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**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

IN RE:

BOSTON SCIENTIFIC  
CORPORATION SPINAL CORD  
STIMULATOR PRODUCTS  
LIABILITY LITIGATION

This Document Relates to:

PERSONAL INJURY TRACK ONLY  
ALL ACTIONS

Case No. 2:26-ml-03181-JLS

MDL 3181

Hon. Josephine L. Staton

**MASTER PERSONAL INJURY  
COMPLAINT**

**DEMAND FOR JURY TRIAL**

## **TABLE OF CONTENTS**

|                                                                                                                                                                                 |    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| I. PRELIMINARY STATEMENT .....                                                                                                                                                  | 1  |
| II. INTRODUCTION .....                                                                                                                                                          | 2  |
| III. PARTIES .....                                                                                                                                                              | 5  |
| A. PLAINTIFFS .....                                                                                                                                                             | 5  |
| B. DEFENDANTS .....                                                                                                                                                             | 5  |
| 1. Boston Scientific Corporation .....                                                                                                                                          | 5  |
| 2. Boston Scientific Neuromodulation Corporation .....                                                                                                                          | 6  |
| IV. JURISDICTION AND VENUE .....                                                                                                                                                | 7  |
| V .FACTUAL ALLEGATIONS .....                                                                                                                                                    | 8  |
| A. APPLICABLE REGULATORY FRAMEWORK .....                                                                                                                                        | 8  |
| 1. Regulatory Framework: Premarket Approval .....                                                                                                                               | 8  |
| 2. Regulatory Framework: Post-Marketing Surveillance and Reporting<br>Obligations .....                                                                                         | 11 |
| 3. Federal Requirements are Paralleled by State Law Duties .....                                                                                                                | 11 |
| B. BOSTON SCIENTIFIC’S SCS DEVICES .....                                                                                                                                        | 15 |
| 1. Overview of Spinal Cord Stimulation Devices .....                                                                                                                            | 15 |
| 2. Boston Scientific’s Original PMA .....                                                                                                                                       | 17 |
| 3. Subsequent SCS Devices Were Created Through Material Changes to<br>Device Architecture and Functionality .....                                                               | 19 |
| C. BOSTON SCIENTIFIC REPEATEDLY VIOLATED FEDERAL REQUIREMENTS AND<br>PARALLEL STATE DUTIES .....                                                                                | 21 |
| 1. Boston Scientific Deviated from the Approved Specifications for the SCS<br>Devices .....                                                                                     | 21 |
| 2. Boston Scientific Manufactured Defective SCS Devices As a Result of its<br>Violations of Current Good Manufacturing Practices (cGMPs) and<br>Parallel State Law Duties ..... | 24 |
| 3. Boston Scientific Failed to Provide the FDA-Approved Warnings .....                                                                                                          | 34 |

|    |                                                                          |     |
|----|--------------------------------------------------------------------------|-----|
| 1  | 4. Boston Scientific Failed to Use the CBE Process to Warn of Newly      |     |
| 2  | Acquired Information Affecting the Safety and Efficacy of the SCS        |     |
| 3  | Devices .....                                                            | 35  |
| 4  | 5. Boston Scientific Failed to Make Required Adverse Event Reports ..... | 37  |
| 5  | D. BOSTON SCIENTIFIC ENGAGED IN TORTIOUS CONDUCT NOT SUBJECT TO          |     |
| 6  | FEDERAL REGULATION OR REQUIREMENTS .....                                 | 38  |
| 7  | 1. Conduct Outside of Federal Requirements .....                         | 38  |
| 8  | 2. Boston Scientific’s Corporate Misconduct .....                        | 53  |
| 9  | 3. Consumer Protection Violations through Patient-Directed Marketing and |     |
| 10 | Communications.....                                                      | 56  |
| 11 | E. BOSTON SCIENTIFIC SCS DEVICE FAILURES AND RESULTING INJURIES .....    | 60  |
| 12 | F. PLAINTIFFS’ CLAIMS ARE TIMELY.....                                    | 64  |
| 13 | G. LIMITATION AND RESERVATION REGARDING FEDERAL REGULATORY               |     |
| 14 | ALLEGATIONS.....                                                         | 67  |
| 15 | H. LIMITATIONS ON AVAILABLE EVIDENCE .....                               | 68  |
| 16 | VI. CAUSES OF ACTION.....                                                | 69  |
| 17 | COUNT I – STRICT LIABILITY – DESIGN DEFECT .....                         | 69  |
| 18 | COUNT II – STRICT LIABILITY – MANUFACTURING DEFECT .....                 | 72  |
| 19 | COUNT III – STRICT LIABILITY – FAILURE TO WARN .....                     | 75  |
| 20 | COUNT IV – NEGLIGENCE- DESIGN DEFECT .....                               | 81  |
| 21 | COUNT V – NEGLIGENCE-MANUFACTURING DEFECT .....                          | 83  |
| 22 | COUNT VI – NEGLIGENCE-FAILURE TO WARN .....                              | 85  |
| 23 | COUNT VII – BREACH OF EXPRESS WARRANTY.....                              | 90  |
| 24 | COUNT VIII – NEGLIGENCE.....                                             | 95  |
| 25 | COUNT IX – BREACH OF IMPLIED WARRANTY.....                               | 103 |
| 26 | COUNT X - NEGLIGENT UNDERTAKING .....                                    | 106 |
| 27 | COUNT XI – NEGLIGENCE PER SE.....                                        | 110 |
| 28 | COUNT XII – NEGLIGENCE PER SE .....                                      | 115 |

|    |                                                   |     |
|----|---------------------------------------------------|-----|
| 1  | COUNT XIII – NEGLIGENT MISREPRESENTATION .....    | 116 |
| 2  | COUNT XIV - FRAUDULENT MISREPRESENTATION .....    | 123 |
| 3  | COUNT XV – FRAUDULENT CONCEALMENT .....           | 130 |
| 4  | COUNT XVI - VICARIOUS LIABILITY .....             | 134 |
| 5  | COUNT XVII – NEGLIGENCE .....                     | 138 |
| 6  | COUNT XVIII – NEGLIGENT HIRING .....              | 140 |
| 7  | COUNT XIX - NEGLIGENT TRAINING .....              | 144 |
| 8  | COUNT XX – NEGLIGENT SUPERVISION.....             | 146 |
| 9  | COUNT XXI - NEGLIGENT RETENTION .....             | 148 |
| 10 | COUNT XXII – VIOLATION OF CONSUMER PROTECTION LAW |     |
| 11 | AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES ..... | 149 |
| 12 | COUNT XXIII – UNJUST ENRICHMENT .....             | 154 |
| 13 | COUNT XXIV – WRONGFUL DEATH .....                 | 157 |
| 14 | COUNT XXV – SURVIVAL ACTION.....                  | 158 |
| 15 | COUNT XXVI – LOSS OF CONSORTIUM.....              | 159 |
| 16 | COUNT XXVII - PUNITIVE DAMAGES ALLEGATIONS.....   | 159 |
| 17 | PRAYER FOR RELIEF.....                            | 161 |
| 18 | DEMAND FOR JURY TRIAL.....                        | 162 |

19  
20  
21  
22  
23  
24  
25  
26  
27  
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1     **I.     PRELIMINARY STATEMENT**

2           1.     Under Pretrial Order No. 06, Plaintiffs' Co-Lead Counsel and the  
3 Plaintiffs' Executive Committee submit this Master Long-Form Complaint. This  
4 complaint is filed as a master pleading pursuant to the Court's governing pretrial  
5 orders. Plaintiffs assert claims against the below-named Defendants:

- 6                     • Boston Scientific Corporation  
7                     • Boston Scientific Neuromodulation Corporation

8           2.     Subject to the Court's governing pretrial orders, this Master Complaint  
9 sets forth questions of fact and law common to those claims subsumed within the  
10 context of this multidistrict litigation for claims related to spinal cord stimulator  
11 systems. It involves allegations regarding products designed, manufactured,  
12 marketed, distributed, packaged, and sold by Defendants in violation of state and  
13 applicable parallel federal laws and standards.

14          3.     This Master Complaint does not necessarily include all claims asserted  
15 in all transferred actions to this Court, and it does not merge actions for trial or  
16 otherwise beyond the effect prescribed by the Court's governing pretrial orders.  
17 Therefore, this complaint does not include every Plaintiff-specific fact alleged in the  
18 underlying complaints or that would be alleged in a short-form complaint. It is  
19 anticipated that individual Plaintiffs may adopt this Master Complaint and the  
20 necessary causes of action herein through use of a separate Short-Form Complaint  
21 which will specify the products and defendants against whom claims are asserted by  
22 that individual plaintiff. Any separate facts and additional claims of individual  
23 Plaintiffs will be set forth in the Short-Form Complaint filed by the respective  
24 Plaintiffs or their counsel. This Master Complaint does not constitute a waiver or  
25 dismissal of any actions or claims asserted in those individual actions, nor does any  
26 Plaintiff relinquish the right to move to amend their individual claims to seek any  
27 additional claims and/or to add additional parties as discovery proceeds and facts and  
28 other circumstances may warrant.

1           4.       Plaintiffs plead all claims in this Master Complaint in the broadest sense,  
2 pursuant to any laws that may apply under choice-of-law principles, including, but  
3 not limited to, the laws of Plaintiffs' resident states, the states in which Plaintiffs were  
4 injured, the laws of the states in which Plaintiffs' complaints were filed, or the laws  
5 of the states where Boston Scientific maintains its headquarters.

## 6       **II.    INTRODUCTION**

7           5.       Plaintiffs are chronic pain patients, many of whom have suffered for  
8 years with debilitating and life-altering pain. Some have suffered for decades, and all  
9 have sought medical treatment for their condition with the ever-present hope of  
10 finding relief. It was in this hopeful search for relief that Boston Scientific targeted  
11 Plaintiffs and convinced them that a Boston Scientific Spinal Cord Stimulator  
12 ("SCS") device would provide the relief that they sought. However, Plaintiffs  
13 ultimately did not receive the relief promised by Boston Scientific, but instead saw  
14 their condition worsened by exacerbated pain and terrible complications.

15          6.       Boston Scientific treated Plaintiffs as vulnerable revenue sources, easy  
16 marks who would agree to be implanted with an expensive, defective medical device  
17 that did not live up to the specific promises made to them. These vulnerable patients  
18 believed Boston Scientific and its sales representatives when they promised that the  
19 SCS device would provide life-changing pain relief.

20          7.       Boston Scientific was not the first healthcare company to take advantage  
21 of their pain-induced vulnerability. Beginning in the 1990s, pharmaceutical  
22 companies aggressively marketed opioid painkillers as safe and effective for chronic  
23 pain, downplaying addiction risk. Opioid prescriptions exploded through the 2000s,  
24 and the consequences of the pharmaceutical industry's dangerous marketing scheme  
25 boiled over.

26          8.       As the opioid crisis of the 1990s and 2000s faded, and the public and  
27 governmental agencies began to address the serious risks of prescription opioid  
28

1 painkillers, many chronic pain patients began to look elsewhere for relief. These were  
2 the circumstances under which Boston Scientific sold its SCS products to Plaintiffs.

3       9.       Using marketing tactics that exceeded even those used by the opioid  
4 painkiller manufacturers, Boston Scientific sold its SCS devices to desperate pain  
5 patients across the country. As part of their extensive operations, Boston Scientific  
6 extended its reach deep into the patient experience, using sales representatives to go  
7 far beyond typical device marketing to physicians. Boston Scientific designed their  
8 products so that adjustments to the devices were made on electronic devices controlled  
9 and operated by their employees, not the physicians.

10       10.       As a result, patients' interactions with their assigned Boston Scientific  
11 sales representatives began with device selection, continued through the operating  
12 room during the placement of the trial device, to initial device programming, to  
13 coaching through the trial period to qualify for a permanent device, to persuasion to  
14 receive the permanent implant, through the second operating room experience, to  
15 programming of the permanent device and, critically, continued long past patients'  
16 follow-up and interactions with their physicians.

17       11.       As Plaintiffs experienced complications and other issues with their  
18 implanted SCS devices, the Boston Scientific sales representatives were their first  
19 contact. Rather than involve the patient's physician, the representatives would address  
20 the patients' concerns themselves and actually make adjustment to the SCS devices  
21 stimulation therapy *without consulting the physician*.

22       12.       As repeatedly and consistently demonstrated in written text messages  
23 and emails with patients, these representatives would make false statements in  
24 response to patient concerns, statements that, among other things, contradicted the  
25 FDA-approved labeling, concealed defects and the cause of injuries from the patients,  
26 made unfounded promises to the patients, and induced the patients to delay reporting  
27 their device issues to their physicians for as long as possible. The sales representatives  
28 reassured Plaintiffs that the SCS devices would allow them to reduce or even eliminate

1 their dependence on opioid painkillers. Boston Scientific thereby stepped into the  
2 space previously occupied by the opioid painkiller manufacturers and assumed the  
3 lucrative revenue stream offered by chronic pain patients.

4 13. The SCS products implanted in Plaintiffs originate from and are  
5 predicated on Premarket Approval (“PMA”) P030017, initially approved by the FDA  
6 in 2004 for the Precision Spinal Cord Stimulator System. Since that time, the devices  
7 have been materially altered through PMA supplements, and other changes affecting  
8 battery chemistry, firmware, waveform control, leads, and user interfaces, and  
9 manufactured outside of the approved design and manufacturing specifications.

10 14. The SCS devices marketed by Boston Scientific under PMA P030017  
11 include:

- 12 a. Precision Spinal Cord Stimulator System
- 13 b. Precision Plus
- 14 c. Precision Spectra
- 15 d. Precision Montage
- 16 e. Precision Montage MRI
- 17 f. Precision Spectra WaveWriter
- 18 g. Precision Novi
- 19 h. WaveWriter Alpha
- 20 i. WaveWriter Alpha Prime

21 15. SCS devices are associated with significant complications and poor  
22 clinical results, including inadequate effectiveness in providing the pain relief their  
23 manufacturers promise. The devices are also associated with complex risks of device  
24 failures, including but not limited to: device failure, inconsistent therapeutic  
25 treatment, device and lead migration, lead breakage, lead insulation failure, battery  
26 failure, IPG overheating, excessive electrical stimulation, and unintended electrical  
27 stimulation.

1           16.     These device failures, in turn, are the proximate cause of foreseeable  
2 injuries in Plaintiffs including but not limited to: exacerbation of pain, burns,  
3 vasovagal responses such as syncope, unexpected shocking, autonomic dysfunction,  
4 and severe and/or permanent electrical-induced neuropathy and neurological injuries  
5 such as paresthesia, nerve pain, urinary and/or fecal incontinence, urinary retention,  
6 dysphagia, gastroparesis, cardiac arrhythmia, and paralysis.

7           17.     Plaintiffs suffered injuries caused by a defective, adulterated,  
8 misbranded, and dangerous medical device designed, manufactured, marketed,  
9 distributed, packaged, and sold by Defendants in violation of state and applicable  
10 parallel federal laws and standards.

### 11     **III. PARTIES**

#### 12         **A.     Plaintiffs**

13           18.     This Master Complaint is filed on behalf of all Plaintiffs whose claims  
14 are filed or transferred into MDL No. 3181.

15           19.     Plaintiffs are citizens and/or residents and/or visitors of the United  
16 States of America who were implanted with a Boston Scientific Spinal Cord  
17 Stimulator system.

18           20.     Plaintiffs in these individual actions suffered personal injuries as a result  
19 of the implantation of a Boston Scientific Spinal Cord Stimulator system.

20           21.     Additionally, and where applicable, this Master Complaint is also filed  
21 on behalf of Plaintiffs' spouses, children, parents, decedents, wards and heirs.

#### 22         **B.     Defendants**

##### 23             **1.     Boston Scientific Corporation**

24           22.     Defendant Boston Scientific Corporation ("Boston Scientific Corp") is  
25 a corporation organized under the laws of the State of Delaware, and its principal place  
26 of business and global headquarters is in Marlborough, Massachusetts.

27           23.     Defendant Boston Scientific is registered and interacts with the United  
28 States Food and Drug Administration ("FDA") through its offices located at 25155

1 Rye Canyon Loop, Valencia, CA 91355. Defendant Boston Scientific conducts  
2 business throughout the United States and within California, including marketing,  
3 selling, and distributing SCS devices, including Precision Spinal Cord Stimulator  
4 System, Precision Plus, Precision Spectra, Precision Montage, Precision Montage  
5 MRI, Precision Spectra WaveWriter, Precision Novi, WaveWriter Alpha, and  
6 WaveWriter Alpha Prime.

## 7 **2. Boston Scientific Neuromodulation Corporation**

8 24. Defendant Boston Scientific Neuromodulation Corporation (“Boston  
9 Scientific Neuromodulation”) is a corporation organized under the laws of the State  
10 of Delaware, and its principal place of business and global headquarters is in  
11 Marlborough, Massachusetts.

12 25. Defendant Boston Scientific Neuromodulation maintains device-  
13 related operations in Valencia, California, as described below. Boston Scientific  
14 Neuromodulation’s registered agent in California is CSC–Lawyers Incorporating  
15 Service located at 2710 Gateway Oaks Drive, Suite 150N, Sacramento, California.

16 26. Defendant Boston Scientific Neuromodulation is registered with the  
17 FDA as the Specification Developer for SCS devices through its facilities located at  
18 25155 Rye Canyon Loop, Valencia, CA 91355.

19 27. Defendant Boston Scientific Neuromodulation conducts business  
20 throughout the United States and within California, including the design, manufacture,  
21 regulatory submission, and distribution of Class III neuromodulation devices,  
22 including the Precision Spinal Cord Stimulator System, Precision Plus, Precision  
23 Spectra, Precision Montage, Precision Montage MRI, Precision Spectra WaveWriter,  
24 Precision Novi, WaveWriter Alpha, and WaveWriter Alpha Prime devices.

25 28. As the Specification Developer for the device at issue in this case,  
26 Boston Scientific Neuromodulation was responsible for the development and design  
27 of the device at issue, including crucial functions such as design validation, gap  
28

1 analysis, and coordination of Corrective and Preventive Actions (“CAPAs”) required  
2 by the Food, Drug & Cosmetic Act.

3 29. Boston Scientific Corporation and Boston Scientific Neuromodulation  
4 Corporation will hereafter be referred to collectively as “Boston Scientific,” “BSC”  
5 or “Defendants.”

6 30. Upon information and belief, Boston Scientific is the employer of all  
7 sales representatives and employees involved in the design, development,  
8 manufacture, marketing, sales and client interactions pertaining to Boston Scientific’s  
9 SCS devices.

#### 10 **IV. JURISDICTION AND VENUE**

11 31. *Subject Matter Jurisdiction.* This Court has subject matter jurisdiction  
12 over various constituent cases in this multidistrict litigation pursuant to 28 U.S.C. §  
13 1332, because there is complete diversity between Plaintiffs and the Defendants in  
14 such cases, and because Plaintiffs allege an amount in controversy in excess of  
15 \$75,000, exclusive of interest and costs.

16 32. *Personal Jurisdiction.* This Court has personal jurisdiction over this  
17 action because Defendants did/do business in and have continuous and systematic  
18 contacts with the State of California, thereby consenting to jurisdiction in the State of  
19 California. Upon information and belief, Defendants also advertised, made material  
20 omissions and representations, and breached warranties in this District. This Court  
21 also has personal jurisdiction over Defendants because they committed the acts  
22 complained of herein in this State and District and, in some cases, caused injury to  
23 persons located in this State and District.

24 33. *Venue.* Venue and pretrial administration are proper as applicable to  
25 each constituent action for one or more of the following reasons: (1) a substantial part  
26 of the events and omissions giving rise to Plaintiffs’ causes of action occurred in this  
27 District; (2) venue is proper in the transferor court in each constituent case; (3) the  
28 action is directly filed under the Court’s applicable direct-filing order; and/or (4) the

1 action is administered in this District for pretrial purposes pursuant to 28 U.S.C. §  
2 1407 and the June 5, 2026, Transfer Order of the Judicial Panel on Multidistrict  
3 Litigation. These allegations do not waive an individual action's applicable remand or  
4 trial-venue rights.

## 5 **V. FACTUAL ALLEGATIONS**

### 6 **A. Applicable Regulatory Framework**

#### 7 **1. Regulatory Framework: Premarket Approval**

8 34. PMA is the FDA process of scientific and regulatory review to evaluate  
9 the safety and effectiveness of Class III medical devices. Class III medical devices are  
10 those that support or sustain human life, are of substantial importance in preventing  
11 impairment of human health, or which present a potential unreasonable risk of illness  
12 or injury. Due to the level of risk associated with Class III devices, these devices  
13 require PMA application under § 515 of the Federal Food, Drug, and Cosmetic Act  
14 ("FDCA") before they can be sold in the United States.<sup>1</sup>

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

23 36. Once an application for PMA is approved, the holder (here, Boston  
24 Scientific) must comply with any and all post-approval requirements established by  
25 statute, the FDA, and federal regulations. Further, any proposed changes to the  
26  
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28 <sup>1</sup>21 U.S.C. § 360e; 21 C.F.R. Part 814.

1 device's design, labeling, intended use, or manufacturing process must be submitted  
2 to the FDA as a PMA supplement. *See* 21 C.F.R. § 814.39(a).

3 37. In particular, federal regulations require a PMA holder such as Boston  
4 Scientific to comply with the following requirements:

- 5 a. Adverse Events. Review, evaluate, and report to the FDA adverse  
6 events associated with the medical device: (i) Report individual  
7 adverse events within 30 days after becoming aware of an adverse  
8 event or aware of a reportable death, serious injury or  
9 malfunction, 21 C.F.R. § 803.10(c)(1); and (ii) Report individual  
10 adverse events no later than five workdays after becoming aware  
11 of a "reportable event that requires remedial action to prevent an  
12 unreasonable risk of substantial harm to the public health," 21  
13 C.F.R. § 803.10(c)(2)(i);
- 14 b. Quality System. Establish and maintain a quality system that is  
15 appropriate for the specific medical devices designed or  
16 manufactured and that meets the requirement of this part. 21  
17 C.F.R. § 820.5;
- 18 c. Management Responsibility. Management with executive  
19 responsibility shall establish its policy and objectives for, and  
20 commitment to quality. 21 C.F.R. § 820.20<sup>2</sup>;
- 21 d. Qualified Personnel. Have sufficient personnel with the necessary  
22 educational background, training, and experience to assure that  
23 all activities required by this part are correctly performed. 21  
24 C.F.R. § 820.25;

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27  
28 <sup>2</sup> Unless otherwise noted, references to 21 C.F.R. § 820 refer to the version effective  
through February 1, 2026.

- 1 e. Corrective and Preventative Action (CAPA). Establish and  
2 maintain procedures for implementing corrective and preventive  
3 action and document all CAPA activities. 21 C.F.R. § 820.100;  
4 f. Complaint Files. Maintain complaint files, processed in a uniform  
5 and timely manner; oral complaints must be documented and  
6 must be evaluated to determine whether the complaint represents  
7 a reportable event under Medical Device Reporting. 21 C.F.R. §  
8 820.198; and  
9 g. Statistical Techniques. Establish and maintain procedures for  
10 identifying valid statistical techniques required for establishing,  
11 controlling and verifying the acceptability of process capability  
12 and product characteristics. 21 C.F.R. § 820.250.

13 38. Among the aforementioned requirements is to provide the FDA with  
14 the evidence required to establish reasonable assurance of the device's safety and  
15 effectiveness under the applicable regulatory standards.

16 39. The FDCA's implementing regulations require that an applicant for  
17 Premarket Approval of a device submit, with respect to the device proposed to be  
18 marketed: results of the clinical investigations involving human subjects with the  
19 device including clinical protocols, number of investigators and subjects per  
20 investigator, subject selection and exclusion criteria, study population, study period,  
21 safety and effectiveness data, adverse reactions and complications.<sup>3</sup> The permissible  
22 evidence and the information needed for a particular original application or  
23 supplement must be assessed under the applicable regulations.

24 40. The MDA distinguishes between different types of PMA supplements  
25 based on the nature and significance of the change. A "panel-track supplement" is  
26 required for changes that affect the safety or effectiveness of the device, such as new  
27

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<sup>3</sup> 21 C.F.R. § 814.20(b)(6)(ii)

1 indications for use, major design modifications, or significant changes to component  
2 materials.<sup>4</sup>

3 41. For any change that could affect safety or effectiveness, the FDA must  
4 receive and approve the PMA supplement before the manufacturer implements the  
5 change.<sup>5</sup> The burden of proof remains with the manufacturer to demonstrate that the  
6 modified device continues to be safe and effective. *See id.*

7 **2. Regulatory Framework: Post-Marketing Surveillance and**  
8 **Reporting Obligations**

9 42. Manufacturers of PMA devices are also required to comply with post-  
10 market surveillance and reporting obligations, including:

- 11 a. Timely submission of adverse event reports under 21 C.F.R. § 803.50;
- 12 b. Maintenance of complaint files under 21 C.F.R. § 820.198;
- 13 c. Evaluation of nonconforming products under 21 C.F.R. § 820.90; and
- 14 d. Implementation of corrective and preventive actions under 21 C.F.R. §  
15 820.100.

16 **3. Federal Requirements are Paralleled by State Law Duties**

17 43. The federal requirements described above are mandatory, not  
18 discretionary. Although those requirements are enforced by the United States, 21  
19 U.S.C. § 337(a), Plaintiffs do not sue to enforce the FDCA. Plaintiffs sue under state  
20 law for the breach of duties that state law independently imposes, that existed before  
21 the Medical Device Amendments, and that are owed directly to patients. Those state-  
22 law duties are parallel to, and impose no requirement different from or in addition to,  
23 the federal requirements identified herein.

24 44. The federal requirements applicable to PMA device manufacturers are  
25 paralleled by state law duties applicable to Plaintiffs' claims. Because this Master  
26

27  
28 <sup>4</sup> *See* 21 C.F.R. § 814.39(c).

<sup>5</sup> 21 C.F.R. § 814.39(a).

1 Complaint is filed on behalf of Plaintiffs whose claims are governed by the laws of  
2 multiple jurisdictions, the specific state law applicable to each Plaintiff will be  
3 identified in that Plaintiff's Short-Form Complaint. The principal sources of those  
4 parallel state-law duties include state statutes, state common law, and state adoptions  
5 of provisions of the Restatement (Second) of Torts, the Restatement (Third) of Torts:  
6 Products Liability, and the Uniform Commercial Code addressing, among other  
7 things, products sold in a defective condition unreasonably dangerous to the user,  
8 products that depart from their intended design and specifications, negligent  
9 manufacture, the failure to warn, post-sale conduct, and affirmative representations  
10 made to the public.

11 45. First, several jurisdictions have codified product-liability duties in  
12 statutes that govern the claims of Plaintiffs from those jurisdictions, including by  
13 consolidating common-law theories into statutory causes of action. For Plaintiffs from  
14 those jurisdictions, the parallel state-law duties arise under the corresponding statutory  
15 provisions for manufacturing defect, inadequate warning (including post-marketing  
16 warning), and nonconformance with representations.

17 46. Most jurisdictions have adopted, by statute or common law, the rule  
18 stated in Restatement (Second) of Torts § 402A (1965) that one who sells a product in  
19 a defective condition unreasonably dangerous to the user is subject to liability for  
20 physical harm caused to the ultimate user, even though the seller has exercised all  
21 possible care. A product manufactured in departure from its manufacturer's own  
22 specifications is in a defective condition under § 402A.

23 47. In the context of a PMA device, the manufacturer's "specifications"  
24 include the design, materials, manufacturing processes, and acceptance criteria  
25 approved by FDA in the device's PMA and PMA supplements, and the conditions of  
26 approval. Federal law<sup>6</sup> prohibits manufacturing a PMA device in a manner  
27

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28 <sup>6</sup> 21 C.F.R. § 814.80.

1 inconsistent with those conditions. The state-law duty not to sell a device that departs  
2 from its specifications is therefore identical to the federal requirement and imposes no  
3 additional obligation.

4 48. Jurisdictions that have adopted the Restatement (Third) of Torts:  
5 Products Liability (1998) impose the same duty. Under § 1, one engaged in the  
6 business of selling or distributing products who sells a defective product is subject to  
7 liability for harm caused by the defect. Under § 2(a), a product contains a  
8 manufacturing defect "when the product departs from its intended design even though  
9 all possible care was exercised in the preparation and marketing of the product."  
10 Section 6(b)(1) applies that standard to prescription medical devices. A device that  
11 departs from its FDA-approved design and specifications departs from its "intended  
12 design" within the meaning of § 2(a).

13 49. Many jurisdictions also recognize the principle stated in Restatement  
14 (Third) of Torts: Products Liability § 4(a) that a product's noncompliance with an  
15 applicable product-safety statute or administrative regulation renders the product  
16 defective with respect to the risks that the statute or regulation seeks to reduce. The  
17 PMA conditions of approval, the quality management system requirements of 21  
18 C.F.R. Part 820, and the reporting requirements of 21 C.F.R. Part 803 are product-  
19 safety regulations within this principle. Under § 4(a), state law treats noncompliance  
20 with those requirements as establishing defect. It does not create any standard beyond  
21 them.

22 50. Every jurisdiction recognizes a common-law duty of reasonable care in  
23 manufacturing products.<sup>7</sup> A manufacturer that fails to follow its own validated  
24 processes, acceptance criteria, and CGMP controls, including inspection, process  
25 validation, nonconforming-product controls, and corrective and preventive action,  
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27 <sup>7</sup> See Restatement (Second) of Torts § 395 (manufacturer who fails to exercise  
28 reasonable care in the manufacture of a chattel that, unless carefully made, involves  
an unreasonable risk of physical harm is subject to liability).

1 breaches that duty. The scope of the duty, as applied to the devices here, is defined by  
2 and coextensive with the federal requirements identified herein.

3 51. Jurisdictions likewise recognize the rule of Restatement (Second) of  
4 Torts § 388 that one who supplies a chattel for another's use is subject to liability if  
5 the supplier knows or has reason to know the chattel is or is likely to be dangerous for  
6 its intended use and fails to exercise reasonable care to inform those whom it expects  
7 to use it.

8 52. Many jurisdictions treat the violation of a statute or regulation designed  
9 to protect a class of persons, including the plaintiff, against the type of harm suffered,  
10 as negligence per se or as evidence of negligence.<sup>8</sup> The federal requirements identified  
11 herein are designed to protect patients implanted with Class III devices against the  
12 very harms alleged here. Where governing state law permits, Plaintiffs invoke the  
13 federal requirements as the standard of care for their state-law negligence claims, not  
14 as an independent cause of action.

15 53. Federal law requires PMA manufacturers to report deaths, serious  
16 injuries, and malfunctions likely to cause or contribute to serious injury within  
17 specified periods.<sup>9</sup> Some jurisdictions recognize a state law duty to report adverse  
18 events to the FDA that are failure to warn claims.

19 54. To the extent Defendants' labeling, instructions for use, or  
20 communications to physicians departed from, minimized, or contradicted the FDA-  
21 approved labeling, or Defendants failed to provide warnings that federal law required,  
22 that conduct breaches state-law warning duties that parallel the federal requirements.<sup>10</sup>

23 55. Jurisdictions adopting Restatement (Third) of Torts: Products Liability  
24 § 10 recognize a duty to provide post-sale warnings when the seller knows or  
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26 <sup>8</sup> See Restatement (Second) of Torts §§ 286, 288B; Restatement (Third) of Torts:  
27 Liability for Physical and Emotional Harm § 14.

28 <sup>9</sup> 21 U.S.C. § 360i; 21 C.F.R. Part 803 § 803.50.

<sup>10</sup> See Restatement (Third) of Torts: Products Liability §§ 2(c), 6(d).

1 reasonably should know a product poses a substantial risk of harm. This parallels the  
2 FDA methods under 21 C.F.R. § 814.39 for Defendants to alert the FDA of newly  
3 acquired information regarding safety and efficacy, or to implement those changes  
4 under the Changes Being Effected regime.

5 56. Plaintiffs do not seek to enforce the FDCA directly. Rather, Plaintiffs  
6 assert state-law tort claims based on duties that parallel and incorporate federal  
7 requirements, as detailed above. Plaintiffs do not assert any claim premised on fraud  
8 on FDA, on any obligation owed solely to FDA, or on the existence of the FDCA  
9 alone. To the extent any federal requirement is referenced, it is referenced only to  
10 establish that the state-law duty Defendants breached is parallel to, and not different  
11 from or in addition to, federal requirements.

## 12 **B. Boston Scientific's SCS Devices**

### 13 **1. Overview of Spinal Cord Stimulation Devices**

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

18 58. The underlying therapeutic premise of SCS devices involves electrical  
19 stimulation to the dorsal columns to "mask" or "override" the transmission of pain  
20 signals to the brain, pursuant to the gate control theory of pain.

21 59. SCS devices' classification as Class III medical devices by the FDA  
22 mean they present the highest risk to patients and require Premarket Approval  
23 ("PMA") demonstrating safety and effectiveness before commercialization.<sup>11</sup> Any  
24 proposed changes to a PMA-approved device's design, labeling, intended use, or  
25 manufacturing process must be submitted to the FDA as a PMA supplement.<sup>12</sup>

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27 <sup>11</sup> 21 U.S.C. § 360e; 21 C.F.R. Part 814.

28 <sup>12</sup> See generally 21 C.F.R. § 814.39(a).

1           60.     SCS devices are prescription devices within the meaning of 21 C.F.R. §  
2 801.109 and may only be used by or upon the order of a licensed healthcare  
3 practitioner.

4           61.     SCS devices are also associated with significant complications and poor  
5 clinical results, including inadequate effectiveness in providing the pain relief their  
6 manufacturers promise. The devices are also associated with complex risks of device  
7 failures, including but not limited to: device failure, inconsistent therapeutic  
8 treatment, device and lead migration, lead breakage, lead insulation failure, battery  
9 failure, IPG overheating, excessive electrical stimulation, and unintended electrical  
10 stimulation.

11          62.     These device failures, in turn, are the proximate cause of foreseeable  
12 injuries including but not limited to: exacerbation of pain, burns, vasovagal responses  
13 such as syncope, unexpected shocking, autonomic dysfunction, and severe and/or  
14 permanent electrical-induced neuropathy and neurological injuries such as  
15 paresthesia, nerve pain, urinary and/or fecal incontinence, urinary retention,  
16 dysphagia, gastroparesis, cardiac arrhythmia, and paralysis.

17          63.     In September 2020, following a Public Citizen report, the FDA issued  
18 a letter to healthcare providers advising that over the preceding four years it had  
19 received 107,728 adverse event reports regarding SCS devices, including 30,321  
20 reports of unsatisfactory pain relief and 428 patient deaths.<sup>13</sup> These figures include  
21 reports involving Boston Scientific's SCS devices.

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26 <sup>13</sup> MedTech Dive, "FDA Flags 428 Spinal Cord Stimulator Patient Deaths, Urges  
27 More Tests Before Implanting" (Sept. 4, 2020), reporting on FDA Letter to Healthcare  
28 Providers regarding 107,728 adverse event reports received over the preceding four-  
year period. Available at: <https://www.medtechdive.com/news/fda-flags-428-spinal-cord-stimulator-patient-deaths-urges-more-tests-befor/584714/>.

