**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

**ANGELA YATES**,

Plaintiff,

v.

**MEDTRONIC, INC.,**

**MEDTRONIC USA, INC.,** and

**UNITED STATES FOOD AND DRUG ADMINISTRATION,**

Defendants.

**COMPLAINT**

Plaintiff Angela Yates, by and through undersigned counsel, brings this Complaint against Defendants Medtronic, Inc., Medtronic USA, Inc., and the United States Food and Drug Administration, and alleges as follows:

## I. PARTIES, VENUE, AND JURISDICTION

1. Plaintiff Angela Yates ("Plaintiff") is and was at all relevant times a resident of Auburn, Kentucky. Plaintiff underwent implantation of a Medtronic-manufactured spinal cord stimulator (SCS) system in June 2015 in Bowling Green, Kentucky. The device was marketed and sold by Medtronic in Kentucky.

2. Defendant Medtronic, Inc. is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business located at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic,

Inc. designs, manufactures, markets, distributes, and services Class III neuromodulation devices, including spinal cord stimulators, and is the sponsor of Premarket Approval (PMA) No. P840001.

3. Defendant Medtronic USA, Inc. is a wholly owned subsidiary of Medtronic, Inc., with its principal place of business located at the same address. It is registered with the FDA as an establishment engaged in the distribution and servicing of implantable neurostimulator systems and provides sales and field support for Medtronic's SCS devices.

4. Defendants Medtronic Inc. and Medtronic USA, Inc. are hereinafter collectively referred to as "Medtronic."

5. Defendant United States Food and Drug Administration ("FDA") is an agency of the United States government with authority and responsibility for regulating medical devices under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the Medical Device Amendments of 1976.

6. Venue is proper in this District under 28 U.S.C. § 1391(b)(1)–(2) because Defendants Medtronic, Inc. and Medtronic USA, Inc. reside in this District and a substantial part of the events and omissions giving rise to the claims occurred in this District, including the design, manufacture, regulatory submission, and commercialization of the device at issue.

7. This Court has subject matter jurisdiction over Plaintiff's claims against the FDA pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 702, because Plaintiff

asserts claims for declaratory and injunctive relief under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701–706.

8. This Court has supplemental jurisdiction over Plaintiff's state-law claims pursuant to 28 U.S.C. § 1367, and diversity jurisdiction under 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000 and the parties are citizens of different states.

9. This Court has personal jurisdiction over Medtronic, Inc. and Medtronic USA, Inc. because both are headquartered in this District and regularly conduct business throughout the United States, including the design, manufacture, and distribution of the spinal cord stimulator implanted in Plaintiff.

**Applicable Law and Choice of Law Considerations**

10. Plaintiff brings certain claims under the substantive law of the Commonwealth of Kentucky, where she resides and where her injuries occurred. However, Plaintiff also invokes the public policy and statutory protections afforded by Minnesota law, including Minn. Stat. §§ 541.31 and 541.33, which govern conflicts of law and borrowing of foreign limitations periods in actions brought against Minnesota defendants.

11. Defendant Medtronic, Inc. is a Minnesota corporate citizen headquartered and operating within this District. Its decisions regarding the design, manufacture, and regulatory strategy for its spinal cord stimulator (SCS)

systems, including the decisions at issue in this case, were undertaken, approved, and directed from its Minnesota headquarters.

12. Minn. Stat. §§ 541.31 and 541.33 provide that, in cases involving claims arising in another state, Minnesota courts shall apply the statute of limitations of the state with the most significant relationship to the claim, unless doing so would violate Minnesota's fundamental public policy. Further, these statutes authorize application of Minnesota law to the conduct of a Minnesota domiciliary when such Minnesota-based conduct causes injury outside the state.

13. Because this action arises from the intentional and ongoing conduct of a Minnesota corporate defendant, undertaken within Minnesota, Plaintiff asserts that Minnesota's borrowing statutes apply. Plaintiff further reserves the right to invoke Minnesota's substantive law to the extent it reflects the state's strong public interest in regulating the conduct of Minnesota corporations that market and distribute nationally regulated medical devices that harm consumers in other states.

## II. FACTUAL ALLEGATIONS REGARDING MEDTRONIC SCS DEVICES AND REGULATORY HISTORY

14. The spinal cord stimulator (SCS) system implanted in Plaintiff was part of a family of neuromodulation devices manufactured by Medtronic, Inc., and approved by the United States Food and Drug Administration (FDA) under Premarket Approval (PMA) No. P840001.

15. Medtronic received original PMA approval for its SCS system in 1984. The approved indication was for the management of chronic intractable pain of the trunk and/or limbs. The original system included an implantable pulse generator (IPG), extension leads, electrodes, and external components for programming and charging.

16. From 1984 onward, Medtronic submitted hundreds of PMA Supplements under P840001. These supplements introduced extensive changes to the design, firmware, power sources, waveforms, surgical interfaces, and indications for use of the SCS system. Examples of material PMA Supplements include:

a. S025 (1992): Approval of the Itrel II family, a redesigned SCS system with revised electronic architecture.

b. S037 (1995): Introduction of the Itrel III system for the treatment of chronic intractable pain.

c. S042 (1999): Approval of the Synergy dual-channel neurostimulation system and MemoryMod software.

d. S074 (2005): Introduction of the Restore rechargeable neurostimulator.

e. S092 (2006): Approval of the RestoreAdvanced and PrimeAdvanced systems with enhanced stimulation capabilities.

f. S185 (2011): Approval of the RestoreSensor system with integrated motion sensing and adaptive stimulation features.

g. S219 (2013): Introduction of MRI-compatible systems under the SureScan label.

h. S344 (2017): Approval of the Intellis SCS system with redesigned battery and stimulation controls.

i. S469 (2022): Expanded indication for the treatment of diabetic peripheral neuropathy of the lower limbs.

j. S512 (2024): Approval of the Inceptiv closed-loop stimulation system with NeuroSense technology.

