IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

MARK C. DUNHAM, *Plaintiff* v. BOSTON SCIENTIFIC CORPORATION (a Massachusetts corporation) *Defendant*.	Case No.:

COMPLAINT

Plaintiff Mark C. Dunham, by and through the undersigned counsel, brings this Complaint at Law against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the tortious conduct of the Defendant named herein related to the implantation and subsequent injurious failure of the WaveWriter Alpha Spinal Cord Stimulator System, a spinal cord stimulation device ("SCS" or "product"). As a result of the wrongful conduct enumerated herein, Plaintiff Mark C. Dunham suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which he may be legally entitled.

2. Plaintiff files this Complaint, alleging violations of state and federal requirements in the manufacture, labeling, warning, reporting and marketing, as well as breach of warranties, and other legal duties and requirements with regards to Boston Scientific's WaveWriter Spinal

Cord Stimulator System.

3. As a direct and proximate result of Boston Scientific's violations of FDA laws, regulations and requirements, and their respective parallel state law requirements, Boston Scientific's implants caused Plaintiff Mark C. Dunham to suffer injuries and losses as enumerated herein.

4. Defendant Boston Scientific (hereinafter, "Defendant" or "Boston Scientific") cannot avoid civil liability for the defective WaveWriter implant by asserting a preemption defense because it failed to comply with: critical quality system regulation (QSR) and current good manufacturing practice (CGMP) requirements required by the Food & Drug Administration ("FDA"); the FDA's Premarket Approval Application requirements; and FDA requirements to warn consumers of the known dangers and known adverse events as required by conditions of approval and post-marketing regulations.[1]

5. Boston Scientific's WaveWriter Alpha system consists of an implantable pulse generator device ("IPG") with output channels which is connected to lead wires with electrodes which are implanted in contact with a patient's spinal cord. The IPG is powered by a battery that can last up to 25 years according to the company.[2] It is capable of stimulating the spinal cord nerves through the electrodes of the leads connected to any combination of the output terminals, using a single current source.

6. One of the requirements imposed by the FDA when it approved the sale of the device in 2003 was that Boston Scientific provide periodic annual reports, and that Boston Scientific share

[1] The failure to follow the CGMPs and QSRs precludes a preemption defense and provides a basis for liability as violations of federal law that are parallel state law claims. See *Warren v. Howmedica Osteonics Corp*., No. 4:10 CV 1346 DDN, 2011 WL 1226975 (E.D. Mo. Mar. 29, 2011). In addition, because Plaintiff alleges the implants were "adulterated" by virtue of failure to conform to applicable performance standards, federal law specifically incorporates CGMPs. 21 U.S.C. § 351.

[2] See, e.g., https://www.bostonscientific.com/content/dam/elabeling/nm/92089818-05_RevA_SCS_System_DFU_multi-OUS_s.pdf (last viewed April 9, 2025).

data on adverse events including serious injury and death.

7. 21 CFR § 898.12 provides that any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the International Electrotechnical Commission (IEC) 601-1: Medical Electrical Equipment.

8. At all relevant times, the WaveWriter was widely advertised and promoted by Defendant as a safe and effective management of chronic back pain, including by Boston Scientific's sales representatives who made direct promises to Plaintiff about the device's safety and efficacy.

9. Also pursuant to FDA regulations, manufacturers of SCS components are required to report "serious adverse events" to the FDA. 21 CFR § 803.50.

10. The phrase "serious adverse event" is an FDA term of art, but for purposes of this case, a serious adverse event includes an event – including a medical device malfunction -- that may jeopardize the patient and may require medical or surgical intervention to prevent one of the other accepted "serious" outcomes. See for example https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

11. The time frame for submitting an adverse event is within either 5 or 30 days of the manufacturer becoming aware of the event and is not based on the time that the event occurred; the shorter five days' time limit is based on if the event necessitates remedial action. 21 CFR § 803.53(a).

12. With respect to medical device safety, malfunction events are potentially attributed to complex failure modes and root causes are not always well understood, either by the FDA, the manufacturer, or by both.

13. Among other things, 21 CFR § 803 requires the submission of an individual malfunction medical device report (MDR) when a manufacturer becomes aware of information,

from any source, which reasonably suggests that one of its marketed devices malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§§ 803.10(c)(1) and 803.50(a)(2)).

14. The FDA refers to these malfunctions as "reportable malfunctions" or "reportable malfunction events."

15. Under section 519(a)(1)(B)(i) of the FD&C Act, Title 21 Chapter 9 of the United States Code, as amended by Food and Drug Administration Amendments Act (FDAAA) of 2007 manufacturers of permanently implantable devices such as the subject SCS must submit malfunction reports in accordance with part 803 (or successor regulations), unless the FDA grants an exemption or variance from, or an alternative to, a requirement under such regulations under § 803.19.

16. Defendant Boston Scientific has not been granted any such exemption.

17. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The Manufacturer and User Facility Device Experience (MAUDE) database houses the MDRs, and is available to the public and to device manufacturers. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

18. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The Manufacturer and User Facility Device Experience (MAUDE) database houses the MDRs, and is available to the public and to device manufacturers.

19. The MAUDE database reveals that prior to 2023, there were reports of IPG malfunctions including "burning," "overheating of device," and "heating at the pocket site."

20. In November 2018, the Associated Press released findings from a nearly yearlong joint

investigation of the global medical devices industry that included NBC, the International Consortium of Investigative Journalists and more than 50 other media partners around the world.[3]

21. The AP's analysis of FDA injury reports found that "shocking" and "burning" had been reported for all major models of spinal-cord stimulators. Id.

22. The subject implanted spinal cord stimulator was manufactured by Boston Scientific and implanted in Plaintiff on Mar. 22, 2023, at Munson Medical Center in Traverse City, Michigan.

23. The WaveWriter is a "Class III" medical device cleared for commercial distribution by the U.S. Food and Drug Administration ("FDA") through the premarket approval (PMA) process.

24. As part of the approval process referred to above, Defendant was required to engage in limited clinical trials.

25. Although discovery is needed to obtain full data from the clinical trials, there were approximately 500 reported adverse events for the WaveWriter device in the three-year period prior to Plaintiff's initial implant surgery with the device in March 2023. Nearly half of those reports were related to battery failure or malfunction, and there were dozens of reports of electrical shock, revision and removal surgeries, and other malfunctions similar to the types of problems Plaintiff experienced.

26. Many of the adverse events were for injuries such as thermal burns, device failure, implant pain, nerve damage and other injuries similar to what Plaintiff experienced.

27. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device. 21 C.F.R. §814.80.

