IN THE UNITED STATES DISTRICT COURT
FOR THE NOTHERN DISTRICT OF ILLINOIS

KAREN F. KRANTZ, ***Plaintiff,*** **v.** **ABBOTT LABORATORIES (a Delaware corporation),** ***Defendant.***	**Case No.: 1:25-cv-2934** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, by and through her undersigned counsel, brings this Complaint at Law against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the tortious conduct of the Defendant named herein related to the implantation and subsequent injurious failure of the Proclaim Neurostimulation System, a spinal cord stimulation device ("SCS" or "product"). As a result of the wrongful conduct enumerated herein, Plaintiff Karen F. Krantz suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which she may be legally entitled.

2. Plaintiff files this Complaint, alleging violations of state and federal requirements in the manufacture, labeling, warning, reporting and marketing, as well as breach of warranties, and other legal duties and requirements with regards to Abbott's Proclaim Neurostimulation System ("Proclaim")).

3. As a direct and proximate result of Abbott's violations of FDA laws, regulations

and requirements, and their respective parallel state law requirements, Abbott's implants caused Plaintiff Karen Krantz to suffer injuries and losses as enumerated herein.

4. Defendant Abbott Laboratories (hereinafter, "Defendant" or "Abbott") cannot avoid civil liability for the defective Proclaim implant by asserting a preemption defense because it failed to comply with: critical quality system regulation (QSR) and current good manufacturing practice (CGMP) requirements required by the Food & Drug Administration ("FDA"); the FDA's Premarket Approval Application requirements; and FDA requirements to warn consumers of the known dangers and known adverse events as required by conditions of approval and post-marketing regulations.[1]

5. Abbott's Proclaim system consists of an implantable pulse generator device ("IPG") with output channels which is connected to lead wires with electrodes which are implanted in contact with a patient's spinal cord. The IPG is powered by a battery that can last up to 10 years at the lowest dose setting of 0.6mA, 500 Ohms. It is capable of stimulating the spinal cord nerves through the electrodes of the leads connected to any combination of the output terminals, using a single current source.

6. One of the requirements imposed by the FDA when it approved the sale of the device in December 2001 was that Abbott provide periodic annual reports, and that Abbott share data on adverse events including serious injury and death.

7. 21 CFR § 898.12 provides that any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the International Electrotechnical Commission (IEC) 601-1: Medical Electrical

[1] The failure to follow the CGMPs and QSRs precludes a preemption defense and provides a basis for liability as violations of federal law that are parallel state law claims. See *Warren v. Howmedica Osteonics Corp*., No. 4:10 CV 1346 DDN, 2011 WL 1226975 (E.D. Mo. Mar. 29, 2011). In addition, because Plaintiffs allege the implants were "adulterated" by virtue of failure to conform to applicable performance standards, federal law specifically incorporates CGMPs. 21 U.S.C. § 351.

Equipment.

8. At all relevant times, the Proclaim was widely advertised and promoted by Defendant as a safe and effective management of chronic back pain.

9. Also pursuant to FDA regulations, manufacturers of SCS components are required to report "serious adverse events" to the FDA. 21 CFR § 803.50.

10. The phrase "serious adverse event" is an FDA term of art, but for purposes of this case, a serious adverse event includes an event – including a medical device malfunction -- that may jeopardize the patient and may require medical or surgical intervention to prevent one of the other accepted "serious" outcomes. See for example https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

11. The time frame for submitting an adverse event is within either 5 or 30 days of the manufacturer becoming aware of the event and is not based on the time that the event occurred; the shorter five days' time limit is based on if the event necessitates remedial action. 21 CFR § 803.53(a).

12. With respect to medical device safety, malfunction events are potentially attributed to complex failure modes and root causes are not always well understood, either by the FDA, the manufacturer, or by both.

13. Among other things, 21 CFR § 803 requires the submission of an individual malfunction medical device report (MDR) when a manufacturer becomes aware of information, from any source, which reasonably suggests that one of its marketed devices malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§§ 803.10(c)(1) and 803.50(a)(2)).

14. The FDA refers to these malfunctions as "reportable malfunctions" or "reportable

malfunction events."

15. Under section 519(a)(1)(B)(i) of the FD&C Act, Title 21 Chapter 9 of the United States Code, as amended by Food and Drug Administration Amendments Act (FDAAA) of 2007 manufacturers of permanently implantable devices such as the subject SCS must submit malfunction reports in accordance with part 803 (or successor regulations), unless the FDA grants an exemption or variance from, or an alternative to, a requirement under such regulations under § 803.19.

16. Defendant Abbott has not been granted any such exemption.

17. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The Manufacturer and User Facility Device Experience (MAUDE) database houses the MDRs, and is available to the public and to device manufacturers. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

18. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The Manufacturer and User Facility Device Experience (MAUDE) database houses the MDRs, and is available to the public and to device manufacturers.

19. The MAUDE database reveals that prior to 2023, there were reports of IPG malfunctions including "burning," "overheating of device," and "heating at the pocket site."

20. In November 2018, the Associated Press released findings from a nearly yearlong joint investigation of the global medical devices industry that included NBC, the International Consortium of Investigative Journalists and more than 50 other media partners around the world.[2]

21. The AP's analysis of FDA injury reports found that "shocking" and "burning" had

[2] https://apnews.com/article/wv-state-wire-us-news-ap-top-news-sc-state-wire-health-86ba45b0a4ad443fad1214622d13e6cb

been reported for all major models of spinal-cord stimulators. Id.

22. The subject implanted spinal cord stimulator was manufactured by Abbott and implanted in Plaintiff in 2021, at TriStar Skyline Medical Center, Tennessee.

23. The Proclaim is a "Class III" medical device cleared for commercial distribution by the U.S. Food and Drug Administration ("FDA") through the premarket approval (PMA) process.

24. As part of the approval process referred to above, Defendant was required to engage in limited clinical trials.

25. Although discovery is needed to obtain full data from the clinical trials, there were 500 reported adverse events for the Proclaim device in the three-year period prior to Plaintiff's initial implant surgery with the device in 2021. Nearly half of those reports were related to battery failure or malfunction, which is precisely what happened to Plaintiff.

26. Many of the adverse events were for injuries such as thermal burns, device failure, implant pain, nerve damage and other injuries similar to what Plaintiff experienced.

27. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device. 21 C.F.R. §814.80.