17. These changes were submitted through the PMA Supplement process despite materially altering the safety profile, therapeutic mechanism, and intended use of the device. In many cases, Medtronic introduced entirely new generations of neurostimulators, functionally distinct from the original system, without obtaining a new PMA or undertaking the clinical validation required for first-time approvals.

18. By utilizing the PMA Supplement process instead of filing a new PMA application, Medtronic avoided the rigorous scientific review, public comment, and clinical trial requirements intended by Congress for Class III medical devices.

19. The FDA, in turn, accepted these material modifications without requiring a comprehensive reassessment of the device's evolving design, cumulative risks, or real-world complication rates.

20. The device implanted in Plaintiff Angela Yates in June 2015 is not meaningfully the same as the system originally approved in 1984. By 2015, Medtronic's SCS systems had undergone extensive hardware and software changes that departed from the scientific and regulatory assumptions underlying the original PMA. These include changes to waveform modulation, lead configuration, power delivery, battery chemistry, remote interfaces, and operative programming.

21. At no point did the FDA require Medtronic to file a new PMA for these substantially redesigned systems. Instead, the agency allowed Medtronic to submit successive Supplements that, individually and collectively, circumvented the statutory mandate for new PMA review when a device undergoes material changes to its safety or effectiveness profile.

22. As a result, the device implanted in Plaintiff, a system materially altered from the original PMA configuration, entered the stream of commerce without adequate scientific validation, post-market safety surveillance, or transparent disclosure of the risks associated with its reengineered components.

23. Plaintiff's injuries were caused by defects and complications traceable to this unvalidated design evolution, enabled by the regulatory loophole of serial PMA Supplement approvals.

## III. REGULATORY FRAMEWORK AND DUTIES UNDER FEDERAL LAW

24. Under the Federal Food, Drug, and Cosmetic Act, medical devices intended to support or sustain human life, or to prevent impairment of human health, are designated as Class III devices. See 21 U.S.C. § 360c(a)(1)(C).

25. Class III devices are subject to the most stringent regulatory controls and require Premarket Approval (PMA) from the FDA. The PMA process mandates the submission of valid scientific evidence establishing a reasonable assurance of the device's safety and effectiveness for its intended use. See 21 U.S.C. § 360e; 21 C.F.R. Part 814.

26. Once a PMA is approved, a manufacturer may not make any change to the device that affects its safety or effectiveness without prior FDA approval. Such changes must be submitted through either a PMA Supplement or, where the change is significant, a new PMA application. See 21 C.F.R. § 814.39(a).

27. According to the FDA's own regulations, if a proposed modification to a device significantly affects its design, intended use, performance, or safety profile, a new PMA is required. See 21 C.F.R. § 814.39(a)(2), (b).

28. The manufacturer of a Class III device is prohibited from unilaterally modifying its design, indications, or performance characteristics in any way that could impact safety or effectiveness without obtaining FDA approval through the proper regulatory pathway.

29. In addition to premarket obligations, manufacturers of Class III devices are subject to post-market surveillance duties. These include compliance with current Good Manufacturing Practices (cGMPs), adverse event reporting, device tracking, and corrective and preventive action requirements under 21 C.F.R. Parts 803 and 820.

a. 21 C.F.R. § 803.50 requires manufacturers to report any information that reasonably suggests a device may have caused or contributed to a death or serious injury, or has malfunctioned in a manner that would likely cause or contribute to such harm if the malfunction recurred.

b. 21 C.F.R. § 820.30 mandates the use of design controls to ensure that modifications to a device are appropriately validated and verified before implementation.

c. 21 C.F.R. § 820.100 requires that manufacturers identify quality issues, investigate root causes, and implement corrective and preventive actions (CAPA) to reduce the likelihood of recurrence.

30. A manufacturer's failure to comply with these requirements, whether by submitting material changes under the improper regulatory pathway or by failing to investigate and mitigate known post-market safety risks, violates federal law and provides the basis for parallel state law claims.

31. Medtronic's obligations under these regulations are non-discretionary. The company may not characterize a substantive design change as "minor" in order to avoid the requirement to submit a new PMA. Such misclassification, if permitted by the FDA, does not shield the manufacturer from liability under state law for injuries resulting from the unauthorized marketing of a materially modified device.

32. As set forth below, Medtronic materially altered its SCS system over the course of multiple PMA Supplements, bypassed the new-PMA requirement, failed to disclose safety risks, and introduced devices into the marketplace that were never subject to the clinical scrutiny Congress intended for Class III products.

## IV. SPECIFIC ALLEGATIONS REGARDING THE FDA, THE APA, AND AGENCY CAPTURE

33. The spinal cord stimulator (SCS) system implanted in Plaintiff was manufactured by Medtronic, Inc. and approved under PMA No. P840001. That original PMA, granted in 1984, authorized the marketing of a basic neurostimulation system to treat chronic pain of the trunk and/or limbs.

34. Since that time, Medtronic has submitted over 500 PMA Supplements to P840001. Many of these Supplements introduced substantive changes to the design, waveform delivery, battery architecture, remote interface, lead configurations, stimulation algorithms, and indications for use of the device.