[3] https://apnews.com/article/wv-state-wire-us-news-ap-top-news-sc-state-wire-health-86ba45b0a4ad443fad1214622d13e6cb

28. The WaveWriter was approved by the FDA in April 2004 as part of P030017.

29. Pursuant to the FDA, the WaveWriter was approved for "…as an aid in the management of chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with … failed back surgery syndrome, intractable low back pain and leg pain ."[4]

30. A medical device manufacturer's responsibilities do not end with FDA approval.

31. The concept of "Post-market surveillance" (PMS) has been discussed in the medical device industry since before 2005.

32. In the United States, the term PMS is used explicitly to grant the US FDA the authority to require manufacturers to perform studies of medical risk devices, such as the device at issue, which have previously been granted PMA approval.

33. 21 CFR Part 822 details the requirements for PMS in the United States.

34. Broadly stated, The FDA has authorization to require post-market surveillance for class III medical devices that are intended to be implanted in the human body for over one year.

35. The subject SCS is intended to be implanted in the human body for over one year.

36. The FDA requires Boston Scientific to "track" its SCS devices, including the subject device, because they are intended to be implanted for over a year. However, Boston Scientific's post-market submissions to FDA appear to grossly underestimate the frequently and severity of adverse events for the WaveWriter device. For example, in a February 2023 submission, Boston Scientific told FDA that out of 212 patients enrolled in a primary clinical study of the WaveWriter SCS systems, only 11 patients completed their 1-year visit and only 1 patient completed their 2-year visit. And although there were 116 adverse events

[4] Approval Order, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017

experienced by study subjects, Boston Scientific downplayed the number of adverse events and claimed they were mostly unrelated to its SCS devices. [5]

37. According to the FDA:

> Post market surveillance is the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device. The data collected under a surveillance order help to address important public health questions on the safety and effectiveness of a device. [6]

38. According to the World Health Organization, "it remains important to continue to collect and evaluate information on the medical device during production and postproduction to meet requirements for the monitoring of products and processes and to ensure the residual risks remain acceptable with respect to benefits. Appropriate processes allow for early detection of any undesirable effects."[7]

39. Independent of PMSs, medical device manufacturers must follow certain requirements and regulations once devices are on the market. These include reporting of device malfunctions.

40. To the extent that manufacturers comply with their FDA surveillance responsibilities, the reports often appear, directly or indirectly, in the MAUDE database.[8]

41. Burning sensation and nerve damage and device malfunction and failure has been associated with the lead wires of the WaveWriter device.

42. Plaintiff brings this action against Boston Scientific in relation to the manufacture,

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[5] See Summary of Safety and Effectiveness Data (SSED) for PMA P030017/S363.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and- cosmetic-act

[7] https://www.who.int/publications/i/item/9789240015319

[8] Underreporting of adverse events is a common problem. "[I]t is evident that [adverse event] reporting does not occur to a great extent, with the rate of reporting estimated to be as low as 0.5% of all occurrences….need for improved vigilance and post-market surveillance has been highlighted in the recent changes to the European Union Medical Device Regulation" Need for Greater Reporting of Medical Device Incidents (EMJ, Jan, 2019)

marketing, reporting, and distribution of the WaveWriter implant, the repeated failure to follow the requirements imposed by FDA, failure to warn Plaintiff's healthcare providers of known dangers and known adverse events, and reckless violation of state law.

PARTIES, VENUE AND JURISDICTION

43. Plaintiff Mark C. Dunham ("Plaintiff") is, and was, at all relevant times, a citizen and resident of Traverse City, Michigan, and the United States.

44. Defendant, Boston Scientific Corp. (hereinafter "Boston Scientific"), now is, and at all times relevant to this action was, a Massachusetts Corporation which has its principal place of business and headquarters in Marlborough, Massachusetts in Middlesex County.

45. Boston Scientific has conducted business and derived substantial revenue from within Michigan and has sufficient minimum contacts and purposefully avail themselves of Michigan so as to render the exercise of jurisdiction over it by the Michigan courts consistent with the traditional notions of fair play and substantial justice. The instant cause of action arises from and is related to Boston Scientific's contacts with and conduct and transactions within the State of Michigan, and specifically the Western District of Michigan. Additionally, diversity jurisdiction exists in this matter because the amount in controversy exceeds $75,000 and there is complete diversity of citizenship by the parties.

46. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. §1965 (a) because a substantial part of the events or omissions giving rise to the claim occurred in this District and the Defendant transacts business affairs and conducts activity that gave rise to the claim of relief in this District.

47. This Court has personal jurisdiction over Defendant as Defendant conducted such business within the State including acts which caused or contributed to Plaintiff's injuries, and because Boston Scientific has substantial contacts in Michigan, including in the Western District of Michigan.

48. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because there is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of $75,000, exclusive of interest and costs.

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

FACTS REGARDING BOSTON SCIENTIFIC'S WAVEWRITER DEVICES

A. Boston Scientific's SCS Products

50. Defendant Boston Scientific designs, manufactures, markets, and distributes the WaveWriter SCS, an implantable device indicated for the treatment of a limited varieties of chronic and intractable pain.

51. Defendant's SCS product includes an Implanted Pulse Generator (IPG) and percutaneous lead wires.

52. The IPG is an implantable device with capable of stimulating the spinal cord nerves through the electrodes of the leads connected to any combination of the output terminals, using a single current source.

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

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

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

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

57. The overstimulation caused by the design of the WaveWriter SCS can lead to dysmotility, arrhythmias and incontinence.

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

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

60. In the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress instituted a process for product review and clearance, using different pathways and processes to permit drugs and medical devices to be sold to U.S. consumers. Three classes of medical devices are regulated by the FDCA, Class I, Class II and Class III, with greater degrees of scrutiny and regulation imposed on the manufacturer as the levels go from I to III.

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

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

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

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

65. Boston Scientific received Pre-Market Approval from the FDA for the initial version of the WaveWriter spinal cord stimulator in April 2004[9].

B. Boston Scientific's Sales and Marketing Practices

66. At all relevant times, Boston Scientific engaged in aggressive and deceptive sales practices in order to market the WaveWriter device to clinicians engaged in the practice of spinal surgery and treatment of chronic pain syndromes.

67. These sales practices involved direct contact between Boston Scientific sales representatives and patients, including Plaintiff.

68. As a prerequisite to reimbursement for the cost of SCS devices, including the Boston Scientific WaveWriter, public and private insurance providers maintain strict requirements to assure that the placement is medically necessary, including:

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

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

[9] As with all such orders, the FDA cautioned Boston Scientific that its statements about the device had to be "truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." PreMarket Approval Order P030017A, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P030017 (last visited April 8, 2024.