64. Peer-reviewed literature has increasingly associated SCS therapy, particularly multiwaveform stimulation platforms like the newer iterations of Boston Scientific's SCS devices, with unexpected autonomic side effects.<sup>14</sup>

65. A 2023 Cochrane Review<sup>15</sup> led by University of Sydney researchers found that, based on all randomized controlled trials and cross-over trials comparing SCS with placebo or no treatment for low back pain, current evidence suggests that SCS probably does not have sustained clinical benefits that would outweigh the costs and risks of this surgical intervention. The review concerned low back pain and is cited for the limitations of that evidence, not as a finding that every SCS model is ineffective for every indication.

## **2. Boston Scientific's Original PMA**

66. Boston Scientific's entire SCS 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. All Boston Scientific SCS products, including those implanted in Plaintiffs. — the Precision SCS System, Precision Plus, Precision Spectra, Precision Montage, Precision Novi, Spectra WaveWriter, WaveWriter Alpha, and WaveWriter Alpha Prime — operate under a single PMA number: P030017.

67. FDA approved PMA P030017 for the original Precision SCS System on April 27, 2004. Critically, the original PMA was not based on a manufacturer-sponsored, patient-level pivotal IDE trial unique to the Precision system. Instead, as documented by Public Citizen's Health Research Group, the only clinical study data provided to support the application was a review of 16 previously published studies

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<sup>14</sup> See, e.g., Steven Smeijers et al., Spinal Cord Stimulation and Urinary Dysfunction, 23 Pain Med. 1204, 1204-1216 (2022).

<sup>15</sup> Traeger AC, Gilbert SE, Harris IA, Maher CG. Spinal Cord Stimulation for Low Back Pain; Cochrane Database of Systematic Reviews 2023, Issue 3; Art. No.: CD014789. DOI: 10.1002/14651858.CD014789.pub2.

1 of other commercially available SCS devices. No formal Neurological Devices  
2 Advisory Panel meeting was convened for the original Precision PMA.<sup>16</sup>

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

11 69. The original approval relied in part on clinical data from “available peer  
12 reviewed published literature for similar implantable spinal cord stimulation (SCS)  
13 systems.”<sup>19</sup> The FDA’s original Summary of Safety and Effectiveness Data describes  
14 published literature concerning similar SCS systems and also reports actual clinical  
15 experience with the Precision system. Later supplements include additional clinical  
16 evidence.

17 70. Plaintiffs allege that Boston Scientific exceeded the scope of  
18 permissible representations and overstated the extent to which clinical studies  
19 established the long-term benefits and safety represented to Plaintiffs and their  
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21 <sup>16</sup> U.S. Food and Drug Administration, PMA P030017 Original Approval, April 27,  
22 2004 Available at:  
23 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030017>.  
24 See also Michael Carome, *Implanted Spinal Cord Stimulators for Pain Relief* (June  
25 10, 2020), [https://www.citizen.org/wp-content/uploads/2526\\_200610\\_Spinal-Cord-](https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf)  
26 [Stimulator-Report\\_FINAL.pdf](https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf).

26 <sup>17</sup> See 21 C.F.R. §§ 814.82, 814.84, 803.50, 803.53 (2025).

27 <sup>18</sup> See 21 U.S.C. §§ 331(a)-(b), 351 (2025); see also 21 C.F.R. § 814.82(c) (2025).

28 <sup>19</sup> Plaintiffs dispute, in the separately tracked APA proceeding where properly  
asserted, whether the FDA’s evidentiary basis for the relevant approval satisfied the  
applicable statutory and regulatory requirements.

1 physicians. The nature, controls, duration, and device-specific applicability of the  
2 studies are material to those allegations.

3 **3. Subsequent SCS Devices Were Created Through Material**  
4 **Changes to Device Architecture and Functionality**

5 71. Since the original approval of P030017, Boston Scientific has  
6 introduced numerous subsequent models and upgrades under PMA supplements,  
7 including the Precision Plus, Precision Spectra, Precision Montage, Precision  
8 Montage MRI, Precision Spectra WaveWriter, Precision Novi, WaveWriter Alpha, and  
9 WaveWriter Alpha Prime.

10 72. Boston Scientific's subsequent SCS system generations received  
11 approval through PMA supplements to P030017: the Precision Plus through  
12 supplement S100 (approved February 2010); the Precision Spectra through  
13 supplement S134 (received May 2012); the Precision Montage and Precision Novi  
14 through supplement S235 (approved May 19, 2016); the Spectra WaveWriter through  
15 supplement S271 (approved March 2017), which was the first FDA-approved SCS  
16 system capable of delivering simultaneous paresthesia-based and sub-perception  
17 therapy; the WaveWriter Alpha through supplement S338 (approved December 1,  
18 2020); and the WaveWriter Alpha Prime through supplements S357 (DPN indication,  
19 approved October 5, 2023) and S363 (NSBP indication, approved February 5, 2024).<sup>20</sup>

20 73. Since the original approval of P030017, Boston Scientific has filed  
21 nearly 400 supplements to P030017.

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24 <sup>20</sup> U.S. Food and Drug Administration, PMA P030017/S100 (Precision Plus,  
25 approved Feb. 2010); PMA P030017/S134 (Precision Spectra, approved 2013); PMA  
26 P030017/S235 (Precision Montage/Precision Novi, approved May 19, 2016); PMA  
27 P030017/S271 (Spectra WaveWriter, approved March. 2017); PMA P030017/S338  
28 (WaveWriter Alpha, approved Dec. 1, 2020); PMA P030017/S357 (WaveWriter  
Alpha Prime DPN indication, approved Oct. 5, 2023); PMA P030017/S363 (NSBP  
indication, approved Feb. 5, 2024). Available at:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030017>.

1        74. The newer generations of Boston Scientific's devices incorporated  
2 significant modifications, including multiwaveform stimulation (simultaneous tonic,  
3 burst, and sub-perception modes), posture-adaptive programming, expanded electrode  
4 arrays, changes in the way in which sales representatives and patients communicate  
5 with the device, and major revisions to battery architecture and lead designs.

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

- 8        a. The addition of simultaneous multiwaveform stimulation, including tonic,  
9 burst, and sub-perception programming;
- 10       b. The redesign of the implantable pulse generator battery system and revision  
11 to communication capabilities;
- 12       c. The integration of posture-adaptive stimulation algorithms; and
- 13       d. The expansion of lead configurations and multi-source current delivery  
14 systems.

15       76. These substantial modifications materially altered the new SCS devices'  
16 safety and effectiveness profiles compared to the originally approved Precision  
17 system.

18       77. By Boston Scientific's own admission, its various newer SCS devices  
19 are updated versions of its earlier SCS technology. For example, the Spectra  
20 WaveWriter SCS was "approved" by the FDA through Supplement S271 to PMA  
21 P030017. In a January 11, 2018, press release, Boston Scientific described the Spectra  
22 WaveWriter system as "industry leading SCS technology." Thus, the spinal cord  
23 stimulator systems implanted in Plaintiffs are materially different in the respects  
24 described herein from the Precision system that was originally approved by the FDA  
25 in 2004.

26       78. Exemplifying the significant changes Boston Scientific has made to its  
27 SCS systems over the years, it currently advertises and markets three distinct systems  
28 on its website: the Precision Montage, Spectra WaveWriter, and the WaveWriter Alpha

1 systems. Despite advertising three distinct systems, along with several others  
2 throughout the years, Boston Scientific has only received one PMA approval.

3 **C. Boston Scientific Repeatedly Violated Federal Requirements and**  
4 **Parallel State Duties**

5 **1. Boston Scientific Deviated from the Approved Specifications**  
6 **for the SCS Devices**

7 79. Boston Scientific deviated from the approved design and manufacturing  
8 specifications for the SCS devices, thereby introducing defective devices that did not  
9 conform to FDA requirements and violating both federal and parallel state law  
10 requirements.

11 80. At the time that Defendants received approval to market the SCS  
12 devices, the specifications featured a polycarbonate polyurethane insulation sheath on  
13 the lead wire for purposes including electrical insulation, biostability, and mechanical  
14 durability within the harsh environment of the human body.

15 81. Polycarbonate polyurethane, generally, is created by reacting (1) a  
16 diisocyanate, (2) an aliphatic chain extender, and (3) a polycarbonate polyol. Among  
17 the three components, the chemical properties of the soft-segment polycarbonate  
18 polyol are chiefly what endow a polyurethane with its functional properties such as  
19 flexibility, tensile strength, flex-fatigue resistance, and resistance to *in vivo*  
20 environmental degradation.

21 82. The specific formulation of polyurethane which Defendants used to  
22 conduct testing, and the specifications which Defendants provided to the FDA to  
23 obtain approval, required a single-source, 2000g/mol polycarbonate polyol called PC-  
24 1122 manufactured by Stahl United (“Stahl”).

25 83. At all times relevant to this action, Defendants obtained the  
26 polyurethane used in lead insulation for the SCS devices from a company called  
27 AdvanSource Biomaterials Corporation (“AdvanSource”), which was acquired in  
28 2020 by Mitsubishi Chemical Performance Polymers, Inc.

1       84. In the years prior to 2006, AdvanSource prepared polycarbonate  
2 polyurethane for Defendants using PC-1122 obtained from Stahl.

3       85. In fact, Stahl's facility in Peabody, Massachusetts was the only source  
4 in the world for PC-1122 and, thus, the sole source of the key component necessary  
5 to manufacture the polyurethane required to meet the approved specifications of the  
6 SCS devices.

7       86. In 2006, Stahl was acquired by French investment firm Wendel SE, and  
8 the new owners ordered closure of the Peabody, Massachusetts facility, thereby  
9 terminating the sole supply of PC-1122.

10       87. AdvanSource promptly notified Defendants of the impending end of the  
11 supply of PC-1122 and, thus, the end of their ability to manufacture the biodurable  
12 polyurethane used in the lead insulation for the SCS devices.

13       88. This news was also well-known among other medical device  
14 manufacturers due to the ubiquity of PC-1122 in polyurethanes used in medical  
15 applications (e.g., Chronoflex®, Bionate®, Carbothane™) in medical device designs  
16 at that time.

17       89. At that point, Defendants had the duty to either obtain an approved  
18 material from another source or seek approval of alternative materials for their  
19 polycarbonate polyurethane insulation and submit notice of the proposed change in a  
20 new PMA application to the FDA.<sup>21</sup>

21       90. Rather than fulfilling this duty to patients, including Plaintiffs in these  
22 actions, Defendants began manufacturing and/or acquiring lead wire insulation for  
23 their SCS devices using polyurethane synthesized from a different polycarbonate  
24 polyol, namely Eternacoll® UH-200 ("UH-200") manufactured by a company called  
25 UBE Corporation.

26  
27  
28       <sup>21</sup> 21 C.F.R. § 814.39(a)(3).

1           91.     Upon information and belief, Defendants did not submit a proper PMA  
2 supplement to the FDA concerning this material change at all including not limited  
3 those times relative to its use.

4           92.     Crucially, UH-200 has chemical properties which differ markedly from  
5 PC-1122, and the polyurethane resulting from synthesis using UH-200 is significantly  
6 stiffer, more prone to environmental stress cracking, and more prone to *in vivo*  
7 environmental degradation. Defendants knew or should have known about the  
8 material weaknesses associated with UH-200 arising from its different chemical  
9 properties and that such weaknesses would introduce significantly increased device  
10 failure risks.

11           93.     Specifically, as a result of these deviations from the FDA-approved  
12 specifications, the resulting properties of the lead wires manufactured and sold by  
13 Defendants significantly increased the risk of critical device failures in patients  
14 including Plaintiffs, including but not limited to:

- 15           a. Insulation failure;
- 16           b. Lead fracture;
- 17           c. Unintended electrical shocking;
- 18           d. Nerve insult at the site(s) of insulation failure;
- 19           e. Unintended electrical stimulation at the site(s) of insulation failure;
- 20           f. Device infection due to degradation of the material surface, resulting in  
21           increased bacterial colonization and biofilm formation.

22           94.     Defendants were on notice of the causal relationship between the  
23 insulation formulation change and the increase in the incidence of the aforesaid device  
24 failures due to basic materials science and the increased rate of adverse events  
25 demonstrated after PC-1122 became unavailable.

26           95.     Further, it was reasonably foreseeable to Defendants that these critical  
27 device failures would cause the injuries complained of by Plaintiffs, including but not  
28 limited to electrical shocks, device infection, vasovagal reactions such as syncope,

1 and severe and/or permanent nerve injuries including nerve pain, electrical-induced  
2 neuropathy, numbness, lower limb paralysis, bowel and/or urinary incontinence,  
3 gastroparesis, and dysphagia.

4 96. Despite actual and constructive notice of the risk of device failure and  
5 subsequent injuries from the material change, Defendants failed to conduct necessary  
6 quality management procedures, including adequate investigations and Corrective  
7 and Preventative Action (CAPA) procedures to address these increased risks. These  
8 failures violated the FDA Quality System Regulations and newer Quality  
9 Management System Regulations<sup>22</sup> and parallel state law requirements.

10 97. Parallel state law requirements include, but are not limited to, those  
11 prohibiting the sale of unreasonably dangerous devices, such as those adopting the  
12 Restatement (Second) of Torts prohibition in §402(A) and comment g.

13 **2. Boston Scientific Manufactured Defective SCS Devices As a**  
14 **Result of its Violations of Current Good Manufacturing Practices**  
15 **(cGMPs) and Parallel State Law Duties.**

16 98. The pattern of lead and device failures in Boston Scientific's SCS  
17 products, as documented in MAUDE reports and reflected in Plaintiff's injuries, is  
18 consistent with deviations from Boston Scientific's FDA-approved manufacturing  
19 specifications and cGMP requirements. When an SCS lead fractures, breaches its  
20 insulation, or migrates in a manner inconsistent with the device's approved design  
21 specifications, or when an IPG resets or malfunctions in a manner inconsistent with  
22 approved performance standards, the device has deviated from Boston Scientific's  
23 approved design specifications, formula, and performance standards.<sup>23</sup>

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26 <sup>22</sup> Effective February 2, 2026. 21 C.F.R. Part 820 was amended to explicitly  
27 incorporate ISO 13485:2016(E), deeming the new version "Quality Management  
28 System Regulations.

<sup>23</sup> U.S. Food and Drug Administration, Summary of Safety and Effectiveness Data  
(SSED), PMA P030017/S338, Boston Scientific WaveWriter Alpha SCS System

1           99. Boston Scientific manufactured, marketed, and sold defective SCS  
2 devices that were not manufactured in conformity with the FDA-approved design and  
3 manufacturing specifications. These deviations from approved specifications resulted  
4 from Boston Scientific's violation of Current Good Manufacturing Practices (cGMPs)  
5 cGMP requirements codified at 21 C.F.R. Part 820 as both the prior Quality System  
6 Regulations and the new Quality Management System Regulations,<sup>24</sup> including those  
7 governing design control, process validation, complaint handling, and CAPAs. These  
8 non-conforming manufacturing processes and the sale of defective devices violated  
9 both federal and parallel state law requirements, including but not limited those  
10 adopting, or otherwise similar to, the Restatement (Second) of Torts §402(A) with  
11 comment g, §395, §398, and the Restatement (Third) of Torts §§ 1 and 2.

12                   a) Deviations in Lead Sheath Material

13           100. First, as described above, Boston Scientific deviated from the specified  
14 and FDA-approved material for its lead wire insulation sheath, PC-1122, to instead  
15 use UH-200. Those deviations from approved design and manufacturing  
16 specifications resulted in the reasonably foreseeable device failures and resulting  
17 injuries described above.

18           101. By deviating in those ways, Boston Scientific committed violations of  
19 the applicable FDA regulations, including:

- 20           a. 21 C.F.R. § 814.39(a)(6): Failure to submit a PMA supplement for review  
21 and approval by FDA before making a change affecting the safety or  
22 effectiveness of the device for which the applicant has an approved PMA,  
23 including a change in performance, design specifications, components and  
24 ingredients;

25  
26 \_\_\_\_\_  
27 (Dec. 1, 2020) (listing lead migration, insulation breaches, and device malfunction  
28 as potential risks inconsistent with approved device performance).

<sup>24</sup> Unless otherwise noted, all references to 21 CFR 820 in this Master Complaint  
refer to the version in effect prior to February 2, 2026.

- 1 b. 21 C.F.R. § 814.39(f): Failure to submit a 30-day notice of modifications  
2 to manufacturing processes that affect the safety and effectiveness of a  
3 device subject to an approved PMA;
- 4 c. 21 C.F.R. § 820.5: Failure to establish and maintain a quality system that is  
5 appropriate for the specific medical device(s) designed or manufactured,  
6 and that meets the requirements of this part;
- 7 d. 21 C.F.R. § 820.30: Failure to establish and maintain adequate design  
8 control procedures for design verification, validation, and changes;
- 9 e. 21 C.F.R. § 820.50: Failure to establish and maintain procedures to ensure  
10 that all purchased or otherwise received product and services conform to  
11 specified requirements;
- 12 f. 21 C.F.R. § 820.70: Failure to develop, conduct, control, and monitor  
13 production processes to ensure that a device conforms to its specifications,  
14 including the failure to establish and maintain procedures for production  
15 and process changes to a specification, method, process, or procedure;
- 16 g. 21 C.F.R. § 820.90: Failure to establish and maintain procedures to control  
17 a product that does not conform to specified requirements;
- 18 h. 21 C.F.R. § 820.100: Failure to establish and maintain procedures for  
19 implementing corrective and preventive action; and
- 20 i. 21 C.F.R. § 820.198: Failure to establish and maintain procedures for  
21 receiving, reviewing, and evaluating complaints by a formally designated  
22 unit. Such procedures shall ensure that: (1) All complaints are processed in  
23 a uniform and timely manner; (2) Oral complaints are documented upon  
24 receipt; and (3) Complaints are evaluated to determine whether the  
25 complaint represents an event which is required to be reported to FDA  
26 under part 803 of this chapter, Medical Device Reporting.

27 102. These federal violations correspond to violations of parallel state law  
28 duties, including but not limited to those adopting or to similar to the Second

1 Restatement (Second) of Tort's prohibition on selling dangerously defective products  
2 under §402(A) and comment g, its provision addressing a manufacturer's failure to  
3 exercise reasonable care in manufacturing a product under § 395, adoption of an  
4 unsafe design under § 398, or the Restatement (Third) of Tort's section on  
5 manufacturing defect in § 2.

6 103. Boston Scientific knew or should have known that failing to follow  
7 these requirements would foreseeably lead to the device failures and subsequent  
8 injuries described above.

9 b) Infinion CX Leads

10 104. Likewise, the failures of the Infinion CX leads used in the SCS device  
11 systems as described in Boston Scientific's June 17, 2026 letter to customers and the  
12 September 3, 2026 recall communications, demonstrate defective leads that lacked  
13 the structural integrity provided for in the FDA designs for the products.

14 105. As noted in the recall materials, lead fractures could occur with these  
15 products, as well as high impedance measures that could lead to inadequate  
16 stimulation and additional intervention such as explantation or replacement. The  
17 variance in stimulation could lead to increased pain due to lack of efficacy in  
18 patients. These are all foreseeable risks Boston Scientific should have been aware  
19 could result from its failure to conform to federal and state requirements.

20 106. The deviations from federal requirements that resulted in the defective  
21 Infinion CX leads include but are not limited to:

- 22 a. 21 C.F.R. § 820.5: Failure to establish and maintain a quality system that is  
23 appropriate for the specific medical device(s) designed or manufactured,  
24 and that meets the requirements of this part;
- 25 b. 21 C.F.R. § 820.30: Failure to establish and maintain adequate design  
26 control procedures for design verification, validation, and changes;
- 27  
28

- 1 c. 21 C.F.R. § 820.50: Failure to establish and maintain procedures to ensure  
2 that all purchased or otherwise received product and services conform to  
3 specified requirements;
- 4 d. 21 C.F.R. § 820.70: Failure to develop, conduct, control, and monitor  
5 production processes to ensure that a device conforms to its specifications,  
6 including the failure to establish and maintain procedures for production  
7 and process changes to a specification, method, process, or procedure;
- 8 e. 21 C.F.R. § 820.90: Failure to establish and maintain procedures to control  
9 a product that does not conform to specified requirements;
- 10 f. 21 C.F.R. § 820.100: Failure to establish and maintain procedures for  
11 implementing corrective and preventive action; and
- 12 g. 21 C.F.R. §820.198: Failure to establish and maintain procedures for  
13 receiving, reviewing, and evaluating complaints by a formally designated  
14 unit. Such procedures shall ensure that: (1) All complaints are processed in  
15 a uniform and timely manner; (2) Oral complaints are documented upon  
16 receipt; and (3) Complaints are evaluated to determine whether the  
17 complaint represents an event which is required to be reported to FDA  
18 under part 803 of this chapter, Medical Device Reporting.

19 107. These federal violations correspond to violations of parallel state law  
20 duties, including but not limited to those adopting or similar to the Restatement  
21 (Second) of Tort's prohibition on selling dangerously defective products under  
22 §402(A) and comment g, its provision addressing a manufacturer's failure to exercise  
23 reasonable care in manufacturing a product under § 395, adoption of an unsafe design  
24 under § 398, or the Restatement (Third) of Tort's section on manufacturing defect in  
25 § 2.

26 108. Boston Scientific knew or should have known that failing to follow  
27 these requirements would foreseeably lead to the device failures and subsequent  
28 injuries described above.

1 c) Defective Hermetic Seals

2 109. Boston Scientific also manufactured SCS devices that included  
3 defective laser welds and seals that allow moisture and fluids to infiltrate the  
4 hermetically sealed IPG enclosure, thereby compromising the sensitive circuitry and  
5 causing humidity and/or moisture induced device failures.

6 110. The hermetic seals<sup>25</sup> of the SCS IPGs are meant to be maintained  
7 using, among other things, laser-welded seams, encapsulation polymers, and  
8 feedthroughs<sup>26</sup> and are intended to maintain appropriate sealing and internal  
9 moisture levels for the duration of the implant's labeled service life.

10 111. Once moisture accumulates or condenses, it can cause corrosion, open  
11 circuits, metal damage, voltage leakage, current leakage, and electrical shorts that  
12 interrupt device function or cause device failure. Since the invention of implanted  
13 devices with circuitry inside, moisture level has often been considered the most  
14 critical piece of information as many electronic failures are directly related to  
15 moisture accumulation and condensation.<sup>27, 28, 29</sup>

16 112. As designed, the IPG in the Boston Scientific SCS devices provides  
17 power for both the electrical stimulation circuits and the Bluetooth transmitter used to  
18 communicate with patient controller application.

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20 <sup>25</sup> G. Jiang & D.D. Zhou, *Technology advances and challenges in hermetic packaging*  
21 *for implantable medical devices. Implantable neural prostheses 2: techniques and*  
22 *engineering approaches* (2010) at page 31, [https://scispace.com/pdf/technology-](https://scispace.com/pdf/technology-advances-and-challenges-in-hermetic-packaging-for-3d0ffwjbhc.pdf)  
23 [advances-and-challenges-in-hermetic-packaging-for-3d0ffwjbhc.pdf](https://scispace.com/pdf/technology-advances-and-challenges-in-hermetic-packaging-for-3d0ffwjbhc.pdf).

24 <sup>26</sup> PAVE Technology Co., *Hermetic feedthrough: Complete Guide to Sealed*  
25 *Electrical Connections*. [https://www.pavetechnologyco.com/2024/10/19/hermetic-](https://www.pavetechnologyco.com/2024/10/19/hermetic-feedthroughs/)  
26 [feedthroughs/](https://www.pavetechnologyco.com/2024/10/19/hermetic-feedthroughs/) (accessed Aug. 17, 2026).

27 <sup>27</sup> R. W. Thomas, *Moisture, myths, and microcircuits*, in *IEEE Trans, On Parts,*  
28 *Hybrids, and Packaging*, p167–171 (1976).

<sup>28</sup> A. DerMarderosian, *Electrochemical migration of metals*, Proceedings of the  
International Microelectronics Symposium, pp. 134–141 (1978).

<sup>29</sup> A.E. Roswell & G.K. Clymer, *Thermal fatigue lead-soldered semiconductor*  
*device*, US Patent 3,735,208 (1971).

1 113. Moisture infiltration into the sealed IPG can affect the performance and  
2 power draw of the Bluetooth transmitter which in turn negatively impacts the power  
3 available for electrical stimulation. These negative effects affect the delivery of  
4 electrical stimulation including uncontrolled excess electrical stimulation, electrical  
5 leakage, increased battery drain, excess heat generated within the IPG, and a disrupted  
6 routine system check to cause a device reset. These device resets can then cause  
7 incorrect or inconsistent electrical stimulation delivery.

8 114. The device failures caused by the moisture infiltration then cause the  
9 injuries affecting Plaintiffs, including lack of efficacy, burns, electrical shocks, device  
10 infection, vasovagal reactions such as syncope, and severe and/or permanent nerve  
11 injuries including nerve pain, electrical-induced neuropathy, numbness, lower limb  
12 paralysis, bowel and/or urinary incontinence, gastroparesis, and dysphagia.

13 115. First, the very device failures and patient injuries alleged by Plaintiffs  
14 and present in MAUDE reports correspond with the expected failures resulting from  
15 moisture ingress.

16 116. Second, evidence corroborating Boston Scientific's knowledge of the  
17 manufacturing defects and the feasibility of implementing processes to avoid  
18 manufacturing defects affecting the hermetic seals including but not limited to weld-  
19 specification nonconformance, can be seen in the corrective measures taken by Boston  
20 Scientific to cure the manufacturing defects. These corrective measures include, but  
21 are not limited to:

- 22 a. The increased capacitor described in PMA P030017 Supplement S371<sup>30</sup>  
23 that implemented a larger tank<sup>31</sup> to reduce the negative effects of the  
24

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25 <sup>30</sup> Notice to Boston Scientific Corp. (Jan. 30, 2024) (regarding PMA Supplement  
26 S371 for PMA P030017),  
27 [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030017S](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030017S371)  
28 371.

<sup>31</sup> Of note, the increased capacitor size can in fact amplify the negative effects of infiltration, creating more drastic power drains and surges. *See* J. Kast, et al., *Chapter*

1 increased power drain created by the damage caused by moisture ingress in  
2 defectively manufactured SCS devices;

- 3 b. The submission of the 30-day notice in PMA P30017 Supplement S353 for  
4 a manufacturing process change to introduce two new laser welders at the  
5 Dorado, Puerto Rico facility<sup>32</sup>;
- 6 c. The submission of the 30-day notice in PMA P30017 Supplement S355 for  
7 a manufacturing process change to introduce a reweld cycle for the IPG at  
8 the Clonmel, Ireland facility<sup>33</sup>;
- 9 d. The 2021 study titled *Laser Weld Technology and Compression Tool*  
10 *Improvement to Increase Capability and Prevent Continuity Failures* <sup>34</sup>  
11 addressing laser weld process problems in Boston Scientific's  
12 neuromodulation operations, including weld variation and continuity-  
13 failure defects in the spinal cord stimulation units;
- 14 e. The submission of the 30-day notice in PMA P30017 Supplement S379 for  
15 a manufacturing process change to introduce a laser weld system for  
16 additional weld seams at the Clonmel, Ireland facility<sup>35</sup>; and  
17

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18 9: *Device Materials, Handling, and Upgradeability*, Essential Neuromodulation.  
19 Academic Press (2011).

20 <sup>32</sup> Notice to Boston Scientific Corp. (Dec. 2, 2022) (regarding PMA Supplement  
21 S353 for PMA P030017),  
22 [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S3](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S353)  
23 53.

24 <sup>33</sup> Notice to Boston Scientific Corp. (Dec. 7, 2022) (regarding PMA Supplement  
25 S355 for PMA P030017),  
26 [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P030017&SupplementNumber=S355)  
27 &PMANumber=P030017&SupplementNumber=S355.

28 <sup>34</sup> J. E. Barrios Torres, *Laser Weld Technology and Compression Tool Improvement*  
to *Increase Capability and Prevent Continuity Failures*. Manufacturing  
Competitiveness Program: Industrial Engineering Competitiveness, Polytechnic  
University of Puerto Rico (2021).

<sup>35</sup> Notice to Boston Scientific Corp. (Nov. 18, 2024) (regarding PMA Supplement  
S379 for PMA P030017),

1 f. The submission of the 30-day notice in PMA P30017 Supplement S380 for  
2 a manufacturing process change to introduce an additional laser weld  
3 system at the Dorado, Puerto Rico facility.<sup>36</sup>

4 117. These repeated corrective actions to address manufacturing defects in  
5 the process for hermetically sealing the IPGs provide sufficient evidence of the  
6 occurrence of these manufacturing defects in Defendants' SCS devices.

7 118. These manufacturing defects occurred because of Boston Scientific's  
8 quality management system failures in violation of federal requirements and parallel  
9 state duties. These failures include but are not limited to:

- 10 a. 21 C.F.R. § 820.5: Failure to establish and maintain a quality system that is  
11 appropriate for the specific medical device(s) designed or manufactured,  
12 and that meets the requirements of this part;
- 13 b. 21 C.F.R. § 820.30: Failure to establish and maintain adequate design  
14 control procedures for design verification, validation, and changes;
- 15 c. 21 C.F.R. § 820.50: Failure to establish and maintain procedures to ensure  
16 that all purchased or otherwise received product and services conform to  
17 specified requirements;
- 18 d. 21 C.F.R. § 820.70: Failure to develop, conduct, control, and monitor  
19 production processes to ensure that a device conforms to its specifications,  
20 including the failure to establish and maintain procedures for production  
21 and process changes to a specification, method, process, or procedure;
- 22 e. 21 C.F.R. § 820.90: Failure to establish and maintain procedures to control  
23 a product that does not conform to specified requirements;

24  
25 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S379>.

26 <sup>36</sup> Notice to Boston Scientific Corp. (Dec. 13, 2024) (regarding PMA Supplement  
27 S380 for PMA P030017),

28 [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?start\\_search=1&PMANumber=P030017&SupplementNumber=S380](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P030017&SupplementNumber=S380).

- 1 f. 21 C.F.R. § 820.100: Failure to establish and maintain procedures for  
2 implementing corrective and preventive action; and
- 3 g. 21 C.F.R. §820.198: Failure to establish and maintain procedures for  
4 receiving, reviewing, and evaluating complaints by a formally designated  
5 unit. Such procedures shall ensure that: (1) All complaints are processed in  
6 a uniform and timely manner; (2) Oral complaints are documented upon  
7 receipt; and (3) Complaints are evaluated to determine whether the  
8 complaint represents an event which is required to be reported to FDA  
9 under part 803 of this chapter, Medical Device Reporting.

10 119. These federal violations correspond to violations of parallel state law  
11 duties, including but not limited to those adopting or to similar to the Restatement  
12 (Second) of Tort's prohibition on selling dangerously defective products under  
13 §402(A) and comment g, its provision addressing a manufacturer's failure to exercise  
14 reasonable care in manufacturing a product under § 395, adoption of an unsafe design  
15 under § 398, or the Restatement (Third) of Tort's section on manufacturing defect in  
16 § 2.

17 120. Boston Scientific knew or should have known that failing to follow  
18 these requirements would foreseeably lead to the device failures and subsequent  
19 injuries described above.

20 121. These cGMP violations are not discretionary; they are binding legal  
21 obligations imposed by the FDA to ensure the safety and effectiveness of devices.  
22 They establish minimum standards for medical device manufacturers and are  
23 incorporated by reference into state laws as parallel duties.

24 122. Boston Scientific's violations of these cGMP requirements caused  
25 Plaintiffs' injuries described herein. It was reasonably foreseeable that these violations  
26 would cause injury to Plaintiffs and others. Specifically, these violations resulted in  
27 unsafe products being marketed to Plaintiffs and deprived Plaintiffs and their  
28

1 physicians of important information about the safety and efficacy of the devices at  
2 issue.

3 123. Boston Scientific's repeated and willful violations of cGMP  
4 requirements caused or substantially contributed to the defects and injuries at issue in  
5 this case, and support Plaintiffs' claims under state laws.

6 124. These state law claims are not preempted under *Riegel v. Medtronic,*  
7 *Inc.*, 552 U.S. 312 (2008), or *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S.  
8 341 (2001) because they are premised on state-law duties that genuinely parallel  
9 federal requirements and do not exist solely by virtue of the FDCA.

10 **3. Boston Scientific Failed to Provide the FDA-Approved**  
11 **Warnings**

12 125. As part of the PMA process, the FDA approves the product labeling,  
13 including the warnings associated with the devices. Boston Scientific is then obligated  
14 to provide that warning for the patients' benefit, often times to their physician.

15 126. As part of the sales representatives' activity described in more detail  
16 below, Boston Scientific's sales representatives, acting within the scope of their  
17 employment, circumvented physicians so that they communicated and provided  
18 warnings directly to patients.<sup>37</sup> This conduct occurred both orally and in confirmed  
19 written communications, thereby depriving patients of their physicians' independent  
20 assessment and communication of those warnings. Through this conduct, Boston  
21 Scientific circumvented the physician-patient relationship by going directly to the  
22 consumer and deprived the patients of any of the benefits of their physician acting as  
23 a learned intermediary. Furthermore, Boston Scientific inserted itself so thoroughly  
24

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25 <sup>37</sup> See, e.g., *Maryann Bozichovich et al. v. Boston Scientific Corporation*, 2:26-cv-  
26 02830-JLS-PD; *Steven Joe Cooper v. Boston Scientific Corporation*, 2:26-cv-12020-  
27 JLS-PD; *Darrin Peterson v. Boston Scientific Corporation*, 2:26-cv-11312-JLS-PD;  
28 *Darcie Christiansen v. Boston Scientific Corporation*, 2:26-cv-10007-JLS-PD; *Jerri*  
*Thomas v. Boston Scientific Corporation*, 2:26-cv-11446-JLS-PD.

1 into the patient experience that any contact between the physicians and patients was  
2 extremely limited.

3 127. In these direct-to-patient communications, Boston Scientific  
4 representatives (1) failed to provide the full breadth of FDA-approved warnings and  
5 (2) undermined and/or nullified FDA-approved warnings through representations  
6 (and misrepresentations) to the patients about safety, efficacy, the lack of risk, lack of  
7 injury causation, and lack of company knowledge, among other topics. These  
8 deviations are further supported by specific allegations to be pleaded in plaintiff-  
9 specific filings included but not limited to Short-Form Complaints.

10 **4. Boston Scientific Failed to Use the CBE Process to Warn of**  
11 **Newly Acquired Information Affecting the Safety and Efficacy of**  
12 **the SCS Devices**

13 128. Although most device warnings must be approved by the FDA prior to  
14 dissemination, the regulations make an exception in 21 C.F.R. § 814.39(d) under the  
15 Changes Being Effected (“CBE”) process.

16 129. Under that process, certain changes to reflect newly acquired  
17 information that enhances the safety of the device or the safety in the use of the device  
18 may be placed into effect by the applicant prior to the receipt under § 814.17 of a  
19 written FDA order approving the PMA supplement provided that certain conditions  
20 are met.

21 130. The kinds of changes allowed are:

- 22 h. Labeling changes that add or strengthen a contraindication,  
23 warning, precaution, or information about an adverse reaction for  
24 which there is reasonable evidence of a causal association.;
- 25 i. Labeling changes that add or strengthen an instruction that is  
26 intended to enhance the safe use of the device;
- 27 j. Labeling changes that delete misleading, false, or unsupported  
28 indications; and

1 k. Changes in quality controls or manufacturing process that add a  
2 new specification or test method, or otherwise provide additional  
3 assurance of purity, identity, strength, or reliability of the device.

4 131. As described below, Boston Scientific at various times possessed this  
5 kind of newly acquired evidence but did not make any CBE labeling changes to  
6 adequately warn the public, including Plaintiffs and their physicians, of the known  
7 risks associated with the SCS devices.