35. The following PMA Supplements illustrate the cumulative and material transformation of the device:

a. S037 (1995): Approval of the Itrel III system for chronic intractable pain.

b. S074 (2005): Approval of the Restore rechargeable neurostimulator.

c. S092 (2006): Introduction of RestoreAdvanced and PrimeAdvanced systems.

d. S185 (2011): Approval of RestoreSensor, incorporating motion-sensing technology.

e. S219 (2013): Approval of SureScan MRI-compatible systems.

f. S344 (2017): Approval of the Intellis SCS system, which was functionally distinct from prior generations.

g. S512 (2024): Approval of the Inceptiv SCS system, incorporating closed-loop “NeuroSense” technology.

36. Each of these changes materially altered the device’s intended use, therapeutic mechanism, risk profile, or engineering platform. Cumulatively, these alterations rendered the 2015 version of the device implanted in Plaintiff markedly different from the system approved in 1984.

37. Despite the scope and substance of these modifications, the FDA did not require Medtronic to submit a new PMA. Instead, the agency permitted the

company to make these changes via the PMA Supplement process, which is reserved for minor modifications that do not affect safety or effectiveness. *See* 21 C.F.R. § 814.39(a).

38. The FDA's continued acceptance of Medtronic's Supplements as minor constituted arbitrary and capricious agency action. It departed from the plain text of the statute and its own regulations, which mandate a new PMA when a change "affects safety or effectiveness" in a material way. *See* 21 C.F.R. § 814.39(a)(2), (b).

39. This pattern of regulatory leniency reflects a broader breakdown in the FDA's gatekeeping function and illustrates the phenomenon of regulatory capture. Rather than independently scrutinizing the safety and efficacy of materially reconfigured SCS devices, the FDA deferred to Medtronic's self-characterization of its changes. It failed to require new clinical trials, public disclosures, or re-validation of the evolving device architecture.

40. This regulatory posture enabled Medtronic to secure the benefits of PMA preemption under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), while sidestepping the obligations that Congress intended to accompany that shield, namely, robust scientific review and high evidentiary standards for Class III devices.

41. In *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___ (2024), the Supreme Court overturned the Chevron doctrine and held that courts may not defer to agency interpretations of federal statutes that conflict with clear

statutory language. The Court affirmed that agencies must act within the limits set by Congress and that judicial review must be independent, not deferential.

42. Here, the FDA's decision to treat Medtronic's extensive design and performance changes as minor, rather than requiring a new PMA, exceeded its lawful authority under the FDCA and its implementing regulations. The agency's conduct directly harmed Plaintiff by permitting the marketing of an SCS system that had never undergone independent clinical evaluation in its modified form.

43. The FDA's acceptance of Medtronic's PMA Supplements in lieu of requiring a new PMA constituted:

a. Agency action not in accordance with law;

b. Arbitrary and capricious conduct;

c. An abuse of discretion; and

d. A failure to act as required by statute.

44. Each of these constitutes a violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2). Plaintiff therefore seeks both declaratory and injunctive relief to address the unlawful agency action that contributed to her injuries.

## V. PLAINTIFF-SPECIFIC FACTS AND DEVICE IMPLANTATION HISTORY

45. Plaintiff Angela Yates is a resident of Auburn, Kentucky, who has suffered from chronic intractable pain for many years. After exhausting

conservative treatment options, Plaintiff's treating physician at Interventional Pain Specialists in Bowling Green, Kentucky, recommended spinal cord stimulation as a long-term solution.

46. In June 2015, Plaintiff underwent surgical implantation of a Medtronic-manufactured spinal cord stimulator (SCS) system for the management of her pain. The surgery was performed at Interventional Pain Specialists, located at 165 Natchez Trace Avenue, Suite 205, Bowling Green, KY 42103.

47. The device model was part of Medtronic's Restore or PrimeAdvanced family, approved under PMA No. P840001.

48. From the outset, Plaintiff experienced adverse effects from the device. These included intense burning sensations, erratic electrical shocks, and exacerbation of her preexisting pain. The stimulation was unpredictable, sometimes triggering without cause or intensifying suddenly during normal activities.

49. Plaintiff's treating physician made multiple attempts to reprogram the device in consultation with Medtronic field representatives. Despite these efforts, the adverse effects persisted. The shocks became increasingly disruptive and dangerous, affecting Plaintiff's ability to perform daily activities and causing emotional distress.

50. In 2018, due to the ongoing and intolerable complications, Plaintiff's treating physician recommended that the SCS device be turned off. Although deactivated, the device remained implanted in Plaintiff's body for five more years.

51. During this period, Plaintiff continued to experience discomfort related to the presence of the device, including localized pain, abnormal sensations, and concerns about the safety of leaving a non-functioning medical implant in situ.

52. Medtronic's local sales and field support personnel failed to provide useful assistance during this period. Their involvement was limited, and when contacted, they were dismissive of Plaintiff's reported complications and provided no meaningful clinical or safety guidance.

53. In August 2023, Plaintiff underwent surgical explantation of the Medtronic SCS system. The explant procedure was medically necessary due to the continued presence of the non-functional device, the physical discomfort it caused, and the foreseeable risk of further complications.

54. At no time did Medtronic inform Plaintiff or her physician that the device implanted in 2015 had been subject to material design and performance changes through the PMA Supplement process, or that it differed significantly from the system originally approved in 1984.

55. Nor was Plaintiff informed that the SCS system had never been validated through updated clinical trials to reflect the safety and effectiveness of the reengineered components included in her device.

56. Had Plaintiff or her physician been adequately informed of these material facts, including the absence of contemporary clinical validation and the known risks associated with the device's evolving design, they would not have consented to implantation.

