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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

DOROTHY FURIA, ROSEANN MAROULIS, and ANITA MCCLELLAN,

Plaintiffs,

v.

ABBOTT LABORATORIES and the UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants.

Case No.

Plaintiffs **DOROTHY FURIA**, **ROSEANN MAROULIS**, and **ANITA MCCLELLAN** (collectively "Plaintiff" or "Plaintiffs") by and through undersigned counsel, and for their Complaint against Defendants **ABBOTT LABORATORIES** and the **UNITED STATES FOOD AND DRUG ADMINISTRATION** seeking damages as well as declaratory and injunctive relief (the "Action") as follows:

INTRODUCTION

This is a product liability and administrative law action involving injuries sustained by Plaintiff following the implantation and failure of a spinal cord stimulator (SCS) system 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.

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.

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

Plaintiff brings this Action under California, Indiana, Oklahoma, and/or Illinois law, and the federal Administrative Procedure Act ("APA"), asserting both traditional product liability and statutory claims. Plaintiff seeks compensatory damages for her injuries and equitable relief requiring the FDA to fulfill its statutory duties and restore integrity to the PMA process.

PARTIES

I. Plaintiffs

1. **Plaintiff** Dorothy Furia is a resident and citizen of the State of California, and a resident of Lake 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 Furia had her Abbott SCS permanent device implanted in June 2024.

2. **Plaintiff** Roseann Maroulis is a resident and citizen of the State of Indiana. At the time this Complaint is filed, Plaintiff resides in Schererville, Indiana. The devices at issue were implanted in Plaintiff in Indiana. Plaintiff has received medical treatment related to the device, including revision and removal of the device, in Indiana. Plaintiff Maroulis had her Abbott SCS permanent device implanted in March 2023.

3. **Plaintiff** Anita McClellan is a resident and citizen of the State of 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 McClellan had her Abbott SCS permanent device implanted in September 2018.

II. Defendants

4. **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, Illinois, Indiana, and Oklahoma. Abbott Laboratories assumed ownership of the SCS device portfolio at issue following its acquisition of St. Jude Medical in 2017.

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

JURISDICTION AND VENUE

6. *Subject Matter Jurisdiction.* 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, Indiana, and Oklahoma, whereas Defendant is an Illinois corporation with its principal place of business located in Illinois.

7. This Court also has federal question jurisdiction over Plaintiff's claims brought under the Administrative Procedure Act, 5 U.S.C. § 701 et seq., pursuant to 28 U.S.C. § 1331, as those claims arise under the laws of the United States.

8. *Personal Jurisdiction.* 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 by maintaining sales representatives in the State, marketing its devices in the State, and causing injuries in the State as a result of the implantation of its devices.

9. *Venue.* 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 device in Plaintiff Furia, adjustment of Plaintiff Furia's device by Abbott's sales representative, and representations made by Abbott's sales representative to Plaintiff Furia.

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FACTUAL ALLEGATIONS

III. APPLICABLE LAW AND CHOICE OF LAW

10. This Action arises under both federal and state law. Plaintiff brings federal claims against the United States Food and Drug Administration under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, and state-law claims against Abbott Laboratories for personal injuries sustained as a result of its defective spinal cord stimulator system, which was designed, regulated, and marketed from within this District.

11. Plaintiff Furia 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.

12. Plaintiff Maroulis 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.

13. Plaintiff McClellan, 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.

14. 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.

15. 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).

16. California, Indiana, and Oklahoma law governs Plaintiffs' personal injury claim 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.

IV. REGULATORY BACKGROUND AND PMA HISTORY

17. 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.

18. 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.

19. The spinal cord stimulator (SCS) system implanted in Plaintiff was 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.

20. 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.

21. 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

22. These changes cumulatively altered the device's 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 Plaintiff.

23. 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.

24. 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.

25. 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.

26. Instead, Abbott was permitted to bypass that obligation. As a result, Plaintiff 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 her significant injury and lasting harm.

27. 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).

V. REGULATORY FRAMEWORK AND FEDERAL DUTIES

28. 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.

29. 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.

30. 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).

31. The spinal cord stimulator implanted in Plaintiff's body was not approved based on independent clinical trial data, but rather on a finding by the FDA that the device was "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.

32. 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.

33. 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.

34. 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.

35. 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.

