KING LAW

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

WILLIAM FULLER, Plaintiff, v. ABBOTT LABORATORIES; UNITED STATES FOOD AND DRUG ADMINISTRATION Defendant.	Case No.: 1:25-cv-12714 **JURY TRIAL DEMAND**

COMPLAINT FOR DAMAGES AND
DECLARATORY AND INJUNCTIVE RELIEF

COMES NOW Plaintiff **William Fuller**, by and through undersigned counsel, and for his Complaint against Defendants **Abbott Laboratories**, and the **United States Food and Drug Administration** states and alleges 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. The device was implanted in Plaintiff's body as a purported treatment for chronic pain, but it failed to perform as promised and instead caused serious harm.

The SCS device at issue received FDA approval in 2001 under PMA P010032, originally granted to Advanced Neuromodulation Systems, later acquired by St. Jude's. 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. He suffered painful neurologic symptoms and worsening pain symptoms that required revision surgery and have left him permanently injured.

Plaintiff brings this action under Florida, New York, and/or Illinois law, and the Administrative Procedure Act, asserting both traditional product liability and statutory claims. He seeks compensatory damages for his injuries and equitable relief requiring the FDA to fulfill its statutory duties and restore integrity to the PMA process.

I. PARTIES, VENUE, AND JURISDICTION

1. Plaintiff William Fuller is a resident and citizen of the State of Florida. At the time this Complaint is filed, Plaintiff resides in Hudson, Florida. The device at issue was implanted in Plaintiff in Glens Falls, New York. Plaintiff has received medical treatment related to the device, including removal of the device, in Hudson, Florida.

2. 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 and the State of New York. Abbott Laboratories assumed ownership of the SCS device portfolio at issue following its acquisition of St. Jude Medical in 2017.

3. 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.

4. 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.

5. Venue is proper in the United States District Court for the Northern District of Illinois pursuant to 28 U.S.C. § 1391(b)(1) and (2) because Defendant Abbott Laboratories resides in this District and a substantial part of the events and omissions giving rise to the claims occurred here, including Defendant's regulatory decisions and corporate conduct relevant to the approval, marketing, and post-market surveillance of the device at issue.

6. This Court has personal jurisdiction over Defendant Abbott Laboratories because it conducts substantial business within this District, maintains its principal place of business here, and has purposefully availed itself of the privileges of conducting activities within the State of Illinois. The causes of action alleged herein arise from Defendant's forum-based conduct.

II. APPLICABLE LAW AND CHOICE OF LAW

7. This action arises under both federal and state law. Plaintiff brings federal claims against the United States Food and Drug Administration ("FDA") 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.

8. Plaintiff was implanted with the subject device in the State of New York, currently resides in Florida, and experienced the injuries giving rise to this lawsuit in Florida. Accordingly, Plaintiff's tort claims are governed by Florida law.

9. 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.

10. 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).

11. New York and Florida law, govern Plaintiff's personal injury claims. Specifically, New York law governs Plaintiff's fraud, misrepresentation, and Consumer Protection Act claims, since the representations made to Plaintiff by Defendant occurred in New York. To the extent this action concerns Abbott's regulatory decisions, FDA submissions, and corporate conduct occurring in Illinois, Plaintiff invokes Illinois law in the alternative for claims that arise from Defendant's forum-based behavior and decisions made within this District.

III. REGULATORY BACKGROUND AND PMA HISTORY

12. 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.

13. 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.

14. 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.

15. 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.

16. 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

17. 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.

18. 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.

19. 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.

20. 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.

21. Instead, Abbott was permitted to bypass that obligation. As a result, Plaintiff received a device that was fundamentally different from the system described in the original PMA, with undisclosed risks and unvalidated functionality that ultimately failed and caused him significant injury and lasting harm.

22. 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 FEDERAL DUTIES

23. 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.

24. 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.

25. 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).

26. 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 device the powerful preemption protections afforded by PMA status.

27. 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.

28. 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.

29. 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 give that protection meaning.

30. 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. ALLEGATIONS REGARDING THE FDA AND THE ADMINISTRATIVE PROCEDURE ACT

31. The Administrative Procedure Act ("APA"), 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.

32. 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.