28. The Proclaim was approved by the FDA in December 2001 as part of P010032.

29. Pursuant to the FDA, the Proclaim was approved for "… spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain."

30. A medical device manufacturer's responsibilities do not end with FDA approval.

31. The concept of "Post-market surveillance" (PMS) has been discussed in the medical device industry since before 2005.

32. In the United States, the term PMS is used explicitly to grant the US FDA the authority to require manufacturers to perform studies of medical risk devices, such as the device at issue, which have previously been granted PMA approval.

33. 21 CFR Part 822 details the requirements for PMS in the United States.

34. Broadly stated, The FDA has authorization to require post-market surveillance for class III medical devices that are intended to be implanted in the human body for over one year.

35. The subject SCS is intended to be implanted in the human body for over one year.

36. The FDA requires Abbott to "track" its SCS devices, including the subject device, because they are intended to be implanted for over a year. However, Abbott's post-market submissions to FDA appear to grossly underestimate the frequently and severity of adverse events for the Proclaim device. For example, in a 2023 submission, Abbott told FDA that out of 36,0004 patients implanted with Abbott SCS systems there were only 23 safety events at 12 months following implantation.[3]

37. Abbott relied on diagnosis codes from Medicare databases, even though it had access to far more detailed information about serious adverse events that it was required to report to FDA itself.

38. According to the FDA:

> Post market surveillance is the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device. The data collected under a surveillance order help to address important public health questions on the safety and effectiveness of a device.[4]

39. According to the World Health Organization, "it remains important to continue to collect and evaluate information on the medical device during production and postproduction to

[3] See Summary of Safety and Effectiveness at 50, Jan. 24, 2023.

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and- cosmetic-act

meet requirements for the monitoring of products and processes and to ensure the residual risks remain acceptable with respect to benefits. Appropriate processes allow for early detection of any undesirable effects."[5]

40. Independent of PMSs, medical device manufacturers must follow certain requirements and regulations once devices are on the market. These include reporting of device malfunctions.

41. To the extent that manufacturers comply with their FDA surveillance responsibilities, the reports often appear, directly or indirectly, in the MAUDE database.[6]

42. Burning sensation and nerve damage and device malfunction and failure has been associated with the lead wires of the Proclaim device.

43. Plaintiff brings this action against Abbott in relation to the manufacture, marketing, reporting, and distribution of the Proclaim implant, the repeated failure to follow the requirements imposed by FDA, failure to warn Plaintiffs' healthcare providers of known dangers and known adverse events, and reckless violation of state law.

PARTIES, VENUE AND JURISDICTION

44. Plaintiff Karen Krantz ("Plaintiff") is, and was, at all relevant times, a citizen and resident of Tennessee and the United States.

[5] https://www.who.int/publications/i/item/9789240015319

[6] Underreporting of adverse events is a common problem. "[I]t is evident that [adverse event] reporting does not occur to a great extent, with the rate of reporting estimated to be as low as 0.5% of all occurrences….need for improved vigilance and post-market surveillance has been highlighted in the recent changes to the European Union Medical Device Regulation" Need for Greater Reporting of Medical Device Incidents (EMJ, Jan, 2019)

45. Defendant, Abbott Laboratories (hereinafter "Abbott"), now is, and at all times relevant to this action was, a Delaware Corporation which has its principal place of business and headquarters in Abbott Park, Illinois in Lake County.

46. Abbott has conducted business and derived substantial revenue from within Tennessee and Illinois and has sufficient minimum contacts and purposefully avail themselves of Tennessee and Illinois so as to render the exercise of jurisdiction over it by the Illinois courts consistent with the traditional notions of fair play and substantial justice. The instant cause of action arises from and is related to Abbott's contacts with and conduct and transactions within the States of Tennessee and Illinois. Additionally, diversity jurisdiction exists in this matter because the amount in controversy exceeds $75,000 and there is complete diversity of citizenship by the parties.

47. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 18 U.S.C. §1965 (a) because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacts business affairs and conducts activity that gave rise to the claim of relief in this District.

48. This Court has personal jurisdiction over Defendant as Defendant conducted such business within the State including acts which caused or contributed to Plaintiffs' injuries, and because Abbott's headquarters are in Illinois.

49. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because there is complete diversity of citizenship between the parties. In addition, Plaintiffs seek damages in excess of $75,000, exclusive of interest and costs.

50. At all relevant times, Abbott negligently and recklessly conveyed false and misleading information concerning the Proclaim implants and concealed the risks of serious adverse events associated with the Proclaim implants from Plaintiff, Plaintiff's healthcare

providers, the FDA and the public. But for Abbott's actions, Plaintiff would not have suffered the severe injuries and harms that have resulted from the implantation of the Proclaim implant into Plaintiff 's body.

FACTS REGARDING ABBOTT'S PROCLAIM DEVICES

A. Abbott's SCS Products

51. Defendant Abbott designs, manufactures, markets, and distributes the Proclaim SCS, an implantable device indicated for the treatment of a limited varieties of chronic and intractable pain.

52. Defendant's SCS product includes an Implanted Pulse Generator (IPG) and percutaneous lead wires.

53. The IPG is an implantable device capable of stimulating the spinal cord nerves through the electrodes of the leads connected to any combination of the output terminals, using a single current source.

54. The IPG component of the SCS is implanted in the patient subcutaneously, and the lead wires are implanted and secured along predetermined locations along the patient's spinal cord.

55. Once implanted and operational, the SCS delivers electrical impulses to the patient's spinal cord, with the purpose of modulating the electrical pain signals which manifest in subjective patient pain.

56. The implantation parameters for the SCS and the magnitude of electrical stimulation delivered by it often results in repeated electrical insult to one or more branches of the vagus nerve.

57. The different branches of the vagus nerve, respectively, modulate such processes as esophageal motility, cardiac rhythm, bowel function, and many others.

58. The overstimulation caused by the design of the Proclaim SCS can lead to dysmotility, arrhythmias and incontinence.

59. Moreover, the magnitude and duration of insult to the vagus nerve caused by the

Proclaim SCS can give way to a process called nociception, whereby the parasympathetic nervous system perpetuates the manifestations of the aforementioned overstimulation, rendering the complications functionally permanent.

60. Defendant is aware of these risks and has failed to adequately warn patients or medical providers, including those of Plaintiff.