VI. ALLEGATIONS REGARDING THE FDA AND THE ADMINISTRATIVE PROCEDURE ACT

36. The Administrative Procedure Act, 5 U.S.C. §§ 701–706, authorizes judicial review of final agency actions where an agency acts arbitrarily, capriciously, or contrary to law, or unlawfully withholds nondiscretionary action.

37. Under 5 U.S.C. § 706(1), a court may compel agency action unlawfully withheld. Under 5 U.S.C. § 706(2)(A), it may set aside agency actions that are arbitrary, capricious, or in excess of statutory authority.

38. The FDA's decision to approve PMA P010032B was based on a regulatory shortcut. In its Summary of Safety and Effectiveness, the FDA explicitly stated that the device

had not been clinically tested in the relevant patient population but was "sufficiently similar" to prior devices. The device was therefore approved on a lower evidentiary basis than required for 510(k) clearance, yet afforded full preemption under *Riegel v. Medtronic*.

39. The FDA's refusal to require a new PMA despite significant changes to the device violates 21 C.F.R. § 814.39(a). Abbott's cumulative modifications, comprising firmware upgrades, battery redesigns, Bluetooth-based interfaces, and waveform expansions, render the current device materially different from that approved in 2001.

40. None of these changes were subject to panel-track review or public advisory panel input. The FDA approved them through real-time or 180-day supplement pathways without updated clinical safety data.

41. The FDA's passive endorsement of these changes, including its allowance of Abbott's continued marketing under an outdated PMA, constitutes a final agency action subject to judicial review. It also constitutes unlawful withholding of action required by law.

42. These regulatory failures were not inadvertent. They reflect the agency's long-standing practice of allowing iterative Class III device changes without substantive oversight, a practice that courts are no longer required to defer to following the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

43. Plaintiff seeks declaratory and injunctive relief under the APA. This includes a judgment that the FDA has violated nondiscretionary statutory and regulatory duties, and an injunction requiring the agency to review the Abbott SCS system through a new PMA, or to take enforcement action consistent with 21 U.S.C. § 360e and 21 C.F.R. § 814.39(a).

44. Plaintiff does not seek to second-guess FDA policy. Rather, she seeks to enforce the letter of the law. Abbott cannot continue to market a materially altered device under the guise of a 2001 approval that was never supported by clinical trial data in the first place.

45. The FDA must fulfill its statutory duties and restore integrity to the PMA process.

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VII. PLAINTIFF-SPECIFIC FACTUAL ALLEGATIONS

46. Plaintiffs Furia, Maroulis, and McClellan all had similar experiences related to their interactions with Abbott's sales representatives as well as the lack of efficacy, and experienced various additional side effects of the device.

47. Plaintiff Furia was initially implanted with a trial Abbott SCS followed by a permanent Abbott Eterna SCS in May 2024.

48. Plaintiff Furia was told by Abbott's sales representative that the permanent device would relieve most of Plaintiff Furia's pain. In reality, the device currently provides minimal pain relief, despite being both initially programmed by the sales representative as well as being reprogrammed multiple times after the initial programming.

49. Plaintiff Furia was met by Abbott's sales representative outside of the presence of her doctor during most of these visits.

50. Rather than experiencing relief of most of her pain, Plaintiff Furia has, instead, experienced bladder incontinence and electric shock sensations as a result of her Abbott SCS implant.

51. On or about January 26, 2023, Plaintiff Maroulis was surgically implanted with an Abbott trial spinal cord stimulator system. This implant procedure was performed by Dr. Vincent Tupper.

52. On or about January 30, 2023, Plaintiff Maroulis' trial spinal cord simulator system was removed.

53. On or about March 1, 2023, Plaintiff Maroulis was surgically implanted with an Abbott spinal cord simulator (SCS) system for the treatment of chronic pain. This implant procedure was performed by Dr. Mark Chang.

54. On or about April 29, 2023, Plaintiff Maroulis underwent revision surgery to revise a battery pocket in the Abbott SCS system. This occurred after Plaintiff Maroulis stated that the device's wires were poking out of her skin. This procedure was performed by Dr. Mark Chang.

55. Prior to the implant of the SCS system, Plaintiff Maroulis met directly with an Abbot sales representative named Jessica about the SCS system. The sales representative advised Plaintiff Maroulis that the permanent Abbott SCS system would provide Plaintiff Maroulis with long term pain relief and called it a "miracle surgery." These meetings occurred at the office of Dr. Mark Chang.

