BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: ABBOTT AND BOSTON SCIENTIFIC SPINAL CORD STIMULATOR PRODUCTS LIABILITY LITIGATION	MDL No. _____

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

Plaintiffs Diona Smith, Ollie Wilson, Linda Guthrie, Brian Martini, Ronat Kelly William Fuller, William Ferguson, Zella Tuttle, Sherri Miyagi, Judith Reuss, Kenneth Davis, and Rick Morris ("Movants") respectfully submit this Memorandum in Support of their Motion to transfer certain cases currently filed against Abbott Laboratories ("Abbott"), Boston Scientific Corporation ("Boston Scientific"), and the United States Food and Drug Administration ("FDA") pursuant to 28 U.S.C. § 1407(c)(ii) and Rule 6.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation ("JPML"). Movants respectfully move for transfer of their individual cases, and all related cases included on the Schedule of Actions attached to their Motion for Transfer, to the United States District Court for the Northern District of Illinois, for coordinated and/or consolidated pre-trial proceedings.[1]

Specifically, Movants seek transfer of cases in which the individual plaintiffs allege that

[1] Movants seek transfer of these cases in a single Motion to avoid duplicative work for the Panel and the parties. While the claims against Abbott and Boston Scientific have some differences, the commonalities among the relevant facts and issues of law predominate, and the claims against the FDA are essentially identical. Therefore, consolidation of all cases in one court and before one judge is the most efficient solution. Movants do not assert a preference on whether these cases should be consolidated under a single MDL caption and number, or multiple MDLs before the same judge.

spinal cord stimulator systems marketed by Abbott and Boston Scientific have caused them injury. As of today's date, based upon counsel's research, there are fifteen substantially similar cases pending against Abbott and Boston Scientific in five different jurisdictions. Almost all of these cases also name the FDA as a defendant pursuant to the Administrative Procedure Act ("APA"). Movants anticipate that many more cases will be filed in the future.

Factors such as the need for judicial economy, consistency in rulings, and the commonality among Movants' claims and the Defendants' defenses all merit consolidation and favor the transfer of these actions. The Northern District of Illinois, where five actions are already pending, is an ideal location for consolidation due to its geographic convenience to the parties and ample lodging and transportation options.

I. BACKGROUND REGARDING LITIGATION STATUS AND SCOPE

a. Abbott and Boston Scientific's Spinal Cord Stimulator Systems

Abbott and Boston Scientific's spinal cord stimulators are implantable neuromodulation systems designed to deliver electrical impulses to the spinal cord to mask or moderate chronic intractable pain. These systems typically consist of an implantable pulse generator (IPG), one or more electrical leads, and external controllers for adjusting patient therapeutic levels. These devices have long been associated with complex risks, including but not limited to device migration, lead breakage, battery failure, infection, stimulation-induced neurological deficits, exacerbation of pain, and autonomic dysfunction. Due to these inherent risks, spinal cord stimulator devices are classified by the FDA as Class III medical devices, requiring Premarket Approval ("PMA") or PMA supplement review for any design or functional changes affecting the safety and effectiveness of the device.

Abbott's entire spinal cord stimulator line originates from and is predicated on the Genesis

spinal cord stimulator, initially approved by the FDA in 2001 via PMA P010032. Boston Scientific's entire spinal cord stimulator line originates from and is predicated on the Precision spinal cord stimulator, initially approved by the FDA in 2004 via PMA P030017. Neither Abbott nor Boston Scientific offered any clinical studies demonstrating the safety and efficacy of their spinal cord stimulators when they submitted PMAs P010032 and P030017, respectively. Instead, and in contravention of the requirements of the Federal Food, Drug and Cosmetic Act, the FDA granted these original PMAs based on published literature related to *similar spinal cord systems manufactured by other companies.*

Since the original grants of PMAs P010032 and P030017, Abbott and Boston Scientific have introduced numerous new spinal cord stimulators under supplements to their original PMAs. These newer generations of devices have incorporated significant modifications, including multi-waveform stimulation (simultaneous tonic, burst, and sub-perception modes), posture-adaptive programming, expanded electrode arrays, Bluetooth-enabled programming, and major revisions to battery architecture and lead designs. These new generation products are technologically unrecognizable from the predicate devices originally approved by the FDA.