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

- 12 a. Unsatisfactory pain relief;
- 13 b. Device migration and loss of therapeutic coverage;
- 14 c. Lead fractures requiring surgical revision;
- 15 d. Battery depletion and communication failures; and
- 16 e. Battery overheating.

17 133. The devices are also associated in MAUDE with injuries foreseeably  
18 caused by the device failures described above, including but not limited to:

- 19 a. Persistent ineffective pain relief despite extensive  
20 reprogramming.
- 21 b. Unexpected and severe shocking;
- 22 c. Nerve damage;
- 23 d. Burns from overheated IPG/batteries;
- 24 e. Delayed healing after implant;
- 25 f. Autonomic dysfunction such as orthostatic hypotension and  
26 syncope; and
- 27 g. Electrical-induced neuropathy and nerve injuries (severe and  
28 permanent) including urinary and fecal incontinence, cardiac

1 arrhythmia, dysphagia; urinary retention, gastroparesis,  
2 paresthesia, and paralysis.

3 134. Despite knowing the adverse outcomes, Boston Scientific failed to  
4 update device labeling timely, issue field safety notices, timely file adverse event  
5 reports, educate its sales representatives on the true risk profile and therapeutic benefit  
6 expectations of its SCS devices, or seek revised PMA approvals as required under  
7 federal regulations.

8 135. Had Plaintiffs, or their physicians, received these warnings, they would  
9 have been heeded, and Plaintiffs would not have experienced the device failures and  
10 subsequent injuries described herein. Thus, Plaintiffs' injuries occurred as a direct and  
11 foreseeable result of Defendant Boston Scientific's conduct.

12 **5. Boston Scientific Failed to Make Required Adverse Event**  
13 **Reports**

14 136. Likewise, upon information and belief, Boston Scientific failed to make  
15 the required adverse event reports when it learned of device issues through the patient-  
16 sales representative interactions, instead persuading patients, including Plaintiffs, that  
17 were no issues with the SCS device.

18 137. Upon learning of a reportable adverse event, rather than alerting the  
19 physician and making the appropriate report, Boston Scientific's sales representatives  
20 would "address" the patients' concerns directly and steer the patient away from  
21 reporting their experiences to their physician. Thus, Boston Scientific could  
22 artificially control the number of reported adverse events associated with the SCS  
23 devices. Upon information and belief, this delay in reporting would amount to months  
24 and even years of elapsed time before proper reports were made and the physicians  
25 were brought back into the fold.

26 138. Had appropriate reports been made, the information would be available  
27 to patients (including Plaintiffs) and their physicians via the MAUDE database, and  
28

1 Plaintiffs, with their physicians would have heeded the warning prior to implantation,  
2 thus avoiding the risks and injuries associated with the SCS devices.

3 **D. Boston Scientific Engaged in Tortious Conduct Not Subject to**  
4 **Federal Regulation or Requirements**

5 **1. Conduct Outside of Federal Requirements**

6 139. Federal preemption under the Medical Device Amendments is limited.  
7 Section 360k(a) displaces only a state-law "requirement" that is "different from, or in  
8 addition to, any requirement applicable under this chapter to the device," and that  
9 relates to the device's safety or effectiveness or to another matter covered by a federal  
10 requirement applicable to the device.<sup>38</sup> FDA's own regulation states that state  
11 requirements "are preempted only when the Food and Drug Administration has  
12 established specific counterpart regulations or there are other specific requirements  
13 applicable to a particular device."<sup>39</sup>

14 140. FDA's premarket approval of Defendants' SCS Devices did not establish  
15 federal requirements governing many of Defendants' activities at issue in this Master  
16 Complaint, including the activities of Defendants' personnel in clinics, operating  
17 rooms, and direct contact with patients. No provision of the FDCA, FDA's regulations,  
18 or the PMA for any SCS Device authorizes, prescribes, or governs the following  
19 conduct, among other conduct:

- 20 a. Defendants' sales and field representatives assessing the cause of a patient's  
21 symptoms;  
22 b. Representatives deciding whether a device or lead had failed;  
23 c. Representatives directing reprogramming in place of clinical evaluation of  
24 hardware failure;

25  
26  
27  
28 <sup>38</sup> 21 U.S.C. § 360k(a).

<sup>39</sup> 21 C.F.R. § 808.1(d).

- d. Representatives advising patients or physicians about whether to revise or explant a device;
- e. Representatives making statements to patients about how their particular devices were working; and
- f. Boston Scientific hiring, training, supervision, compensation, and retention conduct.

141. Plaintiffs' claims based on such conduct rest entirely on duties that state law has long imposed on everyone, independent of the FDCA. These include:

- a. The general duty to use ordinary or reasonable care to avoid harming others;
- b. The duty to use reasonable care when undertaking to provide services;<sup>40</sup>
- c. The duty not to misrepresent material facts, whether intentionally, negligently, or to the public;<sup>41</sup>
- d. Obligations arising from express affirmations and promises under U.C.C. § 2-313 as enacted in each state; and
- e. The statutory and common-law prohibitions, where state law provides a remedy, on the unlicensed practice of medicine and on rendering medical judgments without licensure.

142. Similarly, Plaintiffs bring claims that are solely creatures of state law statutory and common law, such as violations of the applicable consumer protection statutes.

143. Plaintiffs therefore plead two distinct categories of state-law claims. The first category covers conduct that federal law regulates. Plaintiffs assert those claims only to the extent the state-law duty parallels the federal requirement.

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<sup>40</sup> See Restatement (Second) of Torts §§ 323, 324A

<sup>41</sup> See *id.* §§ 310, 311, 402B.

1           144. The second category covers conduct that no federal requirement  
2 reaches. For that conduct, state law alone defines Defendants' duties, and Section  
3 360k(a) has no application.

4           145. Boston Scientific's General Marketing Scheme

5           146. Prior to being permanently implanted with a SCS device, a patient must  
6 first undergo a temporary SCS trial. During the temporary trial, the patient is  
7 implanted with temporary leads which are connected to an external, wearable pulse  
8 generator. The temporary trial usually lasts between seven (7) and fourteen (14) days.

9           147. The temporary SCS trial is required by most healthcare insurance  
10 providers and governmental healthcare payers (e.g., Medicare, Medicaid, and  
11 Veterans Affairs). Further, most third-party payers require the patient to report at least  
12 a fifty percent (50%) reduction in pain during the temporary trial before they will pay  
13 for the permanent SCS device. The Department of Veterans Affairs requires patients  
14 to report a sixty percent (60%) reduction in pain before it will pay for a permanent  
15 SCS device.

16           148. While Boston Scientific's SCS device pricing is not publicly available,  
17 and is subject to negotiated pricing with third-party payers and medical facilities, upon  
18 information and belief, Boston Scientific sells its SCS devices for between \$20,000  
19 and \$30,000.

20           149. According to Boston Scientific's 2025 Annual Report, Boston Scientific  
21 reported approximately \$1.2 billion in sales from its neuromodulation products for  
22 fiscal year 2025. Although Boston Scientific no longer breaks down the SCS portion  
23 of its device revenue, historically SCS revenue has represented over 80 percent of  
24 overall neuromodulation revenue. Thus, upon information and belief, SCS devices are  
25 an important and lucrative part of Boston Scientific's medical device portfolio to this  
26 day.

27           150. Due to the invasiveness of the SCS implant, the significant cost of the  
28 devices and the implant procedure, the risks of the devices, and the overall lack of

1 proven efficacy of the devices, aggressive and effective sales and marketing is, and  
2 always has been, critical to Boston Scientific's SCS portfolio.

3 151. To sell one of its SCS devices, Boston Scientific must, through its sales  
4 representatives, first convince physicians to recommend the devices to their patients.  
5 Once the physicians are convinced to recommend SCS therapy in their practices, the  
6 patients must then be convinced. After the patient is convinced, Boston Scientific must  
7 convince the third-party payer to pay for the device – this is achieved through the  
8 patient's report of the required percentage of reduced pain.

9 152. Boston Scientific achieves the three-step marketing process outlined  
10 above (physician, patient, third-party payer) through extensive, direct interaction  
11 between its sales representatives and physicians and patients.

12 153. Boston Scientific sales representatives extensively and directly interact  
13 with patients, including Plaintiffs, throughout the entire process of SCS therapy.

14 154. After a physician suggested SCS therapy as a potential option for  
15 Plaintiffs, he or she then referred the patient to a Boston Scientific sales representative.  
16 The sales representative then set up a face-to-face meeting or telephone call with the  
17 patient, which often occurred outside the presence of Plaintiffs' physicians. The sales  
18 representative provided extensive information about the risks and benefits of the SCS  
19 device during these meetings and conversations.

20 155. Once Plaintiffs decided to proceed with a temporary SCS trial, the sales  
21 representative consulted, either in person or via telephone, with Plaintiffs about the  
22 trial. In fact, in most cases, the sales representative programmed the trial SCS device,  
23 initially and throughout the trial period. Further, the sales representative  
24 communicated with Plaintiffs, often outside the presence of a physician, about the  
25 trial, including any reduction in pain, or lack thereof, that the patient was  
26 experiencing.

1           156. Boston Scientific sales representatives were present in the operating  
2 room and programmed the temporary trial SCS device and made programming  
3 adjustments throughout the trial period.

4           157. Boston Scientific sales representatives discussed with Plaintiffs the  
5 reduction in pain they had to report for third-party payers to pay for a permanent SCS  
6 device, and encouraged Plaintiffs to report the requisite level of pain reduction.

7           158. Boston Scientific sales representatives represented to Plaintiffs that the  
8 permanent SCS devices would provide a greater therapeutic benefit (i.e., greater level  
9 of pain relief) than the temporary trial SCS device.

10          159. Boston Scientific sales representatives programmed and reprogrammed  
11 the temporary trial SCS device to promote a greater therapeutic benefit (i.e., reduction  
12 in pain) than was feasible with a permanent stimulator on a long-term basis.

13          160. At the conclusion of the temporary SCS trial, Boston Scientific sales  
14 representatives continued to directly interact with Plaintiffs to convince them to agree  
15 to the permanent implant. The cycle then repeated with the sales representatives being  
16 present in the operating room, programming the permanent implant, and maintaining  
17 direct and primary contact with the Plaintiffs regarding their SCS devices post-  
18 implant.

19          161. The marketing sequence described above, including the aggressive  
20 direct-to-patient sales efforts, was experienced by Plaintiffs.

21          162. Sales Representative Conduct

22          163. Face-to-face communications between Boston Scientific sales  
23 representatives and Plaintiffs occurred at medical facilities, Plaintiffs' homes, and  
24 even public places, such as parks, coffee shops, and restaurants.

25          164. Once the Plaintiff decided to proceed with a temporary SCS trial, the  
26 sales representative consulted, either in person or via telephone, with the Plaintiff  
27 about the trial. In fact, in most cases, the sales representative programmed the trial  
28 SCS device. Further, the sales representative communicated with the Plaintiff, often

1 outside the presence of a physician, about the trial, including any reduction in pain, or  
2 lack thereof, that the Plaintiff experienced.

3 165. Boston Scientific sales representatives programmed the temporary trial  
4 SCS device and made programming adjustments throughout the Plaintiffs' trial  
5 period.

6 166. Boston Scientific sales representatives discussed with Plaintiffs the  
7 reduction in pain they had to report for third-party payers to pay for a permanent SCS  
8 device, and encouraged the Plaintiff to report the requisite level of pain reduction.

9 167. Boston Scientific sales representatives represented to the Plaintiff that  
10 the permanent SCS devices would provide a greater therapeutic benefit (i.e., greater  
11 level of pain relief) than the temporary trial SCS device.

12 168. Boston Scientific sales representatives programmed and reprogrammed  
13 the temporary trial SCS device to promote a greater therapeutic benefit, i.e., reduction  
14 in pain, than was feasible with a permanent stimulator on a long-term basis.

15 169. At the conclusion of the temporary SCS trial, Boston Scientific sales  
16 representatives continued to directly interact with the Plaintiff to convince him or her  
17 to agree to the permanent implant.

18 170. The majority of Plaintiffs were informed by Boston Scientific's sales  
19 representatives, beyond the scope of the approved label, that these devices would  
20 relieve most of their pain. In reality, the devices provided minimal pain relief and  
21 caused significant and painful complications.

22 171. Boston Scientific sales representatives, in direct interactions with  
23 Plaintiffs, downplayed and undermined the FDA-approved labeling and warnings for  
24 the SCS devices, including risks and side effects contained in the FDA-approved  
25 labeling and warnings, in contravention of the FDCA and implementing regulations.

26 172. Based on representations made by Boston Scientific sales  
27 representatives before, during, and after the temporary SCS trial, Plaintiffs elected to  
28 be implanted with Boston Scientific SCS systems.

1           173. Boston Scientific sales representatives' intentional programming of the  
2 temporary trial SCS devices was intended to and did cause Plaintiffs to believe the  
3 permanent SCS device would provide significant, long-term pain relief. In fact, the  
4 permanent SCS device rarely, if ever, provided equivalent pain relief to the trial SCS  
5 for any substantial amount of time.

6           174. After implantation, Boston Scientific representatives programmed and  
7 made therapeutic adjustments to Plaintiffs' SCS systems without meaningful  
8 physician supervision, order or direction.

9           175. Boston Scientific representatives frequently reprogrammed Plaintiffs'  
10 SCS systems throughout the time in which they were implanted without meaningful  
11 physician supervision, order or direction.

12           176. On the occasions that Plaintiffs had their SCS devices reprogrammed  
13 without meaningful physician supervision, order or direction, Boston Scientific sales  
14 representatives told Plaintiffs that reprogramming of the SCS device was necessary to  
15 ensure that they received optimal pain relief and to avoid complications. The sales  
16 representatives told Plaintiffs that they only needed to seek reprogramming if they  
17 were not receiving adequate pain relief or were experiencing side effects.

18           177. Boston Scientific sales representatives continued to reprogram  
19 Plaintiffs' SCS devices without meaningful physician supervision, order or direction  
20 after they knew or should have known that the reprogramming was not alleviating the  
21 complications experienced by Plaintiffs.

22           178. Boston Scientific sales representatives continued to reprogram  
23 Plaintiffs' SCS devices without meaningful physician supervision, order or direction  
24 after they knew or should have known that the reprogramming was not providing or  
25 increasing the SCS device therapeutic benefit.

26           179. Boston Scientific sales representatives advised Plaintiffs to keep the  
27 SCS devices in their bodies after they complained about complications and after they  
28 were no longer experiencing therapeutic benefit, which caused Plaintiffs to forgo other

1 necessary medical treatment and pain relief mechanisms. This also caused Plaintiffs  
2 to experience further, unnecessary injury in the form of nerve damage caused by  
3 continued electrical assault on the nerve.

4 180. As a direct and proximate result of the defective and misrepresented  
5 nature of the devices, Plaintiffs suffered physical injury, worsening pain, emotional  
6 distress, and economic damages, including medical expenses and loss of quality of  
7 life.

8 181. As a result of these complications, many Plaintiffs required surgical  
9 removal of their SCS devices.

10 a) Unauthorized Practice of Medicine

11 182. At all relevant times, Boston Scientific employed<sup>42</sup> and deployed  
12 clinical and sales representatives to assist with and actively participate in the selection,  
13 implantation, programming, and post-operative management of its SCS devices  
14 throughout the United States at both the trial and permanent device stages.

15 183. Boston Scientific's sales representatives, including the representative(s)  
16 who interacted with Plaintiffs, were not licensed physicians or healthcare providers.  
17 In fact, the only required qualifications for positions with direct-patient contact were  
18 a bachelor's degree or equivalent combination of education and experience and a  
19 minimum of 2 years' work experience in a sales and/or clinical role.<sup>43</sup>

20 184. Nevertheless, in the course and scope of their employment with Boston  
21 Scientific, these representatives routinely engage in conduct including but not limited  
22 to:

- 23 a. Participated in and directed the programming of Plaintiff's SCS device,  
24 including selection of stimulation parameters, waveforms, amplitude, and  
25 frequency settings, during implantation surgery and post-operative care.  
26

27 \_\_\_\_\_  
28 <sup>42</sup> See Ex. A (Boston Scientific Job Postings).

<sup>43</sup> See *id.*

- b. Made real-time clinical decisions about device settings based on their own assessment of patient responses, substituting their judgment for that of Plaintiff's licensed treating physician.
- c. Advised Plaintiff and Plaintiff's physicians about medical treatment decisions concerning the SCS device, including recommendations to continue implantation therapy, undergo reprogramming, and delay or decline device removal.
- d. Directly reprogrammed Plaintiff's SCS device on post-operative occasions, including on occasions when Plaintiff's treating physician was not present.
- e. Made representations directly to Plaintiff — acting as medical advisors — about the expected therapeutic outcomes of the device, the significance and etiology of complications Plaintiff was experiencing, and the anticipated results of device reprogramming, in a manner intended to and having the effect of influencing Plaintiff's treatment decisions.

185. State laws defining the practice of medicine generally include, among other things, being engaged in the diagnosis or treatment of disease or injuries of human beings, suggesting, recommending, or prescribing any form of treatment for the palliation, relief, or cure of any physical ailment with the intention of receiving, either directly or indirectly, any fee, gift, or compensation. The law applicable to specific Plaintiffs will be identified in plaintiff-specific filings, including but not limited to Short-Form Complaints.

186. Boston Scientific's sales representatives' activities constituted the practice of medicine within the meaning of applicable state laws prohibiting the practice of medicine without a valid license.

187. Furthermore, state law commonly creates civil liability for the violation of statutes or regulations under the theory of negligence per se. For example, Restatement (Second) of Torts §§ 286, 288B; Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 14 address treating the violation of a statute or

1 regulation designed to protect a class of persons, including the plaintiff, against the  
2 type of harm suffered, as negligence per se or as evidence of negligence.<sup>44</sup>

3 188. Upon information and belief, Boston Scientific's representatives were  
4 authorized and directed by Boston Scientific to engage in this conduct as part of  
5 Boston Scientific's device sales and clinical support model. Boston Scientific's  
6 compensation structure for its sales and clinical representatives created incentives for  
7 representatives to prioritize device sales and continued implantation over the medical  
8 welfare of patients.

9 189. Upon information and belief, these activities were undertaken by the  
10 representatives at the direction of Boston Scientific and within the scope of their  
11 employment. Accordingly, Boston Scientific would be vicariously liable for its  
12 employees' unauthorized practice of medicine.

13 190. Boston Scientific and their sales representatives knew or should have  
14 known the risk of harm they were exposing patients with this unqualified and  
15 unauthorized practice of medicine. In reliance on the sales representatives, Plaintiffs  
16 experienced harms arising from decisions including but not limited to:

- 17 a. undergoing continuing reprogramming rather than device removal;
  - 18 b. communicating solely with the sales representative rather than alerting the  
19 physician;
  - 20 c. delaying proper medical treatment while undergoing repeated  
21 reprogramming by the sales representatives;
  - 22 d. exposing themselves to continued nerve insult, thus increasing the severity  
23 and permanence of nerve injuries; and
  - 24 e. choosing replacement with another Boston Scientific SCS device rather  
25 than alternative treatment modalities.
- 26

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27 <sup>44</sup> See Restatement (Second) of Torts §§ 286, 288B; Restatement (Third) of Torts:  
28 Liability for Physical and Emotional Harm § 14.

1           191. These harms were not just foreseeable, but were the intended result of  
2 the sales representatives' conduct.

3           192. The exacerbation and worsening of the patients' injuries as a result of  
4 the delays in treatment resulting from the Plaintiffs' misplaced reliance on the sales  
5 representatives was reasonably foreseeable, particularly in light of Boston Scientific  
6 and its' employees actual knowledge of the adverse events and harms associated with  
7 the use of the medical devices defective due to the deviation from FDA-approved  
8 specifications.

9                           b) Negligent Undertaking

10           193. Because they are not licensed physicians, Boston Scientific's sales  
11 representatives did not initially owe a duty to patients relating to activities including  
12 but not limited to patient assessments, counseling, and determinations with respect to  
13 the therapeutic stimulation adjustments. Once they undertook those tasks, however,  
14 they acquired the duty to, at a minimum, perform such tasks with ordinary or  
15 reasonable care.

16           194. Most jurisdictions recognize, by statute, common law, or adoption of the  
17 Restatement (Second) of Torts, that one who undertakes to render services must  
18 perform them with reasonable care.<sup>45</sup>

19           195. Here, Boston Scientific's sales representatives' failure to exercise such  
20 care increased the risk of harm to Plaintiffs and/or the harm suffered by Plaintiffs  
21 because of their reliance upon sales representatives' undertaking.

22           196. Specifically, the sales representatives undertook conduct including but  
23 not limited to:

24                   a. advising for or against revision or explant.

25                   b. assessing whether a Plaintiff's symptoms were caused by the device or by  
26 something else;

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27  
28 <sup>45</sup> See, e.g., Restatement (Second) of Torts § 323

- c. deciding whether a lead or IPG had failed;
- d. recommending or performing repeated reprogramming instead of referring the Plaintiff for clinical evaluation of possible hardware failure; and
- e. telling a Plaintiff or the Plaintiff's physician that the device was functioning properly.

197. The sales representatives' failure to perform such conduct with the required reasonable care is evident behavior including but not limited to:

- a. attributing symptoms consistent with lead fracture, migration, insulation breach, or IPG malfunction to unrelated causes without adequate basis;
- b. repeatedly reprogramming devices that showed signs of hardware failure instead of recommending clinical evaluation;
- c. failing to tell Plaintiffs and their physicians that device data, including impedance readings, indicated possible hardware failure;
- d. making programming adjustments that caused harm to Plaintiffs; and
- e. telling Plaintiffs and their physicians that devices were functioning properly when they were not.

198. Boston Scientific and its sales representatives knew or should have known of the risk of harm they were exposing patients to by failing to perform their undertakings with reasonable care.

199. Defendants' failure to exercise reasonable care increased the risk of harm to Plaintiffs including but not limited to the following ways:

- a. It delayed diagnosis of device failure;
- b. It prolonged Plaintiffs' exposure to stimulation through failing or displaced hardware; and
- c. It deferred revision or explant.

200. Plaintiffs' resulting and foreseeable harm was also a direct and proximate result of their reliance on the Representatives' assessments and statements in continuing to use their devices and in not seeking other evaluation.

1           201. To the extent a Representative's conduct departed from or contradicted  
2 the FDA-approved labeling and instructions for use, Plaintiffs also assert that conduct  
3 as a basis for the parallel claims set forth herein.

4                           c)     Boston Scientific's Misrepresentations and Concealment  
5                                     Through Its Sales Representatives

6           202. Boston Scientific's sales representatives also made materially false and  
7 misleading statements to Plaintiff to induce Plaintiff to (a) agree to the initial  
8 implantation of the SCS device, and (b) delay or forgo removal of the device after  
9 complications arose.

10          203. These representations before trial and permanent implantations include  
11 but are not limited to Boston Scientific's sales representatives' statements, orally and  
12 in writing, to patients, including Plaintiffs, that:<sup>46</sup>

- 13           a. the SCS Device would provide reliable, long-term pain relief, and
- 14                 stimulation was safe and localized;
- 15           b. quantified the promised efficacy;
- 16           c. the permanent SCS Device would provide pain relief equivalent to the relief
- 17                 obtained during the external trial, so that trial results reliably predicted the
- 18                 performance of the permanent implant;
- 19           d. the SCS Device was uniquely suited to provide the patient with long-term
- 20                 pain relief and was supported by clinical data;

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21  
22           <sup>46</sup> See, e.g., *Ollie Wilson v. Boston Scientific Corporation*, 2:25-cv-09958-JLS-PD;  
23 *Linda Guthrie v. Boston Scientific Corporation*, 2:25-cv-11508-JLS-PD; *Sherri*  
24 *Miyagi v. Boston Scientific Corporation*, 2:26-cv-06419-JLS-PD; *Tone Silas v.*  
25 *Boston Scientific Corporation*, 2:26-cv-03679-JLS-PD; *Steven Joe Cooper v. Boston*  
26 *Scientific Corporation*, 2:26-cv-12020-JLS-PD; *Myra Boyd v. Boston Scientific*  
27 *Corporation*, 2:26-cv-09806-JLS-PD; *Cynthia Galary v. Boston Scientific*  
28 *Corporation*, 2:26-cv-11311-JLS-PD; *Darrin Peterson v. Boston Scientific*  
*Corporation*, 2:26-cv-11312-JLS-PD; *Daniel Carmack v. Boston Scientific*  
*Corporation*, 2:26-cv-12158-JLS-PD; *Gloria Castleberry v. Boston Scientific*  
*Corporation*, 2:26-cv-10953-JLS-PD.

- e. the SCS Device would provide better pain relief than other treatment modalities, including dorsal root ganglion ("DRG") stimulation and other manufacturers' SCS devices; and
- f. that patients would be pain-free with SCS Device.

204. Patients relied on these representations in selecting a Boston Scientific SCS Device for implantation.

205. These representations are part of a consistent and pervasive pattern of conduct by the Defendants and extend beyond those individual Plaintiffs identified in footnote 46. The details of specific representations will be provided in Plaintiff-specific filings, included but not limited to Short-Form Complaints.

206. Insurance coverage for a permanent SCS implant commonly depends on the patient reporting a minimum level of pain relief during the trial, often fifty percent or greater. Boston Scientific's sales representatives knew this. On information and belief, sales representatives encouraged patients whose trial results fell below the coverage threshold to continue the trial. They adjusted the trial stimulator and steered patients' reports of trial pain relief toward the minimum needed for insurance to pay for the permanent implant.

207. After implantation, when patients, including Plaintiffs, reported issues including inadequate pain relief, shocking or burning sensations, stimulation in unintended areas, and other complications described in this Master Complaint, Boston Scientific's sales representatives represented to them, among other things, that:

- a. the patient would get pain relief once the sales representative found the right programming settings;
- b. that inadequate relief or side effects simply meant the device needed reprogramming;
- c. in direct contradiction of the FDA-approved labeling, that side effects such as unintended shocks are not known to be caused by the SCS Device, so

1 the shocks the patient was experiencing could not be coming from the  
2 device;

3 d. the patient's symptoms had other causes, including that the sensations were  
4 imagined or psychosomatic; and

5 e. downplayed the severity of the patients' injuries.

6 208. On those occasions, Boston Scientific's sales representatives adjusted  
7 patients' stimulation settings themselves, often without physician oversight or  
8 involvement.

9 209. Through these representations, Boston Scientific prevented patients  
10 from discovering the true cause of their symptoms, such as a migrated or fractured  
11 lead or a mechanical failure of the device. For some patients, the cause was identified  
12 only when a different physician evaluated the device or when it was revised or  
13 explanted.

14 210. This conduct and accompanying representations are part of a consistent  
15 and pervasive pattern of conduct by the Defendants and extend beyond those  
16 individual Plaintiffs identified in footnote 46. The details of specific representations  
17 will be provided in Plaintiff-specific filings, included but not limited to Short-Form  
18 Complaints.

19 211. Boston Scientific and its sales representatives not only knew or should  
20 have known Plaintiffs would rely on these representations, but that was the desired  
21 outcome.

22 212. As a result of their reliance, Plaintiffs were induced to, among other  
23 things:

24 a. delay diagnosis of device failure;

25 b. prolong Plaintiffs' exposure to stimulation through failing or displaced  
26 hardware; and

27 c. defer revision or explant.  
28

1           213. The reasonably foreseeable harm Plaintiffs experienced due to their  
2 continued exposure to the harmful electrical stimulation and defective devices was an  
3 exacerbation of their injuries and progression to permanent injuries. This is due to the  
4 nature of nerve injuries: the longer the insult on the nerve continues, the more severe  
5 and long-lasting the injury until it reaches permanence.

6           214. Because the sales representatives engaged in this conduct at the  
7 direction of, and in the scope of their employment by, Boston Scientific, the  
8 manufacturer is vicariously liable for the harm and damages suffered by Plaintiffs.

## 9                           **2. Boston Scientific's Corporate Misconduct**

10           215. The clinical and sales representatives supporting Boston Scientific's  
11 SCS devices were employees and/or agents of Boston Scientific and acting within the  
12 scope of that relationship while interacting with patients and respective devices as  
13 described herein.

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

19           217. Defendants do not simply sell SCS Devices and leave their use to  
20 physicians. As a matter of corporate practice, Defendants employ sales  
21 representatives, field clinical representatives, and other personnel (together,  
22 "Representatives"). Defendants deploy them to provide continuing services in  
23 connection with implanted SCS Devices. On information and belief, those services  
24 include:

- 25           a. attending trial and permanent implantation procedures;
- 26           b. performing intraoperative and post-implant programming;
- 27           c. interrogating devices and evaluating impedance and other device data;
- 28           d. troubleshooting patient complaints; and

- 1 e. communicating directly with patients, in person and by telephone, about  
2 their symptoms and how their devices are working.

3 218. Evidence of the employment relationship and intended scope of duties  
4 can be seen, for example, in job postings for positions directly with Boston  
5 Scientific.<sup>47</sup> Calling the positions “clinical specialists” and “territory managers,”  
6 Boston Scientific has identical job descriptions for positions all over the country.

7 219. Job duties for these positions show that these positions were intended to  
8 exceed the permissible scope for non-physicians and have a high degree of patient  
9 interaction by including job duties such as:

- 10 a. Provide expert clinical support through programming, troubleshooting, and  
11 intraoperative guidance for spinal cord stimulation procedures;  
12 b. Deliver patient follow-up care, ensuring optimal therapy performance and  
13 long-term success;  
14 c. Take an integral role in patient follow-up care by regularly monitoring  
15 therapy progress, addressing patient needs, and collaborating with  
16 healthcare teams to ensure optimal outcomes and satisfaction with  
17 company products;  
18 d. Actively participate in surgical cases within hospital and surgery center  
19 environments, providing hands-on support throughout procedures;  
20 e. Serve as a resource for current and prospective customers, providing  
21 updates on innovations and evidence-based therapies to support informed  
22 decision-making in pain management; and  
23 f. Territory Manager will oversee the entire SCS process of patient care, pre-  
24 surgical education, post-surgical follow ups and long-term care of the  
25 device.

26  
27  
28 

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<sup>47</sup> See Ex. A.

1           220. Defendant knew or should have known that its employees were not  
2 qualified for positions to perform these responsibilities, as the only required  
3 qualifications for the positions are a bachelor's degree or an equivalent combination  
4 of education and experience and a minimum of two years' work experience in a sales  
5 and/or clinical role.

6           221. Defendants offered and provided these services to implanting and  
7 managing physicians, to hospitals and clinics, and directly to patients, including  
8 Plaintiffs. Defendants did so for the purpose, among others, of keeping patients using  
9 their SCS Devices and keeping physicians using Defendants' products. Defendants  
10 knew, or should have recognized, that the services were necessary to protect patients.  
11 A patient whose implanted lead has fractured, migrated, or suffered an insulation  
12 breach, or whose IPG is malfunctioning, faces a risk of continuing and progressive  
13 physical injury if the failure is not identified and addressed.

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

20           223. Boston Scientific knew, or in the exercise of reasonable care should have  
21 known, that its representatives were: (a) programming and reprogramming SCS  
22 devices in ways that constituted the practice of medicine; (b) making medical  
23 recommendations and representations to patients outside the representatives'  
24 permissible scope; and (c) misleading patients about device performance and  
25 complications.

26           224. Boston Scientific failed to take reasonable steps to prevent, stop, or  
27 correct this conduct. Specifically, Boston Scientific, among other things:  
28

- a. failed to establish and enforce adequate policies limiting the scope of its representatives' participation in device programming to permissible technical support activities;
- b. Failed to ensure new hires were qualified for the job duties expected;
- c. failed to train its representatives on the legal limits of their permissible conduct;
- d. failed to supervise its representatives to ensure compliance with applicable law and company policy; and
- e. retained representatives whom it knew or should have known were engaging in impermissible conduct.

225. As a direct and proximate result of Boston Scientific's institutional conduct, Plaintiffs were induced to undergo trial and permanent SCS implantation, were misled about device performance, and were dissuaded from seeking timely removal of the device after complications arose, thereby sustaining permanent nerve damage that would not have occurred or would have been less severe but for Defendants' conduct.

### **3. Consumer Protection Violations through Patient-Directed Marketing and Communications**

226. Defendants did not limit their communications about the SCS Devices to physicians. Defendants also marketed and communicated directly to patients and prospective patients, including Plaintiffs, through patient-directed websites, brochures, patient education programs, and other promotional materials and through Defendants' Representatives.

227. Defendants' patient-directed materials and representations made statements about the durability, reliability, longevity, and safety of the SCS Devices including the statements detailed in the section above. On information and belief, these statements went beyond, or were inconsistent with, the FDA-approved labeling for the SCS Devices.

1           228. When these statements were made, Defendants possessed information  
2 inconsistent with them. That information included complaints, adverse-event reports,  
3 returned-product analyses, and failure data about lead fracture, lead migration,  
4 insulation breach, and IPG/battery malfunction

5           229. Defendants' Representatives told Plaintiffs things including but not  
6 limited to that their devices were functioning properly, that their symptoms had causes  
7 unrelated to device failure, and that reprogramming would resolve their complaints.  
8 On information and belief, Representatives made these statements without an  
9 adequate basis. In some instances, device data, including impedance readings,  
10 indicated possible hardware failure when the statements were made.

11           230. Plaintiffs saw, heard, and considered Defendants' patient-directed  
12 statements when deciding to undergo implantation, to continue using their SCS  
13 Devices, and to forgo or delay revision or explant.

14           231. Plaintiffs paid, or incurred liability for, amounts for the SCS Devices,  
15 implantation and revision procedures, follow-up care, and related medical expenses.

16           232. Boston Scientific had adequate notice of Plaintiffs' complaints and the  
17 alleged product defects and issues.

18           233. For one, Boston Scientific received direct reports from Plaintiffs,  
19 including but not limited to reports of pain, loss of therapy, shocking or uncontrolled  
20 stimulation, and other symptoms to Boston Scientific's sales representatives, in  
21 person, by telephone, in writing, and through Defendants' patient support channels.  
22 On information and belief, Boston Scientific recorded those reports in its complaint-  
23 handling systems.

24           234. For another, Boston Scientific receives, investigates, and maintains  
25 records of complaints about the SCS Devices. Federal regulations require them to  
26 evaluate those complaints and report qualifying deaths, serious injuries, and  
27 malfunctions to FDA. 21 C.F.R. Part 803; 21 C.F.R. Part 820. On information and  
28 belief, Boston Scientific received complaint and adverse-event information about

1 Plaintiffs' own devices. They also received such information about the same device  
2 models, lead families, and components implanted in Plaintiffs.

3 235. Furthermore, before this Master Complaint was filed, numerous patients  
4 filed lawsuits against Defendants alleging the same defects, misrepresentations, and  
5 conduct alleged here. On June 5, 2026, the Judicial Panel on Multidistrict Litigation  
6 centralized those actions in this Court as MDL No. 3181. Some Plaintiffs previously  
7 filed actions against Defendants arising from the same devices and injuries, as  
8 identified in their Short-Form Complaints.

9 236. In addition, some Plaintiffs served Defendants with written notices or  
10 demands describing the conduct complained of and the injuries suffered, before filing  
11 or before asserting claims for damages.

12 237. Despite receiving the information described above, Boston Scientific  
13 did not correct, repair, replace, or otherwise remedy the conduct complained of. They  
14 did not offer any remedy to Plaintiffs, nor did they change the patient-directed  
15 statements and conduct described above.

