UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

ZELLA TUTTLE Plaintiff, v. ABBOTT LABORATORIES, Defendants.	Case No.: 1:25-cv-15083 **JURY TRIAL DEMANDED**

COMPLAINT FOR DAMAGES

COMES NOW Plaintiff **Zella Tuttle**, by and through undersigned counsel, and for her Complaint against Defendant **Abbott Laboratories**, and states and alleges as follows:

INTRODUCTION

This is an action involving injuries sustained by Plaintiff following the implantation and failure of a spinal cord stimulator (SCS) system designed, manufactured, and marketed by Defendant Abbott Laboratories. Abbott's Eterna Spinal Cord Stimulator system 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 Medical. Since that time, however, the device has been fundamentally altered through dozens of PMA supplements, modifying its battery chemistry, firmware, waveform control, leads, and user interface, without the benefit of a new PMA or any renewed clinical safety validation.

These cumulative changes, approved outside public view, transformed the device's mechanism of action, performance characteristics, and risk profile. Abbott failed to disclose these material changes to patients, physicians, or regulators. As a result, Plaintiff was implanted with a device that was materially different from what had been tested and originally approved. He suffered painful neurologic symptoms and worsening pain symptoms that required multiple revision surgeries and have left him permanently injured.

Plaintiff brings this action under Texas and/or Illinois law, asserting both traditional product liability and statutory claims. He seeks compensatory damages for her injuries.

I. PARTIES, VENUE, AND JURISDICTION

1. Plaintiff Zella Tuttle is a resident and citizen of the State of Texas. At the time this Complaint is filed, Plaintiff resides in Crandall, Texas. The devices at issue were implanted in Plaintiff in Texas. Plaintiff has received medical treatment related to the device, including revision and removal of the device, in Texas.

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 states of Illinois and Texas. 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. 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.

5. 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

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

7. 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.

8. 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).

9. Texas 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

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. Abbott's Eterna SCS device was first "approved" by the FDA on December 16, 2022, though no independent PMA was ever filed for this device. This approval was granted through PMA Supplement Number S186 to PMA P010032.

16. Had the Eterna SCS device 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.

17. Instead, Abbott bypassed that obligation. As a result, Plaintiff was implanted with 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 her significant injury and lasting harm.

IV. REGULATORY FRAMEWORK AND FEDERAL DUTIES

18. 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.

19. 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.

20. 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).

21. 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 original devices the powerful preemption protections afforded by PMA status.

22. 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 other manufacturers' devices that had been reported about in the literature.

23. That decision 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.

24. 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.

V. PLAINTIFF-SPECIFIC FACTUAL ALLEGATIONS

25. Plaintiff Zella Tuttle is a resident and citizen of the State of Texas. At the time this Complaint is filed, Plaintiff resided in Texas. The device at issue was implanted in Plaintiff in Texas. Plaintiff has received medical treatment related to the device, including removal of the device, in Texas.

26. On or about October 6, 2023, Plaintiff was surgically implanted with an Abbott Eterna spinal cord stimulator system for the treatment of chronic pain.

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

28. Prior to the implant of the trial system, Plaintiff met directly and in-person with Mike Romaniello, an Abbott sales representative and territory manager. Mr. Romaniello was an employee of Abbott, working in the course and scope of his employment with Abbott.

29. Mike Romaniello is not a physician, nor does he hold any medical licensure. In fact, Mr. Romaniello's educational credentials are limited to a Bachelor's Degree.

30. Mr. Romaniello 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.

31. Through the process of agreeing to be implanted with an Abbott SCS system, Plaintiff also met and spoke with two other sales representatives from Abbott, Lexi (last name unknown) and a representative whose name she does not recall.

32. Based on the representations made by Mr. Romaniello, Lexi (last name unknown), and a third representative whose identity Plaintiff does not recall, before, during and after the SCS trial period, Plaintiff elected to be permanently implanted with the Eterna SCS system.

33. Upon information and belief, none of the Abbott representatives with whom Plaintiff communicated were physicians or held any medical licensure, degrees, or certifications.

34. Mike Romaniello was the primary sales representative and had supervisory responsibility over Lexi (last name unknown) and the third Abbott representative whose identity Plaintiff does not recall.

35. Immediately after the permanent implant surgery, Abbott representatives programmed and made therapeutic adjustments to the Eterna SCS system without meaningful physician supervision. This occurred on numerous occasions after Plaintiff was implanted with the Eterna SCS system.

36. The implanted system included components from Abbott's 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.

37. Plaintiff was never informed that the Eterna SCS system implanted in her body was materially different from the original device tested and 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.