33. 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*.

34. 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.

35. 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.

36. 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.

37. 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).

38. 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).

39. Plaintiff does not seek to second-guess FDA policy. Rather, he 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.

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

VI. PLAINTIFF-SPECIFIC FACTUAL ALLEGATIONS

41. Plaintiff William Fuller is a resident and citizen of the State of Florida. At the time this Complaint is filed, Plaintiff resided in Hudson, Florida. The device at issue was implanted in Plaintiff in Glens Falls, New York. Plaintiff has received medical treatment related to the device, including removal of the device, in Hudson, Florida.

42. On or about February 16, 2022, Plaintiff was surgically implanted with an Abbott-manufactured Proclaim Elite spinal cord stimulator system at Glens Falls Hospital in Glens Falls, New York. Dr. Fred Scialabba performed the procedure for the treatment of Plaintiff's chronic pain.

43. According to the medical records relating to the February 16, 2022 implant surgery, two Abbott representatives were present in the operative suite and programmed the Proclaim SCS system during the operation.

44. After the implant surgery, Abbott representatives programmed and made therapeutic adjustments to the Proclaim SCS system without meaningful physician supervision.

45. The implanted system included components from Abbott's Proclaim Elite platform, developed and marketed under PMA P010032 and its numerous supplements. The Proclaim Elite system incorporated functions and features not present in the predicate device originally approved in 2001.

46. Prior to the implant of the Proclaim Elite SCS system, Plaintiff was implanted with a temporary, external trial SCS system for a short period of time.

47. Prior to the implant of the Proclaim Elite SCS system, Plaintiff was directly contacted by telephone by an Abbott sales representative about the SCS system. The sales representative advised that the permanent Proclaim Elite SCS system would provide Plaintiff with long term pain relief, was 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 his chronic pain.

48. Based on the representations made by this sales representative, Plaintiff elected to be implanted with the Proclaim Elite SCS system.

49. On October 18, 2023, Plaintiff complained to a healthcare provider that his SCS system was no longer providing effective pain relief. In November 2023, Plaintiff requested a neurosurgery referral for evaluation and treatment of chronic pain and complications related to

the SCS system. The SCS system had begun to cause him pain in his chest and numbness in his lower extremities. Further, the SCS system no longer provided any pain relief.

50. Plaintiff was never informed that the system implanted in his body was materially different from the original device tested and approved under PMA P010032. Nor was he advised that the Proclaim Elite system had undergone multiple unvalidated changes in waveform programming, firmware, battery chemistry, or wireless programming, all without public clinical review or updated safety data. These waveform changes included high-frequency and burst stimulation modes, which can alter neuronal recruitment and autonomic nervous system response.

51. In January 2024, Plaintiff underwent 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.

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

VII. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

53. At all times relevant to this Complaint, Abbott Laboratories was 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.

54. The device marketed to Plaintiff and his healthcare providers as the Proclaim Elite SCS system bore little resemblance to the device originally approved under PMA P010032. It incorporated multiple significant changes to its hardware, firmware, user interface, waveform

architecture, battery system, and wireless programming, each of which materially impacted the device's safety, performance, and failure modes.

55. Despite these changes, Abbott never submitted a new PMA. Instead, the company submitted more than 230 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.

56. Abbott failed to disclose that the system 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.

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. The defects in the Proclaim Elite system, its 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 his physicians at the time of implantation.

66. 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.

67. 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.

68. 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.

69. 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.

70. The device implanted in Plaintiff was not reasonably safe at the time it left Abbott's control, and its malfunction during regular use, which included loss of therapy and the need for surgical removal, was 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.

VIII. CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

(Against Abbott Laboratories)

71. Plaintiff incorporates by reference Paragraphs 1 through 70 of this Complaint as though fully set forth herein.

72. At all times relevant to this action, Abbott Laboratories was engaged in the business of designing, manufacturing, testing, labeling, distributing, and selling medical devices, including the spinal cord stimulator system implanted in Plaintiff.