16 238. Defendants' Receipt and Retention of Benefits From the Sale and  
17 Servicing of SCS

18 239. Each SCS Device implanted in a Plaintiff was sold by Boston Scientific,  
19 who received payment for each device and its components, including leads,  
20 extensions, IPGs, chargers, and remote controls. Payment came from Plaintiffs or on  
21 their behalf, through hospitals, ambulatory surgery centers, and physician practices,  
22 and through Plaintiffs' health insurers, Medicare, Medicaid, and other payors funded  
23 in part by Plaintiffs' premiums, co-payments, deductibles, and co-insurance.

24 240. Payment for SCS Devices flows from the patient's procedure to  
25 Defendants. The amount Defendants receive for each device depends on that device  
26 being implanted in a specific patient. Each sale was known to Defendants and was  
27 made for the purpose of implantation in a specific patient.

28

1        241. Upon information and belief, Boston Scientific derived substantial  
2 revenue and profit from the sale of SCS Devices, including those implanted in  
3 Plaintiffs.

4        242. Boston Scientific received additional benefits beyond the original sale.  
5 Plaintiffs whose SCS Devices failed underwent revision, replacement, or explant  
6 procedures. On information and belief, many of those procedures used replacement  
7 leads, IPGs, or other components sold by Defendants, generating additional revenue  
8 for Defendants. The services of Boston Scientific's Representatives, including  
9 programming, troubleshooting, and patient follow-up, kept Plaintiffs using the SCS  
10 Devices and kept their physicians using Defendants' products. Boston Scientific  
11 provided those services to support continued sales.

12        243. Boston Scientific knew they were receiving these benefits and accepted  
13 and retained them. Defendants tracked sales of SCS Devices by device, patient,  
14 physician, and facility. Through their Representatives, Defendants had direct,  
15 continuing contact with Plaintiffs after implantation.

16        244. Boston Scientific received and retained these benefits under the  
17 circumstances including but not limited to:

- 18        a. selling SCS Devices that departed from their FDA-approved specifications  
19            and manufacturing requirements;
- 20        b. failing to report complaint and adverse-event information required by  
21            federal law;
- 22        c. communicating to Plaintiffs, through Defendants' Representatives and  
23            patient-directed materials, that their devices were functioning properly and  
24            that their symptoms were unrelated to device failure; and
- 25        d. continuing to receive payment for replacement components and services  
26            while attributing device failures to other causes.

27        245. Plaintiffs did not receive what they paid for: SCS Devices manufactured  
28 in conformity with their FDA-approved specifications and serviced with reasonable

1 care. Instead, Plaintiffs received devices that failed and suffered the injuries alleged  
2 in this Master Complaint. Defendants have not returned or offered to return any  
3 portion of the amounts they received for Plaintiffs' SCS Devices or related  
4 replacement components.

5 246. Plaintiffs allege privity exists with Defendants through course of  
6 conduct, implied representations and express representations. In the alternative, in  
7 the absence of an express contract between Plaintiffs and Boston Scientific governing  
8 Defendants' obligation to return amounts received for nonconforming devices or for  
9 the consequences of Defendants' Representatives' conduct, Boston Scientific would  
10 be unjustly enriched if they inequitably retained the proceeds of their misconduct. To  
11 the extent Defendants contend that a written warranty governs any part of that subject  
12 matter that disclaims any liability for the misconduct alleged herein, Plaintiffs assert  
13 in the alternative that the warranty does not cover the conduct alleged here.

14 **E. Boston Scientific SCS Device Failures and Resulting Injuries**

15 247. The Boston Scientific SCS Products have an unacceptably high rate of  
16 failure, including lead fracture, insulation breach, migration from the implantation  
17 site, and IPG/battery malfunction causing interruption or alteration of therapy  
18 delivery.

19 248. Post-market published data confirm that SCS devices, including the  
20 Boston Scientific SCS Products, are associated with serious complications at high  
21 rates. Lead migration and fracture rates have been reported at between 13.2% and  
22 22.6% of implanted patients in published literature, often requiring surgical revision.<sup>48</sup>

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24 <sup>48</sup>ASRA, Complications of Spinal Cord Stimulator Implantation (Aug. 2019)  
25 available at [https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-](https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation)  
26 [news/2019/08/07/complications-of-spinal-cord-stimulator-implantation](https://asra.com/news-publications/asra-newsletter/newsletter-item/asra-news/2019/08/07/complications-of-spinal-cord-stimulator-implantation)). *See also*  
27 Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic  
28 benign pain: challenges in treatment planning and present status, a 22-year  
experience. *Neurosurgery*. 2006;58(3):481–496.  
<https://doi.org/10.1227/01.NEU.0000192162.99567.96>. *See also* Mekhail NA,

1 A 2025 study confirms that up to 40% of SCS patients experience complications from  
2 hardware failure (including lead migration and breakage), biological complications  
3 (infection, epidural hematoma), or other causes.<sup>49</sup> SCS explant rates have been  
4 reported at up to 38%, with most occurring within the first and second year of  
5 implantation.<sup>50</sup> Public Citizen's 2020 report independently documented that from 2004  
6 to 2019 the FDA received 220,374 adverse event reports for SCS devices, including  
7 156,817 reports of injuries and 931 reports of patient deaths — figures that include  
8 Boston Scientific devices.<sup>51</sup>

9 249. Injuries documented across manufacturers in the 2020 Public Citizen  
10 include spinal cord damage ranging from muscle weakness to paraplegia, device  
11 burns, lead migration, lead fracture, implant-related pain, infection, hematoma,  
12 seroma, cerebrospinal fluid leakage, and — in rare cases — chronic scar tissue  
13 formation around epidural leads causing spinal compression and myelopathy with  
14 paresis and sensory loss.<sup>52</sup>

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17 Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of  
18 707 cases of spinal cord stimulation: indications and complications. *Pain Pract.*  
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19 <sup>49</sup> Vanessa Choi Yin Wong et al., *Risk Factors for Spinal Cord Stimulator Explant*  
20 *After Implantation for Neuropathic Pain: A Systematic Review*,  
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23 <sup>50</sup> Amruta Pai et al., *Spinal Cord Stimulation Explantation and Chronic Pain*, 2025  
24 *J. Pain Res.* (PMC), PMCID: PMC11929510, at *Conclusion* (Mar. 17, 2025),  
25 available at <https://pmc.ncbi.nlm.nih.gov/articles/PMC11929510/>.

26 <sup>51</sup>Public Citizen Health Research Group, "The FDA's Reckless Oversight of  
27 Implanted Spinal Cord Stimulators for Pain Relief Has Seriously Endangered  
28 Patients" (June 10, 2020) (documenting complication rates of 30%-40% across  
literature reviews of implanted SCS devices, and from 2004-2019 the FDA received  
220,374 adverse event reports for SCS devices including 156,817 reports of injuries  
and 931 reports of patient deaths). Available at: [https://www.citizen.org/wp-content/uploads/2526\\_200610\\_Spinal-Cord-Stimulator-Report\\_FINAL.pdf](https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf).

<sup>52</sup> See *id.*

1           250. These failures are not incidental side effects of an otherwise effective  
2 therapy; they are evidence of fundamental defects in the design and manufacture of  
3 Boston Scientific's leads and IPGs resulting from deviations from FDA-approved  
4 design and manufacturing specifications.

5           251. The known device failures of the Boston Scientific SCS devices include  
6 but are not limited to: total device failure, inconsistent therapeutic treatment, device  
7 and lead migration, lead breakage, lead insulation failure, battery failure, IPG  
8 overheating, excessive electrical stimulation, and unintended electrical stimulation.

9           252. When SCS leads or components fail, whether by fracturing, breaching  
10 insulation, or migrating, the electrical current delivered to the spinal cord is no longer  
11 directed to the therapeutic target. Uncontrolled electrical stimulation can cause  
12 burning pain, electrical shocking sensations, nerve irritation, and ultimately  
13 permanent nerve damage if the device is not promptly removed. Similarly, when the  
14 IPG/battery fails or resets unexpectedly, therapy is disrupted in ways that can cause  
15 adverse neurological effects, burns, and require additional surgical intervention.

16           253. The permanence of nerve damage resulting from delayed device  
17 removal is a foreseeable and known consequence of lead failure and IPG/battery  
18 malfunction. When a failing or migrated lead continues to deliver uncontrolled  
19 stimulation, nerve injury progresses over time. The longer a failing device remains  
20 implanted, the greater the potential for permanent neurological harm. Prompt  
21 recognition and removal are therefore essential to preventing permanent injury.

22           254. Representations by Boston Scientific's sales representatives that  
23 discouraged or delayed removal, as described herein, directly and foreseeably  
24 worsened the permanence and severity of Plaintiff's nerve injuries.

25           255. In July 2024, Boston Scientific issued an Urgent Medical Device  
26 Advisory (Field Action 97178176B-FA) advising that WaveWriter Alpha  
27 rechargeable SCS IPGs could experience stimulation therapy transiently suspended  
28 during charging due to a device reset. The reset occurs in response to the presence of

1 potential interference during IPG charging. When the system resets, the patient's  
2 programmed stimulation turns off for approximately 10-15 seconds. The issuance of  
3 this field action is a documented acknowledgment by Boston Scientific that its  
4 WaveWriter Alpha IPG was subject to a defect causing foreseeable, preventable  
5 failure during a routine patient activity — charging the device.<sup>53</sup>

6       256. Boston Scientific's PMA P030017 supplement history includes five  
7 documented Special (Immediate Track) supplements — S004 (November 2004, filed  
8 less than seven months post-original approval), S019 (February 2007), S024 (April  
9 2007, the second Immediate Track supplement within a ten-week period), S090  
10 (November 2008, filed within the high-volume 2008 supplement cluster), and S203  
11 (September 2014). Immediate Track is reserved by the FDA for situations involving  
12 significant risk to the health of persons, warranting review in less than 180 days. The  
13 subject matter of all five Immediate Track supplements is not publicly available and  
14 constitutes evidence of undisclosed, urgent corrections to Boston Scientific's SCS  
15 platform.<sup>54</sup>

16       257. The devices are also associated with complex risks of device failures,  
17 including but not limited to: device failure, inconsistent therapeutic treatment, device  
18  
19

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20 <sup>53</sup> Boston Scientific, Urgent Medical Device Advisory, Field Action 97178176B-FA  
21 (July 17, 2024) (advising of potential for WaveWriter Alpha SCS IPG stimulation  
22 therapy to be transiently suspended during charging due to a device reset; IPG  
23 firmware update developed to prevent reset behavior). Available at:  
24 [https://www.bostonscientific.com/content/dam/bostonscientific/quality/documents/  
Recent%20Product%20Advisories/2024July\\_SCS\\_EffectsResetsRechargeableSCSI  
PGs.pdf](https://www.bostonscientific.com/content/dam/bostonscientific/quality/documents/Recent%20Product%20Advisories/2024July_SCS_EffectsResetsRechargeableSCSI PGs.pdf).

25 <sup>54</sup> P030017 has five documented Special (Immediate Track) supplements: S004  
26 (Nov. 2004, filed less than 7 months post-original approval), S019 (Feb. 2007),  
27 S024 (Apr. 2007, two urgent corrections in 10 weeks), S090 (Nov. 2008, within the  
28 high-volume 2008 supplement cluster), and S203 (Sept. 2014). *See* PMA P030017  
Supplement History. Available at:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030017>.

1 and lead migration, lead breakage, lead insulation failure, battery failure, IPG  
2 overheating, excessive electrical stimulation, and unintended electrical stimulation.

3 258. These device failures, in turn, are the proximate cause of foreseeable  
4 injuries in Plaintiffs including but not limited to: exacerbation of pain, burns,  
5 vasovagal responses such as syncope, unexpected shocking, autonomic dysfunction,  
6 and severe and/or permanent electrical-induced neuropathy and neurological injuries  
7 such as paresthesia, nerve pain, urinary and/or fecal incontinence, urinary retention,  
8 dysphagia, gastroparesis, cardiac arrhythmia, and paralysis.

9 **F. Plaintiffs' Claims Are Timely**

10 259. Plaintiffs discovered the probable causal relationship between their  
11 injuries and Boston Scientific's conduct only after experiencing continued device-  
12 related complications, removal of devices, and/or finally being informed of the  
13 underlying facts of the SCS devices that contradicted representations made by Boston  
14 Scientific and its sales representatives.

15 260. Until Plaintiffs learned the underlying facts of the safety and efficacy of  
16 Boston Scientific's SCS devices, they believed that their conditions and the efficacy  
17 of the devices were an aberration limited to themselves and not caused by a pattern  
18 and practice of Boston Scientific.

19 261. At all times relevant to this Master Complaint, Boston Scientific  
20 fraudulently concealed from Plaintiffs the truth about the safety and efficacy of its  
21 SCS devices, and Plaintiffs could not have discovered that truth through reasonable  
22 diligence. Boston Scientific continues to maintain that its SCS devices are safe and  
23 effective.

24 262. Plaintiffs did not discover the defects and unreasonably dangerous  
25 condition of Defendants' SCS Devices, and could not have discovered them with  
26 reasonable diligence. This includes the defective leads, the inadequate safety features,  
27 and the risks of lead fracture, insulation breach, lead migration, IPG/battery  
28 malfunction, and resulting nerve damage, among others. Each Plaintiff discovered

1 these facts only on a date within the applicable limitations and repose periods, as  
2 alleged in that Plaintiff's Short-Form Complaint. Plaintiffs could not discover them  
3 sooner because Defendants failed to warn and suppressed material information about  
4 the risks of the SCS Devices. For Plaintiffs whose Short-Form Complaints so allege,  
5 a further reason is that Defendants' sales and field representatives actively concealed  
6 device defects and Defendants' fault.

7       263. Plaintiffs did not know, and could not have known with reasonable  
8 diligence, that their injuries were caused by a defect in Defendants' SCS Devices or  
9 by Defendants' wrongful conduct. A Plaintiff may have known in general that spinal  
10 cord stimulator implantation carries risks, including risks described in the device  
11 labeling. That general awareness is different from knowing about the defect, about  
12 Defendants' wrongful conduct, or about the causal link between the two and the  
13 Plaintiff's injuries. It did not start the running of any limitations or repose period. Each  
14 Plaintiff gained knowledge of the facts giving rise to a cause of action within the  
15 applicable limitations and repose periods.

16       264. Defendants had a duty to disclose that their SCS Devices were  
17 unreasonably dangerous. That duty arises under state laws that parallel the federal  
18 requirements. It required Defendants to disclose:

- 19       a. the true rates of lead failure, including as reflected in the complaint and  
20       adverse-event information that Defendants were required to collect,  
21       investigate, and report to FDA;
- 22       b. the known risk that lead fracture and migration cause permanent nerve  
23       damage;
- 24       c. the risk that IPG/battery failure causes uncontrolled stimulation;
- 25       d. the limits of reprogramming as a remedy for hardware failure; and
- 26       e. the serious risk that use of the SCS Devices would cause injuries such as  
27       those Plaintiffs suffered.

28       265. Defendants breached that duty.

1           266. When Plaintiffs were implanted with and used Defendants' SCS  
2 Devices, Plaintiffs did not know, and had no reasonable means of discovering, the  
3 defects in those devices or the true frequency and severity of the risks of using them.  
4 That information was within Defendants' exclusive or superior knowledge.

5           267. Defendants did not notify Plaintiffs, their implanting and treating  
6 physicians, or the public that the SCS Devices were unreasonably dangerous.  
7 Specifically, Defendants did not disclose:

- 8           a. the true rates of lead failure and migration;
- 9           b. that post-implant reprogramming could not fix hardware defects;
- 10           c. the risk of progressive and permanent nerve damage from a retained  
11           defective device; and
- 12           d. that use of the SCS Devices carried a serious risk of injuries such as those  
13           Plaintiffs suffered.

14           268. Defendants failed in their duty to notify Plaintiffs, their physicians, and  
15 the public that the SCS Devices were unreasonably dangerous. For Plaintiffs whose  
16 Short-Form Complaints so allege, Defendants' sales and field representatives also  
17 actively concealed device defects and Defendants' fault. They did so by attributing  
18 Plaintiffs' symptoms to causes other than device failure and by stating that  
19 reprogramming would resolve Plaintiffs' complaints. Because of this conduct,  
20 Defendants are equitably estopped from relying on any statute of limitations or statute  
21 of repose as a defense.

22           269. Separately, the running of any applicable limitations or repose period  
23 was tolled by the discovery rule, by Defendants' fraudulent concealment, and by  
24 equitable tolling, to the extent the governing state law recognizes each doctrine. For  
25 Plaintiffs whose claims are governed by Louisiana law, it was also tolled by the  
26 doctrine of contra non valentem.

27           270. Plaintiffs' injuries were inherently difficult to connect to Defendants'  
28 conduct. That conduct includes the defective leads and IPGs, Defendants' failure to

1 disclose known post-market complication data, and, where alleged, active  
2 concealment of device defects by Defendants' representatives. The difficulty arose in  
3 part because Defendants knowingly suppressed material safety and risk information.  
4 Plaintiffs had no actual or constructive knowledge that their injuries were caused by  
5 Defendants' SCS Devices.

6 271. Many of Plaintiffs' injuries are latent and develop progressively after a  
7 defective device is implanted. Plaintiffs noticed symptoms when they began. But  
8 Plaintiffs did not know, and could not reasonably have known, that the symptoms were  
9 caused by a defect in Defendants' SCS Devices rather than by another condition or by  
10 the natural course of their underlying diagnoses.

11 272. Plaintiffs are lay persons. Until a date within the applicable limitations  
12 and repose periods, they did not know that the defects in Defendants' SCS Devices  
13 could cause or contribute to their injuries. Those defects include leads prone to  
14 fracture, migration, and insulation breach, and IPGs/batteries prone to malfunction  
15 and unexpected reset. Plaintiffs whose Short-Form Complaints so allege also  
16 reasonably relied on statements by Defendants' sales and field representatives that  
17 their devices were working properly and that their symptoms had causes unrelated to  
18 any device defect.

19 273. Plaintiffs were not aware of any publicly available information  
20 sufficient to put a reasonable lay person on notice that Defendants' SCS Devices  
21 caused their injuries. This is particularly so because Defendants concealed post-  
22 market complication data. Where alleged in a Plaintiff's Short-Form Complaint,  
23 Defendants' sales and field representatives also falsely stated that no defect existed.

24 **G. Limitation and Reservation Regarding Federal Regulatory**  
25 **Allegations**

26 274. Plaintiffs assert traditional state-law causes of action arising from the  
27 design, manufacture, labeling, warning, testing, marketing, sale, distribution, and  
28 post-sale handling of Boston Scientific's spinal cord stimulation devices. Plaintiffs

1 plead those state-law claims, including claims Boston Scientific may contend are  
2 expressly or impliedly preempted, to identify fully the legal duties, injuries, and  
3 remedies that would exist under applicable state law in the absence of a valid federal  
4 preemption defense. Plaintiffs do not concede that any such claim is preempted, that  
5 21 U.S.C. § 360k(a) applies to the claim, or that any FDA action upon which Boston  
6 Scientific may rely was lawful, procedurally valid, or entitled to preemptive effect.

7       275. Nothing in this Master Complaint seeks to enforce the Federal Food,  
8 Drug, and Cosmetic Act (“FDCA”) or its implementing regulations; to create or assert  
9 a private right of action arising solely under federal law; to adjudicate a claim of fraud  
10 on the FDA; or to impose liability upon Boston Scientific merely because its conduct  
11 allegedly violated a federal statute, regulation, PMA requirement, approval condition,  
12 reporting obligation, manufacturing specification, or other FDA requirement. Except  
13 where a particular count expressly alleges an independently existing state-law duty  
14 that parallels a specifically identified federal requirement, Plaintiffs’ state-law claims  
15 do not depend upon proof that Boston Scientific violated federal law.

16       276. Plaintiffs’ challenges to the lawfulness or validity of FDA action or  
17 inaction, including PMA P030017 and subsequent approvals, are pursued, if at all, in  
18 the separate APA pleading and procedural track governed by the Court’s orders. Such  
19 challenges are not asserted here as independent grounds for imposing liability on  
20 Boston Scientific or as a request to set aside FDA action in this product-liability  
21 complaint.

22       277. Plaintiffs reserve all arguments properly available against any asserted  
23 preemption defense and all rights in the separate APA proceeding, subject to the  
24 Court’s orders and applicable jurisdictional and procedural requirements.

#### 25       **H. Limitations on Available Evidence**

26       278. Allegations concerning Defendants’ internal material specifications,  
27 supplier changes, validation testing, complaint investigations, adverse-event  
28 reporting, and corporate knowledge are made on information and belief. The factual

1 bases include the specific material substitution, device failures, and representative  
2 conduct alleged below.

3 279. Plaintiffs believe that the underlying specifications, supplier  
4 communications, device and lot records, complaint files, and internal communications  
5 are principally in Defendants' or their suppliers' possession and will provide further  
6 evidentiary support after a reasonable opportunity for discovery.

## 7 **VI. CAUSES OF ACTION**

### 8 **COUNT I – STRICT LIABILITY – DESIGN DEFECT**

9 280. Plaintiffs incorporate by reference all factual allegations set forth above  
10 in ¶¶ 1–279 as if fully set forth herein.

11 281. At all times relevant to this action, Boston Scientific was the  
12 manufacturer, distributor, and/or seller that designed, produced, created, made,  
13 constructed, assembled, and/or sold the SCS devices that were placed into the stream  
14 of commerce.

15 282. The SCS devices were defective at the time they left Defendants'  
16 control, as they were expected to, and did, reach the ultimate users, including  
17 Plaintiffs, without substantial change in condition.

18 283. The Boston Scientific SCS devices were defective in design because the  
19 foreseeable risks of the lead and IPG design exceeded the benefits of that design as a  
20 result of Defendants' deviations from the FDA-approved design specifications.

21 284. By switching to a different polycarbonate polyol, UH-200, that was not  
22 included in the approved device development, design, and manufacture for the lead  
23 wire insulation sheaths, Defendants exposed patients to the risks of serious device  
24 failure including but not limited to insulation failure, lead fracture, unintended  
25 electrical shocking, nerve insult at the site(s) of insulation failure, unintended  
26 electrical stimulation at the site(s) of insulation failure, and device infection due to  
27 material surface degradation.

1           285. These risks consequently caused injuries in patients including electrical  
2 shocks, device infection, vasovagal reactions such as syncope, and severe and/or  
3 permanent nerve injuries including nerve pain, electrical-induced neuropathy,  
4 numbness, lower limb paralysis, bowel and/or urinary incontinence, gastroparesis and  
5 dysphagia, often requiring device removal.

6           286. These device failure risks and resulting injury risks of these devices  
7 deviating from the FDA-approved specifications, weighed against the availability of  
8 approved and alternative lead and IPG designs and materials offering superior  
9 fixation, structural integrity, stimulation reliability and predictability, and battery  
10 reliability, exceed the benefits of the SCS devices.

11           287. In addition and in the alternative, Defendants' SCS devices failed to  
12 perform as safely as an ordinary consumer would have expected them to perform  
13 when used or misused in an intended or reasonably foreseeable manner. Plaintiffs and  
14 their treating physicians used the SCS devices in an intended and reasonably  
15 foreseeable manner, and Plaintiffs were injured during that use.

16           288. A practical and technically feasible alternative design was available at  
17 the time the leads left Defendants' control that would have prevented the harm without  
18 substantially impairing the usefulness or intended purpose of the product and without  
19 imposing excessive cost or other material disadvantages, that is, one conforming to  
20 the FDA-approved specifications.

21           289. Specifically, alternative lead designs as approved by the FDA providing  
22 superior mechanical fixation, improved insulation integrity, and better lead anchoring  
23 mechanisms were available and were used in surgical/paddle leads offered in other  
24 SCS devices. These alternative lead designs reduced the risk of device failures and  
25 injuries described above without substantially impairing the therapeutic utility of the  
26 SCS device.

27           290. Additionally, Boston Scientific made material changes to the design of  
28 its SCS leads following original PMA approval without submitting the required PMA

1 supplements under 21 C.F.R. § 814.39(a), or through PMA supplements that failed to  
2 comply with applicable regulations. These unauthorized design changes altered the  
3 leads' structural and performance characteristics in ways that were not evaluated by  
4 the FDA and were not disclosed to Plaintiffs or Plaintiffs' treating physicians.

5       291. Boston Scientific's provision of an unreasonably dangerous defective  
6 device that deviated from the FDA-approved specifications violated both federal  
7 regulations and the parallel state-law duty not to market unreasonably dangerous  
8 devices, such as those adopting the Restatement (Second) of Torts prohibition in  
9 §402(A) and comment g.

10       292. These defects existed at the time the SCS devices left Boston Scientific's  
11 control and were not detectable or otherwise known by Plaintiffs or Plaintiffs' treating  
12 physicians through reasonable inspection prior to implantation or other due diligence.

13       293. The SCS devices were in an unsafe, defective, and inherently dangerous  
14 condition which was unreasonably dangerous to their users.

15       294. The intended or actual utility of the SCS devices is not of such benefit  
16 as to justify the risks described herein, considering the gravity of the potential harm,  
17 the likelihood that the harm would occur, and the feasibility, cost, and disadvantages  
18 of the alternative designs described above.

19       295. At all times herein mentioned, the SCS devices were in a defective  
20 condition and unsafe, and Boston Scientific knew, or had reason to know, that they  
21 were defective and unsafe, especially when used as instructed by Boston Scientific  
22 and its agents and in the form and manner provided by Boston Scientific and its agents.

23       296. The SCS devices' defective design and failure to perform safely were a  
24 substantial factor in causing Plaintiffs' harm. As a direct and proximate result of  
25 Defendants' design defects of the spinal cord stimulator devices and violations of state  
26 law, the devices failed, and those failures directly and proximately caused Plaintiffs  
27 to sustain the injuries and damages described herein, including chronic pain, and other  
28

1 losses including mental anguish, diminished enjoyment of life, medical, health and  
2 incidental and related expenses.

3 WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief  
4 against Defendants, as contained in the Prayer For Relief.

5 **COUNT II – STRICT LIABILITY – MANUFACTURING DEFECT**

6 297. Plaintiffs incorporate by reference all factual allegations set forth above  
7 in ¶¶ 1–279 as if fully set forth herein.

8 298. At all times relevant to this action, Boston Scientific was engaged in the  
9 business of designing, manufacturing, testing, labeling, distributing, and selling  
10 medical devices, including the spinal cord stimulators implanted in Plaintiffs.

11 299. At all relevant times, the SCS devices implanted in Plaintiffs were  
12 expected to and did reach Plaintiffs without substantial change in their condition as  
13 manufactured, handled, sold, and distributed by Boston Scientific.

14 300. At all relevant times, the defective SCS devices were used by Plaintiffs  
15 in an intended and foreseeable manner. The SCS devices were used as instructed by  
16 Boston Scientific and its agents and in the form and manner provided by Boston  
17 Scientific and its agents.

18 301. The SCS devices implanted in Plaintiffs were not reasonably safe for  
19 their intended use due to manufacturing defect. The devices, as manufactured and  
20 sold, deviated from Defendants’ own FDA-approved specifications and from  
21 applicable federal requirements governing Class III medical devices. These  
22 manufacturing defects existed when the SCS devices left Boston Scientific’s  
23 possession and control.

24 302. The SCS devices did not conform to the design and performance  
25 standards described in PMA P030017 and its associated supplements.

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

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

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

304. The SCS devices implanted in Plaintiffs were manufactured with latent defects, as a result of their deviation from FDA-approved specifications, that affected performance, stability, and safety, including but not limited to:

- a. Lead wire insulation sheaths manufactured with polyurethane synthesized from UH-200 rather than the specified and FDA-approved PC-1122, resulting in insulation failure, lead fracture, unintended electrical shocking, and device infection;
- b. Hermetic seals of the IPGs manufactured with weld-specification nonconformances, compromising the integrity of the IPG enclosure;
- c. Inadequate lead anchoring, resulting in migration, therapeutic failure, and unwanted shocking in patients;
- d. Battery instability contributing to irregular stimulation output and early depletion, including need for battery replacement;
- e. Defects impacting the physical stability of the battery in the bodies of patients;
- f. Faulty firmware or programming inconsistencies affecting waveform delivery, and causing complications in patients, including shocking and unsatisfactory pain relief.

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

1           306. As a result of Defendants' failures to implement adequate design  
2 controls, establish adequate production and process controls, validate manufacturing  
3 processes, implement corrective and preventive action in response to known patterns  
4 of lead failure and IPG/battery malfunction, and take adequate corrective action, the  
5 SCS devices implanted in Plaintiffs deviated in a material way from the design  
6 specifications, formula, or performance standards of the manufacturer, or from  
7 otherwise identical units manufactured to the same design specifications, formula, or  
8 performance standards and thus violated state law requirements that parallel federal  
9 requirements.

10           307. Had Defendant complied with the Current Good Manufacturing  
11 Practices, 21 CFR 820 regulations and parallel state requirements under parallel state-  
12 law duty not to sell defective and unreasonably dangerous devices, such as those  
13 adopting the Restatement (Second) of Torts prohibition in §402(A) and comment g,  
14 the defects in Plaintiffs' devices would not have occurred and/or would have been  
15 timely discovered so as to prevent Plaintiffs from receiving a defective,  
16 malfunctioning SCS Device.

17           308. Plaintiffs' manufacturing defect claim arises under state-law duties that  
18 parallel federal manufacturing obligations imposed on Defendants. These claims are  
19 not expressly or impliedly preempted under 21 U.S.C. § 360k(a), *Riegel*, 552 U.S.  
20 312, or *Buckman Co.*, 531 U.S. 341.

21           309. The manufacturing defects in the SCS devices were a substantial factor  
22 in causing Plaintiffs' harm. As a direct and proximate result of the manufacturing  
23 defects of the spinal cord stimulator devices implanted into Plaintiffs, the devices  
24 failed, and those failures directly and proximately caused Plaintiffs to sustain serious  
25 damages including, but not limited to, the following: bodily injury; severe physical  
26 pain and suffering; emotional distress; diminished enjoyment of life; medical  
27 expenses; loss of earnings; and disability, all of which losses and damages will  
28 continue into the future.

1           WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief  
2 against Defendants, as contained in the Prayer For Relief.

3                   **COUNT III – STRICT LIABILITY – FAILURE TO WARN**

4           310. Plaintiffs incorporate by reference all factual allegations set forth above  
5 in ¶¶ 1–279 as if fully set forth herein.

6           311. At all relevant times, Defendants were engaged in the design,  
7 manufacture, labeling, marketing, distribution, and sale of SCS devices throughout  
8 the United States, including the devices implanted in Plaintiffs.

9           312. The warnings that Defendants provided and that accompanied the SCS  
10 devices failed to provide the level of information that an ordinary consumer, including  
11 Plaintiffs herein, would expect when using the implants in a manner intended by and  
12 reasonably foreseeable to Defendants. In particular, Defendants failed to provide or  
13 adequately convey existing FDA-approved warnings and instructions to Plaintiffs’  
14 treating physicians and, through their sales and clinical representatives, omitted,  
15 minimized, or contradicted that approved safety information in communications with  
16 Plaintiffs and their physicians.

17           313. The SCS devices left Defendants’ control without an adequate warning  
18 or instruction, and created an unreasonably dangerous condition in that Defendants,  
19 as the seller and manufacturer, knew or should have known, and the risks were known  
20 or knowable in light of the scientific and medical knowledge generally accepted in the  
21 scientific community at the time of manufacture, distribution, and sale, that the SCS  
22 devices posed a substantial danger when used or misused in an intended or reasonably  
23 foreseeable way. Neither ordinary consumers, including Plaintiffs, nor Plaintiffs’  
24 implanting and treating physicians would have recognized these potential risks.  
25 Alternatively, after the SCS devices left the Defendants’ control, Defendants became  
26 aware of, or in the exercise of ordinary care should have known, that the devices posed  
27 a substantial risk of harm to patients, including Plaintiffs herein, yet Defendants failed  
28

1 to take reasonable steps to give adequate warning or instruction or to take other  
2 reasonable action under the circumstances.

3 314. Boston Scientific had a duty to warn Plaintiffs' implanting and treating  
4 physicians, Plaintiffs, and the medical community of the material risks associated with  
5 its SCS devices for as long as the devices remained in use, including by providing and  
6 accurately conveying approved FDA-approved warnings and instructions concerning  
7 those risks, including but not limited to:

- 8 a. The risk of lead migration, lead breakage, and device failure requiring  
9 surgical revision;
- 10 b. The risk of autonomic dysfunction, including arrhythmias, urinary and  
11 fecal incontinence, and hypotension;
- 12 c. The risk of neurological injury;
- 13 d. The risk that the temporary trial SCS device would not reliably or  
14 accurately predict the performance of the permanently implanted SCS  
15 device;
- 16 e. The risk of burns from overheating batteries;
- 17 f. The risk of premature and unpredictable battery failure, requiring surgical  
18 revision;
- 19 g. The risk of paralysis; and
- 20 h. The risk of device-related pain exacerbation, unintended electrical  
21 stimulation and shocking, and loss of therapeutic efficacy over time.

22 315. Defendants breached their duty to warn by:

- 23 a. Failing to adequately train sales representatives and clinicians regarding the  
24 safety limitations of multiwaveform stimulation present in many of Boston  
25 Scientific's SCS devices;
- 26 b. Actively promoting their SCS devices as superior and safe without  
27 disclosing material limitations and risks; and

1 c. Failing to provide or adequately convey applicable FDA-approved  
2 warnings and instructions to Plaintiffs and Plaintiffs' treating physicians.

3 316. In addition, Defendants breached their duties by actively conveying,  
4 through Defendants' sales and clinical representatives, information to Plaintiffs that  
5 contradicted, downplayed, and undermined the FDA-approved labeling's risk  
6 disclosures, including by misrepresenting the significance of Plaintiffs' complications  
7 and the efficacy of reprogramming as a remedy.

8 317. These deviations are further supported by specific allegations to be  
9 pleaded in plaintiff-specific filings included but not limited to Short-Form  
10 Complaints.

11 318. Defendants further failed to adequately communicate warnings and  
12 instructions concerning device malfunction and the appropriate response to device-  
13 related symptoms including that device reprogramming could not correct lead failure  
14 or IPG/battery malfunction and that delay in removal following device failure would  
15 worsen nerve injury. Instead, its representatives provided assurances concerning  
16 reprogramming that minimized the significance of reported symptoms and device  
17 failures, including lead failure and IPG/battery malfunction, and the need for timely  
18 medical evaluation and intervention.

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

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

25 320. Boston Scientific and its sales representatives initiated and conducted  
26 significant direct communication with Plaintiffs.

1           321. These communications included direct discussion of risks and benefits  
2 of the SCS devices, including in many cases discussion of risks and benefits outside  
3 the presence and hearing of Plaintiffs' physicians.

4           322. Through its sales representatives, Defendants downplayed and  
5 undermined the FDA-approved labeling and warnings for its SCS devices directly to  
6 Plaintiffs, bypassing Plaintiffs' physicians.

7           323. Defendants' employees and representatives negligently failed to provide  
8 or adequately transmit the applicable FDA-approved warnings and instructions to  
9 Plaintiffs' treating physicians. These failures concerned the communication of  
10 existing approved safety information, not merely the absence of additional or different  
11 warnings.

12           324. Additionally, Defendants' representatives communicated directly with  
13 Plaintiffs concerning the devices' risks, benefits, operation, and the significance of  
14 device-related complications. Having undertaken those communications, the  
15 representatives failed to exercise reasonable care by omitting, minimizing,  
16 contradicting, or failing to provide FDA-approved warnings and instructions and by  
17 providing inaccurate or misleading patient-specific assurances.

