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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CLIVE MAIR, ADRIA SCOTT, BEVERLY ALBERT, CARI GRAVES, EMMA BLUNTZER, GINA SANDONE, JUANA WOOD, HEATHER MARTIE, KATHRYN JONES, PATRICIA BROUSSARD, RHONDA SAVAGE, STEPHANIE TORRES, STEVEN VENCILL, TIMMY COOPER, DEBORAH PENNINGTON, JAMES PORTER and LYNNE POTTER

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

Case No. 3:26-cv-7144

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

COMPLAINT FOR DAMAGES

Plaintiffs **CLIVE MAIR, ADRIA SCOTT, BEVERLY ALBERT, CARI GRAVES, EMMA BLUNTZER, GINA SANDONE, JUANA WOOD, HEATHER MARTIE, KATHRYN JONES, PATRICIA BROUSSARD, RHONDA SAVAGE, STEPHANIE TORRES, STEVEN VENCILL, TIMMY COOPER, DEBORAH PENNINGTON, JAMES PORTER, and LYNNE POTTER** (collectively, "Plaintiffs," and each individually, a "Plaintiff") by and through undersigned counsel, bring this Complaint against Defendant ABBOTT LABORATORIES seeking damages (the "Action") as follows:

I. INTRODUCTION

1. This is a product liability action involving injuries sustained by Plaintiffs following the implantation and failure of spinal cord stimulator (SCS) systems designed, manufactured, and marketed by Defendant Abbott Laboratories ("Abbott"). The devices were implanted in Plaintiffs' bodies as a purported treatment for chronic pain, but they failed to perform as promised and instead caused serious harm.

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

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

4. Plaintiffs bring this Action under California, Arizona, Florida, Oklahoma, Texas, Pennsylvania, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois law, asserting both traditional product liability and statutory claims. Plaintiffs seek compensatory damages for Plaintiffs' injuries.

II. PARTIES, JURISDICTION, AND VENUE

5. Plaintiff Mair is a resident and citizen of the State of California, and a resident of Alameda County, California, a county in this District. At the time this Complaint is filed, Plaintiff resides in California. The devices at issue were implanted in Plaintiff in California. Plaintiff has received medical treatment related to the device in California. Plaintiff Mair had his Abbott SCS permanent device implanted on or about June 20, 2025.

6. Plaintiff Scott is a resident and citizen of the State of Arizona, and a resident of Maricopa County, Arizona. At the time this Complaint is filed, Plaintiff resides in Arizona. The devices at issue were implanted in Plaintiff in Arizona. Plaintiff has received medical treatment related to the device in Arizona. Plaintiff Scott had her Abbott SCS permanent device implanted on or about May 7, 2024.

7. Plaintiff Albert is a resident and citizen of the State of Florida, and a resident of Hernando County, FL. At the time this Complaint is filed, Plaintiff resides in Florida. The devices at issue were implanted in Plaintiff in Florida. Plaintiff has received medical treatment related to the device in Florida. Plaintiff Albert had her Abbott SCS permanent device implanted on or about April 2017.

8. Plaintiff Graves is a resident and citizen of the State of Oklahoma, and a resident of Cleveland County, Oklahoma. At the time this Complaint is filed, Plaintiff resides in Oklahoma. The devices at issue were implanted in Plaintiff in Oklahoma. Plaintiff has received medical treatment related to the device in Oklahoma. Plaintiff Graves had an Abbott SCS permanent device implanted on or about August 23, 2024.

9. Plaintiff Bluntzer is a resident and citizen of the State of Texas, and a resident of Jim Wells County, Texas. At the time this Complaint is filed, Plaintiff

resides in Texas. The devices at issue were implanted in Plaintiff in Texas. Plaintiff has received medical treatment related to the device in Texas. Plaintiff Bluntzer had her Abbott SCS permanent device implanted on or about February 9, 2024.

10. Plaintiff Sandone is a resident and citizen of the State of Pennsylvania, and a resident of Bucks County, Pennsylvania. At the time this Complaint is filed, Plaintiff resides in Pennsylvania. The devices at issue were implanted in Plaintiff in Pennsylvania. Plaintiff has received medical treatment related to the device in Pennsylvania. Plaintiff Sandone had her Abbott SCS permanent device implanted on or about August 8, 2024.

11. Plaintiff Wood is a resident and citizen of the State of Texas, and a resident of Hidalgo County, Texas. At the time this Complaint is filed, Plaintiff resides in Texas. The devices at issue were implanted in Plaintiff in Texas. Plaintiff has received medical treatment related to the device in Texas. Plaintiff Wood had her Abbott SCS permanent device implanted on or about 2022.

12. Plaintiff Martie is a resident and citizen of the State of Ohio, and a resident of Washington County, Ohio. At the time this Complaint is filed, Plaintiff resides in Ohio. The devices at issue were implanted in Plaintiff in Ohio. Plaintiff has received medical treatment related to the device in Ohio. Plaintiff Martie had her Abbott SCS permanent devices implanted on or about July 21, 2023, and December 5, 2023.

13. Plaintiff Jones is a resident and citizen of the State of Georgia, and a resident of Polk County, Georgia. At the time this Complaint is filed, Plaintiff resides in Georgia. Plaintiff Jones was implanted with the subject device in Tennessee, later resided in Georgia, underwent explantation in Georgia, and experienced device-related injuries and treatment in Tennessee and Georgia. Plaintiff Jones had her Abbott SCS permanent device implanted on or about August 19, 2024.

14. Plaintiff Broussard is a resident and citizen of the State of Louisiana, and a resident of Ascension Parish, Louisiana. At the time this Complaint is filed, Plaintiff resides in Louisiana. The devices at issue were implanted in Plaintiff in Louisiana,

where Plaintiff Broussard currently resides. Plaintiff has received medical treatment related to the device in Louisiana. Plaintiff Broussard had her Abbott SCS permanent devices implanted on or about September 2015.

15. Plaintiff Savage is a resident and citizen of the State of Texas, and a resident of Johnson County, Texas. At the time this Complaint is filed, Plaintiff resides in Texas. The devices at issue were implanted in Plaintiff in Texas, where Plaintiff Savage currently resides. Plaintiff has received medical treatment related to the device in Texas. Plaintiff Savage had her Abbott SCS permanent device implanted on or about June 28, 2024.

16. Plaintiff Torres is a resident and citizen of the State of Pennsylvania, and a resident of Lancaster County, Pennsylvania. At the time this Complaint is filed, Plaintiff resides in Pennsylvania. The devices at issue were implanted in Plaintiff in Pennsylvania. Plaintiff has received medical treatment related to the device in Pennsylvania. Plaintiff Torres had her Abbott SCS permanent device implanted on or about April 13, 2023.

17. Plaintiff Vencill is a resident and citizen of the State of Texas, and a resident of Williamson County, Texas. At the time this Complaint is filed, Plaintiff resides in Texas. The devices at issue were implanted in Plaintiff in Texas, where Plaintiff Vencill currently resides. Plaintiff has received medical treatment related to the device in Texas. Plaintiff Vencill had his Abbott SCS permanent device implanted on or about October 13, 2022.

18. Plaintiff Cooper is a resident and citizen of the State of Arizona, and a resident of Maricopa County, Arizona. At the time this Complaint is filed, Plaintiff resides in Arizona. The devices at issue were implanted in Plaintiff in Arizona, where Plaintiff Cooper currently resides. Plaintiff has received medical treatment related to the device in Arizona. Plaintiff Cooper had his Abbott SCS permanent devices implanted on or about December 15, 2017, and April 17, 2024.

19. Plaintiff Pennington is a resident and citizen of the State of Pennsylvania,

and a resident of Luzerne County, Pennsylvania. At the time this Complaint is filed, Plaintiff resides in Pennsylvania. The devices at issue were implanted in Plaintiff in Pennsylvania. Plaintiff has received medical treatment related to the device in Pennsylvania. Plaintiff Pennington had her Abbott SCS permanent device implanted on or about August 13, 2019.

20. Plaintiff Porter is a resident and citizen of the State of Texas, and a resident of El Paso County, Texas. At the time this Complaint is filed, Plaintiff resides in Texas. The devices at issue were implanted in Plaintiff in Texas. Plaintiff has received medical treatment related to the device in Texas. Plaintiff Porter had his Abbott SCS permanent device implanted on or about September 13, 2023.

21. Plaintiff Potter is a resident and citizen of the State of Indiana, and a resident of Lake County, Indiana. At the time this Complaint is filed, Plaintiff resides in Indiana. The devices at issue were implanted in Plaintiff in Indiana. Plaintiff has received medical treatment related to the device in Indiana and Illinois. Plaintiff Potter had her Abbott SCS permanent device implanted on or about May 20, 2019.