Abbott and Boston Scientific submitted successive PMA supplements treating these major modifications as discrete "minor" changes to avoid the heightened scrutiny, public transparency, and rigorous independent clinical evaluation required for new PMA applications. This regulatory strategy deprived physicians, patients, and the FDA of the complete information necessary to evaluate the true risks associated with the modified devices, particularly in neurological safety, device longevity, stimulation safety, and autonomic complications. As a direct consequence of these omissions and regulatory manipulations, the spinal cord stimulator systems entered the market and were widely implanted without sufficient scientific validation of their safety and

effectiveness. As described more fully below, the FDA blindly accepted these PMA supplements, unlawfully approving new products through this regulatory shortcut.

b. Administrative Procedures Act Claims against FDA

Spinal cord stimulator systems are regulated as Class III medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., and the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq*. Class III devices are subject to the most rigorous form of regulatory oversight, including the requirement to obtain Premarket Approval from the FDA prior to introducing such a medical device into interstate commerce. *See* 21 U.S.C. § 360e. To obtain PMA, a manufacturer must submit detailed information demonstrating the proposed device's safety and effectiveness, including clinical trial data, descriptions of manufacturing methods, proposed labeling, and a risk-benefit analysis. *See* 21 C.F.R. § 814.20.

Once a PMA is granted, any proposed changes to the device's design, labeling, intended use, or manufacturing process must be submitted to the FDA as a PMA supplement. *See* 21 C.F.R. § 814.39(a). For any change that could affect safety or effectiveness, the FDA must receive and approve the PMA supplement before the manufacturer implements the change. 21 C.F.R. §814.39(c). The burden of proof remains with the manufacturer to demonstrate that the modified device remains safe and effective. These regulatory obligations are non-discretionary and enforceable under both federal and state law.

Movants allege that Abbott and Boston Scientific have failed to comply with these regulatory requirements and that the FDA has actively excused and passively accepted this noncompliance. Movants further allege that the FDA failed to meaningfully review Abbott and Boston Scientific's original PMAs and PMA supplements as required by the FDCA and the Agency's regulatory implementation of the MDA, particularly because the companies used serial

supplements to bring entirely new products to market. Movants also allege that the FDA's failures constitute agency action unlawfully withheld and final agency action subject to review under 5 U.S.C. §§ 706(1), 706(2)(A)–(D), and seek declaratory and injunctive relief under the Administrative Procedure Act.

c. Abbott and Boston Scientific Spinal Cord Stimulator Litigation

To date, fifteen lawsuits have been filed by three law firms against Abbott and Boston Scientific alleging injury caused by a Boston Scientific or Abbott spinal cord stimulator system. *See* Schedule of Actions. Each of these actions asserts virtually identical claims against Boston Scientific and Abbott, for similar injuries, caused by one of these manufacturers' spinal cord stimulator systems. All but two of these lawsuits also name the FDA as a defendant pursuant to the Administrative Procedure Act, and seek identical declaratory and injunctive relief.

These fifteen claims are pending in five different federal jurisdictions. *Id.*

d. Many More Claims Anticipated

The currently filed cases represent only a small sample of the cases that will be filed against Abbott and Boston Scientific alleging injury caused by these companies' spinal cord stimulators. While Movants do not know the exact number of stimulator systems Abbott and Boston Scientific have sold, the overall spinal cord stimulator market is very large. An estimated 50,000 spinal cord stimulators are implanted annually, and Abbott and Boston Scientific hold a combined majority stake in this overall market. *See* Sdrulla AD, Guan Y, Raja SN. Spinal Cord Stimulation: Clinical Efficacy and Potential Mechanisms. Pain Pract. 2018 Nov;18(8):1048-1067. doi: 10.1111/papr.12692. Epub 2018 Apr 23. PMID: 29526043; PMCID: PMC6391880. In September 2020, in response to a Public Citizen report, the FDA issued a letter to healthcare providers advising that, during the preceding four-year period, it had received 107,728 adverse event reports