56. Following the implant of the SCS system, Plaintiff Maroulis met with this sales representative at least twice more for reprogramming. These meetings occurred at the office of Dr. Mark Chang.

57. Following the implant of the SCS system, this sales representative scheduled a meeting at a Dunkin Donuts coffee shop with Plaintiff Maroulis to ostensibly reprogram her device. The representative later cancelled the meeting.

58. Plaintiff Maroulis underwent final surgical intervention to remove the SCS system due to mechanical and therapeutic failure of the device. Plaintiff continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

59. Plaintiff McClellan was initially implanted with a trial Abbott SCS followed by a permanent Abbott SCS in June 2021.

60. Plaintiff McClellan was encouraged to say that the trial SCS device provided more pain relief than it actually did.

61. Plaintiff McClellan's trial SCS, however, actually was more effective at relieving her pain that her permanent SCS device.

62. Despite being promised pain relief, Plaintiff McClellan's permanent device provided minimal pain relief, despite being both initially programmed by the sales representative as well as being reprogrammed multiple times after the initial programming.

63. Plaintiff McClellan was met by Abbott's sales representative Devin outside of the presence of her doctor during most of these visits.

64. Rather than experiencing relief of most of her pain, Plaintiff McClellan has, instead, experienced numbness and loss of feeling in her extremities, bladder incontinence,

electric shock sensations, burning around the implant, and new and worsening pain as a result of her Abbott SCS implant.

65. Plaintiff McClellan underwent final surgical intervention to remove the SCS system due to mechanical and therapeutic failure of the device. Plaintiff continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

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

67. 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 system.

68. Immediately after the permanent implant surgery, 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.

69. Throughout the time that Plaintiffs were implanted with a SCS system manufactured by Abbott or its predecessors, they were required to undergo additional procedures.

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

71. 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.

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

73. Until Plaintiffs learned the underlying facts of the safety and efficacy of Abbott's SCS devices, they continued to believe that their conditions and the efficacy of the devices were an aberration limited to themselves and not caused by a pattern and practice of Abbott.

74. 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, have determined such truth. In fact, to this day, Abbott continues to insist that its SCS devices are safe and efficacious.

VIII. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

75. 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) system implanted in Plaintiff.

76. The devices marketed to Plaintiff and her 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 their hardware, firmware, user interface, waveform architecture, battery system, and wireless programming, each of which materially impacted the devices' safety, performance, and failure modes.

77. 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.

78. Abbott failed to disclose that the devices implanted in Plaintiff's body 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.

79. 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.

80. 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.

81. 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.

82. 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.

83. 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.

84. 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.

85. 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.

86. 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.

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

88. At all relevant times, Plaintiff used the product as intended and in a foreseeable manner. The product failed to perform as represented, and the manifested risks were not disclosed in the device's labeling, Instructions for Use, or patient education materials.

89. 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.

90. Upon information and belief, the Proclaim Elite SCS system and related system components implanted in Plaintiff 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 of which Plaintiff experienced and have been reported by other users of the same device model.

91. 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.

92. The devices implanted in Plaintiff were not reasonably safe at the time they left Abbott's and its predecessor's control, and their malfunction during regular use, which included loss of therapy and the need for surgical revision and removal, were a direct and foreseeable consequence of Abbott's failure to ensure adherence to its approved manufacturing controls. Plaintiff's injuries were not caused by a known or disclosed risk; rather, they stemmed from a defect in the execution of the product's 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.

CAUSES OF ACTION

I. Count I: Strict Products Liability – Manufacturing Defect (Against Abbott Laboratories)

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

94. 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 Plaintiff.

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

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

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

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

99. Under California, Indiana and Illinois law, Abbott is strictly liable for injuries caused by a manufacturing defect that rendered the device unreasonably dangerous at the time it left its control.

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

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II. Count II: Strict Products Liability – Failure To Warn (*Against Abbott Laboratories*)

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

102. 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 system, including the Eon, Protégé MRI, and Proclaim XR systems.

103. Under California, 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.

104. The spinal cord stimulator devices implanted in Plaintiff were materially altered from the system originally approved under PMA P010032. The systems she 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.