22. Defendant Abbott Laboratories is a corporation organized under the laws of the State of Illinois with its principal place of business located in Abbott Park, Lake County, Illinois. Abbott Laboratories is a global healthcare corporation engaged in the design, manufacture, promotion, and sale of medical devices, including spinal cord stimulation systems, throughout the United States, including in California, Arizona, Florida, Oklahoma, Texas, Pennsylvania, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois. Abbott Laboratories assumed ownership of the SCS device portfolio at issue following its acquisition of St. Jude Medical in 2017.

23. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claims occurred here, including the implantation of the devices in Plaintiff Mair, adjustment of Plaintiff's devices by Abbott's sales representatives, and representations made by Abbott's sales representatives to Plaintiff Mair.

24. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because the matter in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different states – specifically, Plaintiffs are domiciled in California, Arizona, Florida, Oklahoma, Texas, Pennsylvania, Ohio, Georgia, Louisiana, and Indiana, whereas Defendant is an Illinois corporation with its principal place of business located in Illinois.

25. This Court has personal jurisdiction over Defendant Abbott Laboratories because it conducts substantial business within this District, and has purposefully availed itself of the privileges of conducting activities within the State of California, Arizona, Florida, Oklahoma, Texas, Pennsylvania, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois, by maintaining sales representatives in those States, marketing its devices in those States, and causing injuries in those States as a result of the implantation of its devices.

Applicable Law and Choice of Law Considerations

26. This Action arises under state law. Plaintiffs bring state-law claims against Abbott Laboratories for personal injuries sustained as a result of Abbott's defective spinal cord stimulator systems, which were designed, regulated, and marketed from within this District.

27. Plaintiff Mair was implanted with the subject device in the State of California, currently resides in California, and experienced the injuries giving rise to this lawsuit in California.

28. Plaintiff Scott was implanted with the subject device in the State of Arizona, currently resides in Arizona, and experienced the injuries giving rise to this lawsuit in Arizona.

29. Plaintiff Albert was implanted with the subject device in the State of Florida, currently resides in Florida, and experienced the injuries giving rise to this lawsuit in Florida.

30. Plaintiff Graves was implanted with the subject device in the State of

Oklahoma, currently resides in Oklahoma, and experienced the injuries giving rise to this lawsuit in Oklahoma.

31. Plaintiff Bluntzer was implanted with the subject device in the State of Texas, currently resides in Texas, and experienced the injuries giving rise to this lawsuit in Texas.

32. Plaintiff Sandone was implanted with the subject device in the State of Pennsylvania, currently resides in Pennsylvania, and experienced the injuries giving rise to this lawsuit in Pennsylvania.

33. Plaintiff Wood was implanted with the subject device in the State of Texas, currently resides in Texas, and experienced the injuries giving rise to this lawsuit in Texas.

34. Plaintiff Martie was implanted with the subject device in the State of Ohio, currently resides in Ohio, and experienced the injuries giving rise to this lawsuit in Ohio.

35. Plaintiff Jones was implanted with the subject device in the State of Tennessee, had it explanted in the state of Georgia, currently resides in Georgia, and experienced the injuries giving rise to this lawsuit in Tennessee and Georgia.

36. Plaintiff Broussard was implanted with the subject device in the State of Louisiana, currently resides in Louisiana, and experienced the injuries giving rise to this lawsuit in Louisiana.

37. Plaintiff Savage was implanted with the subject device in the State of Texas, currently resides in Texas, and experienced the injuries giving rise to this lawsuit in Texas.

38. Plaintiff Torres was implanted with the subject device in the State of Pennsylvania, currently resides in Pennsylvania, and experienced the injuries giving rise to this lawsuit in Pennsylvania.

39. Plaintiff Vencill was implanted with the subject device in the State of Texas, currently resides in Texas, and experienced the injuries giving rise to this

lawsuit in Texas.

40. Plaintiff Cooper was implanted with the subject device in the State of Arizona, currently resides in Arizona, and experienced the injuries giving rise to this lawsuit in Arizona.

41. Plaintiff Pennington was implanted with the subject device in the State of Pennsylvania, currently resides in Pennsylvania, and experienced the injuries giving rise to this lawsuit in Pennsylvania.

42. Plaintiff Porter was implanted with the subject device in the State of Texas, currently resides in Texas, and experienced the injuries giving rise to this lawsuit in Texas.

43. Plaintiff Potter was implanted with the subject device in the State of Indiana, currently resides in Indiana, and experienced the injuries giving rise to this lawsuit in Indiana.

44. However, significant aspects of the design, manufacture, regulatory strategy, and labeling of the device occurred within the State of Illinois. Defendant Abbott Laboratories is headquartered in Lake County, Illinois, and its spinal cord stimulator operations, including FDA submissions, marketing approvals, and product development, were directed from that location at all relevant times.

45. Under Illinois choice of law principles, courts apply the "most significant relationship" test as set forth in the Restatement (Second) of Conflict of Laws, considering factors such as the place of injury, the place of conduct, the domicile of the parties, and the location where the relationship is centered. See *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 903 (Ill. 2007).

46. California, Arizona, Florida, Oklahoma, Texas, Pennsylvania, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois laws govern Plaintiffs' personal injury claims respectively, however, to the extent this action concerns Abbott's regulatory decisions, FDA submissions, and corporate conduct occurring in Illinois, Plaintiffs invoke Illinois law in the alternative for claims that arise from Defendant's

forum-based behavior.

III. FACTUAL ALLEGATIONS REGARDING ABBOTT LABORATORIES AND REGULATORY HISTORY

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

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

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

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

50. Due to these inherent risks, SCS devices are classified by the FDA as Class III medical devices. The federal regulatory framework is referenced solely to describe the type of safety information ordinarily available to manufacturers of implantable medical devices and relied upon by physicians when making treatment decisions, and not as an independent basis for liability.

B. Abbott Laboratories' Device Portfolio and Regulatory Approval History

51. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., requires that all Class III medical devices undergo pre-market approval ("PMA") by the United States Food and Drug Administration ("FDA") before they may be introduced into interstate commerce. The PMA process is the most rigorous pathway under the FDCA and is intended to ensure the safety and effectiveness of devices that support or sustain human life, prevent impairment of human health, or

present a potential unreasonable risk of illness or injury.

52. Once a PMA is approved, 21 C.F.R. § 814.39(a) prohibits any change to the design, materials, energy source, software, manufacturing process, or labeling of the device that could significantly affect its safety or effectiveness without submission of a new PMA or a panel-track PMA supplement. The manufacturer bears the burden of demonstrating continued safety and effectiveness for all significant changes. Manufacturers may not use the PMA supplement process as a backdoor to avoid new clinical testing or public review.

53. The spinal cord stimulator (SCS) systems implanted in Plaintiffs were marketed under PMA P010032, originally approved in 2001 for a basic neurostimulator system manufactured by Advanced Neuromodulation Systems, Inc. This predicate device consisted of an implantable pulse generator (IPG), fixed stimulation output parameters, a wired programming system, and a battery designed for limited-term use. This predicate system was called the Genesis Neurostimulation (IPG) System.

54. Since that time, Abbott and its predecessors submitted more than 230 PMA supplements, fundamentally transforming the device's internal firmware, waveform architecture, patient interface, battery design, wireless communication, and safety-critical stimulation parameters. Despite these cumulative changes, no new PMA has ever been required or submitted.

C. Material Changes to Device Architecture and Functionality

55. Upon information and belief, the following PMA supplements illustrate material modifications that independently or cumulatively significantly altered the device's safety and effectiveness:

Supplement #	Decision Date	Supplement Type	Device/Model	Description / Relevance
S025	01/29/2009	Real-Time Process	Genesis RC & Eon	Design/components/specification change
S028	03/19/2009	180-Day Track	Eon Mini	Manufacturer/location change

S058	09/14/2012	Real-Time Process	Eon Mini	Design/components/specification change
S066	03/15/2013	Real-Time Process	Eon Mini	Design/components/specification change
S068	05/17/2013	Real-Time Process	Eon Mini 2.0	Design/components/specification change
S073	04/25/2014	180-Day Track	Eon Mini	Manufacturer/location change
S086	11/13/2014	30-day notice	Eon Mini / Protégé / Protégé MRI	Platform/device family expansion
BurstDR Approval	10/2016	Approval	Prodigy / Proclaim Elite	BurstDR therapy approval (new stimulation pattern)
S125	07/21/2017	180-Day Track	Proclaim IPG Family	Platform evolution, new device family approval
S151	09/09/2019	Real-Time Process	Proclaim SCS Family	Labeling change (indications, trade name)
Proclaim XR Launch	09/26/2019	Press Release	Proclaim XR	Recharge-free, low-dose BurstDR launch
S167	08/18/2020	Real-Time Process	SCS IPG	Design/components/specification change
S187	08/19/2022	Real-Time Process	Proclaim SCS	Design/components/specification change
S189	01/24/2023	Panel Track	Prodigy / Proclaim / Proclaim XR	Indication expansion (e.g., DPN)
S213	06/26/2024	180-Day Track	SCS IPG Family	Design/components/specification change

56. These changes cumulatively altered the devices' mode of action, safety controls, stimulation effects, battery stability, and susceptibility to failure. Abbott did not conduct new clinical trials to validate these design changes and failed to disclose material risks to physicians and patients, including Plaintiffs.