18           325. As part of the sales representatives' activity described here, Boston  
19 Scientific's sales representatives, acting within the scope of their employment,  
20 circumvented physicians so that they communicated and provided warnings directly  
21 to patients. This conduct occurred both orally and in confirmed written  
22 communications, thereby depriving patients of their physicians' independent  
23 assessment and communication of those warnings. Through this conduct, Boston  
24 Scientific circumvented the physician-patient relationship by going directly to the  
25 consumer and deprived the patients of any of the benefits of their physician acting as  
26 a learned intermediary. Furthermore, Boston Scientific inserted itself so thoroughly  
27 into the patient experience that any contact between the physicians and patients was  
28 extremely limited.

1           326. In these direct-to-patient communications, Boston Scientific  
2 representatives (1) failed to provide the full breadth of FDA-approved warnings and  
3 (2) undermined and/or nullified FDA-approved warnings through representations  
4 (and misrepresentations) to the patients about safety, efficacy, the lack of risk, lack of  
5 injury causation, and lack of company knowledge, among other topics. This was in  
6 contravention of the FDCA and implementing regulations. As a result of these  
7 activities, the warnings conveyed to Plaintiffs and their physicians were inadequate  
8 under applicable state law.

9           327. Boston Scientific, through their sales representatives, communicated  
10 directly with Plaintiffs about the risks, benefits, programming, and expected results of  
11 SCS therapy, assuming a role in conveying risk information to patients outside the  
12 physician relationship; and Defendants' representatives contradicted, diluted, and  
13 nullified the FDA-approved warnings in communications with Plaintiffs' implanting  
14 and treating physicians and Plaintiffs.

15           328. Had Defendants not done so, Plaintiffs and Plaintiffs' physicians would  
16 have taken action including but not limited to declining implantation, investigating  
17 device issue causes, explanting the device sooner, and not deferring to representative  
18 programming, thereby avoiding the risks and subsequent injuries Plaintiffs  
19 foreseeably experienced.

20           329. Employees negligently failed to warn physician/plaintiff, i.e. failure to  
21 transmit the approved warnings.

22           330. The absence of adequate, complete, and accurate material risk  
23 information, including Defendants' failure to provide applicable FDA-approved  
24 warnings and instructions, prevented Plaintiffs' physicians from evaluating whether  
25 the device was appropriate for Plaintiffs' conditions prior to implantation.

26           331. Plaintiffs' treating physicians reasonably relied on the information  
27 provided by Defendants in recommending implantation of the SCS devices, and  
28 Plaintiffs justifiably relied on those medical recommendations in weighing the risks

1 and benefits of the device. Following implantation, Plaintiffs also relied on patient-  
2 specific representations of the Defendants' representatives concerning the  
3 significance of their symptoms, the functioning of their devices, and the ability of  
4 reprogramming to address their complications.

5 332. Adequate and accurate risk information, including FDA-approved  
6 warnings and instructions presented without contradiction or minimization, would  
7 have been considered by treating physicians when evaluating whether implantation  
8 was appropriate and in determining whether to recommend the SCS devices. That  
9 information also would have been considered in evaluating reported complications  
10 and determining whether continued use, further evaluation, revision, replacement, or  
11 removal was appropriate.

12 333. Adequate and accurate risk information, including FDA-approved  
13 warnings and instructions, would have been considered by Plaintiffs in deciding  
14 whether to consent to implantation with the SCS devices. Following implantation,  
15 accurate information concerning their symptoms and device complications, without  
16 assurances contradicting or undermining the approved warnings and instructions,  
17 would have informed Plaintiffs' decisions concerning continued device use and the  
18 need to seek timely medical evaluation and treatment.

19 334. Because Defendants failed to provide or adequately convey material risk  
20 information contained in applicable FDA-approved warnings and instructions, and  
21 because its representatives contradicted or undermined that information, Plaintiffs and  
22 Plaintiffs' treating physicians made treatment decisions without information a  
23 reasonably prudent manufacturer would disclose, and Plaintiffs suffered the injuries  
24 described herein because of the treatment chosen under those circumstances. The lack  
25 of sufficient warnings and instructions was a substantial factor in causing Plaintiffs'  
26 harm.

27 WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief  
28 against Defendants, as contained in the Prayer for Relief.

**COUNT IV – NEGLIGENCE- DESIGN DEFECT**

335. Plaintiffs incorporate by reference all factual allegations set forth above in ¶¶ 1–279 as if fully set forth herein.

336. Plaintiffs plead claims for negligence under all theories that may be actionable under any applicable state laws.

337. At all relevant times, Defendants negligently designed, manufactured, developed, tested, marketed, sold, detailed, labeled, distributed and advertised their SCS devices, both to consumers and physicians, including the SCS devices implanted in Plaintiffs.

338. Defendants owed Plaintiffs a duty of reasonable care in the design, development, manufacture, labeling, testing, marketing, sale, and post-market surveillance of the SCS systems that they placed into the stream of commerce so that the devices would be reasonably safe when used in an intended or reasonably foreseeable manner. Defendants were required to use the amount of care in designing the SCS devices that a reasonably careful designer and manufacturer would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.

339. Defendants knew or, in the exercise of reasonable care, should have known that defects in the design of the SCS devices’ leads, IPGs, batteries, and firmware could result in lead migration, irregular or unintended stimulation, painful shocks, battery malfunction, loss of therapeutic efficacy, and other device failures capable of causing serious injury. Despite that knowledge of the likelihood and severity of potential harm, Defendants failed to adopt available safety measures, including the feasible alternative designs described above, even though the burden of adopting those measures was outweighed by the risk of harm.

340. Defendants breached their duty in one or more of the following ways:

- a. 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;

- b. By negligently introducing cumulative design changes through successive PMA supplements without proper validation, public clinical testing, or physician disclosure;
- c. By negligently failing to investigate known risks associated with stimulation loss, painful shocks, and therapy failure, despite pre-market complaints, post-market adverse event reports, and internal device testing;
- d. By negligently failing to update its IFU, 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;
- e. By negligently failing to report known adverse events related to its SCS systems in accordance with 21 C.F.R. Part 803;
- f. By negligently 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 Plaintiffs and other patients; and
- g. By negligently failing to adopt feasible, safer alternative designs for the SCS devices' leads and IPGs, including lead insulation conforming to the FDA-approved specifications, despite knowing the likelihood and severity of harm posed by the existing design.

341. Defendants, as the manufacturer, supplier, and seller of these medical devices, had superior knowledge and owed a duty of care to their customers and to the Plaintiffs themselves, who were implanted with the SCS devices.

342. As described in the factual allegations, the SCS devices implanted in Plaintiffs contained design defects affecting their performance, stability, and safety. Those defects resulted from Defendants' failure to use reasonable care in designing the SCS devices and were present when the devices left Defendants' control.

1           343. Plaintiffs used the SCS devices in an intended and reasonably  
2 foreseeable manner. The devices reached Plaintiffs without substantial change in the  
3 design-related conditions alleged herein.

4           344. Defendants' negligence was a substantial factor in causing Plaintiffs'  
5 harm. As a direct and proximate result of Defendants' negligent design, development,  
6 and testing, the SCS devices implanted in Plaintiffs failed, causing lead migration,  
7 stimulation instability, battery malfunction, unintended electrical stimulation, loss of  
8 therapeutic efficacy, and other device failures described herein.

9           345. Those device failures, in turn, directly and proximately caused Plaintiffs  
10 to sustain serious damages including, but not limited to, the following: bodily injury;  
11 severe physical pain and suffering; emotional distress; diminished enjoyment of life;  
12 medical expenses; loss of earnings; and disability, all of which losses and damages  
13 will continue into the future. The injuries were a reasonably foreseeable consequence  
14 of the design-related failures alleged herein.

15           346. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
16 relief against Defendants, as contained in the Prayer For Relief.

17           **COUNT V – NEGLIGENCE-MANUFACTURING DEFECT**

18           347. Plaintiffs incorporate by reference all factual allegations set forth above  
19 in ¶¶ 1–279 as if fully set forth herein.

20           348. At all relevant times, Defendants manufactured, assembled, inspected,  
21 tested, sold, and distributed the SCS devices implanted in Plaintiffs.

22           349. Defendants owed Plaintiffs a duty to exercise reasonable care in  
23 manufacturing, assembling, inspecting, and testing their SCS devices to ensure that  
24 the finished devices conformed to the applicable FDA-approved design,  
25 specifications, and performance standards. Defendants were required to use the  
26 amount of care in manufacturing, inspecting, and testing the SCS devices that a  
27 reasonably careful manufacturer would use in similar circumstances to avoid exposing  
28 others to a foreseeable risk of harm.

1           350. Defendants knew or, in the exercise of reasonable care, should have  
2 known that deviations from the approved design, specifications, or performance  
3 standards could cause lead failure, battery malfunction, irregular stimulation, painful  
4 shocks, and other device failures capable of causing serious injury, in particular with  
5 respect to the lead insulation sheath material, Infinion CX leads, and hermetic sealing  
6 processes. Despite that knowledge of the likelihood and severity of potential harm,  
7 Defendants failed to adopt available manufacturing, inspection, and testing measures  
8 to prevent those deviations, even though the burden of adopting those measures was  
9 outweighed by the risk of harm.

10           351. Defendants breached their duty of reasonable care in one or more of the  
11 following ways:

- 12           a. By failing to ensure that the devices were manufactured in conformity with  
13           the applicable FDA-approved specifications, including specifications  
14           governing lead integrity, firmware, battery safety, and programming  
15           reliability;
- 16           b. By failing to establish and implement adequate production and process  
17           controls to consistently produce devices conforming to the approved design  
18           and specifications;
- 19           c. By failing to adequately validate manufacturing processes and verify the  
20           conformity of finished devices;
- 21           d. By failing to adequately inspect and test the devices to identify  
22           manufacturing deviations before their release; and
- 23           e. By failing to investigate complaints, adverse-event reports, and internal  
24           testing information identifying patterns of lead failure, stimulation  
25           instability, or battery malfunction attributable to manufacturing  
26           nonconformities.

27           352. At the time they left Defendants' control, the SCS devices implanted in  
28 Plaintiffs deviated materially from the applicable FDA-approved design,

1 specifications, or performance standards, or from otherwise identical units  
2 manufactured in conformity with those requirements. These deviations include the use  
3 of UH-200 in place of the specified and FDA-approved PC-1122 in the lead wire  
4 insulation sheaths and weld-specification nonconformances affecting the IPG  
5 hermetic seals.

6 353. These manufacturing deviations affected the devices' performance,  
7 stability, and safety and were not detectable by Plaintiffs or their treating physicians  
8 through reasonable inspection before implantation.

9 354. These devices reached Plaintiffs without substantial change in the  
10 manufacturing-related conditions alleged herein and were used in an intended and  
11 reasonably foreseeable manner.

12 355. As a direct and proximate result of Defendants' negligent manufacture,  
13 assembly, inspection, and testing, the devices implanted in Plaintiffs contained  
14 manufacturing defects when they left Defendants' control. Those defects caused lead  
15 failure, battery malfunction, irregular or unintended stimulation, and other device  
16 failures described herein.

17 356. Defendants' negligence was a substantial factor in causing Plaintiffs'  
18 harm. Those device failures, in turn, directly and proximately caused Plaintiffs to  
19 sustain serious injuries and damages, including, but not limited to, bodily injury;  
20 severe physical pain and suffering; emotional distress; diminished enjoyment of life;  
21 medical expenses; loss of earnings; and disability, all of which losses and damages  
22 will continue into the future.

23 357. WHEREFORE, Plaintiffs respectfully request that they be granted relief  
24 against Defendants as contained in the Prayer for Relief.

25 **COUNT VI – NEGLIGENCE-FAILURE TO WARN**

26 358. Plaintiffs incorporate by reference all factual allegations set forth  
27 above in ¶¶ 1–279 as if fully set forth herein.  
28

1           359. At all relevant times, Defendants manufactured, labeled, marketed,  
2 sold, and distributed the SCS devices implanted in Plaintiffs and communicated  
3 information concerning those devices to Plaintiffs and their treating physicians.

4           360. Defendants owed a duty to exercise reasonable care in warning  
5 Plaintiffs' treating physicians of reasonably foreseeable risks associated with the  
6 intended and reasonably foreseeable use of their SCS devices, including by  
7 providing and accurately conveying applicable FDA-approved warnings and  
8 instructions. Defendants' duty to warn Plaintiffs' treating physicians continued for as  
9 long as the SCS devices remained in use.

10          361. Defendants further undertook, through their sales and clinical  
11 representatives, to communicate directly with Plaintiffs and their treating physicians  
12 concerning device operation, reported symptoms, device-related complications, and  
13 the effectiveness of programming and reprogramming. In undertaking those  
14 communications, Defendants had a duty to exercise reasonable care and not to omit,  
15 minimize, or contradict material safety information contained in the applicable  
16 FDA-approved warnings and instructions.

17          362. Defendants knew, or in the exercise of reasonable care should have  
18 known, that their SCS devices were dangerous or likely to be dangerous when used  
19 or misused in a reasonably foreseeable manner, including through reasonably  
20 foreseeable risks of lead migration, lead failure, battery malfunction, unintended  
21 electrical stimulation, painful shocks, neurological injury, and other complications  
22 described herein. These risks included unreasonable and non-obvious dangers that  
23 Plaintiffs and their treating physicians could not adequately assess without accurate  
24 safety information. Defendants knew or reasonably should have known that  
25 Plaintiffs and their treating physicians would not realize these dangers.

26          363. Defendants acquired or should have acquired knowledge of these risks  
27 through device testing, internal complaint files, adverse-event reports, post-market  
28

1 surveillance, and communications concerning patients' symptoms and device  
2 failures.

3 364. Defendants breached their duty of care to Plaintiffs in one or more of  
4 the following ways:

- 5 a. By failing to provide or adequately convey applicable FDA-approved  
6 warnings and instructions to Plaintiffs' treating physicians;
- 7 b. By failing to adequately train their sales and clinical representatives to  
8 accurately communicate existing warnings, device limitations, and  
9 instructions concerning reported malfunctions;
- 10 c. By providing incomplete or misleading information concerning the risks  
11 and benefits of the devices and the significance of Plaintiffs' reported  
12 symptoms;
- 13 d. By contradicting, minimizing, or undermining existing FDA-approved  
14 warnings and instructions through assurances that Plaintiffs' complications  
15 were unrelated to the devices or could be resolved through further  
16 reprogramming;
- 17 e. By failing to accurately communicate the limitations of reprogramming  
18 when symptoms indicated possible lead failure, IPG/battery malfunction,  
19 or another underlying device defect;
- 20 f. By advising Plaintiffs to continue device use or delay medical evaluation  
21 or removal without adequately communicating the risks of continued  
22 exposure to a malfunctioning device; and
- 23 g. By failing to investigate and respond to known malfunctions and adverse-  
24 event information and to provide resulting safety communications to the  
25 extent required by applicable law.

26 365. Defendants' sales and clinical representatives breached their duty of  
27 care to Plaintiffs in one or more of the following ways:  
28

- a. By programming and reprogramming Plaintiffs' SCS devices without sufficient knowledge, skill, and expertise to do so;
- b. By continuing to reprogram Plaintiffs' SCS devices after they determined or should have determined that the reprogramming was futile, and would not alleviate Plaintiffs' complications or increase therapeutic benefit;
- c. By advising Plaintiffs to forgo or delay other necessary medical treatment while they continued to reprogram Plaintiffs' SCS devices;
- d. By advising Plaintiffs to delay removal of the SCS devices, thereby causing and worsening Plaintiffs' permanent damage;
- e. By advising Plaintiffs that side effects and complications Plaintiffs experienced after being implanted with the SCS devices were not related to the SCS devices or could be alleviated by reprogramming;
- f. By providing inaccurate or incomplete information to Plaintiffs regarding the risks and benefits of the SCS devices;
- g. By providing medical advice to Plaintiffs without the necessary knowledge, experience, or qualification to do so;
- h. By discussing with Plaintiffs the reduction in pain they had to report for third-party payers to pay for a permanent SCS device, and encouraging Plaintiffs to report the requisite level of pain reduction;
- i. By providing device setting recommendations to Plaintiffs' physicians without sufficient knowledge, skill, and expertise to do so;
- j. By influencing intraoperative lead positioning and stimulation testing without sufficient knowledge, skill, and expertise to do so;
- k. By negligently performing the programming, reprogramming, adjustments, and other device-related services they undertook, including by selecting or implementing settings without adequately assessing Plaintiffs' reported symptoms, responses to prior adjustments, or indications of device malfunction;

- 1           l. By performing adjustments, reprogramming, or other device-related  
2           activities beyond the scope of their training, qualifications, or permitted  
3           device-support role, without obtaining appropriate direction from  
4           Plaintiffs' treating physicians;
- 5           m. By failing to discontinue adjustments or reprogramming and refer Plaintiffs  
6           to their treating physicians when the representatives knew or reasonably  
7           should have known that continued reprogramming would not correct the  
8           underlying device malfunction or could cause or aggravate Plaintiffs'  
9           injuries; and
- 10          n. By continuing to undertake device-related services and provide assurances  
11          concerning their effectiveness under circumstances in which Plaintiffs  
12          relied on those services and assurances to continue device use or delay  
13          seeking appropriate medical evaluation and treatment.

14          366. These deviations are further supported by specific allegations to be  
15          pleaded in plaintiff-specific filings included but not limited to Short-Form Complaints

16          367. Plaintiffs' failure-to-warn claim is based principally on Defendants'  
17          failure to provide or convey existing FDA-approved warnings and instructions and  
18          their representatives' affirmative contradiction or minimization of that safety  
19          information, rather than merely the absence of additional or different warnings.

20          368. A reasonably prudent manufacturer possessing the information available  
21          to Defendants would have provided and accurately communicated the applicable  
22          warnings and instructions and would not have undermined them through contrary  
23          patient-specific assurances.

24          369. Plaintiffs' treating physicians relied on the safety information  
25          Defendants provided when evaluating whether to recommend implantation and how  
26          to respond to subsequent complications. Plaintiffs relied on their physicians'  
27          recommendations and on the information communicated directly by Defendants'

1 representatives in consenting to implantation and making decisions concerning  
2 continued use and further medical evaluation.

3 370. Had Defendants provided and accurately conveyed the applicable  
4 warnings and instructions, Plaintiffs would have declined implantation or sought  
5 earlier medical evaluation and removal, as applicable to each Plaintiff.

6 371. Defendants' failure to adequately communicate the warnings and  
7 instructions was a substantial factor in causing Plaintiffs to undergo implantation of  
8 defective devices and, after device failures occurred, to continue using the  
9 malfunctioning devices and delay appropriate medical evaluation and treatment.  
10 Defendants' failure to warn was a substantial factor in causing Plaintiffs' harm.

11 372. The devices failed because of their underlying defects, and those failures  
12 directly and proximately caused Plaintiffs' injuries. Defendants' warning failures  
13 caused Plaintiffs to undergo implantation or remain exposed to those malfunctioning  
14 devices, thereby causing injuries that otherwise would have been avoided or  
15 aggravating injuries that otherwise would have been less severe.

16 373. As a direct and proximate result of Defendants' negligent failure to  
17 warn, Plaintiffs sustained serious injuries and damages, including, but not limited to,  
18 bodily injury; severe physical pain and suffering; emotional distress; diminished  
19 enjoyment of life; medical expenses; loss of earnings; and disability, all of which  
20 losses and damages will continue into the future.

21 374. WHEREFORE, Plaintiffs respectfully request that they be granted relief  
22 against Defendants as contained in the Prayer for Relief.

### 23 **COUNT VII – BREACH OF EXPRESS WARRANTY**

24 375. Plaintiffs incorporate by reference all factual allegations set forth above  
25 in ¶¶ 1–279 as if fully set forth herein.

26 376. At all relevant times, Defendant Boston Scientific expressly warranted,  
27 through its labeling, advertising, marketing materials, website representations, and  
28 sales representatives, that its SCS devices, including the SCS devices implanted in

1 Plaintiffs, were safe, effective, durable, supported by clinical data, and fit for the  
2 treatment of chronic pain conditions.

3 377. Due to the extensive direct communications between Boston Scientific  
4 sales representatives and Plaintiffs, privity of contract existed between Boston  
5 Scientific and each Plaintiff.

6 378. Boston Scientific made numerous express warranties to Plaintiffs,  
7 which it subsequently breached in violation of applicable state laws, including:

- 8 a. Ala. Code § 7-2-313;
- 9 b. Alaska Stat. § 45.02.313;
- 10 c. Ariz. Rev. Stat. Ann. § 47-2313;
- 11 d. Ark. Code Ann. § 4-2-313;
- 12 e. Cal. Com. Code § 2313;
- 13 f. Colo. Rev. Stat. § 4-2-313;
- 14 g. Conn. Gen. Stat. Ann. § 42a-2-313;
- 15 h. Del. Code Ann. tit. 6, § 2-313;
- 16 i. D.C. Code Ann. § 28:2-313;
- 17 j. Fla. Stat. Ann. §§ 672.313;
- 18 k. O.C.G.A. § 11-2-313;
- 19 l. Haw. Rev. Stat. § 490:2-313;
- 20 m. Idaho Code § 28-2-313;
- 21 n. Ill. Comp. Stat. Ann. Ch. 810, 5/2-313;
- 22 o. Indiana Code Ann. § 26-1-2-313;
- 23 p. Iowa Code Ann. § 554.2313;
- 24 q. Kan. Stat. Ann. § 84-2-313;
- 25 r. Ky. Rev. Stat. Ann. § 355.2-313;
- 26 s. La. R.S. 9:2800.58;
- 27 t. Me. Rev. Stat. Ann. tit. 11, § 2-313;
- 28 u. Md. Code Ann., Com. Law § 2-313;

- 1 v. Mass. Gen. Laws Ann. Ch. 106, § 2-313;
- 2 w. Mich. Comp. Laws Ann. § 440.2313;
- 3 x. Minn. Stat. Ann. § 336.2-313;
- 4 y. Miss. Code Ann. § 75-2-313;
- 5 z. Mo. Rev. Stat. Ann. § 400.2-313;
- 6 aa. Mont. Code Ann. § 30-2-313;
- 7 bb. Neb. Rev. Stat. § 2-313;
- 8 cc. Nev. Rev. Stat. § 104.2313;
- 9 dd. N.H. Rev. Stat. Ann. § 382-A:2-313;
- 10 ee. N.J. Stat. Ann. § 12A:2-313;
- 11 ff. N.M. Stat. Ann. § 55-2-313;
- 12 gg. N.Y. U.C.C. Law § 2-313;
- 13 hh. N.C. Gen. Stat. Ann. § 25-2-313;
- 14 ii. N.D. Cent. Code § 41-02-30;
- 15 jj. Ohio Rev. Code Ann. § 1302.26;
- 16 kk. Okl. Stat. Tit. 12A, § 2-313;
- 17 ll. Or. Rev. Stat. § 72.3130;
- 18 mm. 13 Pa. Stat. Ann. § 2313;
- 19 nn. R.I. Gen. Laws § 6A-2-313;
- 20 oo. S.C. Code Ann. § 36-2-313;
- 21 pp. S.D. Codified Laws § 57A-2-313;
- 22 qq. Tenn. Code Ann. § 47-2-313;
- 23 rr. Tex. Bus. & Com. Code Ann. § 2.313;
- 24 ss. Utah Code Ann. § 70A-2-313;
- 25 tt. Va. Code Ann. § 8.2-313 ;
- 26 uu. Vt. Stat. Ann. § 9A-2-313 ;
- 27 vv. Wash. Rev. Code § 62A.2-313;
- 28 ww. W. Va. Code § 46-2-313;

xx. Wis. Stat. Ann. § 402.313; and

yy. Wyo. Stat. Ann. § 34.1-2-313.

379. The express warranties that Boston Scientific made to Plaintiffs, even though the SCS devices deviated from the approved FDA specifications, included, but were not limited to, assurances that:

- a. The safety and effectiveness of the SCS devices were validated by clinical data or clinical evidence;
- b. The permanent SCS devices would provide greater or equivalent pain relief compared to the temporary trial SCS;
- c. The devices' multi-waveform stimulation technology provided superior pain relief without significant risk of adverse side effects;
- d. The devices were 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; and
- e. The devices had been adequately tested for safety and effectiveness consistent with FDA requirements.

380. Such express warranties were made to Plaintiffs' healthcare providers and directly to Plaintiffs through Boston Scientific's promotional materials and sales representatives.

381. Plaintiffs and their healthcare providers reasonably relied on these express warranties in choosing to proceed with implantation of the Boston Scientific systems and in making ongoing treatment decisions.

382. These express warranties became part of the basis of the bargain between Plaintiffs and Boston Scientific – they were critical to Plaintiffs' decision to be implanted with the SCS devices and, therefore, were far more than mere puffery. These assurances were specific, unequivocal affirmations of fact and promises about

1 the safety, testing, durability, and performance of the SCS devices, not statements of  
2 opinion or recommendation.

3 383. Contrary to Boston Scientific's express warranties, due to deviations  
4 from FDA specifications, the SCS devices implanted in Plaintiffs were defective,  
5 unreasonably dangerous, and incapable of delivering the promised therapeutic  
6 benefits. They were also not validated by clinical data, as represented to Plaintiffs  
7 and their physicians. Instead, they caused Plaintiffs to suffer injuries including  
8 persistent ineffective pain relief, nerve damage, device failure, stimulation-related  
9 complications, and ultimately, significant physical and emotional harm.

10 384. Contrary to Boston Scientific's express warranties, the permanent SCS  
11 devices do not—and in Plaintiffs' cases did not—provide greater or equivalent pain  
12 relief compared to the temporary trial SCS devices.

13 385. As such, the SCS devices failed to conform to Boston Scientific's  
14 promises, descriptions, and affirmations of fact and did not perform as Boston  
15 Scientific stated and promised.

16 386. As a result of this failure, Plaintiffs sustained injuries that include, but  
17 are not limited to, therapy loss, painful electrical sensations, device communication  
18 failure, and required surgical revision and removal. The devices were not safe,  
19 effective, or reliable as expressly warranted by Boston Scientific, who failed to  
20 provide adequate warnings or updates contradicting its original claims.

21 387. Boston Scientific therefore breached its express warranties to Plaintiffs  
22 herein in violation of applicable state statutes and common law, by manufacturing,  
23 selling, and marketing the spinal cord stimulator systems to Plaintiffs herein, thereby  
24 causing injuries and damages. The failure of the SCS devices to be as represented  
25 was a substantial factor in causing Plaintiffs' harm.

26 388. Plaintiffs have already been injured by Boston Scientific's breach of the  
27 express warranties described above. As such, Boston Scientific cannot cure the  
28 breach of express warranties. Therefore, any pre-suit notice of the breaches to Boston

1 Scientific would be futile and should not be required of Plaintiffs. In addition and in  
2 the alternative, pre-suit notice is not required because Plaintiffs assert personal injury  
3 claims against the manufacturer of the SCS devices.

4 389. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
5 relief against Defendants, as contained in the Prayer for Relief.

6 **COUNT VIII – NEGLIGENCE**

7 (Sales and Other Representative)

8 390. Plaintiffs incorporate by reference all factual allegations set forth  
9 above in ¶¶ 1–279 as if fully set forth herein.

10 391. This Count is based on the acts and omissions of Defendants' sales  
11 representatives, territory managers, clinical specialists, field clinical representatives,  
12 and other field personnel (together, "Representatives") in their direct dealings with  
13 Plaintiffs and Plaintiffs' physicians. It is not based on the design, manufacture, or  
14 FDA-approved labeling of the SCS Devices. It does not seek to impose any  
15 requirement concerning the content of the FDA-approved labeling, and it does not  
16 depend on any alleged misrepresentation to, or fraud on, FDA.

17 392. At all relevant times, the Representatives who interacted with Plaintiffs  
18 were employed by, and acted as agents of, Boston Scientific. The Representatives  
19 acted within the course and scope of that employment and agency, under policies,  
20 training, and compensation structures that Defendants created and controlled.

21 393. Defendants assigned the Representatives job duties that included  
22 "[p]rovid[ing] expert clinical support through programming, troubleshooting, and  
23 intraoperative guidance," "[d]eliver[ing] patient follow-up care," "regularly  
24 monitoring therapy progress, addressing patient needs," and "oversee[ing] the entire  
25 SCS process of patient care, pre-surgical education, post-surgical follow ups and long-  
26 term care of the device."<sup>55</sup>

27  
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<sup>55</sup> See Ex. A.

1           394. The only stated qualifications for these patient-facing positions were "a  
2 bachelor's degree or an equivalent combination of education and experience and a  
3 minimum of two years' work experience in a sales and/or clinical role." Upon  
4 information and belief, the Representatives who dealt with Plaintiffs were not licensed  
5 physicians, nurses, or other licensed healthcare providers, and many had no clinical  
6 licensure, clinical education, or clinical training beyond Defendants' internal product  
7 and sales training.

8           395. A person who voluntarily acts must exercise reasonable care in doing  
9 so, and must exercise reasonable care to avoid creating an unreasonable risk of  
10 physical harm to others. Defendants, through the Representatives, chose to  
11 communicate directly with Plaintiffs about SCS therapy; to program, interrogate,  
12 troubleshoot, and adjust Plaintiffs' implanted devices; and to respond to Plaintiffs'  
13 reports of symptoms. Defendants and the Representatives knew or should have  
14 recognized that these services were needed for Plaintiffs' protection. Having done so,  
15 Defendants and the Representatives owed Plaintiffs a duty to act with reasonable care  
16 in performing that work.

17           396. A person who undertakes to render services in a trade or profession must  
18 exercise the skill and knowledge normally possessed by members of that trade or  
19 profession in good standing.<sup>56</sup> By holding the Representatives out as providers of  
20 "expert clinical support," device programming, troubleshooting, and "patient follow-  
21 up care," Defendants and the Representatives undertook to perform those services  
22 with the skill and care of a reasonably careful device representative performing them,  
23 and to refer clinical questions to licensed physicians.

24           397. A person who, in the course of business, gives information to another  
25 owes a duty of reasonable care in giving it when the person knows or should know  
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28           <sup>56</sup> See, e.g., Restatement (Second) of Torts § 299A

1 that the other will rely on it in a way that risks physical harm.<sup>57</sup> The Representatives  
2 knew that Plaintiffs would rely on what the Representatives told them about the  
3 devices, their symptoms, and the Representatives' own qualifications in deciding  
4 whether to proceed with implantation, continue therapy, seek medical evaluation, or  
5 request explant.

6 398. A supplier of a product who communicates directly with users about its  
7 risks owes a duty to communicate accurately and completely, and not to contradict,  
8 dilute, or minimize the warnings that accompany the product.<sup>58</sup>

9 399. These duties arise under the general state common law of negligence,  
10 which applies to all persons. They do not depend on, and are not created by, the  
11 Federal Food, Drug, and Cosmetic Act. FDA does not approve or regulate the content  
12 of a representative's unscripted oral and written statements to individual patients,  
13 where a representative meets with patients, or the channels a representative uses to  
14 communicate with patients about their care.

15 400. Defendants, through the Representatives, breached these duties in at  
16 least the following five respects: failing to provide adequate warnings and information  
17 in direct communications with Plaintiffs; failing to meet the standard of care in  
18 performing their jobs; misleading Plaintiffs about the Representatives' training,  
19 experience, and knowledge; and holding patient meetings and consultations in  
20 inappropriate settings.

21 401. The Representatives were frequently Plaintiffs' first and primary point  
22 of contact about their SCS Devices, before and after implantation, and often  
23 communicated with Plaintiffs outside the presence of any physician. In those direct  
24 communications, the Representatives failed to exercise reasonable care to convey, and  
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27 <sup>57</sup> See Restatement (Second) of Torts § 311.

28 <sup>58</sup> See Restatement (Second) of Torts § 388.

1 affirmatively contradicted, diluted, or minimized, risk information contained in the  
2 FDA-approved labeling.

3 402. Among other things, they:

- 4 a. described SCS therapy to Plaintiffs during pre-implant meetings and calls  
5 without disclosing, or while minimizing, the risks of lead migration, lead  
6 fracture, loss of therapy, unintended or uncomfortable stimulation,  
7 shocking, and the need for revision or explant surgery identified in the  
8 labeling;
- 9 b. told Plaintiffs that the permanent device would provide greater pain relief  
10 than the trial device, and that it would relieve most of their pain without  
11 disclosing that results with the permanent device may be less than, and may  
12 decline from, results during the trial;
- 13 c. after implantation, attributed Plaintiffs' reported shocking, burning, jolting,  
14 loss of therapy, and pain to causes other than the device, including in  
15 contradiction of the FDA-approved labeling;
- 16 d. told Plaintiffs that their symptoms could be resolved by reprogramming,  
17 instead of advising them that the symptoms were consistent with known  
18 device failure modes requiring medical evaluation; and
- 19 e. failed to advise Plaintiffs to report their symptoms to their implanting or  
20 treating physician, and in some instances discouraged them from doing so.

21 403. Reasonable care required the Representatives, when they chose to speak  
22 with Plaintiffs about the devices' risks, benefits, and performance, to do so accurately  
23 and consistently with the FDA-approved labeling, and to direct Plaintiffs to their  
24 physicians for clinical evaluation of symptoms. This Count imposes no labeling  
25 requirement different from or in addition to federal requirements. It asks only that the  
26 Representatives not contradict or dilute the existing FDA-approved warnings in their  
27 own communications with patients.  
28

1           404. The Representatives failed to exercise the care and skill of a reasonably  
2 careful device representative performing the same tasks. Among other things, they:  
3           a. programmed and reprogrammed Plaintiffs' trial and permanent devices,  
4           including stimulation parameters, waveforms, amplitude, and frequency,  
5           without a physician's contemporaneous order, review, or supervision;  
6           b. made real-time decisions about device settings based on their own  
7           assessment of Plaintiffs' responses, substituting their judgment for that of  
8           Plaintiffs' licensed physicians;  
9           c. programmed trial devices to produce short-term pain relief that was not  
10          achievable on a long-term basis with a permanent device;  
11          d. directed Plaintiffs' reporting of trial results toward the minimum pain-relief  
12          threshold required for third-party payer coverage, rather than accurately  
13          recording Plaintiffs' actual experience;  
14          e. repeatedly reprogrammed devices in response to symptoms instead of  
15          referring Plaintiffs for imaging or clinical evaluation of possible hardware  
16          failure;  
17          f. upon information and belief, failed to document their programming  
18          changes and Plaintiffs' reported symptoms in a manner that reached  
19          Plaintiffs' treating physicians and medical records; and  
20          g. failed to follow applicable standards governing Representative interaction  
21          with patients.

22          405. The statements and presentations made by the Representatives when  
23 interacting with patients, including Plaintiffs, created the reasonable impression that  
24 the Representatives had clinical training, expertise, and knowledge comparable to  
25 licensed healthcare providers, and the competence to assess Plaintiffs' symptoms and  
26 decide on their treatment. In fact, the Representatives were sales and product-support  
27 employees whose qualifications for patient-facing roles were a bachelor's degree or  
28

1 equivalent combination of education and experience plus two years of sales or clinical  
2 work, and who had no license to diagnose or treat patients.

3 406. The Representatives failed to exercise reasonable care to disclose the  
4 limits of their training, experience, and authority. In particular, they failed to tell  
5 Plaintiffs that they were not licensed clinicians, that (upon information and belief)  
6 their compensation was based, in part, on device sales and patient retention, and that  
7 their assessments of Plaintiffs' symptoms were not medical evaluations.