105. 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 its current form bore little resemblance to the device described in PMA P010032 or its Summary of Safety and Effectiveness Data.

106. 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.

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

108. Plaintiff's injuries were caused in whole or in part by Abbott's failure to warn of known or knowable dangers associated with the use of its product. These failures rendered the device unreasonably dangerous for its intended use and constitute a defect under Indiana and Illinois law.

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

III. Count III: Negligence Per Se – Federal Regulatory Violations (*Against Abbott Laboratories*)

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

111. Under California, 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**.

112. 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:

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

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

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

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

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

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

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

113. The device implanted in Plaintiff materially deviated from the system approved in PMA P010032. It incorporated design and firmware changes that altered its safety profile, yet 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.

114. 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 Plaintiff's implantation and were consistent with reports subsequently leading to Class I recalls in 2023.

115. 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.

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

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

118. As a direct and proximate result of Abbott's violations of federal regulations and California, Illinois, Indiana, and Oklahoma law, Plaintiff suffered compensable physical injury, pain, medical costs, loss of enjoyment of life, and other damages.

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

IV. Count IV: Breach Of Express Warranty (*Against Abbott Laboratories*)

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

121. 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, Indiana, and Oklahoma law are in accord.

122. 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 Plaintiff through its sales representatives that the device was safe, effective, reliable, and had been adequately tested for use in human patients suffering from chronic pain.

123. 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 Plaintiff through Abbott's sales representatives prior to each of her implant decisions.

124. These affirmations and promises became part of the basis of the bargain between Abbott and Plaintiff, as well as Plaintiff's implanting physician. Plaintiff and her physician relied on these representations to proceed with the implantation of the Proclaim Elite system.

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

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

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

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

V. Count V: Breach Of Implied Warranty Of Merchantability And Fitness For A Particular Purpose (*Against Abbott Laboratories*)

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

130. 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, Indiana, and Oklahoma law are in accord.

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

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

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

134. 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.

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

VI. Count VI: Negligence (Against Abbott Laboratories)

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

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

138. 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 experience of Plaintiff and other patients.

139. These negligent acts and omissions constitute breaches of both Abbott's duties under Indiana 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.

140. 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, Indiana, and Oklahoma law are in accord.

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

142. As a direct and proximate result of Abbott's negligence, Plaintiff suffered physical pain, emotional distress, financial harm, and other compensable damages under Indiana and Illinois law.

VII. Count VII: Negligent Misrepresentation (*Against Abbott Laboratories*)

143. Plaintiff incorporates by reference all allegation set forth above as though fully set forth herein.

144. 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.

145. 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.

146. These representations were false. As set forth in the preceding allegations, Abbott failed to disclose that: neither the Eon, Protégé, or Proclaim devices had never been clinically validated in its marketed form; these devices had undergone significant design and firmware changes through more than 230 PMA supplements; These changes materially altered its performance and introduced new, untested risks; and multiple recalls and adverse events had

already emerged related to therapy shutoff, stimulation spikes, battery failure, and wireless programming.

147. 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.

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

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

150. 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.

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

152. For avoidance of doubt, Plaintiff alleges misrepresentations were made to her and her healthcare providers, not the FDA.

VIII. Count VIII: Fraudulent Concealment (*Against Abbott Laboratories*)

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

154. 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 Plaintiff, her treating physician, or the general public.

155. 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.

156. 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 Plaintiff and other patients.

157. 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.

158. Plaintiff and her physician justifiably relied on Abbott's omission of material safety information when consenting to implantation of the SCS systems. Plaintiff was unaware—and had no way of knowing—that Abbott was concealing data and risks that materially affected the safety of thes devices.

159. Abbott's fraudulent concealment directly and proximately caused the Plaintiff's injuries, including her exposure to harmful device malfunctions, surgical intervention, and

resulting physical and emotional harm. Had the concealed risks been disclosed, Plaintiff would not have consented to implantation. The concealment of safety-related defects amounted to active fraud in the context of patient trust and medical device implantation. For the avoidance of doubt, Plaintiff is not alleging fraud on the FDA.

IX. Count IX: Violation Of Consumer Protection Laws (*Against Abbott Laboratories*)

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

161. 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 Plaintiff.

162. 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.

163. Plaintiff was a foreseeable consumer of the device. Although she relied in part on her physician's advice, Abbott engaged in direct-to-consumer advertising and disseminated patient-facing marketing materials that contained false or misleading information.