57. On September 11, 2023, the FDA classified five separate Class I recalls of Abbott's Proclaim-series SCS devices, including the Proclaim DRG IPG, XR 5/7

IPGs, and Plus 5/7 IPGs. These recalls were issued in response to complaints from patients experiencing painful electric shocks, sudden device shutdowns, and failure to deliver therapeutic stimulation. These hazards arose from the very firmware, waveform, and interface changes introduced by the above-listed supplements.

58. On May 16, 2024, Abbott initiated a recall of the Proclaim 5 Elite SCS pulse generator due to a product labeling defect. This hazard arose from changes made through the PMA supplementation process.

59. These recalls illustrate that the cumulative effect of Abbott's modifications significantly impacted device performance and patient safety. Had these changes been submitted for a new PMA, as required by 21 C.F.R. § 814.39(a), the public, medical community, and FDA advisory panels would have had the opportunity to evaluate the altered risk-benefit profile before widespread market use.

60. Instead, Abbott was permitted to bypass that obligation. As a result, Plaintiffs received multiple devices that were fundamentally different from the system described in the original PMA, with undisclosed risks and unvalidated functionality that ultimately failed and caused Plaintiffs significant injuries and lasting harm.

61. That decision, coupled with the FDA's tolerance of nearly 250 design-altering PMA supplements over the next 20 years, allowed Abbott to retain the litigation shield of PMA preemption while evading the corresponding regulatory burdens. This conduct exemplifies a dual-track deception: one track for approval, another for modification and marketing. This pattern of agency leniency is precisely the type of unchecked administrative discretion that the Supreme Court curtailed in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

IV. REGULATORY FRAMEWORK AND DUTIES

62. The FDA regulates Class III medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. Class III devices, including spinal cord stimulators, pose the highest risk to patient safety and are subject to the most stringent regulatory controls, including premarket approval ("PMA") and post-

market surveillance.

63. Manufacturers of PMA devices may not make changes that affect safety or effectiveness without prior approval of a new PMA or a panel-track supplement. See 21 C.F.R. § 814.39(a). This regulation imposes a nondiscretionary duty: material changes, whether in firmware, battery chemistry, stimulation parameters, user interfaces, or surgical instrumentation, require full review and public validation.

64. PMA approval also imposes ongoing federal duties, including:

- Postmarket adverse event reporting under 21 C.F.R. Part 803;
- Compliance with design controls (21 C.F.R. § 820.30);
- Manufacturing process validation (21 C.F.R. § 820.75);
- Complaint investigations and corrections under the CAPA rule (21 C.F.R. § 820.100);
- Truthful and non-misleading labeling, updated through 21 C.F.R. § 814.39(d).

65. The spinal cord stimulators implanted in Plaintiffs' bodies were not approved based on independent clinical trial data, but rather on a finding by the FDA that the devices were "sufficiently similar" to other SCS systems reported in the literature. See Summary of Safety and Effectiveness Data, P010032B, § 1.11. This "sufficient similarity" standard is less rigorous than the "substantial equivalence" requirement for 510(k) Class II clearance. Yet, it served as the evidentiary basis for granting Abbott's devices the powerful preemption protections afforded by PMA status.

66. In 2001, Advanced Neuromodulation Systems (ANS), the original sponsor of this device, submitted a petition asking the FDA to reclassify its SCS system from Class III to Class II. An expert advisory panel reviewed the data and agreed that reclassification was appropriate. The FDA overruled its own panel and denied the petition. Thereafter, the FDA approved the device as a Class III product, based not on new human clinical evidence, but on its alleged similarity to prior-generation devices.

67. That decision, coupled with the FDA's tolerance of nearly 250 design-altering PMA supplements over the next 20 years, allowed Abbott to retain the litigation shield of PMA preemption while evading the corresponding regulatory burdens. This conduct exemplifies a dual-track deception: one track for approval, another for modification and marketing.

68. If spinal cord stimulator manufacturers wish to benefit from PMA preemption, they must also bear the burden of compliance. Courts should not allow them to weaponize preemption as both sword and shield while quietly discarding the regulatory obligations that rationalize and support that protection.

69. The FDA has a statutory duty to prevent this erosion of Class III protections. By permitting Abbott to transform its device architecture without public clinical review, the agency has undermined the integrity of the PMA process.

V. PLAINTIFF-SPECIFIC ALLEGATIONS

70. On or about February 16, 2025, Plaintiff Mair underwent implantation of a trial spinal cord stimulator system (SCS) manufactured by Abbott. The trial implantation device was effective at providing pain relief. Before and during the trial period, Plaintiff Mair consulted with an Abbott representative named Natalie Irbham, who also programmed the trial and permanent devices.

71. On or about June 20, 2025, Plaintiff Mair was surgically implanted with an Abbott permanent spinal cord stimulator system (SCS). The permanent device implantation proved to be ineffective at managing pain.

72. A few months after the permanent spinal cord stimulator (SCS) was implanted, the device stopped working and failed to provide Plaintiff Mair with pain relief. The SCS device provided therapy to Plaintiff Mair's chest and sides instead of his lower back, where his pain was located. Plaintiff Mair complained of the malfunctioning device directly to Abbott without his doctor being present. In response, Abbott representative Natalie Irbham reprogrammed the SCS device. However, the SCS device malfunctioned and stopped working.

73. Abbott representative Natalie Irbham continued to reprogram the SCS device approximately six times, which caused Plaintiff Mair to suffer electric shock sensations on his chest which made him believe that he was having a heart attack. Every adjustment by Abbott representative Natalie Irbham worsened Plaintiff Mair's pain.

74. The Abbott permanent spinal cord stimulator system (SCS) proved to be ineffective at treating Plaintiff Mair's pain. The malfunctioning device caused worsening pain, tingling and pain at the surgery site, chest pain, leg stiffening when activated, back pain, and lead migration.

75. Due to the ineffectiveness of the SCS device and worsening pain, Plaintiff Mair decided to undergo surgical explantation of the SCS device. Plaintiff Mair continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

76. Plaintiff Scott met with an Abbott representative before undergoing a trial implantation with an Abbott spinal cord stimulator (SCS) device. The Abbott representative stated to Plaintiff Scott that the trial and permanent SCS devices "are the best thing in the world" at relieving pain. On or about April 9, 2024, Plaintiff Scott underwent a trial implantation with an Abbott SCS device.

77. On or about May 7, 2024, Plaintiff Scott underwent permanent implantation with an Abbott spinal cord stimulator (SCS) device. Unlike the trial SCS device, the permanent SCS device did not provide Plaintiff Scott pain relief. The SCS device wires were found to be disconnected.

78. Plaintiff Scott complained to Abbott and met with three representatives named Allie, Milton, and Alex, without her doctor being present. The Abbott representatives attempted to reprogram the malfunctioning SCS device. However, the device continued to malfunction and proved ineffective at treating Plaintiff Scott's pain. The Abbott representatives stated to Plaintiff Scott the SCS device was not malfunctioning.

79. The first permanent Abbott spinal cord stimulator (SCS) system was

explanted from Plaintiff Scott due to failure to provide pain relief and disconnected lead wires.

80. On or about September 3, 2024, Plaintiff Scott underwent another implantation with a replacement Abbott spinal cord stimulator (SCS) device. After approximately six months, the permanent SCS, like the initial implantation, proved to be ineffective and failed to provide therapy to Plaintiff Scott.

81. Plaintiff Scott continued to meet with Abbott representatives to reprogram the device without her doctor being present. Abbott representatives continued to state to Plaintiff Scott that the SCS device was not defective.

82. Like the first permanent implantation, the Abbott SCS device failed to provide Plaintiff Scott with pain relief. The initial permanent and replacement implantations with an Abbott SCS device caused Plaintiff Scott worsening pain, electric shock sensations on her chest, increased lower back pain, leg pain, and inability to walk when activated.

83. Plaintiff Scott complained to her doctor of the failure of the two Abbott SCS devices and demanded explantation. Plaintiff Scott's doctor agreed to explant the device.

84. Plaintiff Scott underwent final surgical intervention to remove the spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Scott continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

85. Plaintiff Albert met with Abbott representatives before undergoing trial implantation with an Abbott spinal cord stimulator system (SCS).

86. On or about April 2017, Plaintiff Albert underwent permanent implantation with an Abbott spinal cord stimulator system (SCS). Initially the permanent SCS device provided therapy to Plaintiff Albert. However, the SCS device became painful. Plaintiff Albert met with three Abbott representatives named Michael Lachey, Debbie, and Lorenzo without her doctor being present.

87. The Abbott representatives reprogrammed Plaintiff Albert's SCS device at least three times to relieve the pain. However, the SCS device continued to be ineffective at managing pain.