38. On December 13, 2023, Plaintiff underwent final surgical intervention to remove the SCS system due to mechanical and therapeutic failure of the device, including stimulator lead migration. Plaintiff continues to suffer from pain and symptoms caused and exacerbated by the malfunctioning system.

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

40. 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.

41. Plaintiff discovered the probable causal relationship between her injuries and Defendant's conduct only after the device was permanently removed from her body and she was able to review public disclosures, adverse event reports, and litigation materials that contradicted Defendant's original representations about the Eterna system.

VI. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

42. 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.

43. The device marketed to Plaintiff and her healthcare providers as the Eterna system bore little resemblance to the device originally approved under PMA P010032. This device incorporated multiple significant changes to their hardware, firmware, user interface, waveform architecture, battery system, and wireless programming, each of which materially impacted the device's safety, performance, and failure modes.

44. 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. The defects in the Eterna 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 her physicians at the time of implantation.

51. 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.

52. 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.

53. Upon information and belief, the Eterna 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.

54. The device implanted in Plaintiff was not reasonably safe at the time they 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, 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.

VII. CAUSES OF ACTION

COUNT I – STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

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

56. 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.

57. The device implanted in Plaintiff was not reasonably safe for its 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.

58. 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, lead anchoring, and battery charging performance.

59. 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.

60. 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.

61. Under Texas 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.

62. 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

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

64. 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 Eterna system.

65. Under Texas 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.

66. The spinal cord stimulator device implanted in Plaintiff was 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.

67. 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.

68. 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.

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

70. 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 Texas and Illinois law.

71. 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

(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))

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

73. Under Texas 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**.

74. 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.

75. 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.

76. Abbott also failed to report adverse events linked to stimulation shutoff, therapy loss, electrical shocks, and lead migration under 21 C.F.R. § 803.50. These adverse effects were known to Abbott prior to Plaintiff's implantation.

77. 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.

78. 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.

79. 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.

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

81. 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

(Tex. Bus. & Com. Code §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))

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

83. Under Texas 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* Tex. Bus. & Com. Code §2.313; *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1123–24 (Ill. 2002).

84. 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.

85. The close and substantial nature of the sales tactics used by the Abbott representatives, including Mike Romaniello, Lexi (last name unknown), and a third unknown representative, to promote and sell the Eterna system to Plaintiff gave rise to privity of contract.

86. Abbott expressly warranted that its SCS devices provided consistent pain relief, seamless therapy delivery, safe wireless programming, and a rechargeable platform with superior reliability and patient comfort. Abbott's provider materials represented that its SCS systems were "FDA-approved," "clinically validated," and "designed for long-term use with low complication rates." These claims were repeated in sales brochures, website copy, and Abbott's physician training materials. These claims were repeated directly to Plaintiff through Abbott's sales representatives prior to each of her implant decisions.

87. Mike Romaniello and other sales representatives warranted to Plaintiff that the Eterna SCS system was safe, effective for long term treatment of pain, and was backed by clinical data. They further warranted that the permanent Eterna device would provide the same or a higher level of pain relief as the trial stimulator.

88. 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.

89. 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.

90. The device failed to perform as promised. Plaintiff experienced therapy loss, painful electrical sensations, device communication failure, lead migration, 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. Finally, the Eterna system did not provide the same or a higher level of pain relief as the trial stimulator.

91. 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.

92. As a result of this breach of express warranty, Plaintiff is entitled to recover all compensatory damages allowed under Texas 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

(Tex. Bus. & Com. Code §2.314 and 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))

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

94. Under Texas 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.

95. 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.

96. The close and substantial nature of the sales tactics used by the Abbott representatives, including Mike Romaniello, Lexi (last name unknown), and a third unknown representative, to promote and sell the Eterna system to Plaintiff gave rise to privity of contract.

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

98. 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, lead anchoring, and therapy delivery. Plaintiff experienced painful shocks, therapy failure, lead migration, and ultimately underwent surgical removal due to the product's unreliability and malfunction.

99. 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.

100. 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

(Texas 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))

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

102. 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.

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

a. Accurately communicating with Plaintiff regarding the Eterna system after it was implanted, including about re-programing of the device;

b. Using due care in the programing of the Eterna system, which was undertaken directly by the Abbott representatives at the direction of Abbott.

c. By negligently hiring, training, and supervising its sales representatives, including Mike Romaniello, Lexi (last name unknown), and a third unknown representative, in relation to the marketing and promotion of the Eterna device;

d. By negligently hiring, training, and supervising its sales representatives, including Mike Romaniello, Lexi (last name unknown), and a third unknown representative, in the programing of the Eterna device;

e. By negligently hiring, training, and supervising its sales representatives, including Mike Romaniello, Lexi (last name unknown), and a third unknown representative, in the provision of information, medical advice, and guidance relating to the Eterna device;

f. 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;

g. By negligently introducing cumulative design changes through successive PMA supplements without proper validation, public clinical testing, or physician disclosure;

h. By negligently failing to investigate known risks associated with stimulation loss, painful shocks, lead migration, and therapy failure, despite premarket complaints, post-market adverse event reports, and internal device testing;

i. 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;

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

k. 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.