164. Plaintiff and her physician reasonably relied on Abbott's omissions and misrepresentations when consenting to device implantation. Had the material facts been disclosed, Plaintiff would not have proceeded with implantation.

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

//

X. Count X: Negligence Per Se – Unauthorized Practice Of Medicine (*Against Abbott Laboratories*)

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

167. Both California, Illinois, Indiana, and Oklahoma law prohibits the unauthorized practice of medicine by any individual or corporate entity not licensed in California or Indiana, respectively. These prohibitions reflects a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

168. Abbott Laboratories is not licensed to practice medicine in California, Illinois, Indiana, Oklahoma, or any other state. Nevertheless, Abbott exercised functional control over the administration of Plaintiff's neuromodulation therapy by: actively participating in the implantation of its SCS system in Plaintiff's body, intra operatively programing that SCS system, and programming the SCS system post-operatively; pushing firmware updates and stimulation programming changes remotely after implantation; designing and controlling preset therapy "profiles" that physicians could not override without manufacturer approval; and altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight.

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

170. Under California, Illinois, Indiana, and Oklahoma law, violation of a safety statute gives rise to negligence per se where the injured party is within the class the statute was intended to protect and the injury is of the type the statute was designed to prevent.

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

172. 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.

173. As a direct and proximate result of Abbott's unauthorized and unlicensed manipulation of Plaintiff's therapy, Plaintiff suffered harm, including painful stimulation, surgical revision, and other physical and emotional injuries. This harm was exacerbated by Plaintiff's loss of therapeutic control, wherein 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.

XI. Count XI: Violations Of The Administrative Procedure Act (Against the United States Food and Drug Administration)

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

175. Plaintiff brings this Count pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702–706, seeking judicial review of final agency actions, omissions, and regulatory decisions by the United States Food and Drug Administration related to its handling of Abbott's spinal cord stimulator system approved under PMA P010032 and its associated supplements.

176. The APA authorizes judicial review of agency action where a plaintiff suffers legal wrong due to agency conduct. See *Bennett v. Spear*, 520 U.S. 154, 162–64 (1997). A reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

177. As set forth above, the FDA approved the original spinal cord stimulator device under PMA P010032 in 2001. That approval relied not on device-specific clinical data, but on a conclusion that the device was "sufficiently similar" to existing devices, despite rejecting an advisory panel's recommendation to reclassify spinal cord stimulators to Class II. This allowed

the FDA to preserve Class III preemption status while simultaneously lowering the evidentiary bar for approval below the "substantial equivalence" standard applied to 510(k) Class II devices.

178. Since the original approval, the FDA has permitted Abbott to introduce more than 230 PMA supplements to P010032—many of which materially altered the design, functionality, safety, and risk profile of the device. These changes included: the introduction of new firmware-controlled stimulation algorithms; bluetooth-enabled physician and patient controllers; rechargeable battery platforms with new housing and architecture; and waveform modifications never evaluated in human clinical trials.

179. These modifications, individually and cumulatively, triggered the need for a new PMA under 21 C.F.R. § 814.39(a), which requires new approval when changes significantly affect safety or effectiveness. The FDA's failure to require such a submission constitutes a final agency action that is arbitrary, capricious, and contrary to law.

180. In addition, the FDA failed to take enforcement action under 21 C.F.R. §§ 814.82 and 820.198 despite repeated adverse event signals, public Class I recalls, and internal knowledge of systemic defects in therapy delivery, firmware stability, and wireless programming.

181. The FDA's inaction has permitted Abbott to continue marketing spinal cord stimulator systems, including the Eon, Protégé, and Proclaim systems, that no longer resemble the device originally reviewed and approved, without requiring the clinical validation, public scrutiny, or labeling accuracy that the PMA process is intended to ensure.

182. These omissions and failures have directly harmed Plaintiff and similarly situated patients by depriving them and their physicians of accurate, current, and transparent information necessary for informed medical decision-making, and by preserving federal preemption for a device that no longer qualifies for it under the law.

183. The FDA's conduct violates its statutory duty under 21 U.S.C. §§ 360c and 360e to protect public health by ensuring that PMA devices undergo proper review and are not materially altered without appropriate oversight.