57. As a direct and foreseeable result of Medtronic's actions and omissions, Plaintiff endured years of unnecessary suffering, underwent two surgical procedures, and continues to live with physical and emotional injuries.

## VI. ADDITIONAL FACTUAL ALLEGATIONS SUPPORTING LIABILITY

58. At the time Plaintiff Angela Yates underwent implantation of her Medtronic spinal cord stimulator system in June 2015, Medtronic had already submitted numerous PMA Supplements that introduced material changes to the device's hardware, stimulation patterns, power source, and programming features. These changes included the introduction of rechargeable systems, adaptive stimulation algorithms, and updated surgical interfaces, all without obtaining a new PMA.

59. Medtronic represented to physicians and patients that its SCS systems were FDA-approved and clinically validated. However, the actual configuration of the system implanted in Plaintiff was materially distinct from the device originally approved in 1984, and lacked independent clinical evaluation supporting the safety and effectiveness of the modified architecture.

60. Despite its awareness of increasing reports of adverse events, including burning sensations, painful shocks, device migration, and therapeutic ineffectiveness, Medtronic failed to revise its labeling, marketing materials, or Instructions for Use (IFUs) to reflect these risks.

61. Medtronic also failed to issue safety advisories, initiate recalls, or provide Dear Doctor letters warning physicians about the evolving complication profile of its modified SCS systems.

62. As previously mentioned, the product implanted in Plaintiff had been approved under PMA No. P840001 but materially altered over time through supplements such as:

a. S074 (2005) – Rechargeable battery integration

b. S092 (2006) – Enhanced stimulation system (RestoreAdvanced/PrimeAdvanced)

c. S185 (2011) – Motion-sensing integration

d. S219 (2013) – MRI compatibility expansion

63. These modifications affected both form and function of the device, altering its electrical output, durability, and compatibility with surrounding tissue, all of which are material to patient safety. Yet these changes were never subjected to new clinical trials or public review.

64. Medtronic's representatives, including those assigned to Plaintiff's region, were not trained to disclose the evolving risk profile or to identify signs of

potential device malfunction. In practice, they provided therapy management suggestions that bordered on clinical advice, despite lacking appropriate medical licensure.

65. Plaintiff's reported complications included burning, unpredictable shocks, and exacerbation of pain, which were consistent with failure modes reported in FDA adverse event databases and peer-reviewed studies relating to lead placement, overstimulation, battery malfunction, or software glitches. Medtronic had access to this data but failed to take corrective action.

66. Rather than treating adverse patient outcomes as warning signs of systemic device flaws or specification drift, Medtronic continued to present its SCS systems as safe, effective, and "next-generation" devices without disclosing that the company was operating under a decades-old PMA with no updated efficacy data or formal revalidation of the altered device configuration.

67. Plaintiff's experience was not an isolated incident, but one example of a broader pattern of risk concealment, regulatory avoidance, and failure to comply with both FDA-mandated and state-imposed duties of care.

68. Medtronic's conduct deprived physicians of accurate safety information and misled patients into accepting implantation of devices that had never undergone independent evaluation in their current form. The company's failure to provide adequate post-market risk management violated both federal regulations and parallel state law duties.

69. These failures directly contributed to Plaintiff's injuries, prolonged suffering, and the need for surgical explantation. Medtronic's omissions and misrepresentations were not simply administrative oversights but were part of a calculated commercial strategy to preserve market share, minimize regulatory exposure, and maintain preemption protection under the guise of continuous PMA coverage.

## VII. CAUSES OF ACTION

### COUNT I – MANUFACTURING DEFECT

*(KRS § 411.300 et seq.; 21 C.F.R. §§ 820.30, 820.70, 820.75, 820.100)*

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

71. At all relevant times, Defendants Medtronic, Inc. and Medtronic USA, Inc. were engaged in the design, manufacture, labeling, marketing, and distribution of spinal cord stimulator (SCS) systems in the United States, including the device implanted in Plaintiff.

72. Under the Kentucky Products Liability Act (KRS § 411.300 et seq.), a manufacturer is strictly liable for injuries caused by a product that is in a defective condition and unreasonably dangerous to the user.

73. The spinal cord stimulator implanted in Plaintiff in June 2015 was not reasonably safe as manufactured. The device deviated from applicable

manufacturing specifications and quality standards required under federal law, including:

a. 21 C.F.R. § 820.30: Failure to maintain adequate design controls and validation processes.

b. 21 C.F.R. § 820.70: Failure to establish and follow controlled production processes.

c. 21 C.F.R. § 820.75: Inadequate process validation for components critical to safety and performance.

d. 21 C.F.R. § 820.100: Failure to implement corrective and preventive actions (CAPA) despite known adverse event trends.

74. As a result of these failures, the device implanted in Plaintiff was prone to malfunction, including the delivery of erratic stimulation, electrical shocks, and exacerbation of preexisting pain. These malfunctions occurred during normal, foreseeable use and were not attributable to surgical error or patient misuse.

75. The manufacturing defect was not apparent to Plaintiff or her treating physicians at the time of implantation and could not have been identified through ordinary inspection or post-operative testing.

76. Plaintiff experienced immediate and severe adverse effects following implantation. These complications persisted despite multiple reprogramming

attempts and ultimately necessitated deactivation of the device and, years later, surgical explantation.

77. Medtronic's deviation from its FDA-approved specifications and quality system requirements materially increased the likelihood of product failure and directly caused Plaintiff's injuries. These allegations rest on binding federal regulations and do not impose requirements different from or in addition to federal law. Accordingly, this claim is not preempted under *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

78. As a direct and proximate result of the defective manufacture of the device, Plaintiff suffered physical injury, unnecessary pain and suffering, emotional distress, medical expenses, and the trauma of an additional surgery.