61. In the 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress instituted a process for product review and clearance, using different pathways and processes to permit drugs and medical devices to be sold to U.S. consumers. Three classes of medical devices are regulated by the FDCA, Class I, Class II and Class III, with greater degrees of scrutiny and regulation imposed on the manufacturer as the levels go from I to III.

62. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

63. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

64. Under a Class III PMA, manufacturers have substantial and ongoing duties because of the degree of risk associated with products carrying the classification. Failing to fulfill the duties and complying with the associated requirements can result in the PMA being withdrawn.

65. State law, via common law and statutory enactments, provides financial remedies for personal injuries arising from violations of parallel federal regulations applicable to Class III devices. 21 U.S.C. § 360(k)(a).

66. Abbott received Pre-Market Approval from the FDA for the Proclaim spinal cord

stimulator in December 2001.

B. Abbott's Sales and Marketing Practices

67. At all relevant times, Abbott engaged in aggressive and deceptive sales practices in order to market the Proclaim device to clinicians engaged in the practice of spinal surgery and treatment of chronic pain syndromes.

68. These sales practices involved direct contact between Abbott sales representatives and patients, including Plaintiff.

69. As a prerequisite to reimbursement for the cost of SCS devices, including the Abbott Proclaim, public and private insurance providers maintain strict requirements to assure that the placement is medically necessary, including:

I. The implantation of the stimulator is used only as a late resort or (if not last resort) for patients with chronic intractable pain.

II. With respect to the first condition, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory or are judged to be unsuitable or contraindicated for the given patient.

III. Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation (such screening must include psychological, as well as physical evaluation).

IV. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy the third condition) must be available.

V. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation. Such relief must exhibit either 50% or greater reduction of the patient's pain or 50% or greater reduction of the patient's reliance on analgesic pain medications.[7]

70. In order to assure the placement of a permanent stimulator implant following the trial stimulation and procure reimbursement for an SCS device, Abbott's sales representatives are

[7] See, e.g. CMS NCD Manual, chapter 1, part 2, § 160.7(B)(2), Electrical Nerve Stimulators

trained to make false and/or misleading statements to patients and/or healthcare providers during the trial stimulation period.

71. The aforesaid false and misleading statements are intended to induce patients and healthcare providers to move forward with implantation of the permanent SCS device.

C. Facts Specific to Plaintiff

72. Or or about 2021, Plaintiff was introduced to an Abbott sales representative named Lauren Hall in Nashville, Tennessee, as part of an evaluation for SCS therapy.

73. Although Ms. Hall had an undergraduate degree in biology from Lipscomb University, she has no formal medical training or medical certification in pain management, neurology, or neuromodulation.

74. Following a surgical procedure in 2021 in which the device was implanted in Plaintiff and connected to an external pulse generator, Ms. Hall consulted with Plaintiff and participated in manipulating the electrical pulse settings of the trial device.

75. As part of ongoing direct marketing efforts, Ms. Hall, as an agent of Abbott and within the scope of her employment by Abbott, made the following material representations to Plaintiff, knowing them to be false:

I. That the pain relief results from a permanent Proclaim implant would be equal to or better than those available from other devices, including those made by competitors such as Medtronic;

II. That the permanent Proclaim would permanently deliver substantial pain relief;

III. That Plaintiff would be able to resume normal activities of daily living following implantation of the permanent Proclaim device;

IV. That she and Abbott's other representatives would be readily available to

Plaintiff for the purpose of programming and adjusting device settings to optimize pain relief;

V. That Abbott's sales reps have the medical knowledge and training necessary to make purposeful, effective adjustments to the Proclaim device settings to achieve adequate pain relief;

76. Ms. Hall, as an agent of Abbott and within the scope of her employment by Abbott, committed knowing omissions and suppressions of material facts, such that Plaintiff would not have permitted the Proclaim to be implanted had he known of such facts:

I. That numerous patients have complained to Abbott that the Proclaim implant failed to deliver the pain relief results of the trial stimulator;

II. That a large percentage of Abbott's permanent SCS devices are eventually explanted due to device failure;

III. That Abbott's sales reps lack the necessary training or knowledge to make purposeful adjustments to the device settings in order to achieve adequate pain relief;

IV. That the pain relief delivered by the permanent Abbott SCS is known to be short-lived in a large number of patients and that a substantial proportion of patients that are implanted with a Proclaim device elect to have it surgically removed within two years of implant;

V. That a large proportion of patients implanted with a Proclaim device have reported severe complications not enumerated in the Instructions for Use (IFU) that accompanies the product. These commonly reported complications include:

i. Chronic or permanent visual and/or cognitive disturbances;

ii. Chronic or permanent dysphagia;
iii. Cardiac arrhythmias;
iv. Chronic or permanent bowel and/or bladder incontinence;
v. Chronic or permanent ataxia and/or lower extremity weakness

VI. That the Proclaim loses battery power rapidly, requiring frequent, long periods to recharge the device;

VII. That certain lead wire extenders commonly attached to the device render the device incompatible with Magnetic Resonance Imaging.

77. On or about 2021, Plaintiff underwent placement of a permanent Abbott Proclaim device by Dr. Chine Sp Logan.

78. Despite best efforts by Plaintiff to work with the Abbott sales representative and her medical providers, the device never worked properly. Plaintiff did not become aware of her potential legal claim until recently, when she contacted the undersigned to explore a potential lawsuit. She therefore relies on the discovery rule applicable to her case for purposes of calculating the statute of limitations.

79. Following the aforementioned encounter, Plaintiff began to experience additional complications, including painful electric jolt sensations, excruciating cold pain in her feet, and nerve damage.

80. On or about April 1, 2024, Plaintiff underwent explantation of the permanent Abbott Proclaim device by Dr. Chine Sp Logan at Tristar Skyline Medical Center in Nashville, Tennessee. Due to continuation of the aforementioned complications, Plaintiff turned off device approximately six months prior to removal, after experiencing months of painful electric shocks and other malfunctions.

81. At no relevant time did Plaintiff abuse or misuse her SCS or its component parts.

82. At all relevant times Plaintiff complied with the directives and instructions associated with use of the device, namely, those set forth in the patient user manual and the instructions provided by Abbott personnel.

83. At the time the Abbott device was placed into Plaintiff's body, she was not advised, nor did she have any independent knowledge, that it was associated with or could cause the injuries enumerated herein.

84. Plaintiff's healthcare providers did not warn Plaintiff of the aforementioned risks with use of the Proclaim because they were not warned of the risks.