104. These negligent acts and omissions constitute breaches of both Abbott's duties under Texas 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.

105. Illinois law similarly imposes a duty on manufacturers to exercise ordinary care in the design, manufacture, labeling, marketing, and distribution of medical devices, including duties to investigate known hazards and warn of risks not adequately disclosed.

106. 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.

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

COUNT VII – NEGLIGENT MISREPRESENTATION

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

109. 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.

110. 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;
- Provided same or better results than trial stimulators;
- 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;
- Maintained reliability in therapy delivery, stimulation programming, and battery recharging.

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

- The Eterna device had never been clinically validated in its marketed form;

- The Eterna device had undergone significant design and firmware changes through more than 250 PMA supplements;
- Significant adverse event reports had been received regarding the Eterna device and other devices marketed under the same PMA, including reports regarding poor therapeutic results, lead migration, and need for surgical revision and removal;
- 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 in predicate devices marketed under the same PMA;

112. 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.

113. Abbott also made these misrepresentations directly to Plaintiff through its sales representatives, including Mike Romaniello, who misrepresented to Plaintiff that the permanent Eterna SCS system would provide Plaintiff with long term pain relief, would be equivalent or better than the trial stimulator, was safe and backed by clinical validation, was properly approved under all FDA regulations, would be functionally equivalent to the trial SCS system, and would alleviate Plaintiff's need to receive other treatment for her chronic pain.

114. Plaintiff's treating physician reasonably relied on Abbott's misrepresentations when selecting the Abbott system for implantation. Plaintiff 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.

115. Abbott failed to exercise reasonable care in obtaining or communicating accurate information about the device's clinical validation, efficacy, adverse event history, 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.

116. 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.

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

COUNT VIII – FRAUD AND FRAUDULENT CONCEALMENT

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

119. 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.

120. 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.

121. 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, lead migration, 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.

122. 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.

123. Abbott also made false representations to Plaintiff, through its sales representatives, that the Eterna device was backed by clinical data, was safe and effective, and would provide equivalent (or better) therapeutic benefit to the trial stimulator.

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

125. Abbott's fraud and 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 – NEGLIGENCE PER SE: UNAUTHORIZED PRACTICE OF MEDICINE

(Tex. Occ. Code § 165.152)

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

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

128. Abbott Laboratories is not licensed to practice medicine in Texas or any other state. Further, Abbott's sales representatives are not licensed to practice medicine in Texas 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;
- Providing medical advice to the Plaintiff regarding the implantation of the Eterna system and, post-operatively, the continued use of the system while it was implanted;
- 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;

129. These actions constitute the unauthorized practice of medicine pursuant to Tex. Occ. Code §165.152, 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.

130. Under Texas 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.

131. Plaintiff, as a patient undergoing neuromodulation therapy, is squarely within the protected class under Tex. Occ. Code §165.152. Her injuries, caused by improper therapeutic manipulation and advice regarding the continued use of the device without medical oversight, are the exact type the law is intended to prevent.

132. 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 X – FRAUDULENT MISREPRESENTATION

(In the Alternative)

133. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint as though fully set forth herein.

134. If Abbott's Eterna deivce was not a significantly different system from that originally approved by the FDA in 2001 under PMA P010032, and therefore its use of the PMA supplement process was appropriate, then Plaintiff pleads this allegation in the alternative.

135. At all relevant times, Abbott and its predecessors, acting individually and through their agents, employees, and representatives, made material misrepresentations and omissions of fact regarding the safety and efficacy of its SCS systems, including the Eterna system implanted in Plaintiff.

136. Defendant communicated directly with Plaintiff through sales representatives.

137. Defendant represented to Plaintiff, her healthcare providers, and the general public, through marketing materials, sales presentations, Instructions for Use (IFU), direct to patient communications, and other communications, that:

a. The Eterna system was significantly different than older SCS systems;

b. The design of the Eterna system was significantly better and more advanced than older SCS systems;

c. The Eterna system was a new and improved SCS systems; and

d. The devices' new capabilities reduced the risk of therapy failure and side effects compared to older systems.