**WHEREFORE**, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory, statutory, and punitive damages available under Kentucky law, together with interest, costs of suit, attorney's fees, and such other relief as the Court deems just and appropriate.

## COUNT II – FAILURE TO WARN

(KRS § 411.300 et seq.; 21 C.F.R. §§ 803.50, 814.39, 820.100)

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

80. Under Kentucky law, a manufacturer has a duty to warn physicians and patients of dangers associated with its products that are known or should

have been known in the exercise of ordinary care. See Restatement (Second) of Torts §§ 388, 402A; *Tibbs v. Bunnell*, 448 S.W.3d 796, 800–01 (Ky. 2014).

81. This duty includes an obligation to issue updated warnings when new safety risks become known after a product has entered the market. The Kentucky Products Liability Act (KRS § 411.300 et seq.) imposes strict liability on manufacturers for unreasonably dangerous products resulting from inadequate warnings.

82. At all relevant times, Defendants Medtronic, Inc. and Medtronic USA, Inc. had access to internal post-market surveillance data, adverse event reports, and engineering analyses that indicated the spinal cord stimulator (SCS) systems approved under PMA No. P840001 had known complications, including:

- Unintended electrical shocks;
- Overstimulation leading to burns or neurological disturbances;
- Device failure or migration;
- Ineffectiveness due to software or lead performance issues.

83. Despite this knowledge, Medtronic failed to revise its labeling, Instructions for Use (IFUs), or sales and training materials to reflect the evolving risk profile of the SCS system that had been repeatedly and materially altered via PMA Supplements.

84. Specifically, Medtronic violated its federal obligations to:

- Investigate and report adverse events under 21 C.F.R. § 803.50;

- Update safety disclosures when modifications changed risk characteristics under 21 C.F.R. § 814.39;
- Implement corrective and preventive action procedures in response to post-market data under 21 C.F.R. § 820.100.

85. These regulatory duties mirror Medtronic's state-law obligations to provide accurate, timely, and complete warnings about the dangers of its devices.

86. At no time did Medtronic inform Plaintiff or her treating physician that the device implanted in June 2015 had undergone multiple design changes that were not clinically revalidated or disclosed in updated warnings. Nor did Medtronic advise that the stimulation-related complications Plaintiff experienced were known hazards associated with its evolving device platform.

87. Had adequate warnings been provided, Plaintiff and her physician would not have selected the Medtronic SCS system. Instead, they relied on incomplete and outdated information about the device's risks and performance.

88. Medtronic's failure to disclose known risks deprived Plaintiff and her medical providers of the opportunity to make an informed decision, directly resulting in implantation of a defective and dangerous device.

89. Plaintiff's claim arises under Kentucky law and is based on violations of federal regulations that establish a parallel duty to warn. As such, it is not preempted under *Riegel* or *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

90. As a direct and proximate result of Medtronic's failure to warn, Plaintiff suffered severe and avoidable physical injuries, prolonged suffering, mental anguish, and the need for surgical explantation.

**WHEREFORE**, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory, statutory, and punitive damages available under Kentucky law, together with interest, costs of suit, attorney's fees, and all such other relief as the Court deems just and proper.

## COUNT III – NEGLIGENCE PER SE AND BREACH OF FEDERAL REGULATORY DUTIES

*(KRS § 446.070; 21 U.S.C. § 360e; 21 C.F.R. § 814.39; 5 U.S.C. § 706)*

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

92. Under Kentucky law, violating a federal statute or regulation intended to protect public health and safety may constitute negligence per se. *See* KRS § 446.070; *T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526, 530–31 (Ky. 2006).

93. At all relevant times, Medtronic, Inc. and Medtronic USA, Inc., as manufacturers of a Class III medical device, were required to comply with the FDCA, 21 U.S.C. § 360e, and implementing FDA regulations governing the modification, marketing, and post-market surveillance of approved devices.

94. Under 21 C.F.R. § 814.39(a), Medtronic was required to submit a new PMA when changes to the device design or functionality significantly

affected its safety or effectiveness. Instead, Medtronic repeatedly characterized substantive changes, including the introduction of new waveforms, rechargeable systems, firmware updates, and lead designs, as "minor" and submitted them through the PMA Supplement process.

95. These representations circumvented the statutory requirement for rigorous premarket review of materially altered Class III devices and deprived patients and physicians of the transparency, scientific scrutiny, and labeling accuracy required by law.

96. Medtronic's pattern of regulatory evasion was compounded by its failure to comply with post-market safety obligations under:

- 21 C.F.R. § 803.50: Requiring the reporting of adverse events and device malfunctions;
- 21 C.F.R. § 820.30(g): Requiring risk analysis of design changes;
- 21 C.F.R. § 820.100(a): Mandating corrective and preventive action for known product failures.

97. These regulations were promulgated to protect patients, including the Plaintiff, and their violation constitutes evidence of negligence per se under Kentucky law.

98. Plaintiff was implanted with a device in 2015 that had materially diverged from the configuration approved initially in 1984. Medtronic knew, or should have known, that the modified device had not been adequately validated

through independent clinical testing or subjected to updated risk-benefit analysis.

99. Medtronic's actions directly violated FDA regulations and its duty of care under Kentucky law to ensure that its devices, as marketed and sold, were safe, effective, and compliant with the legal requirements imposed by federal law.

