

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

LAVERNE LIVINGSTON,

Plaintiff,

v.

ABBOTT LABORATORIES;

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendants.

Case No: 1:26-cv-5322

**COMPLAINT FOR DAMAGES AND
DECLARATORY AND INJUNCTIVE RELIEF**

COMES NOW Plaintiff **Laverne Livingston**, 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 originally received FDA approval in 2001 under PMA P010032, originally granted to Advanced Neuromodulation Systems, later acquired by St. Jude Medical. Advanced Neuromodulation Systems did not submit and the FDA did not consider clinical data

or clinical evidence in support of P010032, or for any subsequent Abbott system that used P010032 as a predicate product for marketing purposes.

Abbott's entire SCS product line, including the Eterna system, are predicated on PMA P010032. Since the original approval of P010032, the device has been fundamentally altered through dozens of PMA supplements, modifying its battery chemistry, firmware, waveform control, leads, communication capabilities, 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. She suffered painful neurologic symptoms and worsening pain symptoms have left her permanently injured.

Plaintiff brings this action under Hawaii law, and the Administrative Procedure Act, asserting both traditional product liability and statutory claims. She seeks compensatory damages for her 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 Laverne Livingston is a resident and citizen of the State of Hawaii. At the time this Complaint is filed, Plaintiff resides in Honolulu, Hawaii. The device at issue was implanted in Plaintiff in Hawaii. Plaintiff has received medical treatment related to the device, including revision and removal of the device, in Hawaii.

2. Defendant Abbott Laboratories is a corporation organized under the laws of the State of Illinois with its principal place of business located in 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 States of Illinois and Hawaii. 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 Hawaii and experienced significant injuries giving rise to this lawsuit in Hawaii. Accordingly, Plaintiff's tort claims are governed by Hawaii 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. Hawaii law governs Plaintiff's personal injury claims. 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. These changes cumulatively altered the device's mode of action, safety controls, stimulation effects, battery stability, efficacy, risk profile, 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.

17. 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.

18. 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.

19. 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.

20. 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 him significant injury and lasting harm.

21. 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

22. 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.

23. 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.

24. 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).

25. 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, P010032, § 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.

26. 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.

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.

28. 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.

29. 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

30. 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.

31. 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.

32. The FDA’s decision to approve PMA P010032 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*.

33. 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.

34. 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.

35. 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.

36. 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).

37. 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).

38. 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.

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

VI. PLAINTIFF-SPECIFIC FACTUAL ALLEGATIONS

40. Plaintiff Laverne Livingston is a resident and citizen of the State of Hawaii. At the time this Complaint is filed, Plaintiff resides in Honolulu, Hawaii. The device at issue was implanted in Plaintiff in Hawaii. Plaintiff has received medical treatment related to the device in Hawaii.

41. On or about December 27, 2023, Plaintiff was surgically implanted with an Abbott Eterna spinal cord stimulator system for the treatment of chronic pain.

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

43. Prior to the implant of the Eterna system, Plaintiff met directly with Abbott sales representatives named Katie (last name unknown), Michael Chrysler, and Trevor Batten about

the SCS system. Plaintiff met with one or more of these sales representatives before the trial stimulator was implanted, during the trial, and after the trial was completed, but before the permanent Eterna SCS system was implanted. During each consultation, the sales representatives advised Plaintiff that the permanent Eterna 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 her chronic pain.

44. Based on the representations made by the Abbott sales representatives, before, during and after the SCS trial period, Plaintiff elected to be permanently implanted with the Eterna system.

45. Immediately after the permanent implant surgery, an Abbott representatives programmed and made therapeutic adjustments to the Eterna system without meaningful physician supervision. This occurred on numerous occasions after Plaintiff was implanted with the Eterna system. In fact, between the implant procedure and the date on which the system was eventually removed from Plaintiff's body, the SCS system was reprogrammed by an Abbott sales representative numerous times, including at Plaintiff's home, completely outside the presence, control, or supervision of her physician.

46. On the occasions that he had the SCS device reprogrammed, the Abbott sales representatives represented to Plaintiff that reprogramming of the SCS system after it was implanted was necessary to ensure that she received optimal pain relief and to avoid the side effects she was experiencing, and that if she was not receiving adequate pain relief or experiencing these side effects, she just needed to have the system reprogrammed. Therefore, Plaintiff did not have any reason to know that she should not expect the SCS device to work properly and provide the promised results on the dates that she had the device reprogrammed.