88. Plaintiff Albert experienced electric shocks from the device and turned it off. However, the device continued to shock Plaintiff Albert even when turned off. The Abbott representatives stated to Plaintiff Albert that she should not have been experiencing electric shocks.

89. In approximately 2018, Plaintiff Albert underwent surgical intervention due to the Abbott SCS device migrating and surfacing through the skin and a battery replacement.

90. The permanent SCS device failed to manage Plaintiff Albert's pain, caused worsening pain, electric shock sensations, device migration, and burning sensations around the implantation site.

91. Plaintiff Albert underwent final surgical intervention to remove the spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Albert continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

92. On or about August 23, 2024, Plaintiff Graves underwent permanent implantation with an Abbott spinal cord stimulator (SCS) system after meeting with an Abbott representative named Kennedy without her doctor being present. Abbott representative Kennedy told Plaintiff Graves the permanent SCS device would provide pain therapy and programmed the SCS device.

93. After approximately two weeks, the Abbott SCS device stopped working and no longer provided Plaintiff Graves pain relief. Plaintiff Graves met with Abbott representative Kennedy and complained about the side effects of the SCS device. However, Abbott representative Kennedy appeared unsympathetic towards Plaintiff Graves' side effects.

94. The permanent Abbott spinal cord stimulator (SCS) system was

ineffective at treating Plaintiff Graves' pain and caused worsening pain, knee buckling, numbness, swelling of her legs, and tingling sensations.

95. On or about October 2024, Plaintiff Graves experienced a stroke and deactivated the SCS device.

96. The Abbott spinal cord stimulator (SCS) system is still implanted in Plaintiff Graves and remains turned off as it does not provide therapeutic pain relief. Plaintiff Graves continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

97. Plaintiff Bluntzer met with an Abbott representative named George Garcia prior to undergoing trial implantation with an Abbott spinal cord stimulator system (SCS). The Abbott representative stated the trial implantation would provide therapeutic pain relief and Plaintiff Bluntzer would no longer have to deal with pain. On or about November 23, 2023, Plaintiff Bluntzer underwent implantation with an Abbott trial SCS device. The trial SCS device proved effective at treating Plaintiff Bluntzer's pain. The Abbott representative George Garcia told Plaintiff Bluntzer that the permanent SCS device would work even better than the trial SCS device.

98. On or about February 9, 2024, Plaintiff Bluntzer underwent permanent implantation with an Abbott spinal cord stimulator system (SCS). The permanent Abbott SCS device was programmed by the Abbott representative, George Garcia.

99. Immediately after the permanent implantation with the SCS device, Plaintiff Bluntzer began to experience side effects and no pain relief. Plaintiff Bluntzer complained to the Abbott representative, George Garcia, about the side effects. The Abbott representative told Plaintiff Bluntzer she was not activating the device correctly, and retrained her on how to activate the SCS device. However, Plaintiff Bluntzer continued to experience side effects and pain from the permanent SCS device.

100. Plaintiff Bluntzer was given a new phone to operate the Abbott SCS device. However, the SCS device continued to be ineffective at providing therapy to Plaintiff Bluntzer. The Abbott representative George Garcia met with Plaintiff Bluntzer

several times to attempt to fix the device, but it was found to not be working properly.

101. The permanent Abbott spinal cord stimulator system (SCS) proved to be ineffective at treating Plaintiff Bluntzer's pain, caused worsening pain, electric shock sensations when turning the SCS device on or off, stabbing sensations, and debilitating pain in her back and ribs.

102. Plaintiff Bluntzer underwent final surgical intervention to remove the Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Bluntzer continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

103. On or about July 30, 2024, Plaintiff Sandone underwent implantation with an Abbott trial spinal cord stimulator system (SCS). Prior to the trial implantation, Plaintiff Sandone met with an Abbott representative that explained to her why she was receiving the trial SCS device, and that it would help treat her pain with little to no side effects.

104. On or about August 8, 2024, Plaintiff Sandone underwent implantation with a permanent Abbott spinal cord stimulator (SCS). The permanent SCS device was programmed by an Abbott representative named Dennis.

105. Approximately three weeks after the permanent SCS implantation, Plaintiff Sandone requested the Abbott representative Dennis to reprogram the device, as it was not proving adequate therapy. Abbott representative Dennis reprogrammed the SCS device at least once without Plaintiff Sandone's doctor being present.

106. Plaintiff Sandone felt relief briefly from the SCS device after reprogramming. However, the SCS device stopped working approximately one month after reprogramming. Plaintiff Sandone reached out to the Abbott representative, Dennis, about the lack of therapy from the permanent SCS device but never received a response.

107. The permanent SCS device proved to be ineffective at managing Plaintiff Sandone's pain and caused worsening pain, pain at the SCS unit site, burning

sensations, dizziness, urinary incontinence, abdominal pain and discomfort, diarrhea, and nausea.

108. The Abbott spinal cord stimulator (SCS) system remains implanted in Plaintiff Sandone. Plaintiff Sandone continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

109. After undergoing a spinal cord stimulator (SCS) trial, in or about 2022, Plaintiff Wood underwent permanent implantation with an Abbott spinal cord stimulator (SCS).

110. Plaintiff Wood's injuries worsened significantly after permanent implantation with the SCS device, and she began to experience urinary incontinence and hypertension and was placed on medications to treat those side effects caused by the permanent SCS device.

111. In approximately 2023, Plaintiff Wood experienced worsening pain, was treated with steroid injections, and began to experience electric shock sensations and dizziness.

112. In approximately 2024, Plaintiff Wood experienced burning sensations from the SCS unit itself, numbness in her extremities, and SCS lead wire migration.

113. Plaintiff Wood underwent final surgical intervention to remove the spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Wood continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

114. On or about June 19, 2023, Plaintiff Martie underwent a trial implantation with an Abbott lumbar spinal cord stimulator (SCS) device.

115. An Abbott representative programmed Plaintiff Martie's trial lumbar SCS device and met at least once without her doctor being present. A medical note stated an 85% reduction of pain. However, Plaintiff Martie did not experience therapeutic pain relief from the lumbar SCS trial device.

116. On or about July 21, 2023, Plaintiff Martie underwent permanent

implantation with an Abbott lumbar spinal cord stimulator (SCS) device.

117. Plaintiff Martie immediately started to experience electric shock sensations from the permanent lumbar SCS device along with new and worsening pain.

118. Plaintiff Martie complained of the side effects and worsening pain to an Abbott representative, and the device was reprogrammed by both the representative and her doctor. The permanent lumbar device was reprogrammed approximately three times. However, the lumbar SCS device continued to be ineffective at treating Plaintiff Martie's pain.

119. On or about July 26, 2024, Plaintiff Martie underwent surgical revision and repositioning of the permanent lumbar SCS device as it was causing her pain in the lumbar SCS generator site. The lumbar SCS device continued to cause Plaintiff Martie pain after the revision.

120. On or about October 23, 2023, Plaintiff Martie underwent a trial with a different Abbott device due to cervical pain. This time the device was a cervical spinal cord stimulator (SCS) device. Plaintiff Martie experienced approximately 70% reduction of cervical pain and agreed to proceed with permanent implantation.

121. On or about December 5, 2023, Plaintiff Martie underwent permanent implantation with an Abbott cervical spinal cord stimulator (SCS) device. However, Plaintiff Martie did not experience therapeutic pain relief from the cervical spinal cord stimulator (SCS) device.

122. Plaintiff Martie met with at least one Abbott representative before, during, and after the lumbar and cervical SCS trial and permanent implantations.

123. Both Abbott lumbar and cervical spinal cord stimulator (SCS) devices failed to provide Plaintiff Martie with therapeutic pain relief and instead caused worsening pain, electric shock sensations, left arm pain, and surgical revision.

124. Plaintiff Martie underwent final surgical intervention to remove both the lumbar and cervical spinal cord stimulator (SCS) devices due to mechanical and therapeutic failure of the devices. Plaintiff Martie continues to suffer from pain and

symptoms caused and exacerbated by the malfunctioning systems.

125. On or about June 2024, Plaintiff Jones underwent a trial implantation with an Abbott spinal cord stimulator system (SCS). The trial SCS device provided Plaintiff Jones with some pain relief.

126. On or about August 19, 2024, Plaintiff Jones met with an Abbott representative named Shannon on the day of the implantation at the doctor's office without the doctor present, and Shannon represented that the permanent SCS device would work better than the trial SCS device.

127. Initially, the permanent SCS device provided Plaintiff Jones with therapy. However, on or about August 25, 2024, Plaintiff Jones started to experience side effects of her right leg swelling to twice its normal size. The Abbott representative Shannon reprogrammed the SCS device over the phone approximately four times to treat the side effects.

128. Plaintiff Jones continued to meet with Abbott representative Shannon physically and over the phone, with many of these meetings occurring without Plaintiff Jones's doctor being present.