100. The Food and Drug Administration failed to enforce these requirements. By passively accepting Medtronic's serial Supplements under PMA No. P840001, rather than requiring a new PMA, the FDA acted arbitrarily, capriciously, and contrary to law in violation of the Administrative Procedure Act, 5 U.S.C. § 706.

101. The Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___ (2024), reaffirms that courts must independently interpret statutes and that agencies may not act beyond their delegated authority. The FDA's failure to require a new PMA for materially reconfigured SCS devices represents an ultra vires agency action that directly harmed Plaintiff.

102. Plaintiff's injuries were a foreseeable consequence of Medtronic's decision to bypass required regulatory protections and market a substantially modified Class III device without adequate clinical review or updated safety disclosures.

103. This count is not grounded in a generalized claim that Medtronic violated the FDCA, but rather in specific allegations of regulatory noncompliance

that constitute both negligence per se and parallel state-law violations. Accordingly, this claim is not preempted under *Buckman* or *Riegel*.

**WHEREFORE**, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory, statutory, and punitive damages available under Kentucky law, together with pre- and post-judgment interest, attorney's fees, costs of suit, and such other relief as the Court deems just and proper.

## COUNT IV – BREACH OF IMPLIED WARRANTY
*(KRS §§ 355.2-314 and 355.2-315)*

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

105. At all relevant times, Defendants Medtronic, Inc. and Medtronic USA, Inc. were engaged in the business of designing, manufacturing, marketing, and distributing medical devices, including spinal cord stimulator (SCS) systems, throughout the United States and the Commonwealth of Kentucky.

106. By placing the spinal cord stimulator system into the stream of commerce, Defendants impliedly warranted that the device was:

- Of merchantable quality and reasonably fit for its ordinary purpose, as required by KRS § 355.2-314; and
- Suitable for the particular purpose for which it was recommended, as required by KRS § 355.2-315.

107. Plaintiff and her physician selected the Medtronic SCS system in reliance on Medtronic's representations regarding the safety, durability, and therapeutic efficacy of the device. Medtronic marketed the system as appropriate for the treatment of chronic intractable pain and suitable for long-term implantation.

108. At the time of sale and implantation in June 2015, the device materially differed from the originally approved configuration under PMA No. P840001. Its internal architecture, waveform delivery, battery system, and risk profile had been altered through a series of PMA Supplements without updated clinical validation or adequate safety disclosures.

109. As such, the device failed to conform to Medtronic's own marketing claims, physician-facing product materials, and FDA-cleared labeling, all of which conveyed that the system was safe, effective, and suitable for its stated purpose.

110. Contrary to these representations, the device implanted in Plaintiff:

- Caused erratic and painful shocks;
- Failed to relieve, and in fact exacerbated, Plaintiff's chronic pain;
- Necessitated deactivation within three years of implantation;
- Ultimately required surgical explantation in August 2023.

111. These outcomes rendered the product unfit for its ordinary use as a neuromodulation device and unsuitable for the specific therapeutic purpose for which it was chosen by Plaintiff and her treating physician.

112. Plaintiff and her provider had no knowledge of the undisclosed design changes or the absence of current clinical support for the reconfigured device. They reasonably relied on Medtronic's skill, judgment, and product representations.

113. Medtronic's breach of the implied warranties of merchantability and fitness directly and proximately caused Plaintiff's injuries, including severe pain, diminished quality of life, emotional distress, and the need for surgical intervention.

114. To the extent this claim is based on the failure of the product to conform to specifications approved by the FDA under PMA No. P840001, it does not impose duties or standards different from federal requirements. Instead, it alleges that Medtronic's product failed to meet the fitness and safety characteristics it warranted to physicians and patients based on those federal specifications.

115. Accordingly, this claim is not preempted under *Riegel v. Medtronic* or *Buckman*, and is independently actionable under Kentucky law.

**WHEREFORE**, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory and statutory damages recoverable

under Kentucky law, together with interest, costs of suit, attorneys' fees where allowed, and such other and further relief as the Court deems just and proper.

**COUNT V – FRAUDULENT MISREPRESENTATION**
*(Kentucky Common Law)*

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

117. Under Kentucky law, a claim for fraudulent misrepresentation requires proof that a defendant:

(1) made a material representation;

(2) that was false;

(3) known by the defendant to be false or made recklessly;

(4) intended to induce reliance;

(5) which the plaintiff reasonably relied upon; and

(6) which caused damages. See *Flegles, Inc. v. Truserv Corp.*, 289 S.W.3d 544, 549 (Ky. 2009).

118. At all relevant times, Defendants Medtronic, Inc. and Medtronic USA, Inc., through their agents, representatives, and marketing materials, made numerous material misrepresentations and omissions regarding the safety, effectiveness, and regulatory status of the spinal cord stimulator (SCS) system implanted in Plaintiff.

119. Specifically, Defendants:

- Represented that the SCS system was FDA-approved, clinically validated, and safe for its intended use;
- Presented the device as a proven and reliable treatment for chronic intractable pain, supported by decades of clinical data;
- Implied that the system implanted in Plaintiff in 2015 was substantially equivalent to the device originally approved under PMA No. P840001.

120. In truth, Medtronic had made extensive changes to the device over three decades, including to its waveform modulation, battery system, lead design, and firmware logic, without submitting a new PMA or conducting updated clinical trials.

121. Medtronic also possessed post-market surveillance data and internal reports indicating a growing trend of adverse outcomes, including:

- Burning sensations;
- Painful overstimulation;
- Device ineffectiveness;
- Electrical malfunction.

122. Defendants failed to disclose these risks to physicians or patients and continued to present the device as stable, well-characterized, and low-risk.