47. The implanted system included components from Eterna platform, developed and marketed under PMA P010032 and its numerous supplements. The Eterna system incorporated functions and features not present in the predicate device originally approved in 2001.

48. Plaintiff was never informed that the Eterna system implanted in her body was materially different from the original device approved under PMA P010032. Nor was she advised that the Eterna 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.

49. Plaintiff experienced some initial pain relief from the SCS system. However, Plaintiff subsequently stopped receiving pain relief from the SCS system, and began to experience severe complications from the implant, including undesired stimulation, shocking, numbness in her extremities, increased pain (including nerve pain), falls due to extremity numbness and balance issues, difficulty walking, and incontinence.

50. These complications led to multiple reprogrammings by the Abbott sales representatives referenced above, during which Plaintiff was advised that reprogramming would alleviate her complications and lead to therapeutic success.

51. On May 8, 2024, Plaintiff advised her physician that she wanted to have the stimulator system removed due to the complications and continuing lack of therapeutic relief. Based on information provided by Abbott, Plaintiff's physician told her that her complications were likely not caused by the SCS system, and that she just needed to have the system reprogrammed. Her physician contacted the Abbott representatives, including Katie (last name

unknown), Michael Chrysler, and Trevor Batten and asked them to contact Plaintiff about her SCS system.

52. Plaintiff has been stuck in this cycle ever since, in which she complains to her physicians about the SCS and her complications, they refer her to the Abbott representatives or ask Abbott representatives to contact her regarding the complications, and Plaintiff's complaints are dismissed by the physicians and Abbott representatives.

53. Plaintiff continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system. To date, she has been unable to find a physician who will remove the device.

54. All leads used in the SCS systems implanted in Plaintiff were manufactured and sold by Abbott.

55. The permanent SCS system did not provide equivalent pain relief to Plaintiff's temporary SCS trial on a permanent basis. Despite multiple reprogrammings by the Abbott representative, the system never provided permanent pain relief to Plaintiff.

56. During the time in which the SCS system was implanted in Plaintiff, Abbott representatives, believed to be unlicensed in the State of Hawaii, or elsewhere for that matter, actively participated in implanting the SCS system, and programming the device post-operatively. These actions involved real-time interpretation of patient responses and materially influenced the configuration and function of the implanted system. These actions were essentially medical treatment and had a significant impact on the way the SCS system affected Plaintiff's body.

57. Plaintiff was advised that Abbott representatives were the only individuals who could or would program or reprogram her SCS device.

58. During the time in which the SCS system was implanted in Plaintiff, Abbott representatives provided medical advice to her about the SCS system. This occurred in her home, completely outside the presence of any physician.

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

60. Plaintiff discovered the probable causal relationship between her injuries and Defendant's conduct only after experiencing continued device-related complications and reviewing public disclosures, adverse event reports, and litigation materials that contradicted Defendant's original representations. Plaintiff could not and did not know that she had been injured by Abbott's SCS system or that Abbott's representations to her were false and/or fraudulent until after she reviewed this information.

VII. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

61. 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.

62. The device marketed to Plaintiff and her healthcare providers as the Eterna SCS systems bore little resemblance to the device originally approved under PMA P010032. This device 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.

63. 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.

64. Abbott failed to disclose that the device 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.

65. 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.

66. As previously alleged, between 2020 and 2023, Abbott initiated multiple recalls involving its 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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.

73. The defects in the Eterna system's 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.

74. 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.

75. 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.

76. Upon information and belief, the Eterna system and related system components implanted in Plaintiff deviated from Abbott's FDA-approved manufacturing specifications for firmware execution stability, wireless programming reliability, autonomic side effects, 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.

77. 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. Of note, the Proclaim system preceded the Eterna system in the PMA supplement chain that Abbott used to ultimately bring the Eterna system to market. Therefore, any deficiencies in the Proclaim design, manufacture, and regulatory process impacted the design, manufacture, and regulatory process for the Eterna system.

78. The device implanted in Plaintiff was not reasonably safe at the time it left Abbott's and its predecessor's control, and its 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.

VIII. CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

(Against Abbott Laboratories)

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

80. 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.

81. 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.

82. Specifically, as detailed in preceding allegations, the Eterna 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.

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

84. 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.

85. Under Hawaii 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.

86. 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)

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

88. At all times relevant, Abbott Laboratories had a duty to provide adequate warnings and instructions regarding the known or reasonably foreseeable risks associated with its spinal cord stimulator systems, including the Eterna system.