73. The device implanted in Plaintiff was not reasonably safe for its intended use due to a manufacturing defect. The product, 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.

74. Specifically, as detailed in preceding allegations, the Proclaim Elite 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.

75. 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.

76. 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.

77. Under Florida, New York, 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.

78. 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.

COUNT II – STRICT PRODUCTS LIABILITY: FAILURE TO WARN

(Against Abbott Laboratories)

79. Plaintiff incorporates by reference Paragraphs 1 through 78 of this Complaint as though fully set forth herein.

80. 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 Proclaim Elite system.

81. Under Florida, New York, 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.

82. The spinal cord stimulator system implanted in Plaintiff was materially altered from the system originally approved under PMA P010032. The system he 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.

83. 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 postmarket;
- 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.

84. 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.

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

86. 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 Florida, New York, and Illinois law.

87. 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.

COUNT III – NEGLIGENCE PER SE: FEDERAL REGULATORY VIOLATIONS

(Against Abbott Laboratories)

(21 C.F.R. §§ 803.50, 820.198, 814.39(a), 814.82(a); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001); Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011))

88. Plaintiff incorporates by reference Paragraphs 1 through 87 of this Complaint as though fully set forth herein.

89. Under Florida and New York 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**.

90. 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.

91. 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.

92. 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.

93. 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.

94. 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.

95. 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.

96. As a direct and proximate result of Abbott's violations of federal regulations and Florida and New York law, Plaintiff suffered compensable physical injury, pain, medical costs, loss of enjoyment of life, and other damages.

97. 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.

COUNT IV – BREACH OF EXPRESS WARRANTY

(Against Abbott Laboratories)
*(Fla. Stat. §672.313; NY CLS UCC §2-313; U.C.C. § 2-313; **A**lternatively, Illinois Law – 810 Ilcs 5/2-313; Restatement (Second) of Contracts § 2; In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009))*

98. Plaintiff incorporates by reference Paragraphs 1 through 97 of this Complaint as though fully set forth herein.

99. Under Florida and New York 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 Fla. Stat. §672.313; NY CLS UCC §2-313.

100. Prior to the implantation of the Proclaim Elite spinal cord stimulator system, 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.

101. Abbott expressly warranted that its Proclaim Elite system 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 his implant decision.

102. 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 his physician relied on these representations to proceed with the implantation of the Proclaim Elite system.

103. 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 over 230 PMA supplements, nor that these changes materially affected the device's safety and reliability.

104. The device failed to perform as promised. Plaintiff experienced therapy loss, painful electrical sensations, device communication failure, and ultimately required surgical 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.

105. 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.

106. As a result of this breach of express warranty, Plaintiff is entitled to recover all compensatory damages allowed under Florida and New York law, including medical expenses,

pain and suffering, and other economic and noneconomic losses. Abbott's breach of express warranty gives rise to liability under Florida and New York law and, in the alternative, under Illinois law, which similarly recognizes that affirmations of fact or promise made by a seller to a buyer create an express warranty when relied upon by the buyer. See 810 ILCS 5/2-313; *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123–24 (Ill. 2002).

COUNT V – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE

(Against Abbott Laboratories)
(Fl. Stat §§672.314 and 672.315; NY CLS UCC §§2-314 and 2-315; Illinois Law – 810 Ilcs 5/2-314, 5/2-315); U.C.C. §§ 2-314, 2-315; Restatement (Second) of Contracts §§ 235, 351; In re Digitek Prod. Liab. Litig., 2010 WL 2102330 (S.D. W. Va. 2010))

107. Plaintiff incorporates by reference Paragraphs 1 through 106 of this Complaint as though fully set forth herein.

108. Under Florida and New York 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. See Fl. Stat §672.314 and NY CLS UCC §2-314 (implied warranty of merchantability); Fl. Stat §672.315 and NY CLS UCC §2-315 (implied warranty of fitness for a particular purpose).

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

110. When Abbott marketed and sold the Proclaim system implanted in Plaintiff, it impliedly warranted that the device was of merchantable quality, conformed to FDA-approved

specifications, and was reasonably safe for its intended medical purpose. Abbott also impliedly warranted that the device was fit for the specific purpose of long-term implantation to treat Plaintiff's condition, as recommended by her physician.