85. Had Abbott informed Plaintiff's healthcare providers of the true risks associated with the Proclaim implants, Plaintiff's providers would have advised against implantation of the Proclaim device.

86. Abbott, through its misrepresentations and omissions including their refusals or reckless failures to disclose or report defects and significant events as required by federal law (21 C.F.R. §§ 803.10(c), 803.50, 803.52 and other C.F.R. sections identified herein), and by state law which does not impose duties or requirements materially different from those imposed by federal law, concealed from Plaintiff and her healthcare providers the aforementioned risks associated with the Proclaim implants. All conditions precedent to filing this action have occurred, or have been satisfied or waived.

ABBOTT'S DUTIES PURSUANT TO ITS PMA AND FEDERAL REGULATIONS

87. As conditions of Abbott's PMA approval for its Proclaim device, the FDA required Abbott to conduct the following post-approval studies to characterize the long-term performance and safety of the devices:

I. **"Core Post-Approval Study"** - To assess long-term clinical performance of the device.

II. **"Large Post-Approval Study"** –

III. **"Device Failure Studies"** – to continue preclinical studies to characterize the modes and causes of failure of explanted devices.

IV. **"Focus Group Study"** - To improve the format and content of the patient labeling.

V. **"Informed Decision Process"** – Abbott was required to distribute the approved patient labeling and administer a survey to determine the success of this process and provide a summary of the findings to the FDA.

88. In the PMA approval letter, the FDA further stated, "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

89. In addition to the duties in Abbott's PMAs, Abbott was required to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications set forth in applicable federal regulations, including, but not limited to, 21 C.F.R. Parts 803, 814 and 820.

90. Abbott was also required to notify the FDA of any unexpected serious problems with its Proclaim devices, including failure to operate due to battery defects.

91. Abbott is required by federal law (and parallel state law) to sell and distribute only non-adulterated products pursuant to its PMA. A medical device is deemed adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. This duty is ongoing. *See* 21 U.S.C. § 351.

92. Abbott is prohibited from selling and distributing misbranded products. A medical device is deemed misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling. This duty is ongoing. *See* 21 U.S.C. § 352(a). Moreover, restricted

devices are deemed misbranded if "its advertising is false or misleading in any particular." 21 U.S.C. § 352(q).

93. Abbott was also required to do the following:

I. Report to the FDA information suggesting that one or more of the manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur [21 C.F.R. § 803.50];

II. Monitor the product and report to the FDA any complaints about its performance and any adverse health consequences that are or may be attributable to the product [21 C.F.R. § 814];

III. Follow quality system requirements, found in 21 C.F.R. § 820, the CGMPs, that require manufacturers document all Corrective Action and Preventative Actions taken by the manufacturer to address non-conformance and other internal quality control issues [21 C.F.R. § 820.100];

94. The primary responsibility for timely and accurately communicating complete, accurate and current safety and efficacy information related to medical device, such as the Proclaim implants, rests with the manufacturer.

95. This primary reporting obligation instills in Abbott a duty to vigilantly monitor all reasonably available information, to closely track clinical experiences, and to fully and promptly report all relevant information, specifically but not limited to adverse events, to the FDA, the healthcare community, and consumers.

96. Similarly, under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must precisely monitor its own manufacturing and quality control processes, and its market representations and warranties.

97. These duties establish that time is of the essence for Abbott when reporting adverse events, especially, but not limited to, those adverse events indicating an association between its product and serious injuries.

98. Delayed reporting prevents the healthcare community and the public from timely learning of risks which informs physician and patient decision-making regarding treatments and procedures, and thereby exposes countless of additional women to potential harm.

ABBOTT'S PARALLEL ILLINOIS STATE LAW DUTIES

Abbott's Warning Duties

99. Under Illinois law, Abbott had a duty to provide an adequate warning to end users of its product of known potential harms that may result from use of its product. If the warning is given to an intermediary, here Plaintiff's implanting physician, the manufacturer will have satisfied this duty. Where the manufacturer does not provide warnings to the intermediary, as is the case here, the state-law duty is not satisfied.

Abbott's Reporting Duties

100. Under Illinois law, Abbott had a duty to abide by federal reporting requirements, including the timely and accurate reporting of adverse events.

101. As set forth above, adverse event reports published in the FDA's MAUDE database represent a public communication by a manufacturer about a device's performance and its relationship to a particular adverse health event.

102. These adverse event reports, when prepared properly, serve as an early warning signal for the FDA in monitoring device performance, detecting potential device-related safety issues, and otherwise contributing to benefit-risk assessments of these products.

103. Moreover, such reports are relied upon by the medical and scientific community as a valuable source of information in learning about the genesis of a health event and the nature of any adverse health trends with a medical device.

104. To the extent the medical device reports contain false, inaccurate, or incomplete

information, the FDA is deprived of vital information needed to detect potential device-related safety issues and disseminate public alerts about particular device problems and/or its association to a particular disease.

105. Likewise, the medical and scientific community is deprived of the information needed to educate their patients and obtain informed consent about the risks in choosing a particular device.

106. Further, device user facilities are unable to make informed decisions about the risks of offering for purchase a particular medical device over others on the market.

Abbott's Testing Duties

107. Under Illinois law, a manufacturer has a duty to test adequately for known or foreseeable side effects which the manufacturer knows or has reason to know are inherent in the use of its product as measured by available scientific and medical data. The very purpose of conducting tests is to discover safety issues with a product in order to protect the public.

108. Also under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must adequately test, and validate its product and its components, to assess any association between the product and any dangerous side-effect that could affect the safety of its products.

Abbott's Manufacturing and Design Duties

109. Under Illinois law, Abbott had a duty to comply with all government standards including design validation duties genuinely equivalent to those imposed under federal law. Specifically, Abbott was obligated to use reasonable care in producing any product that, if carelessly made, is likely to injure persons when used in a foreseeable manner.

110. Likewise, a manufacturer has a duty to ensure the product is built in accordance

with its intended specifications and a defect exists when an item is produced in a substandard condition.

111. Moreover, under Illinois law, Abbott had manufacturing processes validation duties genuinely equivalent to those imposed under federal law. This duty requires reasonable care to be exercised in assembling component parts and inspecting and testing them before the product leaves the plant. This duty encompasses a manufacturer's obligation to employ appropriate quality control techniques to prevent manufacturing defects.