138. These material representations were false. Defendant knew or should have known, through reasonable investigation, that its Eterna system was substantially the same as the system originally approved by the FDA in 2001 under PMA P010032.

139. Defendant made these material misrepresentations and omissions intentionally, willfully, recklessly, and with the intent to induce healthcare providers to recommend, and patients to consent to, implantation of its devices.

140. Plaintiff's healthcare providers justifiably relied on Abbott's representations in recommending the Eterna system, and Plaintiff justifiably relied on the same representations in consenting to implantation and subsequent medical decisions.

141. Plaintiff had no reasonable means of independently discovering the falsity of Defendant's statements at the time of implantation, as Abbott had superior knowledge of the device's design changes, clinical performance, and regulatory history, and actively concealed adverse information from physicians, patients, and regulators.

142. Plaintiff also had no reasonable means of independently discovering the falsity of Defendant's statements following implantation, as Abbott had superior knowledge of the device's design changes, clinical performance, and regulatory history, and actively concealed adverse information from physicians, patients, and regulators.

143. Defendant's misrepresentations, including those made by sales representatives, before the implantation procedure caused Plaintiff to consent to the implantation of the Eterna SCS system.

144. 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.

145. As a direct and proximate result of Defendant's fraudulent misrepresentations and omissions, Plaintiff suffered significant injuries, including physical pain, emotional distress, medical expenses, lost income, diminished quality of life, and other consequential damages.

146. Plaintiff's fraud claims arise under Texas common law, and are not based solely on statements made to the FDA, but rather Defendant's intentional misstatements and concealments made to Plaintiff and her physicians to induce reliance.

147. **WHEREFORE,** Plaintiff demands judgment against Defendant Abbott for compensatory damages, punitive damages where permitted, attorneys' fees where allowed, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

COUNT XI – NEGLIGENT MISREPRESENTATION

(In the Alternative)

148. Plaintiff realleges and incorporates by reference all preceding paragraphs of this Complaint as though fully set forth herein.

149. If Abbott's Eterna system was not a significantly different system than that originally approved by the FDA in 2001 under PMA P010032, and therefore its use of the PMA supplement process was appropriate, then Plaintiff pleads this allegation in the alternative.

150. At all relevant times, Defendant Abbott, acting individually and through its agents, employees, and representatives, owed a duty to exercise reasonable care in communicating truthful, accurate, and complete information about its spinal cord stimulator systems, including the Eterma system.

151. Defendant supplied false information in its promotional materials, sales presentations, Instructions for Use (IFU), labeling, and direct communications to healthcare providers and patients regarding the safety, efficacy, and design features, of the Eterna system.

152. Defendant communicated directly with Plaintiff through sales representatives Mike Romaniello, Lexi (last name unknown), and a third unknown representative.

153. Defendant negligently misrepresented to Plaintiff, her healthcare providers, and the general public, through marketing materials, sales presentations, Instructions for Use (IFU), direct to patient communications, and other communications, that:

- The Eterna system was significantly different than older SCS systems;
- The design of the Eterna system was significantly better and more advanced than older SCS systems; and
- The Eterna system was a new and improved SCS system;

154. Defendant made these representations without reasonable grounds for believing them to be true.

155. These material representations were false. Defendant knew or should have known, through reasonable investigation, that its Eterna system was substantially the same as the system originally approved by the FDA in 2001 under PMA P010032.

156. Plaintiff's healthcare providers reasonably relied on Defendant's representations in recommending implantation of the Eterna system, and Plaintiff reasonably relied on the same representations in consenting to implantation.

157. Had Plaintiff and her healthcare providers been accurately and fully informed of the truth about the Eterna device, they would not have elected to proceed with implantation or would have pursued alternative treatment options.

158. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff suffered physical injuries, emotional distress, additional medical expenses, financial losses, and diminished quality of life.

159. Plaintiff's negligent misrepresentation claims arise under state common law, including Texas law. These claims are not premised solely on FDCA enforcement and are not preempted under *Buckman* or *Riegel*.

160. **WHEREFORE**, Plaintiff demands judgment against Defendant Abbott for compensatory damages, attorneys' fees where permitted, costs of suit, pre- and post-judgment interest, and such other and further relief as the Court deems just and proper.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor and against Defendant ABBOTT LABORATORIES, 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. 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;

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

d. The costs of this action; and

e. 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: December 11, 2025

Respectfully submitted,

/s/ Edward A. Wallace

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

ZELLA TUTTLE

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendants.

Case No.: 1:25-cv-15083

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

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

1. Zella Tuttle is now and at the time of filing of this matter a resident of the state of Texas.

Dated: December 11, 2025

Respectfully submitted,

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