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

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

V. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation. Such relief must exhibit either 50% or greater reduction of the patient's pain or 50% or greater reduction of the patient's reliance on analgesic pain medications.[10]

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

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

C. Facts Specific to Plaintiff

71. In early 2024, Plaintiff was introduced to a Boston Scientific sales representative named Henry Warner in Traverse City, Michigan, as part of an evaluation for SCS therapy.

72. Although Mr. Warner holds an undergraduate degree in exercise science from Michigan State University, he has no formal medical training or medical certification in pain management, neurology, or neuromodulation.

73. In August 2022, a Boston Scientific trial stimulator was inserted into Plaintiff's body with percutaneous leads and connected to an external pulse generator by Dr. Richard Burke

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

in Traverse City, Michigan.

74. Following the trial, Dr. Burke implanted Plaintiff with a Boston Scientific spinal cord stimulator and pulse generator at Munson Medical Center on March 22, 2023. At the time, a Boston Scientific sales representative named Tom Mahaney consulted with Plaintiff and participated in manipulating and/or programming the electrical pulse settings of the device. According to his LinkedIn profile, Mr. Mahaney is a territory manager for Boston Scientific, but on information and belief, and like Mr. Warner, he has no formal medical training or medical certification in pain management, neurology, or neuromodulation.

75. The initial Boston Scientific stimulator did not perform well, and on Jan. 8, 2024, Dr. Justin Thomas removed the spinal cord stimulator's percutaneous leads, which had become malpositioned due to migration within Plaintiff's spinal cord, and Dr. Thomas replaced them with a Boston Scientific dorsal column stimulator paddle and pulse generator at McLaren Northern Michigan Hospital in Petoskey, Michigan.

76. Immediately following this new implantation procedure with the paddle leads, Plaintiff began experiencing pain and shocking effects, and Mr. Mahaney was asked to return to the hospital to assist in adjusting the device's settings. Despite this request, Mr. Mahaney failed to return to the hospital and failed to assist Plaintiff and his medical providers.

77. As he continued to experience severe pain and shocks from the WaveWriter device, Mr. Dunham tried calling Boston Scientific's toll-free customer line for assistance and to adjust the settings on the device, but after Mr. Warner met with Plaintiff and adjusted the settings Plaintiff did not receive relief and the device continued to cause severe pain.

78. As part of ongoing direct marketing efforts, Mr. Warner and Mr. Mahaney, as agents of Boston Scientific and within the scope of their employment by Boston Scientific, made the following material representations to Plaintiff, knowing them to be false:

I. That the pain relief results from a permanent WaveWriter implant would be equal to or better than those available from other devices, including those made by competitors such as Medtronic;

II. That the permanent WaveWriter would permanently deliver substantial pain relief;

III. That Plaintiff would be able to resume normal activities of daily living following implantation of the permanent WaveWriter device;

IV. That he and Boston Scientific's other representatives would be readily available to Plaintiff for the purpose of programming and adjusting device settings to optimize pain relief;

V. That Boston Scientific's sales reps have the medical knowledge and training necessary to make purposeful, effective adjustments to the WaveWriter device settings to achieve adequate pain relief;

79. Mr. Warner and Mr. Mahaney, as agents of Boston Scientific and within the scope of their employment by Boston Scientific, committed knowing omissions and suppressions of material facts, such that Plaintiff would not have permitted the WaveWriter to be implanted had he known of such facts:

I. That numerous patients have complained to Boston Scientific that the WaveWriter implant failed to deliver the pain relief results of the trial stimulator;

II. That a large percentage of Boston Scientific's permanent SCS devices are eventually explanted due to device failure;

III. That Boston Scientific's sales reps lack the necessary training or knowledge to make purposeful adjustments to the device settings in order to achieve adequate pain relief;

IV. That the pain relief delivered by the permanent Boston Scientific SCS is known to be short-lived in a large number of patients and that a substantial proportion of patients that are implanted with a WaveWriter device elect to have it surgically removed within two years of implant;

V. That a large proportion of patients implanted with a WaveWriter device have reported severe complications not enumerated in the Instructions for Use (IFU) that accompanies the product. These commonly reported complications include:

i. Chronic or permanent visual and/or cognitive disturbances;
ii. Chronic or permanent dysphagia;
iii. Cardiac arrhythmias;
iv. Chronic or permanent bowel and/or bladder incontinence;
v. Chronic or permanent ataxia and/or lower extremity weakness

VI. That the WaveWriter loses battery power rapidly, requiring frequent, long periods to recharge the device;

VII. That certain lead wire extenders commonly attached to the device render the device incompatible with Magnetic

Resonance Imaging.

80. On or about May 22, 2024, Plaintiff underwent surgery to remove the defective and malfunctioning Boston Scientific WaveWriter device, again by Dr. Justin Thomas. The device was malfunctioning because it was causing unrelenting and spontaneous sharp sensations and parasthesias.

81. Despite best efforts by Plaintiff to work with the Boston Scientific sales representatives and his medical providers, the device leads moved from their original positioning. As a result of this injurious malfunction, Plaintiff was routinely electrocuted by the faulty device, prompting Plaintiff to have the device removed.

82. Following the aforementioned encounter, Plaintiff began to experience additional complications, including spontaneous sharp sensations throughout his back, numerous and repetitive spinal shocks, and, notably, severe numbness in the fingertips of both hands, indicating significant nerve damage.

83. At no relevant time did Plaintiff abuse or misuse his SCS or its component parts.

84. At all relevant times Plaintiff complied with the directives and instructions associated with use of the device, namely, those set forth in the patient user manual and the instructions provided by Boston Scientific personnel.

85. At the time the Boston Scientific device was placed into Plaintiff's body, he was not advised, nor did he have any independent knowledge, that it was associated with or could cause the injuries enumerated herein.

86. Plaintiff's healthcare providers did not warn Plaintiff of the aforementioned risks with use of the WaveWriter because they were not warned of the risks.

87. Had Boston Scientific informed Plaintiff's healthcare providers of the true risks associated with the WaveWriter implants, Plaintiff's providers would have advised against

implantation of the WaveWriter device.

88. Boston Scientific, through its misrepresentations and omissions including their refusals or reckless failures to disclose or report defects and significant events as required by federal law (21 C.F.R. §§ 803.10(c), 803.50, 803.52 and other C.F.R. sections identified herein), and by state law which does not impose duties or requirements materially different from those imposed by federal law, concealed from Plaintiff and his healthcare providers the aforementioned risks associated with the WaveWriter implants. All conditions precedent to filing this action have occurred, or have been satisfied or waived.