111. The device implanted in Plaintiff was not of merchantable quality, nor was it fit for its intended purpose. It 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.

112. 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 device failed to conform to the minimum standards of merchantability and fitness for long-term neuromodulation therapy.

113. 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 he or his physician known the device was unfit for its intended use.

114. As a result of Abbott's breach of implied warranties, Plaintiff is entitled to recover damages under Florida and New York law and, in the alternative, under Illinois law, which similarly recognizes implied warranties of merchantability and fitness for a particular purpose where goods fail to perform as expected. See Brandt v. Boston Scientific Corp., 792 N.E.2d 296, 300 (Ill. 2003).

COUNT VI – NEGLIGENCE

Against ABBOTT LABORATORIES
(Florida and New York Common Law; Alternatively, Illinois Common Law; Restatement (Second) of Torts §§ 388, 395, 398, 402A; Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010); Hill v. Kone, Inc., 602 F. Supp. 2d 1207 (D. Minn. 2009))

115. Plaintiff incorporates by reference Paragraphs 1 through 114 of this Complaint as though fully set forth herein.

116. 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 system that it placed into the stream of commerce.

117. Abbott breached its duty of care in one or more of the following ways:

a. By negligently failing to ensure that the device was 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.

118. These negligent acts and omissions constitute breaches of both Abbott's duties under Florida, New York, 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.

119. 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. See *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 263 (Ill. 2007); *Brandt v. Boston Scientific Corp.*, 792 N.E.2d 296, 303 (Ill. 2003).

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

121. As a direct and proximate result of Abbott's negligence, Plaintiff suffered physical pain, emotional distress, financial harm, and other compensable damages under Florida and New York law, and alternatively, under Illinois law.

COUNT VII – NEGLIGENT MISREPRESENTATION

Against ABBOTT LABORATORIES

122. Plaintiff incorporates by reference Paragraphs 1 through 121 of this Complaint as though fully set forth herein.

123. 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, including the Proclaim Elite system.

124. Abbott represented, through promotional materials, Instructions for Use, patient education resources, and provider training, that its Proclaim system:

- Was safe and effective for the long-term treatment of chronic pain;
- Was fully FDA-approved and compliant with all applicable regulations;
- Had been validated through rigorous clinical trials or otherwise demonstrated safe through FDA-approved testing;
- Maintained reliability in therapy delivery, stimulation programming, and battery recharging.

125. These representations were false. As set forth in the preceding allegations, Abbott failed to disclose that:

- The Proclaim device had never been clinically validated in its marketed form;
- It had undergone significant design and firmware changes through more than 230 PMA supplements;

- These changes materially altered its performance and introduced new, untested risks;
- Multiple recalls and adverse events had already emerged related to therapy shutoff, stimulation spikes, battery failure, and wireless programming.

126. 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.

127. Abbott also made these misrepresentations directly to Plaintiff through its sales representatives, who misrepresented to Plaintiff that the permanent Proclaim Elite SCS system would provide Plaintiff with long term pain relief, was 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 his chronic pain.

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

129. 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 device from its predicate.

130. 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.

COUNT VIII – FRAUDULENT CONCEALMENT

Against ABBOTT LABORATORIES

131. Plaintiff incorporates by reference Paragraphs 1 through 130 of this Complaint as though fully set forth herein.

132. At all times relevant, Abbott Laboratories had superior knowledge of critical facts concerning the safety, efficacy, and approval history of its Proclaim spinal cord stimulator system—information not available to Plaintiff, her treating physician, or the general public.

133. Abbott was under a duty to disclose material facts relating to the performance and risks of the Proclaim system due to:

- Its exclusive access to adverse event reports and internal product complaint data;
- Its control over PMA supplement disclosures and labeling updates;
- Its direct and indirect representations to patients and physicians;
- Its statutory and regulatory duties under 21 C.F.R. §§ 803.50, 814.39, and 820.198 to disclose newly acquired safety information.

