177. As a direct and proximate result of Defendant's statutory violations and its failure to adequately train, supervise, or restrict the conduct of its representatives, Plaintiff suffered harm, including but not limited to: improper lead placement, ineffective stimulation, neurological injury, additional surgeries, and prolonged pain and suffering.

178. Defendant's conduct constitutes negligence per se under California law and entitles Plaintiff to compensatory and punitive damages.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant Boston Scientific Corporation for compensatory and punitive damages, attorneys' fees where permitted, costs of suit, and all other relief the Court deems just and proper.

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

Against Defendant U.S. Food and Drug Administration

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

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

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

181. The APA authorizes judicial review of final agency action, including agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. See 5 U.S.C. §§ 706(1), 706(2)(A)–(D); *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

182. The FDA's passive acceptance and approval of PMA supplements submitted by Defendant Boston Scientific Corporation for its WaveWriter Alpha spinal cord stimulator system constituted final agency action within the meaning of the APA.

183. The FDA acted arbitrarily and capriciously, and contrary to law, by:

- Approving PMA P030017 despite Boston Scientific's failure to supply data required by 21 CFR §814.20, and instead granting approval based on "available peer reviewed published literature for similar implantable spinal cord stimulation (SCS) systems."
- Approving substantial modifications to the original device — including the addition of multiwaveform stimulation, posture-adaptive programming, and battery redesign — without requiring new PMA applications or adequate independent clinical validation;
- Failing to adequately scrutinize PMA supplements that materially altered the device's design, safety profile, and intended use;
- Permitting Boston Scientific to evade full panel-track PMA review through incremental supplement filings, despite knowing or having reason to know that the cumulative changes were substantial;
- Failing to mandate labeling updates or field safety communications in response to known adverse event trends related to stimulation-induced autonomic dysfunction, device migration, and therapy failure;
- Disregarding its statutory duty under 21 U.S.C. § 360e(d) to ensure that significant changes to Class III devices receive the same rigorous review as original PMA applications.

184. The FDA's actions directly enabled Boston Scientific to market a materially altered, insufficiently validated, and defectively designed spinal cord stimulator system to Plaintiff and similarly situated patients without the protections mandated by Congress for high-risk medical devices.

185. The FDA's misconduct is further evidenced by its historical pattern of regulatory capture concerning spinal cord stimulators, including its decision to override an advisory panel recommendation in 2003 that implantable SCS devices be reclassified from Class III to Class II, without requiring manufacturers to complete PMA obligations thereafter. See FDA Docket No. 02P-0321.2

186. Plaintiff suffered direct injury as a result of the FDA's arbitrary and unlawful agency actions. But for the FDA's approval of Boston Scientific's PMA P030017 and cumulative PMA supplement submissions without adequate scrutiny, Plaintiff would not have been implanted with the defective device that caused her injuries.

187. Plaintiff seeks declaratory relief declaring that the FDA's actions regarding the PMA supplements for Boston Scientific's spinal cord stimulator systems were arbitrary, capricious, an abuse of discretion, and contrary to law.

188. Plaintiff further seeks injunctive relief requiring the FDA to reconsider and, if necessary, rescind or suspend the PMA approvals granted for Boston Scientific's spinal cord stimulator systems that failed to undergo appropriate panel-track or original PMA review.

189. Plaintiff's claims under the APA are properly brought under 5 U.S.C. § 702 and 5 U.S.C. § 706, and are not precluded by any statutory or regulatory exemption from judicial review.

WHEREFORE, Plaintiff demands declaratory judgment against Defendant United States Food and Drug Administration, injunctive relief as permitted under the APA, costs of suit, reasonable attorneys' fees where permitted, and such other and further relief as the Court deems just and proper.

[2] In 2001, Advanced Neuromodulation Systems (ANS) petitioned the FDA to reclassify implantable spinal cord stimulators from Class III to Class II. An FDA advisory panel recommended reclassification; however, the FDA headquarters overruled the panel and maintained Class III status without instituting corresponding PMA enforcement or strengthening requirements thereafter. *See* Docket No. 02P-0321 (FDA)

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor and against Defendants Boston Scientific Corporation and the United States Food and Drug Administration, and award the following relief:

1. Compensatory damages for Plaintiff's physical injuries, emotional distress, pain and suffering, loss of enjoyment of life, past and future medical expenses, and other economic and non-economic losses in an amount to be determined at trial;
2. Statutory damages and penalties as permitted under the California Unfair Competition Law and California Consumers Legal Remedies Act;
3. Consequential and incidental damages arising from Defendant's breach of express and implied warranties under California law;
4. Punitive damages as permitted by California law for Defendant's willful, fraudulent, and malicious conduct;
5. Declaratory relief pursuant to the Administrative Procedure Act declaring that the FDA's actions in approving Boston Scientific's PMA supplements without appropriate review were arbitrary, capricious, an abuse of discretion, and contrary to law;
6. Injunctive relief requiring the FDA to reconsider, rescind, or suspend PMA approvals for materially altered spinal cord stimulator devices that failed to undergo the statutorily required review processes;
7. Reasonable attorneys' fees, costs of suit, and expenses incurred in this action as permitted by statute or common law;
8. Pre-judgment and post-judgment interest at the maximum rates permitted by law; and

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

JURY 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: December 3, 2025

Respectfully submitted,

/s/ Trevor B. Rockstad

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