BOSTON SCIENTIFIC'S DUTIES PURSUANT TO ITS PMA AND FEDERAL REGULATIONS

89. As conditions of Boston Scientific's PMA approval for its WaveWriter device, the FDA required Boston Scientific to submit annual post-approval reports pursuant to 21 CFR 814.84 to characterize the long-term performance and safety of the devices, as well as adverse events and device defect reporting.

90. In the PMA approval letter, the FDA further stated, "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

91. In addition to the duties in Boston Scientific's PMAs, Boston Scientific was required to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications set forth in applicable federal regulations, including, but not limited to, 21 C.F.R. Parts 803, 814 and 820.

92. Boston Scientific was also required to notify the FDA of any unexpected serious problems with its WaveWriter devices, including failure to operate due to battery defects.

93. Boston Scientific is required by federal law (and parallel state law in Michigan)

to sell and distribute only non-adulterated products pursuant to its PMA. A medical device is deemed adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. This duty is ongoing. *See* 21 U.S.C. § 351.

94. Boston Scientific is prohibited from selling and distributing misbranded products. A medical device is deemed misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling. This duty is ongoing. *See* 21 U.S.C. § 352(a). Moreover, restricted devices are deemed misbranded if "its advertising is false or misleading in any particular." 21

U.S.C. § 352(q).

95. Boston Scientific was also required to do the following:

I. Report to the FDA information suggesting that one or more of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur [21 C.F.R. § 803.50];

II. Monitor the product and report to the FDA any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 C.F.R. § 814];

III. Follow quality system requirements, found in 21 C.F.R. § 820, the CGMPs, that require manufacturers document all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues [21 C.F.R. § 820.100];

96. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as the WaveWriter implants, rests with the manufacturer.

97. This primary reporting obligation instills in Boston Scientific a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and

promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

98. Similarly, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

99. These duties establish that time is of the essence for Boston Scientific when reporting adverse events, especially, but not limited to, those adverse events indicating an association between its product and serious injuries.

100. Delayed reporting prevents the healthcare community and the public from timely learning of risks which informs physician and patient decision-making regarding treatments and procedures, and thereby exposes countless of additional women to potential harm.

BOSTON SCIENTIFIC'S PARALLEL MICHIGAN STATE LAW DUTIES

Boston Scientific's Warning Duties

101. Under Michigan law, Boston Scientific had a duty to provide an adequate warning to end users of its product of known potential harms that may result from use of its product. If the warning is given to an intermediary, here Plaintiff's implanting physician, the manufacturer will have satisfied this duty. Where the manufacturer does not provide warnings to the intermediary, as is the case here, the state-law duty is not satisfied.

Boston Scientific's Reporting Duties

102. Under Michigan law, Boston Scientific had a duty to abide by federal reporting requirements, including the timely and accurate reporting of adverse events.

103. As set forth above, adverse event reports published in the FDA's MAUDE

database represent a public communication by a manufacturer about a device's performance and its relationship to a particular adverse health event.

104. These adverse event reports, when prepared properly, serve as an early warning signal for the FDA in monitoring device performance, detecting potential device-related safety issues, and otherwise contributing to benefit-risk assessments of these products.

105. Moreover, such reports are relied upon by the medical and scientific community as a valuable source of information in learning about the genesis of a health event and the nature of any adverse health trends with a medical device.

106. To the extent the medical device reports contain false, inaccurate, or incomplete information, the FDA is deprived of vital information needed to detect potential device-related safety issues and disseminate public alerts about particular device problems and/or its association to a particular disease.

107. Likewise, the medical and scientific community is deprived of the information needed to educate their patients and obtain informed consent about the risks in choosing a particular device.

108. Further, device user facilities are unable to make informed decisions about the risks of offering for purchase a particular medical device over others on the market.

Boston Scientific's Testing Duties

109. Under Michigan law, a manufacturer has a duty to test adequately for known or foreseeable side effects which the manufacturer knows or has reason to know are inherent in the use of its product as measured by available scientific and medical data. The very purpose of conducting tests is to discover safety issues with a product in order to protect the public.

110. Also under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must adequately test, and validate

its product and its components, to assess any association between the product and any dangerous side-effect that could affect the safety of its products.

Boston Scientific's Manufacturing and Design Duties

111. Under Michigan law, Boston Scientific had a duty to comply with all government standards including design validation duties genuinely equivalent to those imposed under federal law. Specifically, Boston Scientific was obligated to use reasonable care in producing any product that, if carelessly made, is likely to injure persons when used in a foreseeable manner.

112. Likewise, a manufacturer has a duty to ensure the product is built in accordance with its intended specifications and a defect exists when an item is produced in a substandard condition.

113. Moreover, under Michigan law, Boston Scientific had manufacturing processes validation duties genuinely equivalent to those imposed under federal law. This duty requires reasonable care to be exercised in assembling component parts and inspecting and testing them before the product leaves the plant. This duty encompasses a manufacturer's obligation to employ appropriate quality control techniques to prevent manufacturing defects.

114. As a result of Boston Scientific's failure to establish quality systems as required by 21 C.F.R. § 820—its SCS devices were, at times, adulterated within the meaning of 21 U.S.C. § 351(h) when they were placed in the stream of commerce.

115. Plaintiff further alleges that Defendant failed to take reasonable post-market corrective and preventive action in order to validate its design and properly detect recurring quality problems related to the battery function of the WaveWriter device and to correct such quality problems.

116. Also under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must adequately inspect, test, and

validate its product and its components, and monitor its manufacturing and quality control processes to ensure there are no deviations from product specifications or regulations that could affect the safety of its products, such as Boston Scientific's implants.

PLAINTIFF'S IMPLANT HAD MANUFACTURING DEFECTS BASED ON BOSTON SCIENTIFIC'S VIOLATIONS OF CGMP REQUIREMENTS

117. The fundamental purpose of SCS devices is to provide relief from chronic pain. To continuously ensure that the SCS devices could adequately fulfill this purpose, they were subjected to numerous conditions, including the requirement that every implant manufactured by Boston Scientific would strictly adhere to the approved design standards and current good manufacturing practices.

118. By evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, and utilization of standard operating procedures, Boston Scientific could have assured the production of the WaveWriter implants that complied with its specifications and met the appropriate quality standards. Boston Scientific was under a continuing duty to follow the manufacturing and design specifications mandated by the FDA as part of the PMAs, and the general requirements set forth current good manufacturing practices ("CGMPs") provisions of the MDA governing the safety and effectiveness of a PMA medical device. *See* 21 U.S.C. 351; 21 C.F.R. Part 820.

119. Pursuant to the CGMPs regulations, Boston Scientific was obligated to implement and maintain quality control systems to validate processes and conduct inspections and testing to ensure the conformity with performance standards of the WaveWriter implants and not produce adulterated implants, specifically those which failed to provide the level of pain relief provided by the trial implant 21 U.S.C. 351; 21 C.F.R. § 820.