8 407. Plaintiffs reasonably relied on the Representatives' apparent clinical  
9 training and expertise. In that reliance, they accepted the Representatives'  
10 explanations of their symptoms, allowed the Representatives to adjust their therapy  
11 without physician involvement, delayed seeking medical evaluation, and continued  
12 using malfunctioning devices.

13 408. The Representatives met face-to-face with Plaintiffs to discuss SCS  
14 therapy, trial results, symptoms, and device performance at medical facilities, but also  
15 in Plaintiffs' homes and in public places such as parks, coffee shops, and restaurants.  
16 On information and belief, the Representatives also adjusted or reprogrammed devices  
17 at these non-clinical locations.

18 409. These settings were not appropriate for discussing a patient's medical  
19 condition, assessing symptoms, or adjusting an implanted Class III device. They had  
20 no physician or licensed clinician present, no way to examine the patient or to obtain  
21 imaging or diagnostic testing, and no clinical documentation. They also had no  
22 confidentiality. Patients' symptoms, diagnoses, and treatment decisions were  
23 discussed in front of members of the public.

24 410. By holding these meetings outside clinical settings and away from  
25 Plaintiffs' physicians, the Representatives:

- 26 a. removed Plaintiffs' physicians from decisions about device programming  
27 and symptom evaluation;  
28

- b. ensured that symptoms Plaintiffs reported, and changes the Representatives made, were not recorded in Plaintiffs' medical records or communicated to their physicians;
- c. placed Plaintiffs in informal settings where the Representatives' sales role was blurred and Plaintiffs could not make informed, considered decisions about their care; and
- d. exposed Plaintiffs' confidential health information to third parties.

411. A reasonably careful device representative would not hold patient consultations about symptoms, therapy decisions, or device adjustments outside a clinical setting or without the treating physician's knowledge and involvement.

412. Defendants' breaches were a direct and proximate cause, and a substantial factor, in causing Plaintiffs' injuries. In particular:

- a. but for the Representatives' inaccurate and incomplete communications and their misleading presentation of their own qualifications, Plaintiffs would not have consented to the permanent implants, continued therapy, and/or delayed treatment;
- b. because the Representatives attributed Plaintiffs' symptoms to non-device causes and treated them with reprogramming instead of referring Plaintiffs for medical evaluation, the device failures were not identified and treated promptly. This allowed continued and progressive injury, including prolonged exposure to uncontrolled stimulation, nerve injury, and the need for more extensive revision or explant surgery; and
- c. because symptom reports and programming changes were made in non-clinical settings and through unsecured channels outside the medical record, Plaintiffs' physicians did not receive information that would have led them to order imaging, interrogate the device, investigate hardware failure, or recommend explant sooner.

1           413. The harm Plaintiffs suffered was the foreseeable result of the risks that  
2 made the Representatives' conduct negligent. A device representative who programs  
3 implanted neurostimulators, tells patients what their symptoms mean, and keeps the  
4 physician out of the loop foreseeably causes delayed diagnosis of device failure and  
5 continued physical injury. The Representatives' failure to use reasonable care added  
6 to the risk of harm to Plaintiffs, and Plaintiffs also suffered harm because they relied  
7 on the Representatives' services.

8           414. Defendants are vicariously liable for the Representatives' negligence  
9 under the doctrines of respondeat superior and agency, because the Representatives  
10 acted within the course and scope of their employment and agency, carrying out duties  
11 Defendants assigned under compensation structures Defendants designed within  
12 corporate policies created by Defendants.

13           415. Defendants are also directly liable, because they designed the  
14 Representatives' patient-facing role; authorized, directed, and ratified the conduct  
15 described above; and failed to establish or enforce reasonable policies governing  
16 where and how Representatives communicate with patients and what Representatives  
17 tell patients about their qualifications.

18           416. As a direct and proximate result of Defendants' negligence, Plaintiffs  
19 suffered, and will continue to suffer:

- 20           a. physical injury, pain, and suffering;
- 21           b. additional surgeries, including revision and explant procedures;
- 22           c. nerve injury;
- 23           d. mental anguish and emotional distress;
- 24           e. loss of enjoyment of life;
- 25           f. past and future medical expenses;
- 26           g. lost wages and loss of earning capacity; and
- 27           h. other economic and non-economic damages.

1        417. WHEREFORE, Plaintiffs demand judgment against Defendants for  
2 compensatory damages, punitive damages to the extent permitted by applicable law,  
3 pre- and post-judgment interest, costs, and such other relief as the Court deems just  
4 and proper.

5                    **COUNT IX – BREACH OF IMPLIED WARRANTY**

6        418. Plaintiffs incorporate by reference all factual allegations set forth above  
7 in ¶¶ 1–279 as if fully set forth herein.

8        419. A seller who is a merchant with respect to goods of that kind warrants  
9 that the goods shall be merchantable and fit for the ordinary purposes for which such  
10 goods are used. *See:*

- 11            a. Ala. Code §§ 7-2-314, et seq.;
- 12            b. Alaska Stat. §§ 45.02.314, et seq.;
- 13            c. Ariz. Rev. Stat. Ann. §§ 47-2314, et seq.;
- 14            d. Ark. Code Ann. §§ 4-2-314, et seq.;
- 15            e. Cal. Com. Code §§ 2314, et seq.;
- 16            f. Colo. Rev. Stat. §§ 4-2-314, et seq.;
- 17            g. Conn. Gen. Stat. Ann. §§ 42a-2-314, et seq.;
- 18            h. Del. Code Ann. tit. 6, §§ 2-314, et seq.;
- 19            i. D.C. Code Ann. §§ 28:2-314, et seq.;
- 20            j. Fla. Stat. Ann. §§ 672.314, et seq.;
- 21            k. O.C.G.A. §§ 11-2-314, et seq.;
- 22            l. Haw. Rev. Stat. §§ 490:2-314, et seq.;
- 23            m. Idaho Code §§ 28-2-314, et seq.;
- 24            n. Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, et seq.;
- 25            o. Indiana Code Ann. §§ 26-1-2-314, et seq.;
- 26            p. Iowa Code Ann. §§ 554.2314, et seq.;
- 27            q. Kan. Stat. Ann. §§ 84-2-314, et seq.;
- 28            r. Ky. Rev. Stat. Ann. §§ 355.2-314, et seq.;

- 1 s. La. Civ. Code Ann. art. 2520, et seq. (and is liable for redhibition  
2 under this statute);
- 3 t. Me. Rev. Stat. Ann. tit. 11, §§ 2-314, et seq.;
- 4 u. Md. Code Ann., Com. Law §§ 2-314, et seq.;
- 5 v. Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, et seq.;
- 6 w. Mich. Comp. Laws Ann. §§ 440.2314, et seq.;
- 7 x. Minn. Stat. Ann. §§ 336.2-314, et seq.;
- 8 y. Miss. Code Ann. §§ 75-2-314, et seq.;
- 9 z. Mo. Rev. Stat. Ann. §§ 400.2-314, et seq.;
- 10 aa. Mont. Code Ann. §§ 30-2-314, et seq.;
- 11 bb. Neb. Rev. Stat. §§ 2-314, et seq.;
- 12 cc. Nev. Rev. Stat. §§ 104.2314, et seq.;
- 13 dd. N.H. Rev. Stat. Ann. §§ 382-A:2-314, et seq.;
- 14 ee. N.J. Stat. Ann. §§ 12A:2-314, et seq.;
- 15 ff. N.M. Stat. Ann. § 55-2-314, et seq.;
- 16 gg. N.Y. U.C.C. Law §§ 2-314, et seq.;
- 17 hh. N.C. Gen. Stat. Ann. §§ 25-2-314, et seq.;
- 18 ii. N.D. Cent. Code §§ 41-02-31, et seq.;
- 19 jj. Ohio Rev. Code Ann. §§ 1302.27, et seq.;
- 20 kk. Okl. Stat. Tit. 12A, §§ 2-314 et seq.;
- 21 ll. Or. Rev. Stat. §§ 72.3140, et seq.;
- 22 mm. 13 Pa. Stat. Ann. §§ 2314 et seq.;
- 23 nn. R.I. Gen. Laws §§ 6A-2-314, et seq.;
- 24 oo. S.C. Code Ann. §§ 36-2-314, et seq.;
- 25 pp. S.D. Codified Laws §§ 57A-2-314, et seq.;
- 26 qq. Tenn. Code Ann. §§ 47-2-314, et seq.;
- 27 rr. Tex. Bus. & Com. Code Ann. §§ 2.314, et seq.;
- 28 ss. Utah Code Ann. §§ 70A-2-314, et seq.;

1           tt.     Va. Code Ann. §§ 8.2-314, et seq.;  
2           uu.     Vt. Stat. Ann. §§ 9A-2-314, et seq.;  
3           vv.     Wash. Rev. Code §§ 62A.2-314, et seq.;  
4           ww.     W. Va. Code §§ 46-2-314, et seq.;  
5           xx.     Wis. Stat. Ann. §§ 402.314, et seq.; and  
6           yy.     Wyo. Stat. Ann. §§ 34.1-2-314, et seq.

7           420. At all relevant and material times, Boston Scientific manufactured,  
8 distributed, advertised, promoted, and sold the SCS devices. Plaintiffs, directly or  
9 through the hospitals, surgical centers, and physicians that acquired the devices for  
10 implantation in Plaintiffs, bought the SCS devices from Boston Scientific. In addition  
11 and in the alternative, privity existed between Boston Scientific and each Plaintiff  
12 through the direct dealings between Boston Scientific's sales representatives and  
13 Plaintiffs described above.

14           421. Boston Scientific is a merchant engaged in the business of  
15 manufacturing, marketing, and selling SCS devices, including the devices implanted  
16 in Plaintiffs. These devices are used and intended for the ordinary purpose of treating  
17 chronic pain.

18           422. When Boston Scientific marketed and sold its SCS devices implanted in  
19 Plaintiffs, it impliedly warranted that the devices were of merchantable quality,  
20 conformed to FDA-approved specifications, and were reasonably safe for their  
21 intended medical purpose. Boston Scientific also impliedly warranted that the  
22 devices were fit for the specific purpose of long-term implantation to treat Plaintiffs'  
23 condition, as recommended by their physicians.

24           423. The devices implanted in Plaintiffs were not of merchantable quality,  
25 nor were they fit for their intended purpose. As a result of deviations from the FDA-  
26 approved specifications, they failed to operate as expected due to known defects in  
27 lead composition and fixation, firmware execution, wireless programming, battery  
28 recharging, and therapy delivery. Plaintiffs experienced painful shocks, therapy

1 failure, and ultimately underwent surgical removal due to the devices' unreliability,  
2 defects, and malfunctions.

3 424. These failures were not caused by misuse or physician error. They were  
4 the direct result of design-altering changes Boston Scientific implemented in  
5 deviation from FDA-approved specifications without corresponding clinical testing  
6 or validation, and without disclosing these risks in labeling or provider materials. The  
7 devices failed to conform to the minimum standards of merchantability and fitness for  
8 long-term neuromodulation therapy.

9 425. These deviations are further supported by specific allegations to be  
10 pleaded in plaintiff-specific filings included but not limited to Short-Form  
11 Complaints.

12 426. Boston Scientific's breach of implied warranties was a proximate cause  
13 of Plaintiffs' injuries, including physical pain, surgical intervention, economic loss,  
14 and emotional distress. The failure of the SCS devices to have the expected quality  
15 was a substantial factor in causing Plaintiffs' harm. Plaintiffs would not have  
16 consented to the implantation had their physicians known the devices were unfit for  
17 their intended use. Pre-suit notice of the breach is not required because Plaintiffs assert  
18 personal injury claims against the manufacturer of the SCS devices. In the alternative,  
19 any pre-suit notice would be futile because Plaintiffs have already been injured and  
20 Boston Scientific cannot cure the breach.

21 427. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
22 relief against Defendants, as contained in the Prayer For Relief.

23 **COUNT X - NEGLIGENT UNDERTAKING**

24 428. Plaintiffs incorporate by reference all factual allegations set forth  
25 above in ¶¶ 1–279 as if fully set forth herein.

26 429. Plaintiffs plead this claim in the alternative, to the extent Defendants  
27 contend that they otherwise owed no duty to provide programming, reprogramming,  
28 troubleshooting, or other patient-specific device-support services. This claim arises

1 from Defendants' actual and voluntary undertaking to provide those services and  
2 their failure to exercise reasonable care in performing them.

3 430. At all relevant times, Defendants, through their sales and clinical  
4 representatives, specifically undertook to provide services to Plaintiffs and their  
5 treating physicians concerning the operation and performance of Plaintiffs' SCS  
6 devices. Those services included programming and reprogramming the devices,  
7 adjusting stimulation parameters, troubleshooting reported malfunctions, evaluating  
8 Plaintiffs' responses to adjustments, and recommending responses to device-related  
9 symptoms and complications.

10 431. Defendants' representatives assumed an active role in providing these  
11 services. Their involvement was not limited to selling the devices, supplying general  
12 product information, or passively observing treatment. Rather, they personally  
13 performed device adjustments and reprogramming and provided patient-specific  
14 advice concerning device performance, the significance of reported symptoms, and  
15 the purported ability of further reprogramming to alleviate complications.

16 432. Defendants undertook these services directly for Plaintiffs and,  
17 alternatively, for Plaintiffs' treating physicians for Plaintiffs' benefit and protection.  
18 Defendants knew or reasonably should have recognized that reasonable care in  
19 performing those services was necessary to protect Plaintiffs from physical harm  
20 associated with harmful stimulation, device malfunction, continued use of failing  
21 devices, and delayed medical evaluation and treatment.

22 433. By actually undertaking these services, Defendants assumed a duty to  
23 exercise reasonable care within the scope of the undertaking. That duty included  
24 exercising reasonable care in making adjustments, recognizing the limitations of  
25 reprogramming, accurately communicating the results of troubleshooting, and  
26 recognizing when reported symptoms or persistent malfunctions required evaluation  
27 by Plaintiffs' treating physicians rather than further device adjustments.  
28

1        434. This duty arose from the services Defendants' representatives actually  
2        undertook, including when the representatives performed activities beyond their  
3        training, qualifications, or permitted device-support role. Plaintiffs do not premise this  
4        claim merely on a failure to undertake services that Defendants never agreed or  
5        attempted to provide.

6        435. Defendants, through their representatives, failed to exercise reasonable  
7        care in performing the undertaking in one or more of the following ways:

- 8        a. By programming, reprogramming, or adjusting Plaintiffs' devices without  
9        adequately assessing their reported symptoms, responses to previous  
10       adjustments, or indications of underlying device failure;
- 11       b. By continuing to reprogram the devices when they knew or reasonably  
12       should have known that additional reprogramming would not correct the  
13       underlying malfunction or alleviate Plaintiffs' complications;
- 14       c. By providing patient-specific assurances that symptoms were unrelated to  
15       the devices or resulted merely from suboptimal settings without an  
16       adequate basis for those conclusions;
- 17       d. By representing that further reprogramming would resolve complications  
18       caused by lead failure, lead migration, IPG/battery malfunction, or other  
19       conditions that reprogramming could not correct;
- 20       e. By performing device-related services beyond their training, qualifications,  
21       or permitted role without appropriate physician direction;
- 22       f. By failing to discontinue ineffective troubleshooting and directing  
23       Plaintiffs to their treating physicians when persistent symptoms or  
24       malfunctions required medical evaluation;
- 25       g. By advising Plaintiffs to continue using malfunctioning devices or delay  
26       medical evaluation, treatment, revision, replacement, or removal; and

1 h. By failing to accurately communicate persistent symptoms, unsuccessful  
2 reprogramming, and indications of device failure to Plaintiffs' treating  
3 physicians.

4 436. Defendants' negligent performance increased the risk of physical harm  
5 beyond the risk that would have existed had Defendants not undertaken the services  
6 at all. In particular, Defendants' affirmative adjustments, repeated troubleshooting,  
7 and patient-specific assurances induced continued device use and displaced or  
8 delayed physician evaluation that Plaintiffs otherwise would have sought.

9 437. This increased risk did not arise merely because Defendants failed to  
10 eliminate a preexisting danger. Rather, Defendants' affirmative conduct caused  
11 Plaintiffs to continue using malfunctioning devices and postpone medical evaluation  
12 or removal in reliance on the purported effectiveness of the services being provided,  
13 thereby prolonging exposure to harmful device failures.

14 438. Alternatively, and independently, Plaintiffs suffered harm because they  
15 relied on Defendants' undertaking. Plaintiffs submitted to repeated adjustments and  
16 reprogramming and relied on Defendants' representatives to exercise reasonable care  
17 in performing those services and communicating their limitations. In reliance on the  
18 undertaking and accompanying assurances, Plaintiffs continued device use and  
19 delayed seeking further medical evaluation or removal.

20 439. To the extent Defendants provided troubleshooting and device-  
21 performance information to Plaintiffs' treating physicians, those physicians likewise  
22 relied on the undertaking and the information supplied in determining how to respond  
23 to Plaintiffs' reported symptoms and whether further evaluation or intervention was  
24 necessary.

25 440. Had Defendants not undertaken these services and provided the  
26 accompanying assurances, or had they exercised reasonable care in performing the  
27 services, Plaintiffs would have sought or received earlier physician evaluation and  
28 appropriate treatment, including revision, replacement, or removal where indicated.

441. Plaintiffs' SCS devices failed because of their underlying defects. Defendants' negligent undertaking caused Plaintiffs to continue using the failing devices and delayed appropriate medical evaluation and treatment. The device failures directly and proximately caused physical injuries, while Defendants' negligent performance prolonged Plaintiffs' exposure to those failures and caused additional injury or aggravated injuries that otherwise would have been avoided or less severe.

442. Defendants' failure to exercise reasonable care in performing the services they undertook was a substantial factor in causing Plaintiffs' harm. As a direct and proximate result of Defendants' negligent performance of the services they undertook, Plaintiffs' prolonged exposure to the defective devices caused Plaintiffs serious injuries and damages, including, but not limited to, bodily injury; permanent nerve damage; chronic pain; severe physical pain and suffering; emotional distress and mental anguish; diminished enjoyment of life; medical and related expenses; loss of earnings; and disability, all of which losses and damages will continue into the future.

443. WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as contained in the Prayer for Relief.

## COUNT XI – NEGLIGENCE PER SE

(Unauthorized Practice of Medicine)

444. Plaintiffs incorporate by reference all factual allegations set forth above in ¶¶ 1–279 as if fully set forth herein.

445. No person may practice medicine in the state without being duly licensed, and the practice of medicine includes diagnosing, treating, operating on, or prescribing for any human disease, pain, injury, deformity, or physical condition.

446. Defendants have engaged in unauthorized practice of medicine in violation of:

- a. Alabama Code § 34-24-51;
- b. Alaska Stat. § 08.64.170;

- 1 c. Arizona Rev. Stat. § 32-1455;
- 2 d. Ark. Code Ann. § 17-95-401;
- 3 e. Cal. Bus. & Prof. Code § 2052;
- 4 f. Colo. Rev. Stat. § 12-240-135;
- 5 g. Conn. Gen. Stat. § 20-9;
- 6 h. 24 Del. Code § 1720;
- 7 i. D.C. Code §§ 3-1210.01, et seq.;
- 8 j. Fla. Stat. § 458.327;
- 9 k. O.C.G.A. § 43-34-22;
- 10 l. Hawaii Rev. Stat. § 453-2;
- 11 m. Idaho Code § 54-1804;
- 12 n. 225 ILCS 60/50;
- 13 o. Ind. Code Ann. § 25-22.5-8-1;
- 14 p. Iowa Code § 147.2;
- 15 q. Kan. Stat. Ann. § 65-2803;
- 16 r. Kentucky Rev. Stat. § 311.560;
- 17 s. La. R.S. § 37:1271;
- 18 t. 32 M.R.S. § 3270;
- 19 u. Md. Health Occupations Code Ann. § 14-601;
- 20 v. ALM GL ch. 112, § 6;
- 21 w. MCL § 333.17011;
- 22 x. Minn. Stat. § 147.081;
- 23 y. Miss. Code Ann. § 73-25-127;
- 24 z. R.S. Mo. § 334.010;
- 25 aa. § 37-20-411, MCA;
- 26 bb. R.R.S. Neb. § 38-2025;
- 27 cc. Nev. Rev. Stat. Ann. § 630.400;
- 28 dd. RSA 329:24;

1 ee. N.J. Stat. § 2C:21-20;  
2 ff. N.M. Stat. Ann. § 61-6-20;  
3 gg. N.Y. Educ. Law § 6512;  
4 hh. N.C. Gen. Stat. § 90-18;  
5 ii. N.D. Cent. Code § 43-17-34;  
6 jj. Ohio Rev. Code Ann. § 4731.41;  
7 kk. Okla. Stat. tit. 59, § 491;  
8 ll. ORS § 677.080;  
9 mm. 63 P.S. § 422.10;  
10 nn. 20 L.P.R.A. § 135d;  
11 oo. R.I. Gen. Laws § 5-37-12;  
12 pp. S.C. Code Ann. § 40-47-200;  
13 qq. S.D. Codified Laws § 36-4-8;  
14 rr. Tenn. Code Ann. § 63-6-201;  
15 ss. Tex. Occ Code § 165.152;  
16 tt. Utah Code Ann. § 58-67-301;  
17 uu. 26 V.S.A. § 1314;  
18 vv. Va. Code Ann. § 54.1-2902;  
19 ww. 27 V.I.C. § 16;  
20 xx. Rev. Code Wash. (ARCW) § 18.71.021;  
21 yy. W. Va. Code § 30-3-13;  
22 zz. Wis. Stat. § 448.03; and  
23 aaa. Wyo. Stat. § 33-26-301

24 447. These statutes are designed to protect patients from unqualified persons  
25 making medical treatment decisions, and Plaintiffs are members of the class of  
26 persons these statutes were designed to protect. The harms Plaintiffs suffered are  
27 precisely the type of harms these statutes were designed to prevent.  
28

1           448. The law applicable to specific Plaintiffs will be identified in plaintiff-  
2 specific filings, including but not limited to Short-Form Complaints.

3           449. To the extent that any applicable state law does not recognize negligence  
4 per se or does not permit a statute to create a duty or standard of care, violation of the  
5 above referenced statutes is evidence of Boston Scientific and its representatives'  
6 breach of their duty to act reasonably toward patients, including Plaintiffs.

7           450. The statutes listed above are designed to ensure that those who provide  
8 medical treatment and make medical treatment decisions are qualified to do so. The  
9 medical license represents the qualifications that each state has determined are  
10 necessary for an individual to practice medicine.

11           451. Boston Scientific's sales and clinical representatives, acting within the  
12 scope of their employment with and as agents of Boston Scientific, engaged in  
13 unauthorized practice of medicine by advising, recommending, and administering  
14 device treatment – including programming, reprogramming, and medical  
15 recommendations – for the treatment of Plaintiffs' pain and other medical conditions.  
16 The representatives did so without the direction or supervision of Plaintiffs' licensed  
17 physicians and beyond the scope of any authorized delegation of technical device  
18 support.

19           452. By practicing medicine without a license or the qualifications that such  
20 a license represents, Boston Scientific's sales and clinical representatives' conduct  
21 breached the standard of care created by the statutes that require medical licensure for  
22 the practice of medicine.

23           453. Boston Scientific's sales and clinical representatives, none of whom  
24 were licensed healthcare professionals, routinely and in Plaintiffs' cases:

- 25           a. Entered surgical suites during SCS device implantation procedures;  
26           b. Advised surgeons and operating room staff on intraoperative lead  
27           positioning and stimulation testing;  
28

- c. Participated in real-time programming of the devices based on patient response during surgery;
- d. Provided device setting recommendations to healthcare providers during post-operative care;
- e. Adjusted or instructed adjustment of device parameters that materially influenced treatment decisions;
- f. Directly advised patients, including Plaintiffs, about the safety and efficacy of the SCS system, benefits of the system, and impacts of reprogramming the SCS system;
- g. Directly advised patients, including Plaintiffs, to keep the SCS system in their body despite complications and lack of efficacy of the system;
- h. Provided medical advice to patients, including Plaintiffs, regarding the SCS system, symptoms now alleged to be caused by the SCS system, and decisions related to the SCS system.

454. This claim is based entirely on state law violations and is not preempted by the MDA or the FDCA. Federal regulations confirm that FDA preemption of state medical device requirements does not reach state licensing or other requirements relating to the practice of medicine. 21 C.F.R. § 808.1. This claim does not depend on the content of any FDA requirement, and it seeks to enforce only state laws governing who may practice medicine.

455. The representatives' violations of these statutes were a substantial factor in causing Plaintiffs' harm. As a direct and proximate result of Defendants' violation of state laws prohibiting the unlicensed practice of medicine, Plaintiffs suffered the injuries and damages described herein, including but not limited to chronic pain, incontinence, numbness, and other losses including mental anguish, diminished enjoyment of life, medical, health and incidental and related expenses.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

1 **COUNT XII – NEGLIGENCE PER SE**

2 (Failure to Make Required Reports)

3 456. Plaintiffs incorporate by reference all factual allegations set forth  
4 above in ¶¶ 1–279 as if fully set forth herein.

5 457. Defendants were subject to, and violated, multiple non-discretionary  
6 federal duties that were enacted for the protection of public health and safety. These  
7 duties are embodied in the FDCA, the MDA, and FDA regulations promulgated  
8 thereunder, including the mandated adverse event reporting under 21 C.F.R. §  
9 803.50.

10 458. Boston Scientific failed to report adverse events its sales representatives  
11 learned of from patients, including Plaintiffs, and instead persuaded patients that there  
12 were no issues with the SCS devices.

13 459. Plaintiffs are members of the class of persons these statutes and  
14 regulations are intended to protect, being patients receiving Class III medical implants  
15 under the FDA's PMA regulatory framework. Plaintiffs' injuries are of the kind these  
16 reporting requirements are intended to prevent, specifically, harms resulting from  
17 device malfunctions and injuries that went unreported to FDA and therefore did not  
18 reach patients and their physicians.

19 460. The law applicable to specific Plaintiffs will be identified in plaintiff-  
20 specific filings, including but not limited to Short-Form Complaints.

21 461. To the extent that any applicable state law does not recognize negligence  
22 per se or does not permit a statute to create a duty or standard of care, violation of the  
23 federal reporting requirements described above is evidence of Boston Scientific's  
24 breach of its duty to act reasonably toward patients, including Plaintiffs, particularly  
25 in jurisdictions adopting the rule of Restatement (Second) of Torts § 388 that one who  
26 supplies a chattel for another's use is subject to liability if the supplier knows or has  
27 reason to know the chattel is or is likely to be dangerous for its intended use and fails  
28 to exercise reasonable care to inform those whom it expects to use it.

1           462. As a direct and proximate result of Defendants' violations of federal  
2 regulations and any and all applicable state law, Plaintiffs sustained serious damages  
3 including, but not limited to, the following: bodily injury; severe physical pain and  
4 suffering; emotional distress; diminished enjoyment of life; medical expenses; loss of  
5 earnings; and disability, all of which losses and damages will continue into the future.

6           WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief  
7 against Defendants, as contained in the Prayer for Relief.

8                           **COUNT XIII – NEGLIGENT MISREPRESENTATION**

9           463. Plaintiffs incorporate by reference all factual allegations set forth above  
10 in ¶¶ 1–279 as if fully set forth herein.

11           464. This claim arises from negligent provision of false and incomplete  
12 information to physicians and patients in connection with medical decision-making.

13           465. At all relevant times, Defendants were engaged in the business of  
14 designing, manufacturing, marketing, and distributing Boston Scientific SCS devices  
15 for the treatment of chronic intractable pain. In the course of that business, and for  
16 pecuniary purposes, Defendants supplied information to Plaintiffs and their treating  
17 physicians intended to guide their medical treatment decisions. Defendants had a  
18 pecuniary interest in the transactions in which they supplied this information because  
19 they derived revenue from the sale of their SCS devices.

20           466. At all relevant times, Defendants, acting individually and through their  
21 agents, employees, and representatives, owed a duty to exercise reasonable care in  
22 communicating truthful, accurate, and complete information about their spinal cord  
23 stimulator systems.

24           467. Defendants are responsible for the acts and omissions of their agents,  
25 employees, and representatives acting within the course and scope of their respective  
26 agency and employment relationships, including the sales and clinical representatives  
27 who supplied the information described herein.

1        468. Defendants supplied false information in their promotional materials,  
2 sales presentations, IFU, labeling, and direct communications to healthcare providers  
3 and patients regarding the safety, efficacy, design features, and regulatory status of  
4 their SCS devices.

5        469. As set forth in detail in the preceding allegations, Defendants and their  
6 sales representatives initiated, encouraged, and conducted extensive and aggressive  
7 direct communication with Plaintiffs. These communications were not incidental or  
8 insignificant – they were targeted and intentional sales tactics, intended to convince  
9 Plaintiffs to agree to be implanted with a Boston Scientific SCS device.

10       470. Defendants and their representatives continued to communicate directly  
11 with Plaintiffs during the temporary SCS trials and after implantation of the permanent  
12 SCS devices.

13       471. Through promotional materials, sales presentations, IFU, labeling, and  
14 direct communications, Defendants negligently misrepresented to Plaintiffs and their  
15 physicians that, despite deviating from FDA-approved design and manufacturing  
16 specifications:

- 17       a. The SCS devices were safe and effective for the long-term treatment of  
18       chronic pain;
- 19       b. The devices' multiwaveform stimulation would enhance therapeutic  
20       outcomes and reduce adverse effects compared to previous devices;
- 21       c. The results achieved during trial stimulation were reliable predictors of  
22       permanent implant performance;
- 23       d. The permanent SCS systems would provide greater pain relief than the  
24       temporary SCS trial;
- 25       e. The systems were accompanied by complete safety information necessary  
26       for physicians to evaluate treatment risks;

1 f. The safety and efficacy of the SCS systems were validated by clinical data,  
2 as required for PMA, and the systems were approved for sale based on such  
3 clinical data; and

4 g. The systems had been appropriately validated through regulatory  
5 submissions consistent with FDA standards for safety and effectiveness.

6 472. Defendants' sales representatives also made statements directly to  
7 patients, including Plaintiffs<sup>59</sup>, that include but are not limited to:

8 a. the SCS Device would provide reliable, long-term pain relief, and  
9 stimulation was safe and localized;

10 b. quantifying the promised efficacy;

11 c. the permanent SCS Device would provide pain relief equivalent to the relief  
12 obtained during the external trial, so that trial results reliably predicted the  
13 performance of the permanent implant;

14 d. the SCS Device was uniquely suited to provide the patient with long-term  
15 pain relief and was supported by clinical data;

16 e. the SCS Device would provide better pain relief than other treatment  
17 modalities, including dorsal root ganglion ("DRG") stimulation and other  
18 manufacturers' SCS devices;

19 f. that patients would be pain-free with SCS Device;  
20  
21

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22 <sup>59</sup> See, e.g., *Ollie Wilson v. Boston Scientific Corporation*, 2:25-cv-09958-JLS-PD;  
23 *Linda Guthrie v. Boston Scientific Corporation*, 2:25-cv-11508-JLS-PD; *Sherri*  
24 *Miyagi v. Boston Scientific Corporation*, 2:26-cv-06419-JLS-PD; *Tone Silas v.*  
25 *Boston Scientific Corporation*, 2:26-cv-03679-JLS-PD; *Steven Joe Cooper v. Boston*  
26 *Scientific Corporation*, 2:26-cv-12020-JLS-PD; *Myra Boyd v. Boston Scientific*  
27 *Corporation*, 2:26-cv-09806-JLS-PD; *Cynthia Galary v. Boston Scientific*  
28 *Corporation*, 2:26-cv-11311-JLS-PD; *Darrin Peterson v. Boston Scientific*  
*Corporation*, 2:26-cv-11312-JLS-PD; *Daniel Carmack v. Boston Scientific*  
*Corporation*, 2:26-cv-12158-JLS-PD; *Gloria Castleberry v. Boston Scientific*  
*Corporation*, 2:26-cv-10953-JLS-PD.

- 1 g. the patient would get pain relief once the sales representative found the
- 2 right programming settings;
- 3 h. that inadequate relief or side effects simply meant the device needed
- 4 reprogramming;
- 5 i. in direct contradiction of the FDA-approved labeling, that side effects such
- 6 as unintended shocks are not known to be caused by the SCS Device, so
- 7 the shocks the patient was experiencing could not be coming from the
- 8 device;
- 9 j. the patient's symptoms had other causes, including that the sensations were
- 10 imagined or psychosomatic; and
- 11 k. statements downplaying the severity of the patients' injuries.

12 473. Each of these representations was false when made. Defendants made  
13 these representations without reasonable grounds for believing them to be true. A  
14 reasonable manufacturer exercising appropriate care would have known that,  
15 especially because SCS devices differed from FDA-approved specifications:

- 16 a. The permanent implant differed materially in performance from the
- 17 temporary SCS trial device;
- 18 b. The SCS devices were associated with a materially increased risk of lead
- 19 migration, therapy abandonment, stimulation-induced autonomic
- 20 dysfunction, and device-related complications;
- 21 c. The modified stimulation technologies and battery architecture introduced
- 22 new and significant risks not present in predicate devices;
- 23 d. Clinical data validating the long-term safety and efficacy of the device
- 24 modifications were lacking or insufficient; and
- 25 e. Adverse event trends, including stimulation-related autonomic
- 26 dysfunction, required disclosure to regulators and treating physicians.

27 474. These representations are part of a consistent and pervasive pattern of  
28 conduct by the Defendants and extend beyond those individual Plaintiffs identified in

1 footnote 46. The details of specific representations will be provided in Plaintiff-  
2 specific filings, included but not limited to Short-Form Complaints.

3 475. At the time the representations were made, Defendants had internal  
4 performance information indicating that the permanent implants could perform  
5 differently from the trial device and could present risks not disclosed to treating  
6 physicians. Defendants' representations concerning the devices' safety and  
7 effectiveness failed to accurately reflect or account for the internal performance  
8 information and post-market adverse-event information available to them.

9 476. Defendants had a duty to disclose these materials facts due to their  
10 special relationship with plaintiffs they voluntarily undertook with respect to the SCS  
11 devices

12 477. Plaintiffs' healthcare providers reasonably relied on Defendants'  
13 representations in recommending implantation of the SCS systems, and Plaintiffs  
14 reasonably relied on the same representations in consenting to implantation.

15 478. Plaintiffs had no reasonable basis for independently verifying the  
16 accuracy of Defendants' representations when they were made. Plaintiffs' reliance was  
17 reasonable given the medical setting, Defendants' superior knowledge as the device  
18 manufacturers, and the authority with which Defendants' representatives  
19 communicated.

20 479. Accurate and complete risk information would have been considered by  
21 Plaintiffs and their physicians when evaluating treatment options and deciding  
22 whether to recommend or consent to implantation.

23 480. The incomplete safety information communicated to Plaintiffs and their  
24 treating physicians influenced the decision to implant the device in Plaintiffs.

25 481. The undisclosed risk information would have been considered by  
26 Plaintiffs and their physicians in deciding whether to recommend implantation.

27 482. Had Plaintiffs and their healthcare providers been accurately and fully  
28 informed of the true risks and limitations associated with the device, they would not

1 have elected to proceed with implantation or would have pursued alternative treatment  
2 options.

3 483. Defendants and their representatives continued to communicate directly  
4 with Plaintiffs during the temporary SCS trials and after implantation of the permanent  
5 SCS devices. These communications included patient-specific representations  
6 concerning device performance, inadequate pain relief, reported complications, and  
7 the ability of programming or reprogramming to address those problems.