123. These omissions were material. A reasonable physician or patient would consider the lack of updated clinical validation and the existence of known

adverse outcomes highly relevant in deciding whether to proceed with implantation.

124. Medtronic's field representatives directly interacted with Plaintiff's care team and participated in programming the device. Their conduct reinforced the illusion that the system was safe and effective, and that post-implantation adjustments would resolve complications. These communications omitted material facts and conveyed false assurances.

125. Plaintiff and her physician reasonably relied on Medtronic's representations in deciding to proceed with implantation in June 2015. At no time were they advised that the product had evolved beyond its original PMA approval or that its reengineered components had not been validated in their current form.

126. Medtronic's false representations and material omissions were made knowingly or with reckless disregard for the truth, and with the intent to induce implantation and continued use of the device.

127. As a direct and proximate result of this fraudulent conduct, Plaintiff suffered avoidable injury, prolonged pain and suffering, the costs and trauma of surgical explantation, and ongoing emotional distress.

128. Medtronic's conduct was willful, wanton, and undertaken with reckless disregard for patient safety, entitling Plaintiff to punitive damages under Kentucky law.

**WHEREFORE**, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory, statutory, and punitive damages available under Kentucky law, together with interest, costs of suit, attorney's fees, and such other and further relief as this Court deems just and proper.

## COUNT VI – DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION VIOLATIONS

*(Kentucky Consumer Protection Act, KRS § 367.170 et seq.)*

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

130. The Kentucky Consumer Protection Act (KCPA), KRS § 367.170, prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." The KCPA applies to representations made by manufacturers, distributors, and agents in the marketing of medical devices to consumers in Kentucky.

131. At all relevant times, Defendants Medtronic, Inc. and Medtronic USA, Inc., acting directly and through their agents and representatives, engaged in deceptive trade practices by:

- Marketing their spinal cord stimulator (SCS) systems as FDA-approved, safe, and effective for the treatment of chronic intractable pain;
- Failing to disclose that the system implanted in Plaintiff had undergone multiple, substantive design changes since the original PMA approval in 1984;

- Concealing that the device lacked updated clinical validation for its modified configuration;
- Omitting known adverse outcome trends from marketing materials, training documents, and communications with physicians and patients.

132. Medtronic directed its deceptive messaging toward both healthcare providers and patients in Kentucky, including Plaintiff and her treating physician. Its representatives actively participated in pre- and post-implantation communications with Plaintiff's care team, reinforcing the false impression that the device had a reliable and validated safety profile.

133. Medtronic's omissions and misrepresentations were intended to induce reliance and to persuade physicians and patients to choose its device over other therapeutic options. These representations appeared in physician-facing brochures, product labeling, online materials, and verbal statements made by Medtronic field representatives.

134. At no time was Plaintiff informed that the device's architecture, waveform algorithms, and internal components had changed significantly from the originally approved model, or that those changes had never been subjected to independent clinical testing or post-market evaluation.

135. Plaintiff and her physician reasonably relied on Medtronic's marketing and communications. They believed, based on Medtronic's conduct, that the system was safe, effective, and properly vetted for long-term implantation.

136. Medtronic's conduct constitutes a knowing violation of the KCPA and caused Plaintiff to suffer injury, including physical harm, emotional distress, unnecessary surgical intervention, and economic loss.

137. Under KRS § 367.220, Plaintiff is entitled to recover actual damages, reasonable attorneys' fees, and, where appropriate, punitive damages for Medtronic's willful and reckless disregard of patient safety.

**WHEREFORE**, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory, statutory, and punitive damages available under the Kentucky Consumer Protection Act, together with interest, costs of suit, attorney's fees, and such other and further relief as the Court deems just and proper.

## COUNT VII – NEGLIGENCE PER SE – UNAUTHORIZED PRACTICE OF MEDICINE

(KRS § 311.560; KRS § 446.070)

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

139. Under KRS § 311.560(1)(a), it is unlawful for any person to engage in the practice of medicine in the Commonwealth of Kentucky without a valid license issued by the Kentucky Board of Medical Licensure. The statute applies to both direct and indirect practice, including diagnosis, treatment, or the suggestion of therapeutic interventions.

140. Kentucky recognizes negligence per se under KRS § 446.070 where a person violates a statute intended to protect the public and that violation causes injury to a person within the class the statute was designed to protect. *See T & M Jewelry, Inc. v. Hicks ex rel. Hicks*, 189 S.W.3d 526 (Ky. 2006).

141. Medtronic employs clinical specialists and field representatives who frequently attend surgical implantation procedures, participate in post-operative programming of spinal cord stimulators, and provide recommendations on therapeutic settings and modifications.

142. Following the June 2015 implantation of Plaintiff's Medtronic SCS device, field representatives from Medtronic worked directly with Plaintiff's treating physicians to configure the stimulation parameters. These individuals, while not licensed medical professionals, engaged in:

- Assessing patient response to stimulation in real-time;
- Recommending device reprogramming based on patient symptoms;
- Advising physicians on changes to therapeutic settings, including amplitude, frequency, and pulse width;
- Suggesting programming modifications to address Plaintiff's complaints of burning and erratic shocks.

143. These activities constitute the unauthorized practice of medicine under Kentucky law. Medtronic's representatives did not merely provide

technical support, they participated in diagnostic and therapeutic decision-making specific to Plaintiff's care.

144. Their involvement created a false impression of medical authority and substituted sales-driven guidance for licensed medical judgment.

145. Moreover, the advice provided by these representatives was ineffective and, in some cases, exacerbated Plaintiff's symptoms. Their failure to escalate reported complications to engineering or risk management channels further compounded the harm.