184. Abbott cannot invoke PMA preemption to shield its conduct while disregarding the obligations that give that status legal meaning. This Court must require the FDA to fulfill its statutory duties and restore integrity to the PMA process. If SCS manufacturers wish to benefit from PMA preemption, they must also bear the burden of compliance.

PRAYER FOR RELIEF

185. **WHEREFORE**, Plaintiff respectfully requests that this Court enter judgment in her favor and against Defendant Abbott Laboratories as to all counts other than Count XI, and, with respect to Count XI, against the United States Food and Drug Administration, 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 Abbott's willful, malicious, and/or reckless disregard for the safety and rights of Plaintiff and the public;

d. Declare that the FDA's failure to require a new PMA for Abbott's spinal cord stimulator systems referenced herein violated the APA and applicable statutory and regulatory duties;

e. Declare that the FDA's approval and ongoing allowance of materially altered devices under PMA P010032 without new safety review is arbitrary, capricious, and contrary to law;

f. Enter appropriate injunctive relief requiring the FDA to initiate enforcement proceedings or PMA reevaluation under 21 C.F.R. §§ 814.39 and 814.82;

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

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

i. The costs of this action; and

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

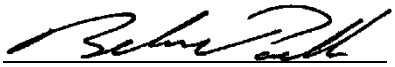
JURY TRIAL DEMAND

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

Dated: March 6, 2026

Respectfully submitted,

WISNER BAUM, LLP



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Facsimile: (310) 820-7444

Counsel for Plaintiffs

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of California

DOROTHY FURIA; ROSEANNE MAROULIS; and ANITA MCLELLAN,

Plaintiff(s)

v.

ABBOTT LABORATORIES; and UNITED STATES FOOD AND DRUG ADMINISTRATION

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Abbott Laboratories
c/o CT Corporation System
208 S. Lasalle St. Suite 814
Chicago, IL 60604-1101

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Behram V. Parekh (SBN: 180361)
bparekh@wisnerbaum.com
WISNER BAUM, LLP
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025
Tel: (310) 207-3233

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____
on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____
, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

JS-CAND 44 (Rev. 04-2025)

CIVIL COVER SHEET – for people without lawyers only

See Civil Local Rule 3-2 (amended April 28, 2025), which requires the filing of a civil cover sheet only by those unrepresented by counsel.

I. PLAINTIFF(S)

DOROTHY FURIA; ROSEANNE MAROULIS; and ANITA MCLELLAN

County of Residence of First Listed Plaintiff: Lake County, CA
Leave blank in cases where United States is plaintiff.

Attorney or Pro Se Litigant Information *(Firm Name, Address, and Telephone Number)*

WISNER BAUM, LLP
11111 Santa Monica Blvd., Suite 1750, Los Angeles, CA 90025; (310) 207-3233

DEFENDANT(S)

ABBOTT LABORATORIES; and UNITED STATES FOOD AND DRUG ADMINISTRATION

County of Residence of First Listed Defendant: Cook County, IL
Use ONLY in cases where United States is plaintiff.

Defendant's Attorney's Name and Contact Information *(if known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ U.S. Government Plaintiff
- ☐ Federal Question *(U.S. Government Not a Party)*
- ☐ U.S. Government Defendant
- ☒ Diversity

III. CAUSE OF ACTION

Cite the U.S. Statute under which you are filing: *(Use jurisdictional statutes only for diversity)*
28 U.S.C. § 1332(a)

Brief description of case: Product liability case related to injuries caused by medical device

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
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- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

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- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
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- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

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- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

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- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
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- ☐ 530 General
- ☐ 535 Death Penalty

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- ☐ 550 Civil Rights
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FORFEITURE/PENALTY
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- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

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- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent–Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 U.S.C. § 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ Original Proceeding
- ☐ Removed from State Court
- ☐ Remanded from Appellate Court
- ☐ Reinstated or Reopened
- ☐ Transferred from Another District
- ☐ Multidistrict Litigation–Transfer
- ☐ Multidistrict Litigation–Direct File

VI. FOR DIVERSITY CASES ONLY: CITIZENSHIP OF PRINCIPAL PARTIES

(Place an "X" in One Box for Plaintiff and One Box for Defendant)

Plaintiff	Defendant	
☒	☐	Citizen of California
☐	☐	Citizen of Another State
☐	☐	Citizen or Subject of a Foreign Country
☐	☐	Incorporated or Principal Place of Business In California
☐	☒	Incorporated and Principal Place of Business In Another State
☐	☐	Foreign Nation

VII. REQUESTED IN COMPLAINT

- ☑ Check if the complaint contains a **jury demand.**
- ☐ Check if the complaint contains a **monetary demand**. Amount:
- ☐ Check if the complaint seeks **class action** status under Fed. R. Civ. P. 23.
- ☐ Check if the complaint seeks a **nationwide injunction** or Administrative Procedure Act vacatur.