8 484. After Plaintiffs experienced complications and inadequate pain relief  
9 following permanent implantation, Defendants, through their sales and clinical  
10 representatives, represented that repeated reprogramming would alleviate Plaintiffs'  
11 complications and increase their pain relief. These representations were made in  
12 connection with the representatives' programming and reprogramming of Plaintiffs'  
13 devices. Defendants intended that Plaintiffs rely on these representations in deciding  
14 whether to continue using their devices and whether to seek further medical evaluation  
15 or removal.

16 485. Defendants' representatives also represented that Plaintiffs' post  
17 implantation complications were unrelated to the SCS devices or were attributable to  
18 suboptimal programming rather than device failure and could be resolved through  
19 reprogramming. These representations prevented Plaintiffs from making informed  
20 decisions concerning continued device use and the need for further medical evaluation  
21 or removal.

22 486. Defendants and their representatives knew or should have known that  
23 these post implantation representations were false or lacked a reasonable factual basis.  
24 In particular, the representatives lacked reasonable grounds for assuring Plaintiffs that  
25 reprogramming would resolve their complications without adequately determining  
26 whether those complications resulted from lead failure, IPG/battery malfunction, or  
27 another condition that reprogramming could not correct.

28

1        487. Plaintiffs relied on these representations in electing not to have the  
2 system removed earlier than they ultimately did, causing them additional and  
3 continued injuries.

4        488. Defendants failed to exercise reasonable care or competence in  
5 obtaining or communicating the post implantation information supplied to Plaintiffs,  
6 including, but not limited to the following:

7        a. Making patient-specific representations concerning the cause and  
8 significance of Plaintiffs' complications without an adequate factual or  
9 clinical basis;

10       b. Permitting sales and clinical representatives to make clinical  
11 representations beyond their training and qualifications concerning the  
12 significance of Plaintiffs' symptoms and the adequacy of reprogramming  
13 as a remedy; and

14       c. Failing to adequately train their representatives to communicate accurate  
15 and complete information concerning lead failure, IPG/battery  
16 malfunction, and the limitations of reprogramming.

17       489. Plaintiffs reasonably relied on these post implantation representations in  
18 continuing to use their SCS devices and delaying further medical evaluation or  
19 removal. In particular, Plaintiffs elected not to have the devices removed earlier than  
20 they ultimately did because they relied on the representatives' assurances that further  
21 reprogramming would alleviate their complications and improve pain relief.

22       490. Had Defendants and their representatives accurately communicated the  
23 limitations of reprogramming and the potential significance of Plaintiffs' reported  
24 complications, Plaintiffs would have sought further medical evaluation and removal  
25 earlier, thereby avoiding or reducing the additional and continued injuries caused by  
26 the delay.

27       491. As a direct and proximate result of Defendants' negligent  
28 misrepresentations, Plaintiffs consented to implantation of the SCS devices and, after

1 complications arose, continued using the devices and delayed seeking their removal.  
2 These misrepresentations thereby caused Plaintiffs to be implanted with and remain  
3 exposed to devices that failed through lead migration, lead failure, IPG/battery  
4 malfunction, and other malfunctions described herein. These device failures directly  
5 and proximately caused Plaintiffs injuries that would not have occurred, or would  
6 have been substantially less severe, absent their reliance on Defendants' false and  
7 incomplete information.

8 492. As a direct and proximate result of Defendants' negligent  
9 misrepresentations, Plaintiffs suffered physical injuries, chronic pain, emotional  
10 distress, additional medical expenses, financial losses, diminished enjoyment of life,  
11 and the other injuries and damages described herein. Absent those misrepresentations,  
12 Plaintiffs would not have undergone implantation or would have sought timely  
13 medical evaluation and earlier removal, thereby avoiding or reducing the injuries  
14 caused by the device failures. Plaintiffs' reliance on Defendants' misrepresentations  
15 was a substantial factor in causing Plaintiffs' harm.

16 493. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
17 relief against Defendants, as contained in the Prayer for Relief.

18 **COUNT XIV - FRAUDULENT MISREPRESENTATION**

19 494. Plaintiffs incorporate by reference all factual allegations set forth above  
20 in ¶¶ 1–279 as if fully set forth herein.

21 495. At all relevant times, Defendants were engaged in the business of  
22 designing, manufacturing, marketing, and distributing Boston Scientific SCS devices  
23 for the treatment of chronic intractable pain. In the course of that business, and for  
24 pecuniary purposes, Defendants supplied information to Plaintiffs and their treating  
25 physicians intended to guide their medical treatment decisions. Defendants had a  
26 pecuniary interest in the transactions in which they supplied this information because  
27 they derived revenue from the sale of their SCS devices.  
28

1           496. At all relevant times, Boston Scientific, acting individually and through  
2 its agents, employees, and representatives, made material misrepresentations and  
3 omissions of fact regarding the safety, efficacy, and regulatory compliance of its SCS  
4 devices.

5           497. Boston Scientific's sales and clinical representatives made the  
6 representations described herein while acting within the course and scope of their  
7 employment and/or agency relationships and in furtherance of Boston Scientific's  
8 business interests. Boston Scientific is responsible for their acts and omissions as  
9 alleged herein.

10           498. In light of SCS devices deviating from FDA-approved specifications,  
11 Defendants supplied false and incomplete information in their promotional materials,  
12 sales presentations, IFU, labeling, and direct communications to healthcare providers  
13 and patients regarding the safety, efficacy, design features, performance, and  
14 regulatory status of their SCS devices.

15           499. As set forth in detail in the preceding allegations, Defendants and their  
16 sales representatives initiated, encouraged, and conducted extensive and aggressive  
17 direct communications with Plaintiffs. These communications were not incidental or  
18 insignificant; they were targeted and intentional sales tactics intended to convince  
19 Plaintiffs to agree to implantation of Boston Scientific SCS devices.

20           500. Through promotional materials, sales presentations, IFU, labeling, and  
21 direct communications, Defendants fraudulently represented to Plaintiffs and their  
22 physicians that, despite deviating from FDA-approved design and manufacturing  
23 specifications:

- 24           a. The SCS devices were safe and effective for the long-term management of
- 25           chronic pain;
- 26           b. The benefits achieved during trial stimulation reliably predicted the success
- 27           of the permanently implanted devices;
- 28

- c. The devices' multiwaveform stimulation capabilities reduced the risk of therapy failure and side effects compared to older systems;
- d. The devices had been adequately validated and reviewed consistent with FDA requirements for significant design and functionality changes.

501. Defendants' sales representatives also made statements directly to patients, including Plaintiffs<sup>60</sup>, that include but are not limited to:

- a. the SCS Device would provide reliable, long-term pain relief, and stimulation was safe and localized;
- b. quantifying the promised efficacy;
- c. the permanent SCS Device would provide pain relief equivalent to the relief obtained during the external trial, so that trial results reliably predicted the performance of the permanent implant;
- d. the SCS Device was uniquely suited to provide the patient with long-term pain relief and was supported by clinical data;
- e. the SCS Device would provide better pain relief than other treatment modalities, including dorsal root ganglion ("DRG") stimulation and other manufacturers' SCS devices;
- f. that patients would be pain-free with SCS Device;
- g. the patient would get pain relief once the sales representative found the right programming settings;

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<sup>60</sup> See, e.g., *Ollie Wilson v. Boston Scientific Corporation*, 2:25-cv-09958-JLS-PD; *Linda Guthrie v. Boston Scientific Corporation*, 2:25-cv-11508-JLS-PD; *Sherri Miyagi v. Boston Scientific Corporation*, 2:26-cv-06419-JLS-PD; *Tone Silas v. Boston Scientific Corporation*, 2:26-cv-03679-JLS-PD; *Steven Joe Cooper v. Boston Scientific Corporation*, 2:26-cv-12020-JLS-PD; *Myra Boyd v. Boston Scientific Corporation*, 2:26-cv-09806-JLS-PD; *Cynthia Galary v. Boston Scientific Corporation*, 2:26-cv-11311-JLS-PD; *Darrin Peterson v. Boston Scientific Corporation*, 2:26-cv-11312-JLS-PD; *Daniel Carmack v. Boston Scientific Corporation*, 2:26-cv-12158-JLS-PD; *Gloria Castleberry v. Boston Scientific Corporation*, 2:26-cv-10953-JLS-PD.

- 1 h. that inadequate relief or side effects simply meant the device needed
- 2 reprogramming;
- 3 i. in direct contradiction of the FDA-approved labeling, that side effects such
- 4 as unintended shocks are not known to be caused by the SCS Device, so
- 5 the shocks the patient was experiencing could not be coming from the
- 6 device;
- 7 j. the patient's symptoms had other causes, including that the sensations were
- 8 imagined or psychosomatic; and
- 9 k. statements downplaying the severity of the patients' injuries.

10 502. Each of these representations was false when made. Defendants made  
11 these representations knowing them to be false, or recklessly and without regard for  
12 their truth, because post-market surveillance and adverse event reporting showed  
13 that:

- 14 a. The SCS systems were associated with a materially increased risk of lead
- 15 migration, therapy abandonment, stimulation-induced autonomic
- 16 dysfunction, premature therapeutic failure, and device-related
- 17 complications;
- 18 b. The permanent device materially differed in performance and risk profile
- 19 from the external trial device;
- 20 c. Boston Scientific had not submitted adequate clinical evidence to
- 21 substantiate the safety and effectiveness of its multiwaveform and
- 22 posture-adaptive programming technologies;
- 23 d. Boston Scientific's devices were being marketed under serial PMA
- 24 supplements rather than undergoing new PMA review.

25 503. These representations are part of a consistent and pervasive pattern of  
26 conduct by the Defendants and extend beyond those individual Plaintiffs identified in  
27 footnote 46. The details of specific representations will be provided in Plaintiff-  
28 specific filings, included but not limited to Short-Form Complaints.

1        504. At the time these representations were made, Boston Scientific  
2 possessed information concerning the devices' actual performance and risks through  
3 internal testing, complaint files, post-market surveillance, adverse-event reports, and  
4 post-approval data. Boston Scientific failed to accurately reflect that information in  
5 its representations to Plaintiffs and their healthcare providers and concealed adverse  
6 material information concerning the devices' safety, performance, and limitations.

7        505. Boston Scientific made these representations and omissions knowing  
8 they were false or misleading, or with reckless disregard for their truth or falsity. The  
9 representations were made intentionally and with the intent to induce Plaintiffs'  
10 healthcare providers to recommend, and Plaintiffs to consent to, trial and permanent  
11 implantation of Boston Scientific SCS devices.

12        506. Defendants had a duty to disclose these materials facts due to their  
13 special relationship with plaintiffs they voluntarily undertook with respect to the SCS  
14 devices.

15        507. Plaintiffs' healthcare providers justifiably relied on Boston Scientific's  
16 representations in recommending the SCS systems, and Plaintiffs justifiably relied on  
17 the same representations in consenting to implantation and subsequent medical  
18 decisions.

19        508. Plaintiffs had no reasonable means of independently discovering the  
20 falsity of Defendants' statements at the time they were made, as Boston Scientific had  
21 superior knowledge of the device's design changes, clinical performance, and  
22 regulatory history, and actively concealed adverse information from physicians,  
23 patients, and regulators.

24        509. Had Plaintiffs and their healthcare providers been accurately informed  
25 of the devices' true risks, limitations, and performance, they would not have elected  
26 to proceed with implantation or would have pursued alternative treatment options.

27        510. After implantation, Boston Scientific, through its sales representatives,  
28 also made misrepresentations to Plaintiffs about complications and inadequate pain

1 relief they experienced after the permanent implant, representing to them that repeated  
2 reprogramming would alleviate their complications and increase their pain relief.  
3 These representations were made at the time of the reprogramming.

4 511. During these communications, including at the time of programming and  
5 reprogramming, Boston Scientific's representatives represented that:

- 6 a. Plaintiffs' complications were attributable to suboptimal device settings  
7 rather than device failure;
- 8 b. Plaintiffs' symptoms and complications were unrelated to the SCS devices;  
9 and/or
- 10 c. Repeated reprogramming would alleviate Plaintiffs' complications and  
11 increase their pain relief.

12 512. These post-implantation representations were materially false or  
13 misleading. Plaintiffs' complications arose from lead failure, lead migration,  
14 IPG/battery malfunction, uncontrolled electrical stimulation, or other device failures  
15 that repeated reprogramming could not correct.

16 513. Defendants knew that these post-implant representations were false, or  
17 made them recklessly and without regard for their truth. Boston Scientific possessed  
18 internal complaint and device-performance information concerning these failure  
19 modes, and its representatives had direct knowledge of Plaintiffs' reported symptoms,  
20 responses to prior reprogramming, and continuing complications.

21 514. Plaintiffs relied on these representations in electing not to have the  
22 system removed earlier than they ultimately did, causing them additional and  
23 continued injuries.

24 515. Boston Scientific and its sales representatives intended for Plaintiffs and  
25 their physicians to rely on these representations by continuing to use the devices,  
26 undergoing additional reprogramming, and refraining from seeking further medical  
27 evaluation or removal.

1           516. Plaintiffs justifiably relied on these representations in continuing to use  
2 their SCS devices and electing not to have them removed earlier than they ultimately  
3 did. Their reliance was reasonable in light of Boston Scientific's superior knowledge  
4 as the manufacturer, the representatives' involvement in device programming, and the  
5 authority with which the representatives communicated.

6           517. Had Boston Scientific and its representatives accurately disclosed the  
7 significance of Plaintiffs' complications and the limitations of reprogramming,  
8 Plaintiffs would have sought further medical evaluation and earlier removal, thereby  
9 avoiding or reducing their continued exposure to malfunctioning devices and the  
10 resulting harm.

11           518. As a direct and proximate result of Defendants' fraudulent  
12 misrepresentations and omissions, Plaintiffs consented to implantation and, after  
13 complications arose, continued using and delayed removal of their SCS devices.  
14 Those misrepresentations thereby caused Plaintiffs to undergo implantation of and  
15 remain exposed to devices that failed through lead migration, lead failure, IPG/battery  
16 malfunction, uncontrolled electrical stimulation, and other malfunctions described  
17 herein. They also caused Plaintiffs to retain the implanted devices longer, thereby  
18 causing exacerbation of their injuries and an escalation to permanence due to the  
19 failure to timely remove the insult on the nerve.

20           519. Those device failures, in turn, directly and proximately caused  
21 Plaintiffs' injuries. Plaintiffs' continued use and delayed removal of the  
22 malfunctioning devices prolonged their exposure to those failures and caused or  
23 aggravated their injuries.

24           520. Plaintiffs' reliance on Defendants' misrepresentations was a substantial  
25 factor in causing Plaintiffs' harm. As a direct and proximate result of the foregoing,  
26 Plaintiffs sustained significant injuries, including physical pain, autonomic  
27 dysfunction, emotional distress, medical expenses, lost income, diminished quality of  
28 life, and other consequential damages.

1           521. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
2 relief against Defendants, as contained in the Prayer for Relief.

3                           **COUNT XV – FRAUDULENT CONCEALMENT**

4           522. Plaintiffs incorporate by reference all factual allegations set forth above  
5 in ¶¶ 1–279 as if fully set forth herein.

6           523. Defendants Boston Scientific Corporation and Boston Scientific  
7 Neuromodulation Corporation concealed material facts relating to the risks,  
8 regulatory status, and performance of the spinal cord stimulator system that was  
9 implanted in Plaintiffs, as well as the qualifications and conduct of the sales and  
10 clinical representatives who interacted with Plaintiffs and their treating physicians.

11          524. As the manufacturers and distributors of the SCS devices, Defendants  
12 possessed superior knowledge concerning the devices’ design, clinical performance,  
13 failure modes, regulatory history, and associated risks. Defendants also possessed  
14 superior knowledge concerning their representatives’ training, qualifications, assigned  
15 responsibilities, and limitations. These facts were not known to Plaintiffs or their  
16 treating physicians and were not reasonably discoverable through inspection of the  
17 devices or independent inquiry by Plaintiffs. Defendants knew that these facts were  
18 not known to, or reasonably discoverable by, Plaintiffs or their treating physicians.

19          525. Defendants made affirmative representations concerning the devices’  
20 safety and efficacy and their representatives’ ability to provide device-related support,  
21 while withholding material information necessary to make those representations  
22 complete and not misleading. Defendants’ superior knowledge, partial disclosures,  
23 and ongoing communications with Plaintiffs and their treating physicians gave rise to  
24 a duty to disclose the concealed facts.

25          526. Defendants obtained or had access to material information concerning  
26 device performance and adverse events through internal testing, complaint files, post-  
27 market surveillance, and their federal reporting and post-approval activities. Plaintiffs  
28 allege that Defendants concealed material information obtained through those

1 activities while continuing to promote the devices and provide patient-specific  
2 assurances concerning their safety, performance, and continued use.

3 527. These material facts Defendants concealed include:

- 4 a. That the SCS devices deviated from the FDA-approved specifications,  
5 including with respect to lead insulation sheath material, lead wire integrity,  
6 and hermetic sealing processes, and that the spinal cord stimulator system  
7 had undergone multiple PMA Supplements that substantially modified  
8 waveform programming; and  
9 b. That Defendants possessed post-market information concerning these  
10 failures that was not accurately reflected in their communications to  
11 Plaintiffs and their treating physicians.

12 528. Despite the contents of the FDA-approved labeling, Defendants failed  
13 to provide those warnings, or nullified the warnings they gave, and thereby also  
14 concealed material facts concerning the significance of device failures and the  
15 limitations of reprogramming, including:

- 16 a. That lead failure and IPG/battery malfunction could cause neurological  
17 injury and permanent nerve damage;  
18 b. That repeated reprogramming could not correct the underlying lead  
19 fracture, insulation breach, lead migration, or IPG/battery malfunction  
20 responsible for Plaintiffs' complications;  
21 c. That assurances concerning further reprogramming did not adequately  
22 disclose the need to evaluate Plaintiffs for underlying device failure; and  
23 d. That continued use or delayed removal of a failing device could prolong  
24 exposure to harmful stimulation and cause or aggravate neurological  
25 injury.

26 529. Defendants and their agents also concealed material facts concerning the  
27 qualifications and conduct of their sales and clinical representatives, including:  
28

- a. That the representatives providing patient-specific advice and performing device-related services lacked the healthcare licenses, training, or qualifications necessary to perform certain functions they undertook;
- b. That the representatives were performing activities beyond their permitted device-support role, including conduct Plaintiffs allege constituted the unauthorized practice of medicine;
- c. That the representatives' role and qualifications did not authorize them to independently determine the medical significance of Plaintiffs' symptoms or whether further medical evaluation, revision, replacement, or removal was necessary; and
- d. That the representatives were trained or incentivized to encourage implantation and continued device use and to discourage removal in a manner that prioritized Defendants' financial interests over Plaintiffs' welfare.

530. These representations and conduct are part of a consistent and pervasive pattern of conduct by the Defendants and extend beyond those individual Plaintiffs identified in footnote 46. The details of specific representations will be provided in Plaintiff-specific filings, included but not limited to Short-Form Complaints.

531. Defendants knew the concealed facts through their design and manufacturing activities, internal testing, complaint investigations, post-market surveillance, and oversight of their representatives. Nevertheless, Defendants intentionally withheld that information while continuing to make affirmative representations concerning the devices' safety and performance and the ability of their representatives to address Plaintiffs' complications.

532. The concealed facts were material to Plaintiffs' and their treating physicians' decisions concerning whether to proceed with trial implantation, whether to proceed with permanent implantation, and whether to continue device use or seek timely medical evaluation and removal after complications arose. A reasonable

1 person in Plaintiffs' position would have considered this information important in  
2 making those decisions.

3 533. Defendants concealed these facts with the intent to deceive Plaintiffs  
4 and their treating physicians and to induce Plaintiffs' healthcare providers to  
5 recommend, and Plaintiffs to consent to, implantation and continued use of the SCS  
6 devices. After complications arose, Defendants continued to withhold material  
7 information to induce Plaintiffs to undergo further reprogramming and delay seeking  
8 removal, thereby generating and preserving Defendants' device-related revenue.

9 534. This concealment was intentional rather than inadvertent and was  
10 undertaken to promote device adoption and continued use by withholding adverse  
11 information from Plaintiffs and their treating physicians.

12 535. Unaware of the concealed facts, Plaintiffs justifiably relied on  
13 Defendants' partial disclosures, affirmative assurances of safety and efficacy, and  
14 failure to disclose information materially qualifying those assurances. Plaintiffs'  
15 treating physicians likewise made recommendations without the material information  
16 Defendants withheld.

17 536. Plaintiffs had no reasonable means of independently discovering the  
18 concealed information concerning device failure rates, IPG/battery malfunction, the  
19 risks of continued use following device failure, or the actual qualifications and  
20 limitations of Defendants' representatives. Plaintiffs' reliance was reasonable given  
21 Defendants' superior knowledge, the medical setting of the interactions, and the  
22 authority with which the representatives presented their device-related advice and  
23 services.

24 537. In reliance on the incomplete and misleading information Defendants  
25 provided, Plaintiffs consented to implantation of the SCS devices and, after  
26 complications arose, continued using the devices and delayed seeking further medical  
27 evaluation or removal. Defendants' concealment thereby deprived Plaintiffs and their  
28

1 treating physicians of the information necessary to make informed implantation and  
2 subsequent treatment decisions.

3 538. Defendants had a duty to disclose these material facts due to their  
4 special relationship with plaintiffs they voluntarily undertook with respect to the SCS  
5 devices.

6 539. Had Defendants disclosed the material facts described herein, Plaintiffs  
7 would not have consented to implantation or would have sought further medical  
8 evaluation and earlier removal after complications arose, thereby avoiding or  
9 reducing the resulting harm.

10 540. Defendants' concealment was a substantial factor in causing Plaintiffs'  
11 harm. As a direct and proximate result of Defendants' fraudulent concealment,  
12 Plaintiffs underwent implantation of and remained exposed to SCS devices that failed  
13 through lead migration, lead fracture, insulation breach, IPG/battery malfunction, and  
14 other malfunctions described herein. Those device failures, in turn, directly and  
15 proximately caused Plaintiffs' injuries, while continued use and delayed removal  
16 prolonged their exposure to the malfunctioning devices and aggravated their injuries.

17 541. As a direct and proximate result of the foregoing, Plaintiffs sustained  
18 serious injuries and damages, including, but not limited to, bodily injury; permanent  
19 nerve damage; chronic pain; severe physical pain and suffering; emotional distress  
20 and mental anguish; diminished enjoyment of life; medical and related expenses; loss  
21 of earnings; disability; and the other injuries and damages described herein.

22 542. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
23 relief against Defendants, as contained in the Prayer for Relief.

24 **COUNT XVI - VICARIOUS LIABILITY**

25 (Respondeat Superior)

26 543. Plaintiffs incorporate by reference all factual allegations set forth above  
27 in ¶¶ 1–279 as if fully set forth herein.

1           544. Plaintiffs provide the following paragraphs as an allegation section to  
2 be applied as needed to the appropriate counts, rather than a request for relief.

3           545. At all relevant times, Boston Scientific's sales and clinical  
4 representatives were employees or agents of Boston Scientific acting within the course  
5 and scope of their employment and/or agency relationship with Boston Scientific in  
6 all respects relevant to this action. All Boston Scientific representatives who interacted  
7 in any way with Plaintiffs or Plaintiffs' physicians, regardless of how Boston  
8 Scientific refers to these individuals, are hereafter referred to as "sales  
9 representatives."

10          546. Evidence of the employment relationship and intended scope of duties  
11 can be seen, for example, in job postings for positions directly with Boston  
12 Scientific.<sup>61</sup> Calling the positions "clinical specialists" and "territory managers,"  
13 Boston Scientific has identical job descriptions for positions all over the country.

14          547. The sales representatives' conduct — including actively participating in  
15 device selection, actively participating in device programming, making medical  
16 representations to Plaintiffs, and advising Plaintiffs on treatment decisions regarding  
17 the SCS devices — was undertaken in furtherance of Boston Scientific's business  
18 interests, within the scope of the sales representatives' assigned duties, and in the  
19 manner authorized, directed, or ratified by Boston Scientific.

20          548. In undertaking these activities, the sales representatives acted on Boston  
21 Scientific's behalf to promote the implantation and continued use of its SCS devices  
22 and to provide device-related support to Plaintiffs and their treating physicians.

23          549. By voluntarily undertaking programming, reprogramming, adjustments,  
24 and other device-related services, the sales representatives assumed a duty to exercise  
25 reasonable care in performing those services. Plaintiffs allege that the representatives  
26 negligently performed the services they undertook, including when they exceeded the  
27

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28          <sup>61</sup> See Ex. A.

limits of their training, qualifications, or permitted device-support role while carrying out their assigned responsibilities on Boston Scientific's behalf.

550. The sales representatives' negligent and wrongful acts and omissions included, but were not limited to:

- a. Participating in device selection and making recommendations concerning Plaintiffs' suitability for implantation without sufficient knowledge, training, or qualifications;
- b. Negligently programming, reprogramming, or adjusting Plaintiffs' SCS devices without sufficient knowledge, skill, or expertise;
- c. Continuing to reprogram or adjust Plaintiffs' devices when they knew or reasonably should have known that further reprogramming would not correct the underlying malfunction or alleviate Plaintiffs' complications;
- d. Providing medical advice and making patient-specific treatment recommendations beyond their qualifications and permitted device-support role, including conduct alleged herein to constitute the unauthorized practice of medicine;
- e. Providing false, misleading, or incomplete information concerning the devices' safety, performance, risks, and expected therapeutic benefits;
- f. Failing to provide or accurately convey existing FDA-approved warnings and instructions and making statements that contradicted, minimized, or undermined those warnings and instructions;
- g. Misrepresenting that Plaintiffs' complications were unrelated to the SCS devices or could be resolved through additional programming or reprogramming;
- h. Advising Plaintiffs to continue using malfunctioning devices or to forgo or delay appropriate medical evaluation and treatment; and

- 1           i. Advising Plaintiffs to delay revision, replacement, or removal of the  
2           devices, thereby prolonging their exposure to malfunctioning devices and  
3           causing or aggravating their injuries.

4           551. These acts and omissions occurred in the course of the sales  
5 representatives' performance of their assigned sales and device-support  
6 responsibilities for Boston Scientific. Although particular acts exceeded the  
7 representatives' training, qualifications, or permitted device-support role, those acts  
8 were undertaken while performing services on Boston Scientific's behalf and in  
9 furtherance of its business interests. Those acts were reasonably related to the kinds  
10 of tasks the sales representatives were employed to perform, including device  
11 selection, programming, troubleshooting, and patient-facing device support, and were  
12 reasonably foreseeable in light of Boston Scientific's business and the representatives'  
13 job responsibilities.

14           552. Under the respondeat superior doctrine, Boston Scientific is vicariously  
15 liable for all of the negligent and wrongful acts and omissions of its sales  
16 representatives committed within the scope of their employment and/or agency  
17 relationships, including the conduct described herein.

18           553. As a direct and proximate result of the sales representatives' acts and  
19 omissions, Plaintiffs underwent implantation of SCS devices that subsequently failed,  
20 received negligently performed programming and adjustment services, and/or  
21 continued using malfunctioning devices while delaying appropriate medical  
22 evaluation, treatment, or removal. The device failures and negligently performed  
23 services, together with the prolonged exposure to malfunctioning devices, directly and  
24 proximately caused Plaintiffs' injuries. The sales representatives' acts and omissions,  
25 committed within the scope of their employment and agency, were a substantial factor  
26 in causing Plaintiffs' harm.

27           554. As a direct and proximate result of the foregoing conduct, for which  
28 Boston Scientific is vicariously liable, Plaintiffs sustained serious injuries and

1 damages, including, but not limited to, bodily injury; permanent nerve damage;  
2 chronic pain; severe physical pain and suffering; emotional distress and mental  
3 anguish; diminished enjoyment of life; medical and related expenses; loss of earnings;  
4 and disability, all of which losses and damages will continue into the future.

5 555. To the extent the Court determines that any applicable state statutory  
6 product-liability or exclusive-remedy provision governs or supersedes a common-law  
7 theory alleged herein, Plaintiffs alternatively seek relief under that applicable statutory  
8 provision based on the same acts, omissions, injuries, and damages alleged in this  
9 Complaint.

10 556. WHEREFORE, Plaintiffs demand judgment against Defendants for  
11 compensatory damages, punitive damages where permitted, attorneys' fees where  
12 allowed by statute, costs of suit, pre- and post-judgment interest, and all such other  
13 and further relief as the Court deems just and proper.

#### 14 **COUNT XVII – NEGLIGENCE**

15 (Corporate – Against Boston Scientific Defendants)

16 557. Plaintiffs incorporate by reference all factual allegations set forth above  
17 in ¶¶ 1–279 as if fully set forth herein.

18 558. Boston Scientific owed Plaintiffs a direct, non-delegable corporate duty  
19 of care to exercise ordinary care with respect to Boston Scientific's own institutional  
20 conduct. This Count rests on Boston Scientific's own conduct in designing, staffing,  
21 compensating, training, and supervising its field sales and clinical support operation.  
22 It does not depend on whether any individual representative acted within the scope of  
23 employment, and it applies with particular force where representatives exceeded their  
24 permitted role.

1           559. As a result of its possession of sales representative notes and complaints  
2 from patients and physicians,<sup>62</sup> Boston Scientific knew or should have known its sales  
3 and clinical representatives were engaged in the unauthorized practice of medicine  
4 and were making material misrepresentations to patients, and Boston Scientific  
5 constructed and maintained the corporate structure and compensation scheme that  
6 enabled and incentivized this conduct.

7           560. Evidence of the employment relationship and intended scope of duties  
8 can be seen, for example, in job postings for positions directly with Boston  
9 Scientific.<sup>63</sup> Calling the positions “clinical specialists” and “territory managers,”  
10 Boston Scientific has identical job descriptions for positions all over the country.

11           561. Moreover, Boston Scientific had a duty to conduct itself as a reasonable  
12 medical device company in same or similar circumstances. In this instance, that  
13 includes selling medical devices for pain relief to vulnerable patient populations  
14 suffering from chronic pain. In addition, it is a company with devices controlled by  
15 the sales representatives, thereby introducing an increased degree of patient-sales  
16 representative contact.

17           562. Boston Scientific breached its corporate duty of care by: (a) designing  
18 and implementing a business model that deployed sales and clinical representatives in  
19 the operating room and in post-operative care settings in a role that exceeded  
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21  
22 <sup>62</sup> See, e.g., *Ollie Wilson v. Boston Scientific Corporation*, 2:25-cv-09958-JLS-PD;  
23 *Linda Guthrie v. Boston Scientific Corporation*, 2:25-cv-11508-JLS-PD; *Sherri*  
24 *Miyagi v. Boston Scientific Corporation*, 2:26-cv-06419-JLS-PD; *Tone Silas v.*  
25 *Boston Scientific Corporation*, 2:26-cv-03679-JLS-PD; *Steven Joe Cooper v. Boston*  
26 *Scientific Corporation*, 2:26-cv-12020-JLS-PD; *Myra Boyd v. Boston Scientific*  
27 *Corporation*, 2:26-cv-09806-JLS-PD; *Cynthia Galary v. Boston Scientific*  
28 *Corporation*, 2:26-cv-11311-JLS-PD; *Darrin Peterson v. Boston Scientific*  
*Corporation*, 2:26-cv-11312-JLS-PD; *Daniel Carmack v. Boston Scientific*  
*Corporation*, 2:26-cv-12158-JLS-PD; *Gloria Castleberry v. Boston Scientific*  
*Corporation*, 2:26-cv-10953-JLS-PD.

<sup>63</sup> See Ex. A.

1 permissible technical support and constituted the practice of medicine; (b)  
2 establishing a compensation structure that financially incentivized representatives to  
3 maximize device implantations and discourage device removal; (c) failing to establish  
4 adequate policies and procedures limiting representatives to permissible conduct; (d)  
5 failing to train, supervise, and discipline representatives to ensure compliance with  
6 applicable state medical practice laws; (e) affirmatively directing and ratifying the  
7 representatives' unlawful conduct; and (f) failing to ensure the SCS devices were  
8 manufactured and promoted in compliance with FDA-approved specifications.

9       563. Boston Scientific's corporate negligence was a substantial factor in  
10 causing Plaintiffs' harm and was a direct and proximate cause of Plaintiffs' injuries,  
11 including Plaintiffs' initial implantation of the SCS devices based on  
12 misrepresentations, Plaintiffs' delayed removal of the SCS devices based on  
13 continuing misrepresentations, and the resulting injuries and damages, including  
14 bodily injury, permanent nerve damage, chronic pain, severe physical pain and  
15 suffering, emotional distress and mental anguish, diminished enjoyment of life,  
16 medical and related expenses, loss of earnings, and disability.

17       564. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
18 relief against Defendants, as contained in the Prayer For Relief.

### 19                               **COUNT XVIII – NEGLIGENT HIRING**

20       565. Plaintiffs incorporate by reference all factual allegations set forth above  
21 in ¶¶ 1–279 as if fully set forth herein.

22       566. At all relevant times, Defendants employed the sales and clinical  
23 representatives who interacted with Plaintiffs and their treating physicians, including  
24 the representatives who programmed and reprogrammed Plaintiffs' SCS devices,  
25 adjusted stimulation settings, provided troubleshooting services, and made patient-  
26 specific representations concerning device performance and complications.

27       567. Defendants owed Plaintiffs a duty to exercise reasonable care in hiring  
28 individuals to perform these responsibilities. That duty included reasonably

1 evaluating whether prospective employees possessed the knowledge, training,  
2 experience, competence, and judgment necessary to safely perform their assigned  
3 device-support functions and recognize the limits of their permitted role.

4 568. Evidence of the employment relationship and intended scope of duties  
5 can be seen, for example, in job postings for positions directly with Boston  
6 Scientific.<sup>64</sup> Calling the positions “clinical specialists” and “territory managers,”  
7 Boston Scientific has identical job descriptions for positions all over the country.

8 569. Defendants knew or reasonably should have anticipated that the  
9 representatives they hired would interact with patients experiencing device-related  
10 symptoms and would participate in programming, reprogramming, and  
11 troubleshooting implanted SCS devices. Defendants further knew or reasonably  
12 should have anticipated that patients and treating physicians would rely on those  
13 representatives’ claimed device expertise.

14 570. Job duties for these positions show that these positions were intended to  
15 exceed the permissible scope for non-physicians and have a high degree of patient  
16 interaction by including job duties such as:

- 17 a. Provide expert clinical support through programming, troubleshooting, and  
18 intraoperative guidance for spinal cord stimulation procedures;
- 19 b. Deliver patient follow-up care, ensuring optimal therapy performance and  
20 long-term success;
- 21 c. Take an integral role in patient follow-up care by regularly monitoring  
22 therapy progress, addressing patient needs, and collaborating with  
23 healthcare teams to ensure optimal outcomes and satisfaction with  
24 company products;
- 25 d. Actively participate in surgical cases within hospital and surgery center  
26 environments, providing hands-on support throughout procedures;

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27  
28 <sup>64</sup> See Ex. A.

- e. Serve as a resource for current and prospective customers, providing updates on innovations and evidence-based therapies to support informed decision-making in pain management; and
- f. Territory Manager will oversee the entire SCS process of patient care, pre-surgical education, post-surgical follow ups and long-term care of the device.

571. Defendants knew or should have known that the representatives they hired were not qualified to perform these responsibilities, because the only required qualifications for the positions are a bachelor's degree or an equivalent combination of education and experience and a minimum of two years' work experience in a sales and/or clinical role.