120. Notwithstanding this obligation, Boston Scientific distributed, at times, adulterated

implants that failed to perform in the same manner as the trial device in violation of manufacturing/ design specifications and CGMP regulations designed to ensure device quality and patient safety.

121. As a result, Boston Scientific failed to perform its duties properly, and failed to implement and maintain quality aware that its WaveWriter implants often could, and in Plaintiff's case, did fail the prescribed control systems with respect to performance standards for its WaveWriter implants, even though it was performance standards of 21 C.F.R. § 820 and 21 U.S.C. 351.

122. Plaintiff's implants were adulterated within the meaning of 21 U.S.C. 351(h) when they were placed in the stream of commerce by Boston Scientific, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the manufacturing/design specifications and CGMP design controls enumerated in 21 C.F.R. Part 820 designed to prevent exposing patients to risks of serious injury or death when the device is used as intended by the surgeon.

123. Boston Scientific violated these regulations, in part, by failing to establish norms and guidelines for functional validation. It was Boston Scientific's duty to comply with the PMAs and the FDA's Quality System Regulations and Current Good Manufacturing Practices as well as its state law duties.

124. Had Boston Scientific fulfilled its CGMP duties, as set forth above, it would have detected the broad nonconformance to performance standards for its devices and could have disposed of them prior to them being introduced into the stream of commerce.

125. As a result of Boston Scientific's post-market negligence in adhering to its CGMP requirements, the dangerous nature of the product became known only after having been implanted in Plaintiff and causing the injuries enumerated herein.

126. Had Boston Scientific fulfilled its CGMP duties, the non-conforming implant

would never have been implanted into Plaintiff's body.

127. Notwithstanding these duties, Boston Scientific violated 21 U.S.C. §§ 331, 351(h), and 21 C.F.R. Part 820 and its parallel state duties by introducing adulterated devices into interstate commerce.

A. Boston Scientific Violated 21 C.F.R. §§ 820.30(a)-(g), 820.70(a), 820.75 By Failing To Maintain Procedures To Control The Implant's Design and Manufacturing

128. The FDA mandates that medical device manufacturers must implement design control processes to assure: 1) user needs and intended uses are met, and 2) design is adequately transferred into manufacturing. Design controls are an interrelated set of practices and procedures incorporated into the design and development process, *i.e.*, a system of checks and balances. A manufacturer must develop a design control consistent with the design's risk, which will, in turn, determine the depth/level of actions required. Design controls make a systematic assessment of the design an integral part of post-approval requirements.

129. Design control does not end with the transfer of a design to production. Design control applies to all changes to the device or manufacturing process design, including those occurring long after a device has been introduced to the market. This includes evolutionary changes such as performance enhancements, and revolutionary changes such as corrective actions resulting from failed product analysis. The changes are part of a continuous, ongoing effort to design and develop a device that meets the user and/or patient's needs. Thus, a manufacturer must revisit the design control process frequently during the life of a product.

130. The quality system requirements dictate that, no matter what a manufacturer's processes may be, design controls must be applied appropriately to ensure device quality. That is, to say, manufacturers must establish and maintain procedures *at all stages* of the production process to ensure quality by requiring the ultimate output to conform to specified design

requirements. 21 C.F.R. § 820.30(a). Pursuant to 21 C.F.R. § 820.3(s), quality refers to the totality of features and characteristics that bear on the device's ability to satisfy fitness-for-use, including safety and performance.

131. Boston Scientific violated 21 C.F.R. §§ 820.30(a)-(g), 820.70(a), 820.75 by failing to establish and maintain procedures for validating the design of the implants. In particular, after the receipt of complaints of serious injuries demonstrating the device's failure to satisfy fitness-for-use, Boston Scientific failed to maintain proper procedures to ensure those finished devices were in conformance with the PMA quality requirements. Boston Scientific likewise failed to update its design quality procedures following corrective actions resulting from the analysis of products involved in serious injury events.

B. Boston Scientific Violated 21 C.F.R. § 820.50(a) By Failing To Ensure All Product Components Conform To Quality Requirements.

132. Pursuant to 21 C.F.R. § 820.50(a), manufacturers are required to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to quality requirements. Product refers to the components, manufacturing materials, in-process devices, finished devices, and returned devices. 21 C.F.R. § 820.3(r). Component includes any raw material, substance, piece, part, software, firmware, labeling, or assembly, which is intended to be included as part of the finished, packaged, and labeled device. 21 C.F.R. § 820.3(c).

133. The intent of Section 820.50(a) is to ensure that device manufacturers select only those suppliers, contractors, and consultants who can provide quality product and services. This is because the finished medical device's quality depends on the quality of the components and raw materials. Poor quality can cause injuries from the medical device, as well as recalls. Moreover, manufacturer diligence in complying with these requirements is critical because the FDA does not inspect component suppliers. Product or service suppliers are to be reviewed at intervals consistent

with the significance of the product or service provided and demonstrate conformance to specified requirements.

134. Boston Scientific violated 21 C.F.R. § 820.50(a) with respect to, *inter alia*, the lead extensions used in some devices which render the HFX incompatible with magnetic resonance imaging (MRI) in conformance with quality requirements. In contravention to federal requirements, the lead extensions used in of Plaintiff's implant procedure could not satisfy basic fitness for use.

C. Boston Scientific Violated 21 C.F.R. § 820.90(a) by Failing to Identify and Address Nonconforming Product and Processes

135. Anytime a device, or component thereof (21 C.F.R. § 820.3(r)), fails to meet any of its specifications (21 C.F.R. § 820.3(y)) that constitutes a nonconformity (21 C.F.R. 820.3(q)). Pursuant to 21 C.F.R. § 820.90(a), manufacturers shall establish and maintain procedures to control such nonconforming product that does not meet specifications. Nonconformances can occur in both product and process, and importantly, nonconforming processes, like Boston Scientific's manufacturing practices, can lead to nonconforming product.

136. When a nonconforming product or process is identified, a manufacturer must evaluate the nonconforming product. The evaluation of nonconformance must include a determination of the need for an investigation into the nonconformance. Investigations are required unless one has already been performed on a similar issue.

137. Upon identifying a nonconforming product or process, a manufacturer must segregate those devices to ensure they are not released and are ultimately disposed. Disposition of nonconforming product must be documented, including the justification for use of nonconforming product. Any such justification is to be based on objective scientific evidence.