regarding spinal cord stimulators. The letter also disclosed 30,321 reports of unsatisfactory pain relief. Based on this adverse event reporting disclosed by the FDA, approximately seventy percent of all recipients of spinal cord stimulators either experienced an adverse event or unsatisfactory pain relief. Neither Abbott nor Boston Scientific have made any substantial safety or efficacy improvements to their spinal cord stimulators since 2020, though they have continued to market these dangerous products with the FDA's blessing. Therefore, there are likely tens of thousands of patients with potential claims against Abbott, Boston Scientific, and the FDA. In fact, approximately four hundred individuals who were injured by an Abbott or Boston Scientific spinal cord stimulator system have retained the undersigned law firm.

The undersigned Counsel has conferred with four distinct law firms that represent individuals injured by spinal cord stimulators sold by Abbott and Boston Scientific, but that have not yet filed cases against these manufacturers. All four of these law firms intend to file cases against Abbott and Boston Scientific in the near future.

II. ARGUMENT

Title 28, Section 1407 of the United States Code provides: "When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). The presence of common factual questions necessitates transfer under § 1407 in order to prevent duplication of discovery and eliminate the possibility of inconsistent pretrial rulings. *In re Eastern Airlines, Inc. Flight Attendant Weight Program Litig.*, 391 F. Supp. 763, 764 (J.P.M.L. 1975). Transfer under § 1407, however, does not require complete identity or even majority of common factual or legal issues as a prerequisite to transfer. *In re Rembrandt Techs., L.P.*, 493 F. Supp. 2d 1367, 1369 (J.P.M.L. 2007); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173

F. Supp. 2d 1377, 1379 (J.P.M.L. 2001).

a. Movants' Claims Involve Common Questions of Law and Fact against the Same Defendants

Movants all assert that they suffered injuries and damages as a result of being implanted with a spinal cord stimulator manufactured and marketed by Abbott or Boston Scientific. Questions common to all suits arise from the underlying facts and course of conduct alleged in each complaint. To be clear, Abbott and Boston Scientific manufacture and sell different spinal cord stimulators, so there are minor differences among the products at issue and there will be differences between the cases against these manufacturers. However, it is not unusual for product liability MDLs to involve different defendants and products. *See In re Social Media Adolescent Addiction/Personal Injury Prods. Liab. Litig.*, 637 F. Supp. 3d 1377, 1378 (J.P.M.L. 2022); *In re Gadolinium Contrast Dyes Prods. Liab. Litig.*, 536 F. Supp. 2d 1380 (J.P.M.L. 2008); *In re Proton-Pump Inhibitor Prods. Liab. Litig*., 261 F. Supp. 3d 1351 (J.P.M.L. 2017).

In the spinal cord stimulator case, the commonality of the defendants' defenses is more important than the differences between the cases against them. Specifically, Abbott and Boston Scientific will both argue that the Movants' claims are preempted by federal law due to the purported Class III status of their spinal cord stimulators. In fact, Abbott and Boston Scientific have already filed motions to dismiss asserting this preemption defense in venues across the country. Further, the FDA's defenses to the Movants' Administrative Procedures Act claims will be nearly identical, regardless of whether Abbott or Boston Scientific sold the product at issue. Thus, coordination will promote judicial efficiency and prevent conflicting rulings on these complex common defenses across districts. *See, e.g.*, *In re Roblox Corp. Child. Sexual Exploitation*, 2025 U.S. Dist. LEXIS 260195, at *5 (J.P.M.L. 2025).