572. The representatives who provided services to Plaintiffs were unfit or insufficiently competent for the responsibilities Defendants hired them to perform. Their deficiencies included insufficient knowledge, skill, experience, or judgment to:

- a. Safely perform programming, reprogramming, adjustments, and troubleshooting within their assigned role;
- b. Recognize when persistent symptoms or unsuccessful reprogramming indicated a need for physician evaluation rather than further adjustments;
- c. Accurately communicate the limitations of reprogramming as a response to lead failure, lead migration, IPG/battery malfunction, and other device failures;
- d. Distinguish permissible technical support from patient-specific medical assessment and treatment advice; and
- e. Refrain from providing unsupported assurances concerning the cause of symptoms, the effectiveness of further reprogramming, or the need for medical evaluation or removal.

573. At the time of hiring, Defendants knew or, through the exercise of reasonable care in evaluating the representatives' qualifications and suitability, should

1 have known of these deficiencies. Defendants also knew or should have known that  
2 these deficiencies created a particular risk of harm to patients, including Plaintiffs,  
3 because Defendants hired the representatives to interact with patients experiencing  
4 device-related symptoms and to program, reprogram, and troubleshoot implanted SCS  
5 devices, and Defendants knew that patients and treating physicians would rely on the  
6 representatives' claimed device expertise.

7 574. Defendants breached their duty of reasonable care by hiring these  
8 representatives for patient-facing and device-support responsibilities despite their  
9 known or reasonably discoverable lack of competence or fitness for those  
10 responsibilities, including by:

- 11 a. Failing to adequately evaluate their relevant education, technical training,  
12 experience, and qualifications;
- 13 b. Failing to reasonably assess their ability to safely perform the  
14 programming, reprogramming, and troubleshooting responsibilities they  
15 would be assigned;
- 16 c. Failing to reasonably assess their ability to recognize and adhere to the  
17 limits of a nonphysician device-support role; and
- 18 d. Hiring them for responsibilities requiring patient-safety judgments they  
19 were not competent to make.

20 575. After being hired, these representatives engaged in conduct reflecting  
21 the deficiencies that Defendants knew or reasonably should have discovered at hiring.  
22 That conduct included continuing ineffective reprogramming, providing unsupported  
23 assurances that Plaintiffs' symptoms were unrelated to device failure or could be  
24 resolved through further adjustments, and advising Plaintiffs to continue device use  
25 or delay appropriate medical evaluation and removal.

26 576. The representatives' acts and omissions caused Plaintiffs to rely on  
27 ineffective troubleshooting and inaccurate patient-specific assurances, continue using  
28

1 malfunctioning devices, and delay seeking appropriate medical evaluation and  
2 treatment.

3 577. Defendants' negligent hiring placed the representatives in positions to  
4 provide the services and assurances on which Plaintiffs relied. The resulting harm was  
5 a foreseeable consequence of the representatives' lack of competence or fitness for the  
6 responsibilities Defendants hired them to perform.

7 578. Plaintiffs' SCS devices failed because of their underlying defects. The  
8 representatives' acts and omissions caused Plaintiffs to remain exposed to the failing  
9 devices and delayed appropriate medical evaluation and treatment. The device failures  
10 directly and proximately caused Plaintiffs' physical injuries, while the continued use  
11 and delayed treatment prolonged their exposure to those failures and caused additional  
12 injury or aggravated injuries that otherwise would have been avoided or less severe.

13 579. Defendants' negligence in hiring the representatives was therefore a  
14 substantial factor in causing Plaintiffs' harm and a direct and proximate cause of the  
15 additional or aggravated injuries resulting from the representatives' conduct.

16 580. As a direct and proximate result of Defendants' negligent hiring,  
17 Plaintiffs sustained serious injuries and damages, including, but not limited to, bodily  
18 injury; permanent nerve damage; chronic pain; severe physical pain and suffering;  
19 emotional distress and mental anguish; diminished enjoyment of life; medical and  
20 related expenses; loss of earnings; and disability, all of which losses and damages will  
21 continue into the future.

22 581. WHEREFORE, Plaintiffs respectfully request that they be granted relief  
23 against Defendants as contained in the Prayer for Relief.

#### 24 **COUNT XIX - NEGLIGENT TRAINING**

25 582. Plaintiffs incorporate by reference all factual allegations set forth above  
26 in ¶¶ 1–279 as if fully set forth herein.

27 583. Defendants owed a duty to Plaintiffs to adequately train its sales and  
28 clinical representatives on: (a) the legal scope of their permissible activities in clinical

1 settings, including the prohibition on the unauthorized practice of medicine; (b) the  
2 accurate, truthful, and complete disclosure of the risks and limitations of the Boston  
3 Scientific SCS Products to patients and physicians; and (c) the proper response to  
4 patient complaints, complications, and signs of device failure, including advising  
5 patients to seek timely medical evaluation and, where warranted, device removal.

6       584. Defendants breached their duty to train their representatives by: (a)  
7 failing to provide training on the applicable prohibitions against the unauthorized  
8 practice of medicine; (b) training representatives to minimize, dismiss, and counter  
9 patient concerns about device complications and to encourage continued device use  
10 regardless of patient symptoms; (c) training representatives to represent that  
11 reprogramming would resolve complications without disclosing that reprogramming  
12 cannot remediate lead failure or IPG/battery malfunction; and (d) failing to train  
13 representatives on the known risk of permanent nerve damage arising from delayed  
14 removal of a failing device. In doing so, Defendants failed to act with reasonable care  
15 and knew, or should have known, that their training was inadequate.

16       585. Defendants' breach of their duty to train their representatives was a  
17 substantial factor in causing Plaintiffs' harm and a direct and proximate cause of  
18 Plaintiffs' injuries. Had the representatives been adequately trained, they would not  
19 have engaged in the unauthorized practice of medicine with respect to Plaintiffs,  
20 would not have made material misrepresentations about device performance and the  
21 significance of complications, and would not have discouraged Plaintiffs from seeking  
22 timely removal of the failing devices. Plaintiffs' harm was a foreseeable consequence  
23 of Defendants' failure to train their representatives on the limits of their role.

24       586. As a direct and proximate result of Defendants' negligent training, their  
25 sales and clinical representatives failed to appropriately respond to signs that  
26 Plaintiffs' SCS devices were failing due to underlying defects and instead continued  
27 reprogramming and advised Plaintiffs to continue using the devices, delaying  
28 appropriate medical evaluation and treatment. The device failures directly and

1 proximately caused Plaintiffs' injuries, while the continued use and delayed treatment  
2 prolonged Plaintiffs' exposure to the malfunctioning devices and aggravated those  
3 injuries. Plaintiffs thereby sustained the injuries and damages described herein,  
4 including bodily injury; permanent nerve damage; chronic pain; severe physical pain  
5 and suffering; emotional distress and mental anguish; diminished enjoyment of life;  
6 medical and related expenses; loss of earnings; and disability, all of which losses and  
7 damages will continue into the future.

8 587. WHEREFORE, Plaintiffs demand judgment against Defendants for  
9 compensatory damages, punitive damages where permitted, attorneys' fees where  
10 allowed by statute, costs of suit, pre- and post-judgment interest, and all such other  
11 and further relief as the Court deems just and proper.

#### 12 **COUNT XX – NEGLIGENT SUPERVISION**

13 588. Plaintiffs incorporate by reference all factual allegations set forth above  
14 in ¶¶ 1–279 as if fully set forth herein.

15 589. Defendants employed the sales and clinical representatives who  
16 interacted with Plaintiffs and Plaintiffs' treating physicians, and Defendants had the  
17 right and the duty to control those representatives' conduct. Defendants owed a duty  
18 to Plaintiffs to adequately supervise their sales and clinical representatives to ensure  
19 those representatives did not: (a) engage in the unauthorized practice of medicine; (b)  
20 make material misrepresentations to patients regarding the safety and efficacy of  
21 Defendants' SCS devices; or (c) advise patients to retain failing devices contrary to  
22 Plaintiffs' medical interests.

23 590. Defendants knew or should have known that their representatives were  
24 engaging in the unauthorized practice of medicine, making material  
25 misrepresentations to patients, and inducing patients to delay device removal. This  
26 knowledge arose from, among other sources: (a) the nature of the representatives'  
27 assigned roles, which placed them in clinical settings with patients and physicians; (b)  
28 the compensation structure, which incentivized the conduct described herein; and (c)

1 actual notice through complaints, adverse event reports, and publicly filed litigation.  
2 Defendants also knew or should have known that this conduct created a particular risk  
3 of harm to patients, including Plaintiffs.

4 591. Defendants failed to exercise ordinary care in supervising their  
5 representatives and breached their duty of supervision by failing to adequately  
6 monitor, review, and correct the conduct of their representatives; by failing to  
7 implement and enforce compliance protocols limiting representatives to permissible  
8 non-medical technical support activities; by failing to discipline representatives for  
9 known violations of those limits; and by failing to take corrective action upon learning  
10 of instances of impermissible conduct.

11 592. Defendants' representatives committed tortious acts against Plaintiffs,  
12 including the negligent conduct, misrepresentations, and unauthorized practice of  
13 medicine alleged above. Defendants' breach of their supervisory duty was a  
14 substantial factor in causing Plaintiffs' harm and a direct and proximate cause of  
15 Plaintiffs' injuries, in that the absence of adequate supervision allowed the sales  
16 representatives' unlawful conduct to continue unchecked, resulting in Plaintiffs'  
17 implantation and delayed removal of defective devices and the permanent nerve  
18 damage resulting therefrom.

19 593. As a direct and proximate result of Defendants' negligent supervision,  
20 their sales and clinical representatives failed to appropriately respond to signs that  
21 Plaintiffs' SCS devices were failing due to underlying defects and instead continued  
22 reprogramming and advised Plaintiffs to continue using the devices, delaying  
23 appropriate medical evaluation and treatment. The device failures directly and  
24 proximately caused Plaintiffs' injuries, while the continued use and delayed treatment  
25 prolonged Plaintiffs' exposure to the malfunctioning devices and aggravated those  
26 injuries. Plaintiffs thereby sustained the injuries and damages described herein,  
27 including bodily injury; permanent nerve damage; chronic pain; severe physical pain  
28 and suffering; emotional distress and mental anguish; diminished enjoyment of life;

1 medical and related expenses; loss of earnings; and disability, all of which losses and  
2 damages will continue into the future.

3 594. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
4 relief against Defendants, as contained in the Prayer For Relief.

5 **COUNT XXI - NEGLIGENT RETENTION**

6 595. Plaintiffs incorporate by reference all factual allegations set forth above  
7 in ¶¶ 1–279 as if fully set forth herein.

8 596. Defendants employed the sales and clinical representatives who  
9 interacted with Plaintiffs and Plaintiffs’ treating physicians. Defendants owed a duty  
10 to Plaintiffs not to retain sales and clinical representatives whom they knew, or in the  
11 exercise of reasonable care should have known, were engaging in conduct that posed  
12 an unreasonable risk of harm to patients, including by engaging in the unauthorized  
13 practice of medicine and making material misrepresentations to induce device  
14 implantation and discourage removal.

15 597. Upon information and belief, Defendants knew or should have known  
16 that the representatives who interacted with Plaintiffs had become unfit and  
17 incompetent for their patient-facing roles, and that this unfitness created a particular  
18 risk of harm to patients, because before their interactions with Plaintiffs those  
19 representatives had engaged in the same pattern of conduct with other patients and in  
20 other clinical settings — engaging in the unauthorized practice of medicine, making  
21 misleading representations, and improperly discouraging device removal.

22 598. This knowledge arose from, inter alia, the systemic nature of the conduct  
23 (which reflected Defendants’ institutional practices rather than individual deviation),  
24 prior patient and physician complaints, sales representative notes and complaint logs,  
25 and prior adverse event reports.

26 599. Despite this knowledge, Defendants retained the representatives in their  
27 positions, and the representatives continued to engage in this conduct with Plaintiffs,  
28 including the negligent programming, misrepresentations, and unauthorized practice

1 of medicine alleged above. Defendants' decision to retain the representatives in these  
2 roles, despite knowledge of their propensity for the conduct described herein, was a  
3 substantial factor in causing Plaintiffs' harm and a direct and proximate cause of  
4 Plaintiffs' injuries.

5       600. As a direct and proximate result of Defendants' negligent retention of  
6 their agents, their sales and clinical representatives failed to appropriately respond to  
7 signs that Plaintiffs' SCS devices were failing due to underlying defects and instead  
8 continued reprogramming and advised Plaintiffs to continue using the devices,  
9 delaying appropriate medical evaluation and treatment. The device failures directly  
10 and proximately caused Plaintiffs' injuries, while the continued use and delayed  
11 treatment prolonged Plaintiffs' exposure to the malfunctioning devices and aggravated  
12 those injuries. Plaintiffs thereby sustained the injuries and damages described herein,  
13 including bodily injury; permanent nerve damage; chronic pain; severe physical pain  
14 and suffering; emotional distress and mental anguish; diminished enjoyment of life;  
15 medical and related expenses; loss of earnings; and disability, all of which losses and  
16 damages will continue into the future.

17       601. WHEREFORE, Plaintiffs demand judgment against Defendants for  
18 compensatory damages, punitive damages where permitted, attorneys' fees where  
19 allowed by statute, costs of suit, pre- and post-judgment interest, and all such other  
20 and further relief as the Court deems just and proper.

21       **COUNT XXII – VIOLATION OF CONSUMER PROTECTION LAW**  
22       **AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES**

23       602. Plaintiffs incorporate by reference all factual allegations set forth above  
24 in ¶¶ 1–279 as if fully set forth herein.

25       603. Defendants have a statutory duty to refrain from unfair or deceptive acts  
26 or trade practices in the design, development, manufacture, promotion, and sale of  
27 their SCS devices, including those devices implanted in Plaintiffs. Plaintiffs are  
28 consumers who acquired the SCS devices by purchase, directly or through the

1 hospitals, surgical centers, and physicians that acquired the devices for implantation  
2 in Plaintiffs, for personal purposes, namely the treatment of Plaintiffs' own chronic  
3 pain.

4 604. Defendants initiated, conducted, and participated in unfair methods of  
5 competition or deceptive acts or practices that were proscribed by law, including the  
6 following:

- 7 a. Advertising the device as safe and effective without disclosing the  
8 deviations from FDA-approved specifications associated with its creation  
9 and marketing;
- 10 b. Omitting material risks from marketing materials, sales presentations, and  
11 direct-to-patient communications;
- 12 c. Representing that goods or services have characteristics, ingredients, uses,  
13 benefits, or quantities that they do not have;
- 14 d. Advertising goods or services with the intent not to sell them as advertised;
- 15 e. Discussing with Plaintiffs the reduction in pain they had to report for third-  
16 party payers to pay for a permanent SCS device, and encouraging Plaintiffs  
17 to report the requisite level of pain reduction; and
- 18 f. Engaging in fraudulent or deceptive conduct that creates a likelihood of  
19 confusion or misunderstanding.

20 605. Plaintiffs were injured by the cumulative and indivisible nature of  
21 Defendants' conduct, particularly because Plaintiffs relied on Defendants'  
22 representations and omissions. The cumulative effect of Defendants' conduct directed  
23 at patients, physicians and consumers was to create demand for and sell the SCS  
24 devices. Each aspect of Defendants' conduct combined to artificially create sales of  
25 the SCS systems.

26 606. Had Defendants not engaged in the deceptive conduct described herein,  
27 Plaintiffs, their physicians and hospitals and medical centers would not have  
28

1 purchased and/or paid for the SCS systems, and would not have incurred related  
2 medical costs and injuries.

3 607. Defendants engaged in wrongful conduct while at the same time  
4 obtaining, under false pretenses, moneys from Plaintiffs, their physicians and  
5 hospitals for the SCS systems that would not have been paid had Defendants not  
6 engaged in unfair and deceptive conduct.

7 608. Defendants' deceptive, unconscionable, or fraudulent representations  
8 and material omissions to patients, physicians and consumers, including Plaintiffs,  
9 constituted unfair and deceptive acts and trade practices in violation of the state  
10 consumer protection statutes listed.

11 609. Defendants' actions, as complained of herein, constitute unfair  
12 competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices  
13 in violation of state consumer protection statutes, as listed below.

14 610. Defendants have engaged in unfair competition or unfair or deceptive  
15 acts or trade practices or have made false representations in violation of the statutes  
16 listed below, as well as any additional consumer protection statutes identified in  
17 Plaintiffs' Short-Form Complaints:

- 18 a. Ala. Code §§ 8-19-1 et seq.;
- 19 b. Alaska Stat. §§ 45.50.471 et seq.;
- 20 c. Ariz. Rev. Stat. Ann. §§ 44-1522 et seq.;
- 21 d. Ark. Code Ann. §§ 4-88-101 et seq.;
- 22 e. Cal. Civ. Code §§ 1770 et seq. and Cal. Bus. & Prof. Code §§  
23 17200 et seq.;
- 24 f. Colo. Rev. Stat. §§ 6-1-105 et seq.;
- 25 g. Conn. Gen. Stat. §§ 42-110a et seq.;
- 26 h. Del. Code Ann. tit. 6, §§ 2511 et seq. and §§ 2531 et seq.;
- 27 i. D.C. Code Ann. §§ 28-3901 et seq.;
- 28 j. Fla. Stat. Ann. §§ 501.201 et seq.;

- 1 k. O.C.G.A. §§ 10-1-370 et seq. and §§ 10-1-390;
- 2 l. Haw. Rev. Stat. §§ 480-1 et seq.;
- 3 m. Idaho Code Ann. §§ 48-601 et seq.;
- 4 n. Ill. Comp. Stat. Ann. ch. 815, 505/1 et seq.;
- 5 o. Ind. Code Ann. §§ 24-5-0.5-1 et seq.;
- 6 p. Iowa Code Ann. §§ 714.16 et seq.;
- 7 q. Kan. Stat. Ann. §§ 50-623 et seq.;
- 8 r. Ky. Rev. Stat. Ann. §§ 367.170 et seq.;
- 9 s. La. Rev. Stat. Ann. §§ 51:1401 et seq.;
- 10 t. Me. Rev. Stat. Ann. tit. 5, §§ 205A et seq.;
- 11 u. Md. Code Ann., Com. Law §§ 13-101 et seq.;
- 12 v. Mass. Gen. Laws Ann. Ch. 93A et seq.;
- 13 w. Mich. Comp. Laws §§ 445.901 et seq.;
- 14 x. Minn. Stat. §§ 325D.43 et seq. and §§ 325F.67 et seq.;
- 15 y. Miss. Code Ann. §§ 75-24-1 et seq.;
- 16 z. Mo. Ann. Stat. §§ 407.010 et seq.;
- 17 aa. Mont. Code Ann. §§ 30-14-101 et seq.;
- 18 bb. Neb. Rev. Stat. §§ 59-1601 et seq.;
- 19 cc. Nev. Rev. Stat. §§ 598.0903 et seq.;
- 20 dd. N.H. Rev. Stat. Ann. §§ 358-A:1 et seq.;
- 21 ee. N.J.S.A. §§ 56:8-1 et seq.;
- 22 ff. N.M. Stat. Ann. §§ 57-12-1 et seq.;
- 23 gg. N.Y. Gen. Bus. Law §§ 349 et seq.;
- 24 hh. N.C. Gen. Stat. §§ 75-1.1 et seq.;
- 25 ii. N.D. Cent. Code §§ 51-12-01 et seq. and §§ 51-15-01 et seq.;
- 26 jj. Ohio Rev. Code Ann. §§ 1345.01 et seq.;
- 27 kk. 15 Okl. St. §§ 751 et seq.;
- 28 ll. Or. Rev. Stat. §§ 646.605 et seq.;

mm. 73 Pa. Stat. §§ 201-1 et seq.;  
nn. R.I. Gen. Laws §§ 6-13.1-1 et seq.;  
oo. S.C. Code Ann. §§ 39-5-10 et seq.;  
pp. S.D. Codified Laws §§ 37-24-1 et seq.;  
qq. Tenn. Code Ann. §§ 47-18-101 et seq.;  
rr. Tex. Bus. & Com. Code Ann. §§ 17.41 et seq.;  
ss. Utah Code Ann. §§ 13-11-1 et seq.;  
tt. Vt. Stat. Ann. tit. 9, §§ 2451 et seq.;  
uu. Va. Code Ann. §§ 59.1-196 et seq.;  
vv. Wash. Rev. Code §§ 19.86.010 et seq.;  
ww. W. Va. Code §§ 46A-6-101 et seq.;  
xx. Wis. Stat. Ann. §§ 100.20 et seq.; and  
yy. Wyo. Stat. Ann. §§ 40-12-101 et seq.

611. Under the statutes listed above, which protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

612. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the SCS systems were safe and effective.

613. Defendants had adequate notice under the applicable law as described in ¶¶ 231-235.

614. The law and facts applicable to specific Plaintiffs will be identified in plaintiff-specific filings, including but not limited to Short-Form Complaints.

615. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers

1 against unfair, deceptive, fraudulent and unconscionable trade and business practices  
2 and false advertising.

3 616. These deviations are further supported by specific allegations to be  
4 pleaded in plaintiff-specific filings included but not limited to Short-Form  
5 Complaints.

6 617. Plaintiffs and the medical community relied upon Defendants'  
7 misrepresentations and omissions in determining which SCS system to use.  
8 Defendants' misrepresentations and omissions were a substantial factor in Plaintiffs'  
9 decisions to undergo implantation of the SCS devices and to continue using them. The  
10 misrepresented and omitted facts were material because a reasonable consumer would  
11 consider them important in deciding whether to acquire an SCS device.

12 618. Defendants' deceptive, unconscionable or fraudulent representations  
13 and material omissions to patients, physicians, and consumers, constituted unfair and  
14 deceptive acts and practices. Defendants' conduct was likely to mislead a reasonable  
15 consumer and, indeed, did mislead Plaintiffs and their healthcare providers.

16 619. By reason of the unlawful acts engaged in by Defendants, and as a direct  
17 and proximate result thereof, Plaintiffs have suffered ascertainable losses and  
18 damages.

19 620. As a direct and proximate result of Defendants' deceptive conduct in  
20 violation of the provided states' consumer protection laws, Plaintiffs have sustained  
21 economic losses and other damages and are entitled to statutory and compensatory  
22 damages in an amount to be proven at trial.

23 621. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
24 relief against Defendants, as contained in the Prayer For Relief.

25 **COUNT XXIII – UNJUST ENRICHMENT**

26 622. Plaintiffs incorporate by reference all factual allegations set forth above  
27 in ¶¶ 1–279 as if fully set forth herein.

1           623. This Count is asserted under the common law of unjust enrichment,  
2 restitution, or quasi-contract of each jurisdiction whose law governs a Plaintiff's  
3 claims. For Plaintiffs whose claims are governed by the law of a jurisdiction that does  
4 not recognize unjust enrichment as an independent cause of action, this Count is  
5 asserted as a quasi-contract claim for restitution. Where that jurisdiction's law permits,  
6 it is also asserted as a basis for restitutionary relief under the other Counts of this  
7 Master Complaint.

8           624. This Count is pleaded in the alternative under Fed. R. Civ. P. 8(d)(2)–  
9 (3). It is asserted only to the extent Plaintiffs do not have an adequate remedy at law  
10 and no enforceable express contract governs the subject matter of this Count.

11           625. Plaintiffs conferred a benefit on Defendants. Plaintiffs, and others  
12 paying on their behalf, paid money for the SCS Devices and components implanted  
13 in Plaintiffs, and for replacement components used in revision procedures, as alleged  
14 herein. That money passed through hospitals, surgical facilities, physician practices,  
15 and payors to Defendants. Defendants received this money because those devices and  
16 components were implanted in Plaintiffs.

17           626. Defendants knew of, appreciated, and accepted that benefit. Defendants  
18 tracked each sale by device, patient, physician, and facility. Through their  
19 Representatives, Defendants maintained direct, continuing contact with Plaintiffs  
20 after implantation, as alleged herein.

21           627. Under circumstances alleged herein, it would be inequitable and unjust  
22 for Defendants to retain the benefit without paying its value to Plaintiffs. Those  
23 circumstances include:

- 24           a. Defendants sold Plaintiffs SCS Devices that departed from their FDA-  
25           approved specifications and manufacturing requirements;
- 26           b. Defendants' Representatives told Plaintiffs that their devices were  
27           functioning properly and that their symptoms were unrelated to device  
28           failure;

1 c. Defendants continued to receive payment for replacement components and  
2 related services while attributing device failures to other causes.

3 628. This Count does not challenge the FDA-approved design, the FDA-  
4 approved labeling, or the FDA's premarket approval of any SCS Device. It does not  
5 assert that any SCS Device manufactured in conformity with its FDA-approved  
6 specifications was worth less than its price. This Count rests on Defendants' deviations  
7 from FDA-approved specifications and requirements, asserted only to the extent the  
8 state-law duty parallels those requirements, and on conduct of Defendants'  
9 Representatives that no federal requirement governs.

10 629. No enforceable express contract between Plaintiffs and Defendants  
11 governs the subject matter of this Count. That subject matter is Defendants' retention  
12 of payment for nonconforming devices and for components and services obtained  
13 through the conduct of Defendants' Representatives. To the extent Defendants contend  
14 that any written warranty governs any part of that subject matter, Plaintiffs allege that  
15 the warranty does not cover the conduct alleged here, and Plaintiffs assert this Count  
16 in the alternative.

17 630. Plaintiffs lack an adequate remedy at law for the benefit Defendants  
18 unjustly retained, for the following reasons:

19 a. Plaintiffs' legal claims may be barred, limited, or displaced under the law  
20 of particular jurisdictions, including by product liability statutes,  
21 limitations on recoverable damages, or defenses specific to those claims.  
22 Restitution is measured by Defendants' gain, not by Plaintiffs' loss.

23 b. Restitution reaches the revenue and profit Defendants obtained from the  
24 sale of replacement components and from the continued use of their  
25 products that the Representatives' conduct secured. Damages on Plaintiffs'  
26 legal claims would not necessarily reach those amounts.

27 c. The elements of this Count differ from the elements of Plaintiffs' legal  
28 claims. This Count does not require proof of a product defect at the time of

1 sale, a duty to warn, reliance, or the statutory prerequisites of the Consumer  
2 Protection Statutes.

3 631. It is unjust to allow Defendants to earn revenues and retain the benefits  
4 and profits from these devices while Plaintiffs suffered injuries and damages as  
5 specified herein. Plaintiffs therefore seek restitution and disgorgement of the benefits  
6 Defendants unjustly retained, measured by Defendants' gain.

7 632. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
8 relief against Defendants, as contained in the Prayer for Relief.

9 **COUNT XXIV – WRONGFUL DEATH**

10 633. Plaintiffs incorporate by reference all factual allegations set forth above  
11 in ¶¶ 1–279 as if fully set forth herein.

12 634. Plaintiffs allege, on information and belief, that the sudden, premature,  
13 and untimely deaths of Decedents were caused by the defective SCS devices that  
14 Defendants designed, manufactured, distributed, and sold, and by Defendants' other  
15 tortious conduct alleged in this Complaint.

16 635. Decedents would not have received the SCS devices but for Defendants'  
17 intentional and negligent tortious conduct alleged in this Complaint. Defendants are  
18 also strictly liable for Decedents' deaths for the reasons alleged in this Complaint.  
19 Defendants' wrongful acts were a substantial factor in causing Decedents' deaths.  
20 Plaintiffs seek to recover damages for all legally compensable injuries relating to  
21 Decedents' wrongful deaths.

22 636. Decedents' heirs, and where required by applicable law the personal  
23 representatives of Decedents' estates, bring this claim as the persons entitled to  
24 recover under the wrongful death statutes of the state or states whose law governs  
25 each claim.

26 637. As a direct and proximate result of Decedents' deaths, their heirs have  
27 suffered and will continue to suffer the loss of the financial support and services that  
28 Decedents provided and would have provided; the loss of Decedents' love,

1 companionship, comfort, care, assistance, protection, affection, society, and moral  
2 support; and funeral and burial expenses.

3 638. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
4 relief against Defendants, as contained in the Prayer for Relief.

5 **COUNT XXV – SURVIVAL ACTION**

6 639. Plaintiffs incorporate by reference all factual allegations set forth above  
7 in ¶¶ 1–279 as if fully set forth herein.

8 640. Before their deaths, Decedents had causes of action against Defendants  
9 for the conduct alleged in this Complaint, and those causes of action survive  
10 Decedents' deaths. Defendants' wrongful conduct was a substantial factor in causing  
11 Decedents' pre-death losses. As a direct and proximate result of Defendants' wrongful  
12 conduct as outlined above, Decedent Plaintiffs suffered bodily injury and resulting  
13 pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the  
14 enjoyment of life, expenses of hospitalization, medical and nursing care and  
15 treatment, and loss of earnings as well as loss of ability to earn money before  
16 Decedents' deaths.

17 641. The personal representatives of Decedents' estates or, where applicable  
18 law permits, Decedents' successors in interest, bring this claim on behalf of  
19 Decedents' estates to recover the damages Decedents sustained or incurred before  
20 their deaths.

21 642. The personal representatives or successors in interest of Decedents  
22 further plead all survival damages allowed by statute and law in the state or states in  
23 which the causes of action accrued, including any penalties or punitive or exemplary  
24 damages that Decedents would have been entitled to recover had they lived.

25 643. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
26 relief against Defendants, as contained in the Prayer for Relief.

1                                   **COUNT XXVI – LOSS OF CONSORTIUM**

2           644.   Plaintiffs incorporate by reference all factual allegations set forth above  
3 in ¶¶ 1–279 as if fully set forth herein.

4           645.   At all relevant times stated herein, Plaintiffs’ spouses (hereinafter  
5 referred to as “Spouse Plaintiffs”) were lawfully married to Plaintiffs, including at the  
6 time of Plaintiffs’ injuries. Plaintiffs suffered tortious injuries caused by Defendants’  
7 conduct alleged in this Complaint, and Spouse Plaintiffs have suffered losses and  
8 injuries as a result of those injuries to their spouses.

9           646.   As a direct and proximate result of Defendants’ conduct, as outlined  
10 above, Spouse Plaintiffs paid and have become liable to pay for treatment,  
11 medications, and medical aid, and will necessarily incur further expenses of a similar  
12 nature in the future.

13           647.   Defendants’ conduct was a substantial factor in causing Spouse  
14 Plaintiffs’ harm. As a direct and proximate result of Defendants’ conduct, Spouse  
15 Plaintiffs have suffered and will continue to suffer the loss of their spouses’ love,  
16 companionship, comfort, care, assistance, protection, affection, society, moral  
17 support, and services, and the loss of the enjoyment of sexual relations, as well as an  
18 alteration of marital association, thereby causing the Spouse Plaintiffs current and  
19 future mental anguish and emotional distress.

20           648.   WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted  
21 relief against Defendants, as contained in the Prayer For Relief.

22                                   **COUNT XXVII - PUNITIVE DAMAGES ALLEGATIONS**

23           649.   Plaintiffs incorporate by reference all factual allegations set forth above  
24 in ¶¶ 1–279 as if fully set forth herein.

25           650.   Defendants acted with malice, oppression, and fraud. Defendants’  
26 conduct was despicable and was carried out with a willful and knowing disregard of  
27 the rights and safety of Plaintiffs and similarly situated patients. Defendants were  
28

1 aware of the probable dangerous consequences of their conduct and deliberately failed  
2 to avoid those consequences, including by:

- 3 a. Knowingly marketing and distributing SCS devices that deviated from  
4 FDA-approved manufacturing specifications and cGMP requirements,  
5 while concealing known lead failure risks and IPG/battery malfunction  
6 risks from patients and physicians;
- 7 b. Constructing and operating a corporate scheme by which sales and clinical  
8 representatives were deployed to engage in the unauthorized practice of  
9 medicine and to make material misrepresentations to patients for the  
10 purpose of maximizing device sales, in knowing violation of applicable  
11 state law;
- 12 c. Making material misrepresentations to Plaintiffs about the performance of  
13 the SCS devices, the nature of Plaintiffs' complications, and the efficacy of  
14 reprogramming as a remedy, while knowing these representations were  
15 false;
- 16 d. Encouraging patients to falsify their pain reduction during trials; and
- 17 e. Retaining and continuing to deploy the sales representatives after having  
18 actual or constructive knowledge of the sales representatives' pattern of  
19 impermissible conduct.

20 651. Defendants, on their own and through their sales representatives,  
21 engaged in fraudulent misrepresentation and fraudulent concealment as pleaded in  
22 Counts XIV and XV. Defendants intentionally misrepresented and concealed  
23 material facts concerning the safety, efficacy, and regulatory compliance of their  
24 SCS devices, the causes of the issues Plaintiffs experienced, and the representatives'  
25 knowledge, skill, and qualifications to address SCS device issues, including  
26 programming and reprogramming. Defendants did so intending to deprive Plaintiffs  
27 of their rights and to cause Plaintiffs to undergo implantation and continue using the  
28 devices despite the resulting harm.

652. Defendants' conduct reflects a systematic, willful, and conscious disregard for the rights and safety of Plaintiffs and similarly situated patients and subjected Plaintiffs to cruel and unjust hardship, making an award of punitive damages appropriate to punish Defendants and deter similar conduct.

653. Defendants' officers, directors, and managing agents, who exercised substantial independent authority and judgment in corporate decision-making such that their decisions determined Defendants' corporate policy, committed, authorized, and ratified the conduct described above. Among other things, they designed and approved the field sales and clinical support model that placed representatives in operating rooms and patient-facing settings, established the compensation structure that rewarded implantations and discouraged device removal, and adopted the uniform nationwide job descriptions for clinical specialists and territory managers. They also received notice of the representatives' conduct through patient and physician complaints, adverse event reports, and publicly filed litigation, and they adopted and approved that conduct by continuing to deploy, compensate, and retain the representatives without corrective action.

654. WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer for Relief.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above referenced claims and causes of action, jointly and severally, as follows:

- a) Awarding compensatory damages for physical injury, pain and suffering, emotional distress, medical expenses, loss of enjoyment of life, and all other actual damages recoverable under applicable law, based on Defendants' fraud and willful, malicious, and/or reckless disregard for the safety and rights of Plaintiffs and the public;
- b) Awarding statutory damages and attorneys' fees and costs pursuant to any applicable consumer protection statutes;

- 1 c) Awarding punitive or exemplary damages, as allowed by law, based on  
2 Defendants' fraud and willful, malicious, and/or reckless disregard for the  
3 safety and rights of Plaintiffs and the public;  
4 d) Awarding attorneys' fees and costs associated under applicable law;  
5 e) Awarding pre-judgment and post-judgment interest to Plaintiffs;  
6 f) Awarding all statutory damages and relief;  
7 g) Awarding the costs and the expenses of this litigation to Plaintiffs;  
8 h) Awarding punitive damages, where appropriate, to the Plaintiffs;  
9 i) Granting Plaintiffs equitable relief in the nature of disgorgement and  
10 restitution to remedy Boston Scientific's unjust enrichment; and  
11 j) Granting all such other relief as the Court deems necessary, just and proper.

12 **DEMAND FOR JURY TRIAL**

13 Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by  
14 jury of all claims in this Complaint so triable.

15  
16 Dated: October 23, 2026

Respectfully Submitted,

17 /s/Behram V. Parekh

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 23, 2026 I electronically filed the foregoing with the Clerk of Court using the CM/ECF system and thereby served it on all counsel of record.

/s/Behram V. Parekh  
Behram V. Parekh