129. After numerous attempts at reprogramming Plaintiff Jones' permanent SCS device, Abbott representative Shannon noted that the SCS system was having problems and suggested explantation of the SCS device.

130. On or about September 2025, Plaintiff Jones started to experience severe electrical shock pains across her back and SCS device migration.

131. The permanent SCS device proved to be ineffective at managing Plaintiff Jones' pain, worsening symptoms following implantation, nerve damage, tremors when walking, bone disease not present prior to the permanent SCS implantation, suspected SCS device battery leakage, and two bacterial infections at or near the explantation site.

132. Plaintiff Jones underwent final surgical intervention to remove the spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device.

Plaintiff Jones continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

133. On or about September 2015, Plaintiff Broussard underwent permanent implantation with an Abbott spinal cord stimulator (SCS). Immediately following the permanent implantation with the SCS device, Plaintiff Broussard experienced burning and electric shock sensations from the SCS battery site.

134. Approximately three months post permanent SCS implantation, Plaintiff Broussard developed severe indigestion and symptoms consistent with gastroparesis.

135. Plaintiff Broussard met with an Abbott representative at her doctor's office and sometimes without the doctor present. The Abbott representative reprogrammed the SCS device to address the side effects Plaintiff Broussard was experiencing, as well as attempted to place the SCS device in MRI mode. The SCS device could not be placed in MRI mode, which prevented Plaintiff Broussard from receiving necessary MRI imaging.

136. The permanent SCS device continued to malfunction and was ineffective at managing Plaintiff Broussard's pain and caused worsening of pain.

137. Plaintiff Broussard underwent surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device.

138. On or about September 2023, Plaintiff Broussard was implanted with a second Abbott spinal cord stimulator (SCS) to replace the initial malfunctioning SCS device.

139. On or about November 2023, Plaintiff Broussard again started to experience burning and electric shock sensations at the SCS battery site. The second SCS device was ineffective at treating Plaintiff Broussard's pain, caused worsening pain and remained MRI incompatible.

140. Plaintiff Broussard underwent surgical intervention to remove the second malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and

therapeutic failure of the device.

141. On or about September 2024, Plaintiff Broussard underwent implantation with a third Abbott spinal cord stimulator (SCS) to replace the second malfunctioning SCS unit. Like the previous two implantations, Plaintiff Broussard experienced burning and electric shock sensations at the SCS battery site. The third SCS device proved to be completely ineffective at providing Plaintiff Broussard with therapy. The MRI mode did not function even after an Abbott representative attempted to program the device, which caused Plaintiff Broussard to be unable to get necessary MRI imaging on her back.

142. Plaintiff Broussard underwent final surgical intervention to remove the third malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device.

143. The three Abbott spinal cord stimulators implanted and explanted in Plaintiff Broussard were ineffective at providing pain relief, worsened her pain, caused burning and electric shock sensations at the SCS battery site, caused symptoms of gastroparesis, urinary incontinence, and multiple surgical interventions to replace the three malfunctioning SCS devices.

144. On or about June 2, 2024, Plaintiff Savage met with an Abbott representative during the trial of an Abbott spinal cord stimulator (SCS) system. The Abbott representative stated the trial SCS device would relieve her pain. The trial SCS device provided Plaintiff Savage with pain relief.

145. On or about June 28, 2024, Plaintiff Savage underwent permanent implantation with an Abbott spinal cord stimulator (SCS). An Abbott representative was present during the implantation surgery and told Plaintiff Savage the permanent SCS device would work better than the trial SCS device.

146. The permanent SCS device initially worked and provided Plaintiff Savage therapeutic pain relief for approximately one month after the permanent implantation and then stopped working.

147. Plaintiff Savage complained of the lack of pain therapy from the SCS device to the Abbott representative that was present during the permanent SCS implantation surgery. The Abbott representative reprogrammed the permanent SCS device approximately three times. However, the SCS device continued to malfunction and proved ineffective at treating Plaintiff Savage's pain.

148. Plaintiff Savage met with the Abbott representative approximately five times. Many of the meetings occurred without Plaintiff Savage's doctor present.

149. Plaintiff Savage continued to complain about the lack of therapy to the Abbott representative and was told to give the SCS device time to work.

150. The permanent SCS device proved to be ineffective at treating Plaintiff Savage's pain, caused worsening pain, burning sensations from the leg down to her ankle, and severe leg pain.

151. The Abbott spinal cord stimulator (SCS) system is still implanted in Plaintiff Savage and continues to malfunction and not provide therapeutic pain relief. Plaintiff Savage continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

152. Plaintiff Torres underwent a trial implantation with an Abbott spinal cord stimulator (SCS) after meeting with an Abbott representative before and after the implantation surgery through telephone, text messaging, emails and in person. Several of the meetings between Plaintiff Torres and the Abbott representative occurred at Plaintiff Torres's home without her doctor being present.

153. The permanent SCS device implanted in Plaintiff Torres was different from the SCS device used during the trial. The trial SCS device implanted provided Plaintiff Torres with pain relief.

154. On or about April 13, 2023, Plaintiff Torres underwent permanent implantation with an Abbott spinal cord stimulator (SCS). Unlike the trial SCS device, the permanent SCS device did not provide Plaintiff Torres with therapeutic pain relief.

155. After the permanent SCS device implantation, Plaintiff Torres began to

experience side effects, which include numbness and/or loss of feeling in her extremities, burning around the implantation site, and worsening pain.

156. Plaintiff Torres complained of the side effects to her doctor, who instructed her to contact an Abbott representative. An Abbott representative reprogrammed the SCS device approximately eleven times to alleviate the side effects Plaintiff Torres experienced. However, the SCS device reprogramming attempts were ineffective, and the side effects persisted.

157. Due to the malfunctioning SCS device, Plaintiff Torres experienced ineffective pain management, new and worsening pain, SCS device discomfort on her left buttock, acute lower back pain, SCS device-related neuropathic pain, numbness and/or loss of feeling on her extremities, burning around the implantation site, low blood pressure, nausea, vomiting, diarrhea, sleep disruption and insomnia.

158. Plaintiff Torres underwent final surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Torres continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

159. On or about September 22, 2022, Plaintiff Vencill underwent a trial implantation with an Abbott spinal cord stimulator (SCS). An Abbott representative programmed the SCS trial device after implantation in a recovery room. Plaintiff Vencill experienced pain relief from the trial SCS device and wished to proceed with permanent SCS device implantation.

160. On or about October 13, 2022, Plaintiff Vencill underwent permanent implantation with an Abbott spinal cord stimulator (SCS). The permanent SCS device was programmed by an Abbott representative.

161. The permanent SCS device was ineffective at providing therapeutic pain relief to Plaintiff Vencill and caused worsening pain.

162. After permanent SCS device implantation, Plaintiff Vencill began to experience severe neuropathy on both legs, frequent falls due to lower extremity

weakness, severe chronic leg pain, and pain at the implantation site. Plaintiff Vencill's doctor diagnosed him with mechanical complications of the SCS device and turned off the SCS device.

163. Plaintiff Vencill underwent final surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Vencill continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

164. On or about December 2017, Plaintiff Cooper underwent implantation of an Abbott spinal cord stimulator (SCS). An Abbott representative named Alex Palma assisted Plaintiff Cooper's doctor with the trial implantation.

165. On or about December 15, 2017, Plaintiff Cooper underwent permanent implantation with an Abbott spinal cord stimulator.

166. Plaintiff Cooper initially experienced relief from the permanent SCS device. However, the SCS lead migrated and fractured causing him severe shocking and burning pain. Plaintiff Cooper met with an Abbott representative approximately five to eight times to reprogram the device hoping to resolve the side effects, several of which occurred without his doctor present.

167. On or about April 20, 2022, Plaintiff Cooper underwent surgical intervention to replace the permanent SCS device battery due to the lead migration and fracturing.

168. On or about December 1, 2023, the permanent Abbott spinal cord stimulator (SCS) was explanted due to extreme discomfort experienced by Plaintiff Cooper caused by the SCS device battery on his right side.

169. Post explantation of the permanent SCS device, Plaintiff Cooper experienced significantly worsening back and bilateral buttock pain and requested another SCS device to be implanted to relieve the worsening pain.

170. On or about April 17, 2024, Plaintiff Cooper underwent implantation with a second Abbott spinal cord stimulator (SCS). Approximately four months post

implantation with the second SCS device, Plaintiff Cooper again reported continued burning pain on his right thoracic region, right flank wrapping-like pain, and right-sided rib pain that worsened when the SCS device was adjusted or he laid down.

171. Despite multiple reprogramming attempts of the second SCS device, Plaintiff Cooper was not experiencing therapeutic pain relief from the second SCS device.

172. Epidural fibrosis was identified in Plaintiff Cooper and became a concern that precluded revision or repositioning of the SCS device's paddle lead. However, Plaintiff Cooper requested complete removal of the second SCS device after exhausting all reprogramming options.