VIII. RELATED CASE(S) OR MDL CASE

Provide case name(s), number(s), and presiding judge(s).

IX. DIVISIONAL ASSIGNMENT pursuant to Civil Local Rule 3-2

(Place an "X" in One Box Only) ☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA-MCKINLEYVILLE

DATE 03/05/2026 **SIGNATURE OF ATTORNEY OR PRO SE LITIGANT**

COMPLETING THE CIVIL COVER SHEET

Complete the form as follows:

I. Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.

Attorney/Pro Se Litigant Information. Enter the firm name, address, telephone number, and email for attorney of record or pro se litigant. If there are several individuals, list them on an attachment.

II. Jurisdiction. Under Federal Rule of Civil Procedure 8(a), pleadings must establish the basis of jurisdiction. If multiple bases for jurisdiction apply, prioritize them in the order listed:

(1) *United States plaintiff.* Jurisdiction based on 28 U.S.C. §§ 1345 and 1348 for suits filed by the United States, its agencies or officers.

(2) *United States defendant.* Applies when the United States, its agencies, or officers are defendants.

(3) *Federal question*. Select this option when jurisdiction is based on 28 U.S.C. § 1331 for cases involving the U.S. Constitution, its amendments, federal laws, or treaties (but use choices 1 or 2 if the United States is a party).

(4) *Diversity of citizenship.* Select this option when jurisdiction is based on 28 U.S.C. § 1332 for cases between citizens of different states and complete Section VI to specify the parties' citizenship. Note: Federal question jurisdiction takes precedence over diversity jurisdiction.

III. Cause of Action. Enter the statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless jurisdiction is based on diversity. Example: U.S. Civil Statute: 47 U.S.C. § 553. Brief Description: Unauthorized reception of cable service.

IV. Nature of Suit. Check one of the boxes. If the case fits more than one nature of suit, select the most definitive or predominant.

V. Origin. Check one of the boxes:

(1) *Original Proceedings*. Cases originating in the United States district courts.

(2) *Removed from State Court*. Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C. § 1441. When the petition for removal is granted, check this box.

(3) *Remanded from Appellate Court*. Check this box for cases remanded to the district court for further action, using the date of remand as the filing date.

(4) *Reinstated or Reopened*. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

(5) *Transferred from Another District*. Check this box for cases transferred under Title 28 U.S.C. § 1404(a). Do not use this for within-district transfers or multidistrict litigation (MDL) transfers.

(6) *Multidistrict Litigation Transfer*. Check this box when a multidistrict (MDL) case is transferred into the district under authority of Title 28 U.S.C. § 1407.

(7) *Multidistrict Litigation Direct File.* Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

VI. Residence (citizenship) of Principal Parties. Mark for each principal party *only* if jurisdiction is based on diversity of citizenship.

VII. Requested in Complaint.

(1) *Jury demand.* Check this box if plaintiff's complaint demanded a jury trial.

(2) *Monetary demand*. For cases demanding monetary relief, check this box and enter the actual dollar amount being demanded.

(3) *Class action.* Check this box if plaintiff is filing a class action under Federal Rule of Civil Procedure 23.

(4) *Nationwide injunction.* Check this box if plaintiff is seeking a nationwide injunction or nationwide vacatur pursuant to the Administrative Procedures Act.

VIII. Related Cases. If there are related pending case(s), provide the case name(s) and number(s) and the name(s) of the presiding judge(s). If a short-form MDL complaint is being filed, furnish the MDL case name and number.

IX. Divisional Assignment. Identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated." Note that case assignment is made without regard for division in the following case types: Property Rights (Patent, Trademark and Copyright), Prisoner Petitions, Securities Class Actions, Anti-Trust, Bankruptcy, Social Security, and Tax.