112. As a result of Abbott's failure to establish such quality systems as required by 21 C.F.R. § 820—its SCS devices were, at times, adulterated within the meaning of 21 U.S.C. § 351(h) when they were placed in the stream of commerce by Abbott.

113. Plaintiff further alleges that Defendant failed to take reasonable post-market corrective and preventive action in order to validate its design and properly detect recurring quality problems related to the battery function of the Proclaim device and to correct such quality problems.

114. Also under state law, which does not impose duties or requirements materially different from those imposed by federal law, the manufacturer must adequately inspect, test, and validate its product and its components, and monitor its manufacturing and quality control processes to ensure there are no deviations from product specifications or regulations that could affect the safety of its products, such as Abbott's implants.

PLAINTIFF'S IMPLANT HAD MANUFACTURING DEFECTS BASED ON ABBOTT'S VIOLATIONS OF CGMP REQUIREMENTS

115. The fundamental purpose of SCS devices is to provide relief from chronic pain. To continuously ensure that the SCS devices could adequately fulfill this purpose, they were subjected to numerous conditions, including the requirement that every implant manufactured by Abbott would strictly adhere to the approved design standards and current good manufacturing practices.

116. By evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, and utilization of standard operating procedures, Abbott could have assured the production of the Proclaim implants that complied with its specifications and met the appropriate quality standards. Abbott was under a continuing duty to follow the manufacturing and design specifications mandated by the FDA as part of the PMAs, and the general requirements set forth current good manufacturing practices ("CGMPs") provisions of the MDA governing the safety and effectiveness of a PMA medical device. *See* 21 U.S.C. 351; 21 C.F.R. Part 820.

117. Pursuant to the CGMPs regulations, Abbott was obligated to implement and maintain quality control systems to validate processes and conduct inspections and testing to ensure the conformity with performance standards of the Proclaim implants and not produce adulterated implants, specifically those which failed to provide the level of pain relief provided by the trial implant 21 U.S.C. 351; 21 C.F.R. § 820.

118. Notwithstanding this obligation, Abbott distributed, at times, adulterated implants that failed to perform in the same manner as the trial device in violation of manufacturing/ design specifications and CGMP regulations designed to ensure device quality and patient safety.

119. As a result, Abbott failed to perform its duties properly, and failed to implement and maintain quality control systems with respect to performance standards for its Proclaim implants, even though it was aware that its Proclaim implants often could, and in Plaintiff's case, did fail the prescribed performance standards of 21 C.F.R. § 820 and 21 U.S.C. 351.

120. Plaintiff's implants were adulterated within the meaning of 21 U.S.C. 351(h) when they were placed in the stream of commerce by Abbott, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the manufacturing/design specifications and CGMP design controls enumerated in 21 C.F.R.

Part 820 designed to prevent exposing patients to risks of serious injury or death when the device is used as intended by the surgeon.

121. Abbott violated these regulations, in part, by failing to establish norms and guidelines for functional validation. It was Abbott's duty to comply with the PMAs and the FDA's Quality System Regulations and Current Good Manufacturing Practices as well as its state law duties.

122. Had Abbott fulfilled its CGMP duties, as set forth above, it would have detected the broad nonconformance to performance standards for its devices and could have disposed of them prior to them being introduced into the stream of commerce.

123. As a result of Abbott's post-market negligence in adhering to its CGMP requirements, the dangerous nature of the product became known only after having been implanted in Plaintiff and causing the injuries enumerated herein.

124. Had Abbott fulfilled its CGMP duties, the non-conforming implant would never have been implanted into Plaintiff's body.

125. Notwithstanding these duties, Abbott violated 21 U.S.C. §§ 331, 351(h), and 21 C.F.R. Part 820 and its parallel state duties by introducing adulterated devices into interstate commerce.

A. Abbott Violated 21 C.F.R. §§ 820.30(a)-(g), 820.70(a), 820.75 By Failing To Maintain Procedures To Control The Implant's Design and Manufacturing

126. The FDA mandates that medical device manufacturers must implement design control processes to assure: 1) user needs and intended uses are met, and 2) design is adequately transferred into manufacturing. Design controls are an interrelated set of practices and procedures incorporated into the design and development process, *i.e.*, a system of checks and balances. A

manufacturer must develop a design control consistent with the design's risk, which will, in turn, determine the depth/level of actions required. Design controls make a systematic assessment of the design an integral part of post-approval requirements.

127. Design control does not end with the transfer of a design to production. Design control applies to all changes to the device or manufacturing process design, including those occurring long after a device has been introduced to the market. This includes evolutionary changes such as performance enhancements, and revolutionary changes such as corrective actions resulting from failed product analysis. The changes are part of a continuous, ongoing effort to design and develop a device that meets the user and/or patient's needs. Thus, a manufacturer must revisit the design control process frequently during the life of a product.

128. The quality system requirements dictate that, no matter what a manufacturer's processes may be, design controls must be applied appropriately to ensure device quality. That is, to say, manufacturers must establish and maintain procedures *at all stages* of the production process to ensure quality by requiring the ultimate output to conform to specified design requirements. 21 C.F.R. § 820.30(a). Pursuant to 21 C.F.R. § 820.3(s), quality refers to the totality of features and characteristics that bear on the device's ability to satisfy fitness-for-use, including safety and performance.

129. Abbott violated 21 C.F.R. §§ 820.30(a)-(g), 820.70(a), 820.75 by failing to establish and maintain procedures for validating the design of HFX implants. In particular, after the receipt of complaints of serious injuries and deaths demonstrating the device's failure to satisfy fitness-for-use, Abbott failed to maintain proper procedures to ensure those finished devices were in conformance with the PMA quality requirements. Abbott likewise failed to update its design quality procedures following corrective actions resulting from the analysis of products involved in serious injury events.

B. Abbott Violated 21 C.F.R. § 820.50(a) By Failing To Ensure All Product Components Conform To Quality Requirements.

130. Pursuant to 21 C.F.R. § 820.50(a), manufacturers are required to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to quality requirements. Product refers to the components, manufacturing materials, in-process devices, finished devices, and returned devices. 21 C.F.R. § 820.3(r). Component includes any raw material, substance, piece, part, software, firmware, labeling, or assembly, which is intended to be included as part of the finished, packaged, and labeled device. 21 C.F.R. § 820.3(c).