146. The statute prohibiting unlicensed medical practice is designed to protect patients like Plaintiff from the risks of receiving treatment from individuals lacking the requisite education, training, and accountability. Medtronic's violation of that statute directly resulted in Plaintiff's continued suffering and delayed intervention.

147. Plaintiff is within the class of persons the law was designed to protect, and her injuries were the foreseeable result of the unlawful conduct. As such, Medtronic is liable under Kentucky law for negligence per se.

WHEREFORE, Plaintiff demands judgment against Medtronic, Inc. and Medtronic USA, Inc. for all compensatory and statutory damages available under Kentucky law, together with interest, costs of suit, attorneys' fees where permitted, and such other and further relief as the Court deems just and proper.

**COUNT VIII – ADMINISTRATIVE PROCEDURE ACT (APA) – DECLARATORY AND INJUNCTIVE RELIEF AGAINST THE FDA**
*(5 U.S.C. §§ 701–706; Loper Bright Enterprises v. Raimondo, 603 U.S. ___ (2024))*

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

149. The United States Food and Drug Administration ("FDA") is a government agency subject to judicial review under the Administrative Procedure Act (APA), 5 U.S.C. §§ 701–706.

150. Pursuant to the Medical Device Amendments of 1976 and the Federal Food, Drug, and Cosmetic Act, the FDA is authorized to approve Class III medical devices only upon a finding that valid scientific evidence demonstrates a reasonable assurance of safety and effectiveness. *See* 21 U.S.C. § 360e(d)(2); 21 C.F.R. § 814.20.

151. When a device sponsor seeks to make a significant change affecting the safety or effectiveness of an already-approved Class III device, FDA regulations require the sponsor to submit a new PMA. *See* 21 C.F.R. § 814.39(a)–(b).

152. Despite this mandate, the FDA has allowed Medtronic to introduce hundreds of changes to its spinal cord stimulator (SCS) system, including modifications to waveform delivery, battery systems, lead architecture, user interfaces, indications for use, and software logic, all under the guise of PMA Supplements to P840001, originally granted in 1984.

153. These changes, individually and cumulatively, materially altered the device's safety profile, intended use, and engineering platform. Yet the FDA did not require a new PMA, nor did it require Medtronic to conduct clinical trials or submit updated safety and efficacy data for its substantially reengineered products.

154. Plaintiff was injured by a device that bore little resemblance to the originally approved system but was nevertheless marketed as "FDA-approved" based solely on the agency's continued acceptance of Medtronic's supplements.

155. The FDA's failure to require a new PMA for the materially modified device implanted in Plaintiff was:

a. Arbitrary, capricious, and an abuse of discretion within the meaning of 5 U.S.C. § 706(2)(A);

b. Not in accordance with law, as required by 5 U.S.C. § 706(2)(D);

c. In excess of statutory jurisdiction or authority, in violation of 5 U.S.C. § 706(2)(C).

156. The Supreme Court's ruling in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___ (2024), clarified that agencies are not entitled to judicial deference when their interpretation of statutes conflicts with the plain text enacted by Congress. The FDA's pattern of permitting significant device reconfigurations under the supplement pathway is incompatible with the

statutory requirement that Class III devices demonstrating material change must undergo new PMA review.

157. Plaintiff seeks declaratory relief establishing that the FDA acted unlawfully in permitting Medtronic to market materially reconfigured SCS devices without requiring a new PMA. Plaintiff further seeks injunctive relief restraining the FDA from continuing to accept future PMA Supplements from Medtronic (or other SCS manufacturers) where the underlying change affects the safety or effectiveness of the device in a material way.

158. Plaintiff has no adequate remedy at law for this ongoing administrative failure, and she is entitled to equitable relief to prevent future harm to herself and similarly situated individuals.

**WHEREFORE**, Plaintiff requests that this Court:

a. Declare that the FDA's continued acceptance of PMA Supplements under P840001, without requiring a new PMA for materially altered SCS devices, constitutes unlawful agency action under the APA;

b. Enter an injunction prohibiting the FDA from approving further substantive changes to Class III SCS systems without requiring a new PMA;

c. Award Plaintiff her reasonable attorneys' fees and costs under the Equal Access to Justice Act, where applicable; and

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

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff Angela Yates repeats and realleges all prior claims for relief and respectfully requests that this Court enter judgment in her favor and against Defendants Medtronic, Inc., Medtronic USA, Inc., and the United States Food and Drug Administration, and award the following relief:

1. **Compensatory damages** for physical pain and suffering, mental and emotional distress, past and future medical expenses, and all other economic and non-economic damages allowed under Kentucky law;
2. **Statutory damages** and **punitive damages** where permitted by law, including for Medtronic's fraudulent misrepresentations, reckless indifference to public safety, and willful violation of consumer protection laws;
3. **Declaratory relief** that the FDA's continued approval of material device modifications under PMA No. P840001 without requiring a new Premarket Approval constitutes unlawful agency action under the Administrative Procedure Act (APA), 5 U.S.C. § 706;
4. **Injunctive relief** enjoining the FDA from further accepting PMA Supplements that introduce material changes to spinal cord stimulator

systems without requiring a new PMA under 21 U.S.C. § 360e and 21 C.F.R. § 814.39;

5. **Attorneys' fees and costs** pursuant to all applicable state and federal statutes, including the Equal Access to Justice Act, where applicable;
6. **Pre-judgment and post-judgment interest** as allowed by law; and
7. **Such other and further relief** as the Court deems 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: April 18, 2025

Respectfully submitted,

*/s/ Rachel P. Richardson*
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