89. Under Hawaii 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.

90. 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.

91. 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;
- Risk of autonomic complications and nervous system injury;
- A significant risk of severe shocking and undesired stimulation;
- The postmarket evidence that the SCS system was less or equally effective as placebo;
- 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.

92. 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.

93. Through its sales representatives, Abbott provided information to Plaintiff and his physicians that was inconsistent with the FDA approved labeling and warnings for the Eterna system, in contravention of the FDCA and implementing regulations. As a result, the warnings conveyed to Plaintiff and her physicians was inadequate under Hawaii state law.

94. Through its sales representatives, Abbott downplayed and undermined the FDA approved labeling and warnings for the Eterna system, including risks and side effects contained in the FDA approved labeling and warnings, in contravention of the FDCA and implementing regulations. As a result, the warnings conveyed to Plaintiff and her physicians was inadequate under Hawaii state law.

95. 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 and benefits of the SCS device, the device would not have been implanted, or alternative treatments would have been pursued.

96. 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 Hawaii law.

97. 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))

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

99. Under Hawaii 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**.

100. 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.

101. 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.

102. 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.

103. 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.

104. 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, which Plaintiff suffered.

105. 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.

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

107. 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)

(HI Rev Stat § 490:2-313; Restatement (Second) of Contracts § 2; *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009))

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

109. Under Hawaii and 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* HI Rev Stat § 490:2-313; *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123–24 (Ill. 2002).

110. Prior to the implantation of the Eterna spinal cord stimulator device, 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.

111. 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.” Abbott warranted that its permanent SCS devices would provide equivalent or greater pain relief than its trial stimulators.

112. 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 her decision to consent to implantation with the Eterna system.

113. 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 Eterna system.

114. In fact, the Eterna 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.

115. 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.

116. 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, permanent nerve injury, or required surgical intervention.

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

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

(Against Abbott Laboratories)

(HI Rev Stat § 490:2-314-315; 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))

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

119. Under Hawaii and 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.

120. 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.

121. When Abbott marketed and sold its SCS system implanted in Plaintiff, it impliedly warranted that the device was of merchantable quality, conformed to FDA-approved specifications, and were 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.

122. 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.

123. 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.

124. 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.

COUNT VI – NEGLIGENCE

Against ABBOTT LABORATORIES

(Hawaii 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))

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

126. 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.

127. 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 Eterna 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.

128. These negligent acts and omissions constitute breaches of both Abbott's duties under Hawaii 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.

129. 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.

130. 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.

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

COUNT VII – NEGLIGENCE MISREPRESENTATION

Against ABBOTT LABORATORIES

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

133. 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.

134. 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;
- Provided equivalent or superior effects to the temporary trial stimulators;
- Maintained reliability in therapy delivery, stimulation programming, and battery recharging.

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

- The Eterna device was never been clinically validated in its marketed form;
- These devices had undergone significant design and firmware changes through more than 230 PMA supplements;
- The permanent Eterna did not provide equivalent or superior effects to the temporary trial stimulator;
- 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.

136. 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.

137. Abbott also made these misrepresentations directly to Plaintiff through its sales representatives, including Katie (last name unknown), Michael Chrysler, and Trevor Batten, 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 his chronic pain.

138. 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 sales representatives, including assurance of FDA approval, therapy safety, and reliability, when consenting to implantation.

139. 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.

140. 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.

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

COUNT VIII – FRAUDULENT CONCEALMENT

Against ABBOTT LABORATORIES

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

143. 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.

144. Abbott was under a duty to disclose material facts relating to the performance and risks of the Eterna 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.

145. 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;
- 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.

- The permanent SCS system was known not to provide equivalent pain relief to that provided by the trial stimulator.
- Reprogramming of the SCS system was unlikely to lead to greater pain relief or elimination of side effects.

146. 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.

147. 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 these devices.

148. 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.

COUNT IX – VIOLATION OF HAWAII'S UNFAIR OR DECEPTIVE ACTS AND PRACTICES (UDAP) STATUTE

Against ABBOTT LABORATORIES
(HI Rev. Stat. § 480-2, *et seq.*)

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

150. 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.

151. 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;
- Misrepresenting the scope and meaning of FDA approval to patients and providers.

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

153. 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.

154. 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
(HI Rev. Stat. § 453-2; RESTATEMENT (SECOND) OF TORTS § 286; ALTERNATIVELY,
225 ILCS 60/1 et seq.)