In addition to the threshold preemption issue, Movants' cases share common issues relating

to the design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of Abbott and Boston Scientific's spinal cord stimulator systems. Such common questions, many of which directly influence Abbott and Boston Scientific's preemption defense and ultimate liability, include:

1) Whether the spinal cord stimulators materially deviated from their intended design specifications and from applicable federal requirements governing Class III medical devices;

2) Whether Abbott and Boston Scientific failed to warn and/or adequately warned innocent consumers and physicians about the known risks of their spinal cord stimulator systems;

3) Whether Abbott and Boston Scientific breached their duty to comply with federal medical device regulations in the design, manufacture, sale, and post-market monitoring of their spinal cord stimulator systems;

4) Whether Abbott and Boston Scientific intentionally, deliberately, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed, or suppressed material and important information regarding the true and known risks, benefits, and regulatory status of their spinal cord stimulator systems from physicians and patients;

5) Whether Abbott and Boston Scientific's conduct, and the conduct of their sales representatives, in marketing, promoting, and participating in the process of recommending, implanting, programing, and reprograming their spinal cord stimulator systems constituted the practice of medicine without a license and, therefore, negligence per se;

6) Whether Abbott and Boston Scientific's misconduct constitutes a breach of any warranty or warranties recognized by law; and

7) Whether Abbott and Boston Scientific's misconduct constitutes a violation of any applicable consumer protection and/or fair trade practices laws.

While each of these enumerated questions will require defendant-specific discovery and analysis, there will be overlap and the overarching scientific, factual, and legal framework will be the same between all cases. Therefore, it is most efficient to permit a single judge, through § 1407 coordination, to preside over this framework and answer these common questions.

Ultimately, while there are differences among the individual cases against Abbott and Boston Scientific, the products at issue are essentially the same. Of course, these manufacturers will assert that their products are unique, but in actuality, each consists of an implantable pulse generator (IPG), one or more electrical leads, and external controllers for adjusting patient therapeutic levels. Additionally, both PMAs were unlawfully approved by the FDA under a standard more closely aligned with the reduced Pre-Market Notification standard reserved for less dangerous Class II Devices, a literature review of substantially similar devices already approved, and not particularized, scientifically valid information. Further, the underlying therapeutic premise of all spinal cord stimulator devices is that electrical stimulation of the spinal column can override the transmission of pain signals to the brain, thereby providing pain relief.

Finally, all Movants allege similar injuries caused by the spinal cord stimulators, regardless of whether the case involves an Abbott or Boston Scientific stimulator. These injuries include unsatisfactory pain relief, shocking, burning, lead migration, autonomic dysfunction, and neurological injuries. The transferee judge can adequately address any minor differences between the products at issue through separate discovery and motion tracks. *See, e.g.*, *In re Social Media Adolescent Addiction/Personal Injury Prods. Liab. Litig.*, 637 F. Supp. 3d 1377, 1378 (J.P.M.L. 2022).

Transfer is therefore appropriate and necessary given the significant number of common questions of law and fact present in this litigation.

b. Coordination Serves the Best Economic and Equitable Interests of the Parties, Counsel, and Judiciary

Coordinated pretrial proceedings conserve the time, effort, and financial resources of the judiciary and the parties, while simultaneously eliminating the possibility of inconsistent rulings

from sister courts in parallel proceedings that might impair the equitable and orderly administration of justice. See, e.g., *In re Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig*., 883 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012) ("Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel and the judiciary"); *In re DePuy Orthopaedics, Inc*., 753 F. Supp. 2d 1378, 1379 (J.P.M.L. 2010) ("Centralization under Section 1407 will eliminate duplicate discovery, prevent inconsistent trial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and the judiciary").

Coordination of these actions serves the best interests of the parties, parties' counsel, and the judiciary by conserving economic resources and preventing inconsistent rulings. Unless Movants' claims are coordinated, the parties and courts will be forced to spend a great deal of time, effort, and money litigating common issues of both fact and law. Furthermore, the parties may be prejudiced by various courts entering contradictory rulings on discovery, evidentiary, and legal issues common to all claims. Such disparate rulings will lead to more litigation and, ultimately, to incongruous results and bad precedent.