138. Boston Scientific violated 21 C.F.R. § 820.90(a) by failing to establish and maintain

procedures to control SCS devices that do not conform to specification. This includes failing to identify nonconformities in relation to device impedance levels and other basic performance standards and evaluating the cause of the nonconformity. Rather than disposing of nonconforming products as required by the prevailing scientific evidence, Boston Scientific allowed them to be sold on the open market to consumers, including Plaintiff.

D. Boston Scientific Violated 21 C.F.R. § 820.100(a) by Failing to Take Necessary and Required Corrective and Preventive Action

139. A manufacturer's Corrective and Preventive Action ("CAPA") subsystem is intended to be the ultimate fail-safe against product and quality problems. CAPA requirements include collecting and analyzing information to identify actual and potential product and quality problems, investigating any problems discovered, taking appropriate and effective, and validate the effectiveness of the action taken. Whereas corrective action deals with eliminate the cause of a detected non-conformity or other undesirable situation, preventative action is designed to eliminate the cause of a potential non-conformity or other undesirable situation. Preventative action is required even when there is more than one cause for a potential nonconformity.

140. The procedures for implementing corrective and preventive action required under 21 C.F.R. § 820.100(a) must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities. CAPA requirements likewise apply to process and quality system nonconformities. The need for such action can be triggered by information coming from internal sources, such as test/inspection data and process control data, and external sources such as medical device reporting, customer complaints, and issues in similar devices from competitors.

141. Once a nonconformity is identified, a manufacturer must investigate the root cause of the nonconformities relating to product, processes, and the quality system. Nonconforming

product discovered before or after distribution must be investigated to the degree commensurate with the significance and risk of the nonconformity. Similarly, the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered.

142. Rather than engage in the required CAPA processes, Boston Scientific suppressed adverse events and inaccurately reported others as being unrelated to the device.

143. Despite possessing knowledge of the widespread product nonconformities and patient injuries, including but not limited to battery failure and malfunction, Boston Scientific failed to take corrective action with respect to its own manufacturing practices to mitigate the risk to patients like Plaintiff.

144. Boston Scientific, in violation of 21 C.F.R. § 820.100(a), failed to establish and maintain procedures for implementing corrective and preventive action in order to properly detect recurring quality problems related to the continued failures of the WaveWriter implants, investigate causes of nonconformities in these processes and products, identify necessary action to correct and prevent recurrence of nonconforming implants, and implement changes in methods to correct such quality problems. Despite repeatedly receiving reports and information about injuries such as those suffered by Plaintiff from internal and external sources, Boston Scientific conducted no investigations into the nonconformities and failed to take appropriate and required corrective action. Worse yet, out of pecuniary interests, Boston Scientific failed to thereafter take preventive action to prevent reoccurrence of the nonconformity.

E. Boston Scientific's Violations of Current Good Manufacturing Practices Rendered the WaveWriter Implants Adulterated Which Led to Plaintiff's Harm

145. Boston Scientific's post approval misconduct violated the PMAs, the manufacturing and design specifications, CGMPs, QSRs, other federal regulations and parallel

state law, resulting in the injuries which Plaintiff suffered.

146. The harms described above directly resulted from the variations from the approved design and manufacturing specifications. Had Boston Scientific utilized CGMPs and complied with QSRs, and undertaken the manufacturing process in an appropriate manner, it would have consistently produced a product in conformity with its approved specifications. Moreover, by evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, as well as utilization of standard operating procedures, Boston Scientific could have assured the production of the WaveWriter implants that complied with its specifications and met the appropriate quality standards.

147. The Boston Scientific WaveWriter device that was implanted into Plaintiff was *adulterated* in that they were not manufactured in conformity with the CGMP requirements identified above. *See* 21 U.S.C. §§ 351(h), 360j(f)

148. 21 C.F.R. § 808.1(d)(2)(ii) provides that, generally, § 521(a) of the FDCA *does not preempt* a state or local requirement prohibiting the manufacture of adulterated or misbranded devices.

149. Adulterated medical devices are not subject to preemption.

150. These specific allegations of violations of the federal PMAs, laws, regulations, and requirements due to manufacturing in violation of federal law are not subject to federal preemption.[16]

151. Boston Scientific's violations of the PMAs and violations of FDA requirements set forth in the QSRs and CGMPs, specifically, failure to adhere to 21 C.F.R. § 820.80 requiring the sequestration of devices that don't meet performance standards, was a direct cause of Plaintiff's injuries.

152. But for Boston Scientific's failure to comply with the above requirements,

including established post-market validation and correction obligations, Plaintiff would have decided against implantation and her injuries would not have occurred.

153. Similarly, Boston Scientific violated its parallel state law duties in failing to ensure conformity to its own PMA specifications and compliance with CGMPs, resulting in adulterated devices.

F. Boston Scientific Violated 21 C.F.R. § 803.19(b) And 21 C.F.R. §§ 803.50, *et seq*. By Employing A Flawed Database Algorithm That Ignored Cases of Serious Injuries from SCS Devices

154. A manufacturer must report adverse events no later than 30 calendar days after the day that it received or otherwise become aware of information, *from any source*, that reasonably suggests that a device may have caused or contributed to a death or serious injury or malfunctioned. 21 C.F.R. § 803.50 (emphasis added).

155. This reporting duty is triggered not just for events occurring within the United States and its territories, but also adverse events occurring in a foreign country concerning the device. *See* 21 C.F.R. § 803.52(e)(3) (incorporating by reference FDA Form 3500A, Block G).[24] Under the FDA's Medical Device Reporting for Manufacturers Guidance for Industry, the FDA considers an event that occurs in a foreign country reportable under the MDR regulations if it involves a device that has been cleared or approved in the United States—or a device similar to a device marketed by the manufacturer that has been cleared or approved in the United States—and is also lawfully marketed in a foreign country.

156. Boston Scientific's reporting requirements under federal law are stringent and any deviations therefrom requires express authorization by the FDA. 21 C.F.R. § 803.19(b). Absent an affirmative exemption, Boston Scientific was required to collect all of the information required by 21 C.F.R. § 803.52 that is known or reasonably known. By deliberating excluding pertinent event

information, Boston Scientific failed to comply with 21 C.F.R. § 803.19(b) through its use of its algorithm in this manner and as a result excluded reportable events from reporting despite never being granted an exemption to do so by the FDA. Boston Scientific was well-versed in the information to be collected and disclosed and had been fulfilling that obligation for decades for a variety of adverse events. And yet, when presented with numerous severe and life-threatening complications from its devices, it deliberately implemented a system that turned a blind eye to it.

157. As a result, Boston Scientific was engaged in inadequate post-market surveillance concerning:

f. The analysis of the incident outcomes broken down by SCS devices by device specification, in order to allow the inter-comparison of the Benefit/Risk ratio of the various SCS models;

g. the exhaustive list of the typologies of reported incidents, from the most frequent to the rarest ones; and

h. the in-depth analysis of the key points, issues and stakes stemming from the data related to adverse event cases, including the demonstration of the preservation of the SCS devices' Benefit/Risk ratio.