131. The intent of Section 820.50(a) is to ensure that device manufacturers select only those suppliers, contractors, and consultants who can provide quality product and services. This is because the finished medical device's quality depends on the quality of the components and raw materials. Poor quality can cause injuries from the medical device, as well as recalls. Moreover, manufacturer diligence in complying with these requirements is critical because the FDA does not inspect component suppliers. Product or service suppliers are to be reviewed at intervals consistent with the significance of the product or service provided and demonstrate conformance to specified requirements.

132. Abbott violated 21 C.F.R. § 820.50(a) with respect to, *inter alia*, the lead extensions used in some devices which render the HFX incompatible with magnetic resonance imaging (MRI) in conformance with quality requirements. In contravention to federal requirements, the lead extensions used in of Plaintiff's implant procedure could not satisfy basic fitness for use.

C. Abbott Violated 21 C.F.R. § 820.90(a) by Failing to Identify and Address Nonconforming Product and Processes

133. Anytime a device, or component thereof (21 C.F.R. § 820.3(r)), fails to meet any of its specifications (21 C.F.R. § 820.3(y)) that constitutes a nonconformity (21 C.F.R. 820.3(q)). Pursuant to 21 C.F.R. § 820.90(a), manufacturers shall establish and maintain procedures to control

such nonconforming product that does not meet specifications. Nonconformances can occur in both product and process, and importantly, nonconforming processes, like Abbott's manufacturing practices, can lead to nonconforming product.

134. When a nonconforming product or process is identified, a manufacturer must evaluate the nonconforming product. The evaluation of nonconformance must include a determination of the need for an investigation into the nonconformance. Investigations are required unless one has already been performed on a similar issue.

135. Upon identifying a nonconforming product or process, a manufacturer must segregate those devices to ensure they are not released and are ultimately disposed. Disposition of nonconforming product must be documented, including the justification for use of nonconforming product. Any such justification is to be based on objective scientific evidence.

136. Abbott violated 21 C.F.R. § 820.90(a) by failing to establish and maintain procedures to control SCS devices that do not conform to specification. This includes failing to identify nonconformities in relation to device impedance levels and other basic performance standards and evaluating the cause of the nonconformity. Rather than disposing of nonconforming products as required by the prevailing scientific evidence, Abbott allowed them to be sold on the open market to consumers, including Plaintiff.

D. Abbott Violated 21 C.F.R. § 820.100(a) by Failing to Take Necessary and Required Corrective and Preventive Action

137. A manufacturer's Corrective and Preventive Action ("CAPA") subsystem is intended to be the ultimate fail-safe against product and quality problems. CAPA requirements include collecting and analyzing information to identify actual and potential product and quality problems, investigating any problems discovered, taking appropriate and effective, and validate the effectiveness of the action taken. Whereas corrective action deals with eliminate the cause of a

detected non-conformity or other undesirable situation, preventative action is designed to eliminate the cause of a potential non-conformity or other undesirable situation. Preventative action is required even when there is more than one cause for a potential nonconformity.

138. The procedures for implementing corrective and preventive action required under 21 C.F.R. § 820.100(a) must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities. CAPA requirements likewise apply to process and quality system nonconformities. The need for such action can be triggered by information coming from internal sources, such as test/inspection data and process control data, and external sources such as medical device reporting, customer complaints, and issues in similar devices from competitors.

139. Once a nonconformity is identified, a manufacturer must investigate the root cause of the nonconformities relating to product, processes, and the quality system. Nonconforming product discovered before or after distribution must be investigated to the degree commensurate with the significance and risk of the nonconformity. Similarly, the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered.

140. Rather than engage in the requires CAPA processes, Abbott suppressed adverse events and inaccurately reported others as being unrelated to the device.

141. Despite possessing knowledge of the widespread product nonconformities and patient injuries, including but not limited to battery failure and malfunction, Abbott failed to take corrective action with respect to its own manufacturing practices to mitigate the risk to patients like Plaintiff.

142. Abbott, in violation of 21 C.F.R. § 820.100(a), failed to establish and maintain

procedures for implementing corrective and preventive action in order to properly detect recurring quality problems related to the continued failures of the Proclaim implants, investigate causes of nonconformities in these processes and products, identify necessary action to correct and prevent recurrence of nonconforming implants, and implement changes in methods to correct such quality problems. Despite repeatedly receiving reports and information about injuries such as those suffered by Plaintiff from internal and external sources, Abbott conducted no investigations into the nonconformities and failed to take appropriate and required corrective action. Worse yet, out of pecuniary interests, Abbott failed to thereafter take preventive action to prevent reoccurrence of the nonconformity.

E. Abbott's Violations of Current Good Manufacturing Practices Rendered the Proclaim Implants Adulterated Which Led to Plaintiff's Harm

143. Abbott's post approval misconduct violated the PMAs, the manufacturing and design specifications, CGMPs, QSRs, other federal regulations and parallel state law, resulting in the injuries which Plaintiff suffered.

144. The harms described above directly resulted from the variations from the approved design and manufacturing specifications. Had Abbott utilized CGMPs and complied with QSRs, and undertaken the manufacturing process in an appropriate manner, it would have consistently produced a product in conformity with its approved specifications. Moreover, by evaluation, recordkeeping, study and analysis, validation and review of processes, equipment, supplies, as well as utilization of standard operating procedures, Abbott could have assured the production of the Proclaim implants that complied with its specifications and met the appropriate quality standards.

145. The Abbott Proclaim device that was implanted into Plaintiff was *adulterated* in that they were not manufactured in conformity with the CGMP requirements identified above. *See* 21 U.S.C. §§ 351(h), 360j(f)

146. 21 C.F.R. § 808.1(d)(2)(ii) provides that, generally, § 521(a) of the FDCA *does not preempt* a state or local requirement prohibiting the manufacture of adulterated or misbranded devices.

147. Adulterated medical devices are not subject to preemption.

148. These specific allegations of violations of the federal PMAs, laws, regulations, and requirements due to manufacturing in violation of federal law are not subject to federal preemption.[16]

149. Abbott's violations of the PMAs and violations of FDA requirements set forth in the QSRs and CGMPs, specifically, failure to adhere to 21 C.F.R. § 820.80 requiring the sequestration of devices that don't meet performance standards, was a direct cause Plaintiff's injuries.

150. But for Abbott's failure to comply with the above requirements, including established post-market validation and correction obligations, Plaintiff would have decided against implantation and her injuries would not have occurred.