173. Plaintiff Cooper underwent final surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Cooper continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

174. In or about 2019, Plaintiff Pennington underwent trial with an Abbott spinal cord stimulator (SCS). Plaintiff Pennington experienced pain relief from the trial SCS device. Upon recommendation of her doctor, Plaintiff Pennington agreed to undergo permanent implantation with a SCS device.

175. On or about August 13, 2019, Plaintiff Pennington underwent permanent implantation with an Abbott spinal cord stimulator (SCS).

176. Shortly after implantation with the SCS device, Plaintiff Pennington reported having difficulty with programming the SCS device. An Abbott representative worked with Plaintiff Pennington to adjust the SCS device to provide adequate coverage and intensity.

177. Plaintiff Pennington started to experience electric shock sensations in her buttocks. The SCS device became ineffective at managing Plaintiff Pennington's pain and she began to experience chest pain, and rapid heartbeat.

178. In or about 2020, Plaintiff Pennington began to experience severe

dizziness and fainting.

179. In or about 2023, Plaintiff Pennington was diagnosed with gastroparesis and started to experience electric shocks from the SCS device.

180. Plaintiff Pennington continued to get her SCS device adjusted by Abbott representatives to resolve these side effects and worsening pain. However, the SCS device continued to be ineffective at pain management. Plaintiff Pennington started to experience increased lower back pain radiating into her lower thigh to the knee.

181. The permanent SCS device was ineffective at treating Plaintiff Pennington's pain, caused worsening pain, electric shock sensations, chest pain, rapid heartbeats, gastroparesis, severe dizziness and fainting, and increased lower back pain radiating into her thigh to her knee.

182. Plaintiff Pennington underwent final surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Pennington continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

183. On or about August 8, 2023, Plaintiff Porter underwent a trial implantation with an Abbott spinal cord stimulator (SCS). An Abbott representative reprogrammed the trial SCS device approximately two times. Plaintiff Porter experienced pain relief from the trial SCS device.

184. On or about September 13, 2023, Plaintiff Porter underwent permanent implantation with an Abbott spinal cord stimulator (SCS) device. An Abbott representative was present during the surgical implantation and programmed the SCS device.

185. Immediately after the permanent surgical implantation with the SCS device, Plaintiff Porter developed a severe headache.

186. On or about September 15, 2023, Plaintiff Porter was admitted to an emergency room due to a persistent headache, nausea, vomiting, and neck pain that began immediately after the permanent implantation with the SCS device. A CT scan

revealed that Plaintiff Porter had developed a hematoma and was admitted to a surgical intensive care unit. An additional CT scan revealed that Plaintiff Porter had developed tissue swelling around the SCS device.

187. On or about September 20, 2023, Plaintiff Porter again returned to the emergency room due to headaches, neck pain, and vomiting.

188. On or about November 7, 2023, an Abbott representative evaluated Plaintiff Porter's SCS device and noted it to be functioning adequately, even though Plaintiff Porter reported the SCS was turning on and off.

189. On or about February 5, 2024, Plaintiff Porter reported no longer receiving therapy from the permanent SCS device and could not place the SCS device in MRI mode. An Abbott representative attempted to reprogram the device to address those issues.

190. Due to the ineffective pain management of the permanent SCS device, Plaintiff Porter suffered worsening pain, severe headache, nausea, vomiting, neck pain, a subdural hematoma, loss of balance and dizziness, and spinal cord leakage.

191. Plaintiff Porter underwent final surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Porter continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

192. On or about April 9, 2019, Plaintiff Potter met with an Abbott representative named Ryan before undergoing a trial implantation with an Abbott spinal cord stimulator (SCS). The Abbott representative stated to Plaintiff Potter that the device would relieve her pain with little to no side effects. The trial device did provide Plaintiff Potter with pain relief.

193. On or about May 20, 2019, Plaintiff Potter underwent permanent implantation with an Abbott spinal cord stimulator (SCS).

194. Abbott representative Ryan programmed the permanent SCS device and stated to Plaintiff Potter that it would work better than the trial SCS device.

195. On or about August 15, 2019, Plaintiff Potter began to experience side effects from the permanent SCS device.

196. Plaintiff Potter met with an Abbott representative named Jessica, and other Abbott representatives, multiple times to reprogram the device. Many of these meetings occurred without Plaintiff Potter's doctor present at public parks, a Starbucks, a parking lot, Plaintiff Potter's home, and at the doctor's office.

197. The reprogram attempts by the Abbott representatives were ineffective and Plaintiff Potter continued to experience side effects and pain from the permanent SCS device.

198. Plaintiff Potter complained to her doctor about the ineffectiveness of the device and was directed to contact Abbott representative Jessica for continued adjustments.

199. Due to the ineffectiveness of the device and the side effects from the permanent SCS implantation, Plaintiff Potter decided to have the SCS device explanted.

200. Plaintiff Potter underwent final surgical intervention to remove the malfunctioning Abbott spinal cord stimulator (SCS) system due to mechanical and therapeutic failure of the device. Plaintiff Potter continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

201. Abbott's conduct with regard to these Plaintiffs represented a consistent pattern and practice.

202. Based on the representations made by the sales representatives, before, during and after the SCS trial period, Plaintiffs elected to be permanently implanted with the Abbott SCS systems.

203. Immediately after permanent implantation, Abbott representatives programmed and made therapeutic adjustments to the SCS system without meaningful physician supervision. This continued to occur on multiple occasions after Plaintiffs were implanted with the SCS system.

204. Throughout the time that Plaintiffs were implanted with SCS systems manufactured by Abbott or its predecessors, Plaintiffs were required to undergo additional procedures.

205. All leads used in the SCS systems implanted in Plaintiffs were manufactured and sold by Abbott or its predecessors.

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

207. Plaintiffs discovered the probable causal relationship between Plaintiffs' injuries and Abbott's conduct only after experiencing continued device-related complications, removal of the devices, and finally being informed about the underlying facts of the SCS that contradicted Abbott's representations.

208. Until Plaintiffs learned the underlying facts of the safety and efficacy of Abbott's SCS devices, Plaintiffs continued to believe that Plaintiffs' conditions and the efficacy of the devices were aberrations limited to Plaintiffs and not caused by a pattern and practice of Abbott.

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

VI. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

210. At all times relevant to this Complaint, Abbott Laboratories or its predecessors were responsible for the design, manufacture, testing, labeling, promotion, sale, post-market surveillance, and regulatory compliance of the spinal cord stimulator (SCS) systems implanted in Plaintiffs.

211. The devices marketed to Plaintiffs and Plaintiffs' healthcare providers as the Eon, Protégé MRI, and Proclaim XR 5 SCS systems bore little resemblance to the

device originally approved under PMA P010032. These devices incorporated multiple significant changes to the devices' hardware, firmware, user interface, waveform architecture, battery system, and wireless programming, each of which materially impacted the devices' safety, performance, and failure modes.

212. Despite these changes, Abbott never submitted a new PMA. Instead, the company submitted nearly 250 piecemeal supplements—many of which were processed under expedited review programs, including 30-day notices and real-time reviews—avoiding panel-track scrutiny and clinical revalidation.

213. Abbott failed to disclose that the devices implanted in Plaintiffs' bodies had never been tested through a full PMA-level clinical trial in human patients. The original approval of PMA P010032 was based not on manufacturer-sponsored trials, but on FDA conclusions that the Genesis system was "sufficiently similar" to other devices discussed in the literature. This flawed evidentiary standard was accepted by the FDA only after it overruled its own expert advisory panel, which had recommended reclassifying SCS devices from Class III to Class II.

214. Abbott relied on the full preemption shield of PMA status to market its device as safe and effective, while knowingly and repeatedly altering the system beyond what was originally validated. It failed to notify physicians or patients that the implanted device:

- Used firmware-dependent control systems absent from the predicate;
- Allowed smartphone-based patient programming via Bluetooth;
- Delivered burst and high-frequency stimulation patterns not subject to human testing under the PMA;
- Was affected by lead migration, communication delays, and unpredictable charging performance, as documented in MAUDE reports and adverse event summaries.

215. As previously alleged, between 2020 and 2023, Abbott initiated multiple recalls involving the Proclaim system. On September 11, 2023, the FDA classified five

recalls of Abbott's Proclaim XR and Proclaim DRG IPGs as Class I—its most serious category, reserved for devices that may cause serious injury or death.

216. These recalls were issued in response to patient complaints of:

- Painful electrical shocks;
- Sudden unintended stimulation;
- Loss of therapy;
- Device failure during recharging;
- Malfunctioning wireless communication and programming failures.

217. These malfunctions were directly linked to design and firmware changes made in PMA supplements between 2017 and 2022, including supplements S036 (Bluetooth programming), S043 (Proclaim XR rebranding), and subsequent firmware updates approved in S051–S062. Abbott knew or should have known that these cumulative changes significantly altered the device's safety and effectiveness.