158. Under federal law, a medical device report must contain all the information required by 21 C.F.R. § 803.52 that is known or reasonably known to the manufacturer. Information considered reasonably known includes any information: 1) that can be obtained by contacting a user facility, importer, or other initial reporter; 2) that is in the manufacturer's possession; or 3) that can be obtained by analysis, testing, or other evaluation of the device. 21 C.F.R. § 803.50(b).

159. Likewise, the information to be disclosed is equally expansive. The reporting requirements are expansive, and a manufacturer "must include," amongst other items:

i. an identification of the adverse event or product problem;

j. a description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;

k. a summary of the evaluation of the device, or an explanation of why an evaluation was not performed;

l. evaluation codes;

m. whether remedial action was taken and the type of action; and

n. an explanation of why any required information was not provided in the MDR and the steps taken to obtain this information.

21 C.F.R. § 803.52.

160. Rather than complying with these obligations, Boston Scientific deliberately limited its reports to medical and scientific literature, *without further investigation.* This conduct falls well-short of the requirements of 21 C.F.R. §§ 803.50, *et seq*. Despite the public health crisis implicated by the product complaints it was receiving, for years Boston Scientific deliberately and unlawfully limited the information it was collecting about injuries from its devices, concealed how and when it was collecting it, and performed virtually no assessment of production impact on these events.

G. Boston Scientific Violated 21 C.F.R. §§ 803.1, 803.19(b), And 803.50 and Parallel State Law By Concealing Pertinent Adverse Event Reports

161. As complaints continued to rise in frequency, rather than complying with the federal statute and regulations on medical device reporting, Boston Scientific devised a scheme to use vague, boilerplate MDR analyses in connection with events associated with its products.

162. Had Boston Scientific lawfully reported adverse events until the time of Plaintiff's implantation or symptoms, he would not have suffered the injuries enumerated herein. Instead, the Plaintiff and his physician were both unaware of the extent of the risk of the injuries enumerated herein when the subject device was implanted, causing his serious injuries.

H. Boston Scientific's Reporting Abuses and Plaintiff's Harm Are Causally Related

163. The medical and scientific community relies on the FDA's MDR information, in particular the MAUDE database, for studying and evaluating new and emerging treatments and complications.

164. Also under Michigan law, which imposes duties genuinely equivalent to those

imposed by federal law, the manufacturer must act reasonably in conveying warnings concerning the safety of its products. Boston Scientific was, thus, under a continuing duty under state law to adequately report injuries and problems with its devices, including the products, to the FDA.

165. As a result of Boston Scientific's post-market failure to report to the FDA and as a result of Boston Scientific's post-market misconduct, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise would have never would have been implanted in the Plaintiff at all.

166. Had Boston Scientific properly reported the adverse events associated with its WaveWriter implants, the FDA would have included accurate accounts of those adverse event reports in the MAUDE database. Plaintiff's implanting physician, who visits the MAUDE database and reads adverse event reports prior to making product recommendations, would have seen the adverse event reports related to the WaveWriter and would have recommended safer treatment modalities for Plaintiff.

CAUSES OF ACTION
COUNT I –MANUFACTURING DEFECT

167. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

168. Defendant Boston Scientific designed, manufactured, distributed, and sold the WaveWriter Alpha SCS device, an inexcusably dangerous and malfunctioning product to Michigan consumers, including Plaintiff Dunham.

169. The WaveWriter implants were expected to, and did reach, Plaintiff without substantial change to their condition which was defective and unsafe, ultimately causing significant damages and permanent personal injury to Plaintiff.

170. Due to Defendant's injuriously defective product, Defendant is strictly liable to

Plaintiff for the injuries caused by Defendant's WaveWriter device.

171. No ordinary consumer would have contemplated or reasonably expected that the WaveWriter implants they had chosen would cause such injuries, because the devices are expected to work properly, when, in fact, they have caused serious injury as a result of their defective nature.

172. Neither Plaintiff nor his medical providers could, in the exercise of reasonable care, have discovered the manufacturing defect.

173. As a direct and proximate result of Defendant's defective product and in violation of Michigan and Federal statutes and regulations, Plaintiff has been caused to undergo reasonable and necessary medical examination and treatment. Plaintiff will also likely endure future medical care and treatment (including, but not necessarily limited to, surgery) with associated medical expenses.

174. As a direct and proximate result of Defendant's defective product and in violation of Michigan and Federal statutes and regulations, Plaintiff Dunham has been caused to endure physical and emotional pain and suffering associated with receiving random electrical shocks, intensive nerve damage in his hands, loss of enjoyment of the pleasures of life, lost past and future income, a decreased earning capacity, and restrictions and limitations of physical activities.

175. Boston Scientific manufactured Plaintiff's defective implants, in deviation of its specifications, which caused Plaintiff's injury.

176. Such manufacturing is in violation of state law, which does not impose duties or requirements materially different from those imposed by federal law including the PMA post-approval specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff.

177. Boston Scientific had parallel duties under state and federal law pursuant to the federal post- approval requirements, to exercise reasonable care in manufacturing the products

without deviations and defects.

178. Boston Scientific's duties do *not* add to or change Boston Scientific's manufacturing requirements. Nor does it require that Boston Scientific's implants be manufactured in a manner different from the FDA approved manner.

179. This claim parallels the FDA requirements that Boston Scientific manufacture its SCS devices to avoid plaintiff defect-related injury, in accordance with the FDA regulations and PMA specifications.

COUNT II– BREACH OF IMPLIED WARRANTIES

180. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

181. As set forth in the manufacturing defect section above, Boston Scientific sold its WaveWriter implants to Plaintiff in a defective condition which violated the FDA's requirements. Specifically, Boston Scientific, through material Boston Scientific has and continues to publish, misrepresented (prior to, at the time of, and after Dunham's surgery) the longevity, safety, and utility of the WaveWriter SCS device.

182. Boston Scientific knew that Plaintiff and his physician were purchasing the implants for chronic pain management, and both were relying on Boston Scientific to furnish suitable goods that adhered to its FDA specifications, including those that have percutaneous leads that maintain their position and function properly.

183. Plaintiff and his physicians also relied on the promises and representations of Boston Scientific's sales representatives, who told Plaintiff that he would be able to return to normal activities with the assistance of the WaveWriter device, and that he would be free of the chronic pain that plagued him for years prior to the implantation of the device. After they convinced

Plaintiff to have the device implanted, they abandoned him, and refused to provide assistance even after he began to experience severe shocks and pain from the malfunctioning device. The actions of the sales representatives fall outside the protections of the PMA for the WaveWriter, and are a violation of Boston Scientific's duty to provide truthful and accurate information about its medical devices.