151. Similarly, Abbott violated its parallel state law duties in failing to ensure conformity to its own PMA specifications and compliance with CGMPs, resulting in adulterated devices.

F. Abbott Violated 21 C.F.R. § 803.19(b) And 21 C.F.R. §§ 803.50, *et seq*. By Employing A Flawed Database Algorithm That Ignored Cases of Serious Injuries from SCS Devices

152. A manufacturer must report adverse events no later than 30 calendar days after the day that it received or otherwise become aware of information, *from any source*, that reasonably suggests that a device may have caused or contributed to a death or serious injury or malfunctioned. 21 C.F.R. § 803.50 (emphasis added).

153. This reporting duty is triggered not just for events occurring within the United States and its territories, but also adverse events occurring in a foreign country concerning the device. *See* 21 C.F.R. § 803.52(e)(3) (incorporating by reference FDA Form 3500A, Block G).[24] Under the FDA's Medical Device Reporting for Manufacturers Guidance for Industry, the FDA considers an event that occurs in a foreign country reportable under the MDR regulations if it involves a device that has been cleared or approved in the United States—or a device similar to a device marketed by the manufacturer that has been cleared or approved in the United States—and is also lawfully marketed in a foreign country.

154. Abbott's reporting requirements under federal law are stringent and any deviations therefrom requires express authorization by the FDA. 21 C.F.R. § 803.19(b). Absent an affirmative exemption, Abbott was required to collect all of the information required by 21 C.F.R. § 803.52 that is known or reasonably known. By deliberating excluding pertinent event information, Abbott failed to comply with 21 C.F.R. § 803.19(b) through its use of its algorithm in this manner and as a result excluded reportable events from reporting despite never being granted an exemption to do so by the FDA. Abbott was well-versed in the information to be collected and disclosed and had been fulfilling that obligation for decades for a variety of adverse events. And yet, when presented with numerous severe and life-threatening complications from its devices, it deliberately implemented a system that turned a blind eye to it.

155. As a result, Abbott was engaged in inadequate post-market surveillance concerning:

f. The analysis of the incident outcomes broken down by SCS devices by device specification, in order to allow the inter-comparison of the Benefit/Risk ratio of the various SCS models;

g. the exhaustive list of the typologies of reported incidents, from the most frequent to the rarest ones; and

h. the in-depth analysis of the key points, issues and stakes stemming from the data related to adverse event cases, including the demonstration of the preservation of the SCS devices' Benefit/Risk ratio.

156. Under federal law, a medical device report must contain all the information required by 21 C.F.R. § 803.52 that is known or reasonably known to the manufacturer. Information considered reasonably known includes any information: 1) that can be obtained by contacting a user facility, importer, or other initial reporter; 2) that is in the manufacturer's possession; or 3) that can be obtained by analysis, testing, or other evaluation of the device. 21 C.F.R. § 803.50(b).

157. Likewise, the information to be disclosed is equally expansive. The reporting requirements are expansive, and a manufacturer "must include," amongst other items:

i. an identification of the adverse event or product problem;

j. a description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;

k. a summary of the evaluation of the device, or an explanation of why an evaluation was not performed;

l. evaluation codes;

m. whether remedial action was taken and the type of action; and

n. an explanation of why any required information was not provided in the MDR and the steps taken to obtain this information.

21 C.F.R. § 803.52.

158. Rather than complying with these obligations, Abbott deliberately limited its reports to medical and scientific literature, *without further investigation.* This conduct falls well-short of the requirements of 21 C.F.R. §§ 803.50, *et seq*. Despite the public health crisis implicated by the product complaints it was receiving, for years Abbott deliberately and unlawfully limited the information it was collecting about injuries from its devices, concealed how and when it was collecting it, and performed virtually no assessment of production impact on these events.

G. Abbott Violated 21 C.F.R. §§ 803.1, 803.19(b), And 803.50 and Parallel State Law By Concealing Pertinent Adverse Event Reports

159. As complaints continued to rise in frequency, rather than complying with the federal statute and regulations on medical device reporting, Abbott devised a scheme to use vague, boilerplate MDR analyses in connection with events associated with its products.

160. Had Abbott lawfully reported adverse events until the time of Plaintiff's implantation or symptoms, she would not have suffered the injuries enumerated herein. Instead, the Plaintiff and her physician were both unaware of the extent of the risk of the injuries enumerated herein when the subject device was implanted, causing her serious injuries.

H. Abbott's Reporting Abuses and Plaintiff's Harm Are Causally Related

161. The medical and scientific community relies on the FDA's MDR information, in particular the MAUDE database, for studying and evaluating new and emerging treatments and complications.

162. Also under Illinois law, which imposes duties genuinely equivalent to those imposed by federal law, the manufacturer must act reasonably in conveying warnings concerning the safety of its products. Abbott was, thus, under a continuing duty under state law to adequately report injuries and problems with its devices, including the products, to the FDA.

163. As a result of Abbott's post-market failure to report to the FDA and as a result of Abbott's post-market misconduct, the defective and unreasonably dangerous nature of the product became known only after having been implanted in Plaintiff, and otherwise would have never would have been implanted in the Plaintiff at all.

164. Had Abbott properly reported the adverse events associated with its Proclaim implants, the FDA would have included accurate accounts of those adverse event reports in the MAUDE database. Plaintiff's implanting physician, who visits the MAUDE database and reads

adverse event reports prior to making product recommendations, would have seen the adverse event reports related to the Proclaim and would have recommended safer treatment modalities for Plaintiff.

CAUSES OF ACTION
COUNT I –MANUFACTURING DEFECT

165. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

166. Abbott's Proclaim implants were in a defective condition at the time of sale, beyond which would be contemplated and expected by the ordinary consumer.

167. Proclaim implants were expected to, and did reach, Plaintiff without substantial change to their condition which was defective unsafe and unable to be used without subjecting Plaintiff to a significant risk of injury.

168. No ordinary consumer would have contemplated that the Proclaim implants she had chosen for would cause her injuries, because she expected them to work properly and in fact they never worked properly after the trial.

169. Neither Plaintiff nor her medical providers could, in the exercise of reasonable care, have discovered the manufacturing defect.

170. The Proclaim implant Plaintiff received were not the SCS devices approved by the FDA as they deviated from specifications and the battery did not work properly.

171. Abbott manufactured Plaintiff's defective implants, in deviation of its specifications, which caused Plaintiff's injury.