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

156. Hawaii law prohibits the unauthorized practice of medicine by any individual or corporate entity not licensed in Hawaii. These prohibitions reflects a clear public policy interest in ensuring that only licensed professionals make medical decisions affecting patient care.

157. Neither Abbott Laboratories nor its sales representatives are licensed to practice medicine in Hawaii 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;
- Meeting with Plaintiff, programming her SCS device, and providing medical advice in Plaintiff's home, outside the presence, control, or supervision of her physician;
- Altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight;

158. 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.

159. Under Hawaii 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.

160. Plaintiff, as a patient undergoing neuromodulation therapy, is squarely within the protected class under HI Rev. Stat. § 453-2. Her injuries, caused by improper therapeutic manipulation and medical advice without medical oversight, are the exact type the law is intended to prevent.

161. 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.

162. 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))

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

164. This cause of action is brought against Defendant United States Food and Drug Administration solely in its official capacity under the Administrative Procedure Act, 5 U.S.C. §§ 701–706.

165. The APA authorizes judicial review of final agency action, including agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. See 5 U.S.C. §§ 706(1), 706(2)(A)–(D); *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

166. The FDA’s passive acceptance and approval of original PMA applications and subsequent supplements submitted by Defendant Abbott Laboratories for its Eterna spinal cord stimulator system constituted final agency action within the meaning of the APA.

167. 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.

168. 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.

169. 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.

170. 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.

171. The FDA's inaction has permitted Abbott to continue marketing spinal cord stimulator systems, including the Eterna, 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.

172. 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.

173. 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.

174. The FDA's actions and omissions enabled Abbott Laboratories to market materially altered, insufficiently validated, and defectively designed spinal cord stimulator systems to Plaintiff and similarly situated patients without the protections mandated by Congress for high-risk medical device.

175. The FDA's actions and omissions allowed Abbott Laboratories to market its SCS systems, including the Eterna system, as Class III devices without subjecting these devices to the statutorily and regulatorily required review.

176. Plaintiff suffered direct injury as a result of the FDA's arbitrary and unlawful agency actions. But for the FDA's approval of Abbott's original PMA and cumulative PMA supplement submissions without adequate scrutiny, Plaintiff would not have been implanted with the defective device that caused her injuries.

177. Plaintiff also suffered direct legal injury as a result of the FDA's arbitration and unlawful agency actions. But for the FDA's actions and omissions, Abbott would not have received PMA approval for the SCS systems implanted in Plaintiff, and therefore, would not be able to invoke federal preemption to shield itself from liability for the physical injuries that the SCS system caused Plaintiff.

178. The legal injury experienced by Plaintiff was a foreseeable result of the FDA's actions.

179. Plaintiff seeks declaratory relief declaring that the FDA's actions regarding PMA P010032 and the subsequent supplements thereto for Abbott's spinal cord stimulator systems were arbitrary, capricious, an abuse of discretion, and contrary to law.

180. Plaintiff further seeks injunctive relief requiring the FDA to reconsider and, if necessary, rescind or suspend the PMA approvals granted for materially altered spinal cord stimulator systems that failed to undergo appropriate panel-track or original PMA review, including the Eterna system.

181. Plaintiff's claims under the APA are properly brought under 5 U.S.C. § 702 and 5 U.S.C. § 706, and are not precluded by any statutory or regulatory exemption from judicial review.

182. WHEREFORE, Plaintiff demands declaratory judgment against Defendant United States Food and Drug Administration, injunctive relief as permitted under the APA, costs of suit, reasonable attorneys' fees where permitted, and such other and further relief as the Court deems just and proper.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his 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 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. 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: May 7, 2026

Respectfully submitted,

/s/ Edward A. Wallace
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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

LAVERNE LIVINGSTON,

Plaintiff,

v.

ABBOTT LABORATORIES;

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendants.

Case No: 1:26-cv-5322

**DISCLOSURE STATEMENT FILED PURSUANT TO FED. R. CIV. P.
7.1(A)**

Pursuant to Fed. R. Civ. P. 7.1(a), Plaintiff Laverne Livingston, by her attorneys, provides the following disclosure:

1. Laverne Livingston is now and at the time of filing of this matter a resident of the state of Hawaii.

Dated: May 7, 2026

Respectfully submitted,

/s/ Edward A. Wallace

Edward A. Wallace

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