Of particular significance here, the manufacturer defendants' preemption defense and the Administrative Procedure Act claims against the FDA will be most efficiently and consistently litigated and decided in a coordinated proceeding. Piecemeal litigation of these issues may yield inconsistent rulings across jurisdictions, with multiple appeals and potentially different outcomes. In contrast, coordination avoids the pitfalls of piecemeal litigation by resolving disputes arising from each of these common issues in a single ruling. *See In re StarLink Corn Prods. Liab. Lit.,* 152 F.Supp.2d 1378, 1380 (J.P.M.L. 2001); *see also In re Cartiva Synthetic Cartilage Implant Prods. Liab. Litig.*, 2026 U.S. Dist. LEXIS 26709 *2-3 (J.P.M.L. 2026).

Movants' cases, along with the related cases, are well-suited for coordination at this time, as there have been no rulings on either the manufacturing defendants' preemption defense or the FDA's defense to the Administrative Procedures Act claims. However, the risk of disparate rulings is real and imminent, as there is at least one case in which Boston Scientific's preemption defense is fully briefed and awaiting a ruling by the Western District of Michigan. *See Mark Dunham v. Boston Scientific Corporation*, 1:25-cv-00481 (W.D. Mich.). This risk increases with each passing month, as plaintiffs file more cases in different jurisdictions and motion practice progresses in the cases already filed. While the defendants have filed motions, the parties have not completed significant discovery workup in any case. As such, there is no risk of wasting significant past litigation work.

Coordination is especially important in these cases because it will allow the FDA and the Justice Department to avoid unnecessary expenditure of taxpayer resources by defending the FDA's actions and omissions in a single venue. FDA regulations address this precise concern in 21 CFR § 10.45(g) ("If petitions [for judicial review of a particular matter] are filed in more than one jurisdiction, the Commissioner will take appropriate action to prevent a multiplicity of suits in various jurisdictions….").

Coordination will also prevent costly and inefficient duplication of discovery efforts, benefiting all parties. In the absence of Section 1407 coordination, it may be necessary for Abbott, Boston Scientific, and the FDA's employees and witnesses to be deposed multiple times. Further, the defendants will respond to multiple different sets of discovery requests from different plaintiffs' counsel. On the other hand, if the cases are coordinated, the parties can work together and with the transferee court to prevent duplication of discovery, thereby preventing waste of time and resources by all parties and the judiciary.

Finally, informal coordination of these actions pursuant to 28 U.S.C. § 1404 is not preferable to § 1407 centralization. Multiple different attorneys represent the plaintiffs in the related cases, and Counsel anticipates that additional attorneys will file cases in the near future, complicating informal coordination. Further, it is unlikely that the three involved defendants will informally agree upon a § 1404 transferee venue, given their diverse locations. In fact, Movants' counsel proposed to defendants a § 1404 transfer of all pending cases to a single forum, but this proposal was not accepted. Separate informal coordination of the claims against each manufacturing defendant, in forums acceptable to each defendant, would still require the FDA to litigate in multiple forums.

Therefore, Section 1407 coordination is necessary to avoid disparate rulings from district courts across the country, unnecessary and duplicative work for the judiciary, and inefficient litigation of these cases.

c. <u>The Northern District of Illinois is an Ideal Transferee Forum</u>

The Movants request that these cases be transferred to the Northern District of Illinois,. The criteria used by the Judicial Panel on Multidistrict Litigation in determining the most appropriate transferee forum under 28 U.S.C. § 1407 include the convenience of the parties and witnesses; the relative degree of progress achieved in pending actions; the location of parties, witnesses, and documents; the likelihood that a given district's location would enhance the prospects for cooperation among the federal and state courts; and, when no clear choice emerges from these factors, the preference of the majority of the parties. *In re Factor VIII or IX Concentrate Blood Prods. Liab. Litig*., 853 F. Supp. 454, 455 (J.P.M.L. 1993); *In re New Mexico Natural Gas Antitrust Litig*., 482 F. Supp. 333, 337 (J.P.M.L. 1979). For example, in the phenylpropanolamine (PPA) MDL, the Panel selected a transferee court based in part on the fact that it was "a major

metropolitan court that (i) is not currently overtaxed with other multidistrict dockets, and (ii) possesses the necessary resources to be able to devote the substantial time and effort to pretrial matters that this complex docket is likely to require." *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 173 F. Supp. 2d 1377, 1379-80 (J.P.M.L. 2001).