184. As demonstrated by the random electric shocks Plaintiff Dunham sustained which replicated those experienced by others who had the WaveWriter, and by the fact Dunham has had the WaveWriter SCS device surgically removed, Dunham's WaveWriter was defective and did not have long term effectiveness and it did not aid in the management of his chronic intractable pain.

185. Plaintiff's claim for breach of warranty is based on Boston Scientific's non-compliance with its FDA specifications, and the false promises and omissions of its sales representatives, and does not add to or change anything required by the FDA.

186. The SCS did not mask pain impulses before they reach the brain to help patients including Plaintiff to manage their pain.

187. This breach of implied warranty claim, or the selling of non-conforming implants as though they have met all federal requirements, caused Plaintiff's injuries.

188. Plaintiff seeks to hold Boston Scientific accountable *only* for what federal law mandated - nothing more. Nothing in this claim is different from, or in addition to, the federal requirements.

189. Boston Scientific impliedly warranted that the product was fit for its particular purpose for which it was intended and of merchantable quality.

190. Boston Scientific breached the implied warranty of merchantability by selling products that were not of merchantable qualify and were not safe and fit for their intended use.

191. Plaintiff and Plaintiff's physician relied upon Boston Scientific's implied

warranties that the implants were manufactured in accordance with federal specifications, and that they would provide immediate relief from his chronic pain, and that Boston Scientific would provide programming assistance if the device malfunctioned.

192. Plaintiff's injuries are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

COUNT III–FAILURE TO WARN

A. Violation of Michigan Law for Failure to Provide Warnings

193. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

194. In Michigan, a manufacturer of a defective product owes a duty to warn of known risks associated with its products. A manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the learned intermediaries.

195. Likewise, under federal law, manufacturers of medical devices have an affirmative duty to include the FDA approved label with adequate directions for use with its products. *See* 21 U.S.C. § 352(f).

196. Boston Scientific failed to provide a label or warning, in any form, to Plaintiff's physician.

197. At the time Plaintiff Dunham purchased and had Defendant's WaveWriter implanted, Defendant Boston Scientific knew or should have known of the potential for and/or actual presence of the defect associated with the WaveWriter which directly led to Plaintiff's injuries. Having such knowledge, Defendant failed to provide adequate warnings and/or

instructions, both at the time of marketing and afterwards. Such failure constitutes a violation of Michigan law.

198. Had Plaintiff's physician been warned of the risk of the injuries Plaintiff suffered, he would have recommended a safe alternative and Plaintiff would not have been injured.

199. The state-based requirement to warn prescribing physicians does not add to or change any federal requirement and therefore is not preempted.

200. Defendants breached their duty by failing to provide any warning of the risk of Plaintiff's injuries with its devices to Plaintiff's physician.

201. Defendants' breach of their duty effectively stripped Plaintiff's physician, of the ability to provide accurate risk information and allow Plaintiff to make an informed decision about having Boston Scientific's implant implanted into his body.

202. Defendants' breach was the substantial and proximate factor in causing Plaintiff's injuries and suffering arising therefrom.

COUNT IV- NEGLIGENCE- PRODUCT LIABILITY

203. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

204. At all relevant times, Boston Scientific had a duty to Plaintiff to manufacture the implants properly in compliance with applicable regulations and FDA specification.

205. As set forth throughout this Complaint, Boston Scientific breached its parallel state and federal duties to Plaintiff and Plaintiff's physician, in the following ways, among others:

I. Failing to establish procedures for conducting quality audits and to conduct such audits to assure that the quality system was in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 C.F.R. § 820.22;

II. Failing to perform proper risk analysis as required by 21 C.F.R. § 820.30(g);

III. Failing to establish and maintain procedures for monitoring and control process parameters for validated processes to ensure that the specified requirements continue to be met as required by 21 C.F.R. §820.75(b);

IV. Failing to develop, conduct, control, and monitor production processes to ensure that devices conformed to specifications as required by 21 C.F.R. § 820.70(a);

V. Failing to investigate the cause of nonconformities relating to product, processes, and the quality system as required by 21 C.F.R. §820.100(a)(2); and

VI. Failing to identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems as required by 21 C.F.R. 820.100(a)(3);

206. Each of the above acts of negligence, whether acts of omission or commission, were a proximate cause of Plaintiff's injuries.

207. Nothing within this claim adds to or changes any federal requirements.

208. In violation of Michigan law, Defendant provided a defective product which failed to conform to the representations made by Defendant and its sales representatives with regard to its WaveWriter Alpha SCS device. Defendant also negligently and/or fraudulently misrepresented the safety and utility of Defendant's WaveWriter, and failed to render assistance to Plaintiff after the device malfunctioned. Specifically, Boston Scientific warranted the WaveWriter:

a) Would "aid in the management of chronic intractable pain."

b) Would "mask pain signals traveling to the brain" to help patients manage their pain."[11]

c) Would interrupt pain signals so that Dunham would not perceive them as pain.

d) Would reduce Dunham's pain significantly "by at least 50%".[12]

e) Was "safe and effective" for Dunham.[13]

209. Such misrepresentations (and others similar to them, including those made by

[11] See Boston Scientific, How Does SCS Therapy Work, available at https://www.bostonscientific.com/en-US/patients-caregivers/device-support/scs/how-scs-works.html (last visited April 9, 2025).
[12] Id.
[13] Id.

Boston Scientific sales representatives directly to Plaintiff) were relied upon by Dunham and/or his doctor when he decided to have the WaveWriter surgically implanted.

210. Boston Scientific's state law-based duties do *not* add to or change Boston Scientific's manufacturing requirements. Nor does it require that WaveWriter implants be manufactured in a manner different from the FDA approved manner.

211. This claim parallels the FDA requirements in that it requires Boston Scientific to manufacture its WaveWriter implants in accordance with the FDA regulations and PMA specifications.

JURY DEMAND

Plaintiff demands a trial by jury on all of the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter judgment in their favor and against Boston Scientic, awarding Plaintiff:

I. actual or compensatory damages including pain and suffering, emotional distress, disfigurement, loss of consortium, past and future medical expenses, and lost wages in such amount to be determined at trial and as provided by applicable law;

II. exemplary damages sufficient to punish and deter Boston Scientific and others from future negligent and reckless practices;

III. pre-judgment and post-judgment interest;

IV. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

V. any other relief the Court may deem just and proper.

Dated: April 29, 2025

Respectfully submitted,

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