134. Abbott actively concealed or failed to disclose that:

- The Proclaim system had undergone extensive, untested design and firmware changes;

- The FDA had approved the device 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;
- 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.

135. 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.

136. Plaintiff and her physician justifiably relied on Abbott's omission of material safety information when consenting to implantation of the Proclaim Elite system. Plaintiff was unaware—and had no way of knowing—that Abbott was concealing data and risks that materially affected the safety of the product.

137. Abbott's fraudulent concealment directly and proximately caused the Plaintiff's injuries, including his 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.

COUNT IX – VIOLATION OF THE NEW YORK CONSUMER PROTECTION ACT

Against ABBOTT LABORATORIES
(NY CLS Gen Bus §349 et seq.; ALTERNATIVELY, ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT, 815 ILCS 505/1 et seq.)

138. Plaintiff incorporates by reference Paragraphs 1 through 137 of this Complaint as though fully set forth herein.

139. 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 Proclaim spinal cord stimulator system.

140. These acts include:

- Falsely advertising the device 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;
- Misrepresenting the scope and meaning of FDA approval to patients and providers.

141. 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.

142. 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.

143. Abbott's conduct violates NY CLS Gen Bus §349 *et seq*. which prohibits "[d]eceptive acts or practices in the donduct of any business, trade or commerce or in the

furnishing of any service in [New York]" and entitles Plaintiff to recover damages under New York law.

144. In the alternative, Abbott's conduct violated Illinois' Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, by concealing material safety information and misrepresenting the nature and approval status of the device from its corporate headquarters in Illinois.

145. 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.

COUNT X – NEGLIGENCE PER SE: UNAUTHORIZED PRACTICE OF MEDICINE

Against ABBOTT LABORATORIES
(NY CLS Educ. §6512; Fla. Stat. §458.327; RESTATEMENT (SECOND) OF TORTS § 286; ALTERNATIVELY, 225 ILCS 60/1 et seq.)

146. Plaintiff incorporates by reference Paragraphs 1 through 145 of this Complaint as though fully set forth herein.

147. New York and Florida law prohibit the unauthorized practice of medicine by any individual or corporate entity not licensed in those states. These prohibitions reflects a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

148. Abbott Laboratories is not licensed to practice medicine in Florida or New York 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;
- Altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight;

149. 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.

150. Under Florida and New York 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.

151. Plaintiff, as a patient undergoing neuromodulation therapy, is squarely within the protected class under NY CLS Educ. §6512; Fla. Stat. §458.327. His injuries, caused by improper therapeutic manipulation without medical oversight, are the exact type the law is intended to prevent.

152. 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.

153. 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.

COUNT XI – VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT (APA)

Against the U.S. Food and Drug Administration
(5 U.S.C. §§ 702–706; 21 U.S.C. §§ 360c, 360e; 21 C.F.R. §§ 814.39, 814.82; Loper Bright Enters. v. Raimondo, 603 U.S. 369 (2024); Bennett v. Spear, 520 U.S. 154 (1997))

154. Plaintiff incorporates by reference Paragraphs 1 through 150 of this Complaint as though fully set forth herein.

155. 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 ("FDA") related to its handling of Abbott's spinal cord stimulator system approved under PMA P010032 and its associated supplements.

156. 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).

157. As set forth in Section V, 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.

158. 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;
- Waveform modifications never evaluated in human clinical trials.

159. 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.

160. 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.

161. The FDA's inaction has permitted Abbott to continue marketing a spinal cord stimulator system that no longer resembles the device originally reviewed and approved, without

requiring the clinical validation, public scrutiny, or labeling accuracy that the PMA process is intended to ensure.

162. 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.

163. 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.

164. 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.

WHEREFORE, Plaintiff respectfully requests that this Court:

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

b. 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;

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

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

e. Grant such other relief as the Court deems just and proper.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in their favor and against Defendant ABBOTT LABORATORIES, 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 NY CLS Gen Bus §349 *et seq*. and any other 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. Declaratory and injunctive relief against the FDA as set forth in Count XI, pursuant to 5 U.S.C. §§ 702–706;

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 DEMAND

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

Dated: October 17, 2025

Respectfully submitted,

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