The Northern District of Illinois offers a convenient venue for Movants' claims, as five actions are already pending in that District, four against Abbott and the FDA and one against Boston Scientific and the FDA. No pending action has progressed beyond motion to dismiss briefing, so relative progress of litigation in other districts does not weigh against the Northern District of Illinois. Also, the Northern District of Illinois offers ample lodging options and two convenient airports.

This District is home to Abbott's principal place of business, so it is clearly the most geographically convenient venue for Abbott. Additionally, this district is centrally located, offering an adequate geographical compromise between Boston Scientific's principal place of business in Massachusetts and its neuromodulation division in California, where a substantial portion of the relevant corporate conduct was carried out. While the case against Abbott is largely centered in the Northern District of Illinois, witnesses and evidence related to the Boston Scientific cases are located in both California, where the spinal cord stimulators were developed and manufactured, and Massachusetts, where global corporate strategy was developed and implemented. While not exactly in the middle of California and Massachusetts, it is at least conveniently accessible from both. Finally, the Northern District of Illinois offers a convenient and accessible forum for plaintiffs from across the country, should bellwether trials be appropriate and necessary. Therefore, this venue will be convenient for all witnesses, parties, and counsel who are involved in these actions.

Therefore, under the Section 1407 criteria, the Northern District of Illinois is the best location for coordination of these actions.

III. CONCLUSION

Movants respectfully move this Panel, pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, for an order transferring all related Abbott and Boston Scientific Spinal Cord Stimulator Product Liability cases to the Northern District of Illinois for coordinated and/or consolidated proceedings.

Dated: February 20, 2026

Respectfully submitted,

/s/ Trevor B. Rockstad
Trevor B. Rockstad
MS Bar No. 103614
Davis & Crump, P.C.
2601 14th Street
Gulfport, Mississippi 39501
T: (228) 863-6000
F: (228) 864-0907
trevor.rockstad@daviscrump.com
Counsel for Movants-Plaintiffs

COUNSEL FOR PLAINTIFFS IN THE FOLLOWING ACTIONS:

Diona Smith v. Boston Scientific Corporation, et al.; 2:25-cv-08821-JLS-E (C.D. California)
Ollie Wilson v. Boston Scientific Corporation, et al.; 2:25-cv-09958-JLS-E (C.D. California)
Linda Guthrie v. Boston Scientific Corporation, et al.; 2:25-cv-11508-SPG-MAA(C.D. California)
Brian Martini v. Boston Scientific Corporation, et al.; 2:26-cv-00825-JLS-E (C.D. California)
Ronat Kelly v. Boston Scientific Corporation, et al.; 2:26-cv-00832-JLS-E (C.D. California)
William Fuller v. Abbott Laboratories, et al.; 1:25-cv-12714-MMR (N.D. Illinois)
William Ferguson v. Abbott Laboratories, et al.; 1:25-cv-13341-JBG (N.D. Illinois)
Zella Tuttle v. Abbott Laboratories; 1:25-cv-15083-LCJ (N.D. Illinois)
Sherri Miyagi v. Boston Scientific Corporation, et al.; 1:26-cv-01902 (N.D. Illinois)
Judith Reuss v. Abbott Laboratories, et al.; 1:26-cv-01905 (N.D. Illinois)
Kenneth Davis v. Boston Scientific Corporation, et al.;1:26-cv-00014-SA-DAS (N.D. Mississippi)
Rick Morris v. Boston Scientific Corporation, et al.; 1:25-cv-00364-TBM-RPM (S.D. Mississippi)