218. On May 16, 2024, Abbott initiated a recall of the Proclaim 5 Elite SCS pulse generator due to a product labeling defect, arising from product labeling changes it had made to the device in Supplement S151. The product labeling of the Proclaim Elite SCS system was never subjected to PMA review and scrutiny.

219. Abbott failed to update product labeling, device manuals, or promotional materials to reflect the true performance characteristics of the altered device. Nor did it warn physicians or patients of the risks of stimulation failure, lead migration, charging errors, nerve damage, and device failure—despite mounting adverse event reports and internal design change documentation.

220. Abbott also failed to maintain adequate design validation and risk analysis documentation as required under 21 C.F.R. § 820.30(g), and failed to investigate and address post-market complaints as required by 21 C.F.R. § 820.198 and § 820.100.

221. These violations of FDA-mandated Current Good Manufacturing Practices (cGMPs) were not isolated or inadvertent. They reflect a systemic disregard for regulatory obligations, a practice of iterative design without public revalidation,

and a prioritization of market expansion over patient safety.

222. The defects in the Eon, Protégé MRI, and Proclaim systems, including the devices' design, firmware, labeling, and risk disclosure, were a direct and proximate cause of Plaintiffs' injuries. These defects existed at the time the devices left Abbott's control and were not known or reasonably knowable to Plaintiffs or Plaintiffs' physicians at the time of implantation.

223. At all relevant times, Plaintiffs used the products as intended and in a foreseeable manner. The products failed to perform as represented, and the manifested risks were not disclosed in the devices' labeling, Instructions for Use, or patient education materials.

224. Abbott's conduct was knowing, deliberate, and reckless. It knowingly placed a materially altered medical device into the stream of commerce, misrepresented its safety and approval status, and failed to correct known defects through regulatory pathways available under federal law.

225. Upon information and belief, the Proclaim Elite SCS systems and related system components implanted in Plaintiffs deviated from Abbott's FDA-approved manufacturing specifications for firmware execution stability, wireless programming reliability, and charging cycle consistency. These deviations resulted in stimulation shutoff, painful electric shocks, and therapy loss, all or some of which Plaintiffs experienced and have been reported by other users of the same device model.

226. The malfunctions leading to recalls of the Proclaim system reflect systemic deficiencies in Abbott's manufacturing processes and a failure to conform to its Quality System Regulation (QSR) obligations under 21 C.F.R. §§ 820.30(g), 820.75, 820.198, and 820.100. Abbott failed to adequately validate or monitor these performance characteristics post-market, despite prior complaints and adverse event reports.

227. The devices implanted in Plaintiffs were not reasonably safe at the time the devices left Abbott's and its predecessor's control, and the devices' malfunction

during regular use, which included loss of therapy and the need for surgical revision and removal, was a direct and foreseeable consequence of Abbott's failure to ensure adherence to its approved manufacturing controls. Plaintiffs' injuries were not caused by a known or disclosed risk; rather, Plaintiffs' injuries stemmed from defects in the execution of the products' firmware and power management systems, which were neither tested nor monitored in accordance with binding federal regulations. Moreover, these injuries resulted from latent manufacturing deviations, particularly in firmware execution and power management, that were not reflected in labeling or Instructions for Use and were undetectable by implanting physicians.

VII. CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Applicable State Product Liability Law)

228. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

229. At all times relevant to this action, Abbott Laboratories (hereafter reference to Abbott Laboratories shall include any applicable predecessor company, including St. Jude Medical) was engaged in the business of designing, manufacturing, testing, labeling, distributing, and selling medical devices, including the spinal cord stimulator systems implanted in Plaintiffs.

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

231. Specifically, as detailed in preceding allegations, the Proclaim XR systems implanted in Plaintiffs failed to conform with federal Quality System Regulations, including 21 C.F.R. §§ 820.30(g) (design validation), 820.75 (process

validation), 820.100 (corrective and preventive action), and 820.198 (complaint handling). These violations resulted in systemic defects in firmware execution, wireless programming reliability, and battery charging performance.

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

233. Plaintiffs' injuries were not caused by known or inherent risks of the devices when properly manufactured, but rather by departures from the devices' intended and approved construction. The products failed to perform as represented, and those products would not have failed but for Abbott's failure to comply with FDA-mandated specifications and manufacturing protocols.

234. Under California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Indiana, Tennessee, and Illinois law, Abbott is strictly liable for injuries caused by manufacturing defects that rendered the devices unreasonably dangerous at the time the devices left Abbott's control.

235. As a direct and proximate result of the manufacturing defects in the devices, Plaintiffs suffered physical injury, pain, medical expenses, loss of enjoyment of life, and other damages.

COUNT II – FAILURE TO WARN

(Failure to Warn Under Applicable State Law)

236. Plaintiffs incorporate by reference allegations set forth above as though fully set forth herein.

237. At all times relevant, Abbott Laboratories had a duty to provide adequate warnings and instructions regarding the known or reasonably foreseeable risks associated with its spinal cord stimulator systems, including the Eon, Protégé MRI, and Proclaim XR systems.

238. Under California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois law, a product is defective

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

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

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

241. The failure to warn was compounded by Abbott's internal knowledge of these risks, including MAUDE reports, post-market complaint data, and prior design and validation issues. Despite this knowledge, Abbott continued to represent the device as "safe and effective" and failed to initiate field safety notifications, device labeling changes, or provider education consistent with 21 C.F.R. § 814.39(d) or 21 C.F.R. § 820.198.

242. Plaintiffs and Plaintiffs' healthcare providers reasonably relied on Abbott's representations and omissions in deciding to proceed with implantation of the SCS devices. Had Plaintiffs and Plaintiffs' healthcare providers been adequately warned of the known risks, the devices would not have been implanted, or alternative treatments would have been pursued.

243. Plaintiffs' injuries were caused in whole or in part by Abbott's failure to warn of known or knowable dangers associated with the use of Abbott's products.

These failures rendered the devices unreasonably dangerous for the devices' intended use and constitute defects under California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois law.

244. As a direct and proximate result of Abbott's failure to warn, Plaintiffs suffered physical injury, pain, medical costs, surgical intervention, emotional distress, and other damages.

COUNT III – NEGLIGENCE PER SE – FEDERAL REGULATORY VIOLATIONS

(Under Applicable State Law)

245. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

246. Under California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois law, a person injured by the violation of a statute or regulation intended to protect the class of persons to which that person belongs may recover damages under a theory of negligence per se.

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

248. 21 C.F.R. § 814.39(a) – requiring new PMAs for changes that may affect device safety or effectiveness;

249. 21 C.F.R. § 803.50 – mandating adverse event reporting;

250. 21 C.F.R. § 820.30(g) – requiring design validation under expected use conditions;

251. 21 C.F.R. § 820.75 – requiring process validation to ensure consistent device output;

252. 21 C.F.R. § 820.198 – requiring investigation of complaints;

253. 21 C.F.R. § 820.100 – mandating corrective and preventive action (CAPA) when product failures are identified;

254. 21 C.F.R. § 814.39(d) – requiring labeling updates in response to known risks.

255. The devices implanted in Plaintiffs materially deviated from the systems approved in PMA P010032. The devices incorporated design and firmware changes that altered the devices' safety profiles, yet Abbott failed to file a new PMA or submit panel-track supplements, as required by 21 C.F.R. § 814.39(a). Abbott instead submitted piecemeal supplements and exploited expedited review programs to bypass clinical safety validation.

256. Abbott also failed to report adverse events linked to stimulation shutoff, therapy loss, and electrical shocks under 21 C.F.R. § 803.50. These adverse effects were known to Abbott prior to Plaintiffs' implantations and were consistent with reports subsequently leading to Class I recalls in 2023.

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

258. Each of these violations constitutes a breach of federal laws that were designed to protect a class of persons, of which Plaintiffs are members, against a particular type of harm.

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

260. As a direct and proximate result of Abbott's violations of federal regulations and California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois laws, Plaintiffs suffered compensable physical injury, pain, medical costs, loss of enjoyment of life, and other damages.

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

COUNT IV – BREACH OF EXPRESS WARRANTY

(Under Applicable State Law)

262. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

263. Under Illinois law, an express warranty is created when a seller makes an affirmation of fact or promise to the buyer that relates to the goods and becomes part of the basis of the bargain. See 810 ILCS 5/2-313; Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1123–24 (Ill. 2002). California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois laws are in accord.

264. Prior to the implantation of the Eon, Protégé, and Proclaim spinal cord stimulator devices, Abbott Laboratories made explicit representations in its promotional materials, device labeling, Instructions for Use (IFU), public statements, and directly to Plaintiffs through its sales representatives that the devices were safe, effective, reliable, and had been adequately tested for use in human patients suffering from chronic pain.