172. Such manufacturing is in violation of state law, which does not impose duties or requirements materially different from those imposed by federal law including the PMA post-approval specifications and regulatory requirements, resulting in product failure and serious injury

to Plaintiff.

173. Abbott had parallel duties under state and federal law pursuant to the federal post-approval requirements, to exercise reasonable care in manufacturing the products without deviations and defects.

174. Abbott's duties do *not* add to or change Abbott's manufacturing requirements. Nor does it require that Abbott implants be manufactured in a manner different from the FDA approved manner.

175. This claim parallels the FDA requirements that Abbott manufacture its SCS devices to avoid plaintiff defect-related injury, in accordance with the FDA regulations and PMA specifications.

COUNT II– BREACH OF IMPLIED WARRANTIES

176. Plaintiff re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

177. As set forth in the manufacturing defect section above, Abbott sold its Proclaim implants to Plaintiff in a defective condition which violated the FDA's requirements.

178. Abbott knew that Plaintiff and her physician were purchasing the implants for chronic pain management, and both were relying on Abbott for furnish suitable goods that adhered to its FDA specifications, including having a battery that functions properly.

179. Abbott's violations of its federal requirements caused Plaintiff's HFX implants to be defective such that they did not conform to Abbott's implied warranty that they were fit for their ordinary and intended purpose, based in part on the promises made by the Abbott sales representative Ms. Hall.

180. Plaintiffs' claim for breach of warranty is based on Abbott's non-compliance with

its FDA specifications and does not add to or change anything required by the FDA.

181. This breach of implied warranty claim, or the selling of non-conforming implants as though they have met all federal requirements, caused Plaintiff's injuries.

182. Plaintiffs seek to hold Abbott accountable *only* for what federal law mandated - nothing more. Nothing in this claim is different from, or in addition to, the federal requirements.

183. Abbott impliedly warranted that the product was fit for its particular purpose for which it was intended and of merchantable quality.

184. Abbott breached the implied warranty of merchantability by selling products that were not of merchantable quality and were not safe and fit for their intended use.

185. Plaintiff and Plaintiff's physician relied upon Abbott's implied warranties that the implants were manufactured in accordance with federal specifications.

186. Plaintiff's injuries are permanent and continuing in nature, required and will require medical treatment and hospitalization, have become and will become liable for medical and hospital expenses, lost and will lose financial gains, have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

COUNT III–FAILURE TO WARN

A. Violation of Illinois and/or Tennessee Law for Failure to Provide Warnings

187. Plaintiffs re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

188. In Illinois and Tennessee, a manufacture of a defective product owes a duty to warn of known risks associated with its products. A manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the learned intermediaries.

189. Likewise, under federal law, manufacturers of medical devices have an affirmative duty to include the FDA approved label with adequate directions for use with its products. *See* 21 U.S.C. § 352(f).

190. Abbott failed to provide a label or warning, in any form, to Plaintiff's physician.

191. In violation of federal law and parallel, genuinely equivalent state claims, Abbott failed to provide adequate warnings related to the injuries Plaintiff suffered through package inserts, brochures or its sales representatives to Plaintiff's physician who was therefore unable to warn Plaintiff.

192. Had Plaintiff's physician been warned of the risk of the injuries Plaintiff suffered, she would have recommended a safe alternative and Plaintiff would not have been injured.

193. The state-based requirement to warn prescribing physicians does not add to or change any federal requirement and therefore is not preempted.

194. Defendants breached their duty by failing to provide any warning of the risk of Plaintiff's injuries with its devices to Plaintiff's physician.

195. Defendants' breach of their duty effectively stripped Plaintiff's physician, of the ability to provide accurate risk information and allow Plaintiff to make an informed decision about having Abbott's implant implanted into her body.

196. Defendants' breach was the substantial and proximate factor in causing Plaintiff's injuries and suffering arising therefrom.

COUNT IV- NEGLIGENCE- PRODUCT LIABILITY

197. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

198. At all relevant times, Abbott had a duty to Plaintiffs to manufacture the implants

properly in compliance with applicable regulations and FDA specification.

199. As set forth throughout this Complaint, Abbott breached its parallel state and federal duties to Plaintiffs and Plaintiff's physician, in the following ways, among others:

I. Failing to establish procedures for conducting quality audits and to conduct such audits to assure that the quality system was in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 C.F.R. § 820.22;

II. Failing to perform proper risk analysis as required by 21 C.F.R. § 820.30(g);

III. Failing to establish and maintain procedures for monitoring and control process parameters for validated processes to ensure that the specified requirements continue to be met as required by 21 C.F.R. §820.75(b);

IV. Failing to develop, conduct, control, and monitor production processes to ensure that devices conformed to specifications as required by 21 C.F.R. § 820.70(a);

V. Failing to investigate the cause of nonconformities relating to product, processes, and the quality system as required by 21 C.F.R. §820.100(a)(2); and

VI. Failing to identify the actions needed to correct and prevent recurrence of nonconforming product and other quality problems as required by 21 C.F.R. 820.100(a)(3);

200. Each of the above acts of negligence, whether acts of omission or commission, were a proximate cause of Plaintiff's injuries.

201. Nothing within this claim adds to or changes any federal requirements.

202. At all material times, Abbott owed to Plaintiff a duty to use reasonable care, pursuant to the federal post-approval requirements, in the manufacture of its SCS devices and breached this duty by manufacturing and selling Plaintiff defective implants.

203. Abbott breached these duties as set forth above.

204. Abbott's state law-based duties do *not* add to or change Abbott's manufacturing requirements. Nor does it require that Proclaim implants be manufactured in a manner different from the FDA approved manner.

205. This claim parallels the FDA requirements in that it requires Abbott to manufacture

its Proclaim implants in accordance with the FDA regulations and PMA specifications.

JURY DEMAND

Plaintiffs demand a trial by jury on all of the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court enter judgment in their favor and against Abbott, awarding Plaintiffs:

I. actual or compensatory damages including pain and suffering, emotional distress, disfigurement, loss of consortium, past and future medical expenses, and lost wages in such amount to be determined at trial and as provided by applicable law;

II. exemplary damages sufficient to punish and deter Abbott and others from future negligent and reckless practices;

III. pre-judgment and post-judgment interest;

IV. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

V. any other relief the Court may deem just and proper.

Dated: March 19, 2025

Respectfully submitted,

/s/ Edward A. Wallace

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