265. Abbott expressly warranted that its SCS devices provided consistent pain relief, seamless therapy delivery, safe wireless programming, and a rechargeable platform with superior reliability and patient comfort. Abbott's provider materials

represented that its SCS systems were "FDA-approved," "clinically validated," and "designed for long-term use with low complication rates." These claims were repeated in sales brochures, website copy, and Abbott's physician training materials. These claims were repeated directly to Plaintiffs through Abbott's sales representatives prior to Plaintiffs' implant decisions.

266. These affirmations and promises became part of the basis of the bargain between Abbott and Plaintiffs, as well as Plaintiffs' implanting physicians. Plaintiffs and Plaintiffs' physicians relied on these representations to proceed with the implantation of the Proclaim Elite systems.

267. In fact, the Proclaim Elite systems implanted in Plaintiffs had never undergone clinical validation in their final marketed forms. The FDA approved the systems based on "sufficient similarity" to earlier devices, not on Abbott-sponsored clinical trial data specific to the devices actually implanted. Abbott failed to disclose that its devices had been significantly altered through nearly 250 PMA supplements, nor that these changes materially affected the devices' safety and reliability.

268. The devices failed to perform as promised. Plaintiffs experienced therapy loss, painful electrical sensations, device lead migration, urinary incontinence, device communication failure, and required surgical revision and removal. The products were not safe, effective, or reliable as expressly warranted by Abbott, and Abbott failed to provide adequate warnings or updates contradicting its original claims.

269. Abbott's breach of its express warranties directly and proximately caused Plaintiffs' injuries. Had the devices performed as warranted, Plaintiffs would not have suffered worsening pain, adverse neurological symptoms, or required surgical intervention.

270. As a result of this breach of express warranty, Plaintiffs are entitled to recover all compensatory damages allowed under Illinois law, including medical expenses, pain and suffering, and other economic and noneconomic losses.

COUNT V – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

AND FITNESS FOR A PARTICULAR PURPOSE

(Under Applicable State Law)

271. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

272. Under Illinois law, a seller who is a merchant with respect to goods of that kind warrants that the goods shall be merchantable and fit for the ordinary purposes for which such goods are used. California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois laws are in accord.

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

274. When Abbott marketed and sold its SCS systems implanted in Plaintiffs, it impliedly warranted that the devices were of merchantable quality, conformed to FDA-approved specifications, and were reasonably safe for their intended medical purpose. Abbott also impliedly warranted that the devices were fit for the specific purpose of long-term implantation to treat Plaintiffs' conditions, as recommended by Plaintiffs' physicians.

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

276. These failures were not caused by misuse or physician error. They were the direct result of design-altering changes Abbott implemented without corresponding clinical testing or validation, and without disclosing these risks in labeling or provider materials. The devices failed to conform to the minimum standards of merchantability

and fitness for long-term neuromodulation therapy.

277. Abbott's breach of implied warranties was a proximate cause of Plaintiffs' injuries, including physical pain, surgical intervention, economic loss, and emotional distress. Plaintiffs would not have consented to the implantation had Plaintiffs or Plaintiffs' physicians known the devices were unfit for the devices' intended use.

COUNT VI – NEGLIGENCE

(Under Applicable State Law)

278. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

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

280. Abbott breached its duty of care 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 premarket complaints, post-market adverse event reports, and internal device testing;

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

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

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

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

282. Illinois law similarly imposes a duty on manufacturers to exercise ordinary care in the design, manufacture, labeling, and distribution of medical devices, including duties to investigate known hazards and warn of risks not adequately disclosed. California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois laws are in accord.

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

284. As a direct and proximate result of Abbott's negligence, Plaintiffs suffered physical pain, emotional distress, financial harm, and other compensable damages under California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Indiana, Tennessee, and Illinois law.

COUNT VII – NEGLIGENT MISREPRESENTATION

285. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

286. At all times relevant, Abbott Laboratories, in the course of its business, made representations to healthcare providers, patients, and the general public regarding the safety, effectiveness, regulatory status, and performance of its spinal cord stimulator systems.

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

288. These representations were false. As set forth in the preceding allegations, Abbott failed to disclose that: neither the Eon, Protégé, nor Proclaim devices had ever been clinically validated in their marketed forms; these devices had undergone significant design and firmware changes through more than 230 PMA supplements; these changes materially altered the devices' performance and introduced new, untested risks; and multiple recalls and adverse events had already emerged related to therapy shutoff, stimulation spikes, battery failure, and wireless programming.

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

290. Abbott also made these misrepresentations directly to Plaintiffs through its sales representatives, who misrepresented to Plaintiffs that the permanent SCS systems would provide Plaintiffs with long-term pain relief, were safe and backed by clinical validation, would be functionally equivalent to the trial SCS system, and would alleviate Plaintiffs' need to receive other treatment for Plaintiffs' chronic pain.

291. Plaintiffs' treating physicians reasonably relied on Abbott's

misrepresentations when selecting the Abbott system for implantation. Plaintiffs, in turn, relied on the statements made by Abbott in patient-directed materials and directly to Plaintiffs by Abbott and St. Jude Medical sales representatives, including assurance of FDA approval, therapy safety, and reliability, when consenting to implantation.

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

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

294. For avoidance of doubt, Plaintiffs allege misrepresentations were made to Plaintiffs and Plaintiffs' healthcare providers, not the FDA.

COUNT VIII – FRAUDULENT CONCEALMENT

295. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

296. At all times relevant, Abbott Laboratories had superior knowledge of critical facts concerning the safety, efficacy, and approval history of its spinal cord stimulator systems—information not available to Plaintiffs, Plaintiffs' treating physicians, or the general public.

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

298. Abbott actively concealed or failed to disclose that: the SCS systems had undergone extensive, untested design and firmware changes; the FDA had approved the devices based only on similarity to legacy SCS systems—not on new clinical trial data; known issues with therapy interruption, device shutdown during charging, and unintended stimulation had been internally reported, but not publicly disclosed; and that these issues resulted in multiple FDA recalls, including Class I recalls in 2023 and Class II recalls in 2024, matching the adverse experiences of Plaintiffs and other patients.

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

300. Plaintiffs and Plaintiffs' physicians justifiably relied on Abbott's omission of material safety information when consenting to implantation of the SCS systems. Plaintiffs were unaware—and had no way of knowing—that Abbott was concealing data and risks that materially affected the safety of these devices.

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

COUNT IX – Violation Of Consumer Protection Laws

302. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

303. Abbott Laboratories, through its consumer-oriented marketing, labeling, promotional efforts, and public communications, engaged in false, misleading, and deceptive acts and practices in connection with the promotion and sale of its spinal cord

stimulator systems that were implanted in Plaintiffs.

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

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

306. Plaintiffs and Plaintiffs' physicians reasonably relied on Abbott's omissions and misrepresentations when consenting to device implantation. Had the material facts been disclosed, Plaintiffs would not have proceeded with implantation.

307. As a result of Abbott's statutory violations, Plaintiffs suffered personal injury and economic loss and are entitled to recover all damages, equitable relief, and attorneys' fees available under state consumer protection laws.

COUNT X – NEGLIGENCE PER SE – UNAUTHORIZED PRACTICE OF MEDICINE

308. Plaintiffs incorporate by reference all allegations set forth above as though fully set forth herein.

309. The laws of California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois prohibit the unauthorized practice of medicine by any individual or corporate entity not licensed in California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, or Illinois, respectively. These prohibitions reflect a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

310. Abbott Laboratories is not licensed to practice medicine in California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, Illinois, or any other state. Nevertheless, Abbott exercised functional control over the administration of Plaintiffs' neuromodulation therapy by: actively participating in the implantation of Abbott's SCS systems in Plaintiffs' bodies, intraoperatively programming those SCS systems, and programming the SCS systems post-operatively; pushing firmware updates and stimulation programming changes remotely after implantation; designing and controlling preset therapy "profiles" that physicians could not override without manufacturer approval; and altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight.

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

312. Under California, Arizona, Florida, Oklahoma, Pennsylvania, Texas, Ohio, Georgia, Louisiana, Tennessee, Indiana, and Illinois law, violation of a safety statute gives rise to negligence per se where the injured parties are within the class the statute was intended to protect and the injuries are of the type the statute was designed to prevent.

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

314. In the alternative, Illinois law also prohibits the unlicensed practice of medicine. See 225 ILCS 60/3, 60/49. Abbott's corporate conduct originating from its Illinois headquarters violated that statute by enabling automated therapy changes and device behavior modulation outside the physician-patient relationship.

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

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

VIII. PRAYER FOR RELIEF

316. WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor and against Defendant Abbott Laboratories as to all counts and award the following relief:

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

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

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

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

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

f. The costs of this action; and

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

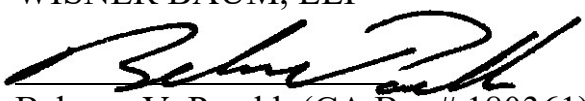
JURY TRIAL DEMAND

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

Dated: July 13, 2026

Respectfully submitted,

WISNER BAUM, LLP



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