BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re: ABBOTT LABORATORIES 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 Ray Lavigne and Renee Moss ("Movants") respectfully submit this Memorandum in Support of their Motion to transfer certain cases currently filed against Abbott Laboratories ("Abbott") 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 Central District of California, for coordinated and/or consolidated pre-trial proceedings.

Specifically, Movants seek transfer of cases in which the individual plaintiffs allege that spinal cord stimulator systems marketed by Abbott have caused them injury. As of today's date, based upon counsel's research, there are twelve (12) substantially similar cases, filed by thirty-three (33) unique plaintiffs, pending against Abbott in six different jurisdictions. Ten (10) 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 Defendant's defenses all merit consolidation and favor the transfer of these actions. The Central District of California, where the JPML recently transferred a group of similar claims filed against another spinal cord stimulator manufacturer, Boston Scientific Corporation, is an ideal location for centralization.

I. BACKGROUND REGARDING LITIGATION STATUS AND SCOPE

a. Abbott's Spinal Cord Stimulator Systems

Abbott'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. Abbott never conducted any clinical studies demonstrating the safety and efficacy of its spinal cord stimulator when it submitted PMAs P010032. 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 grant of PMAs P010032, Abbott has introduced numerous new spinal cord stimulators under supplements to its original PMA. 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 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 has 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's original PMAs and PMA supplements as required by the FDCA and the Agency's regulatory implementation of the MDA, particularly because Abbott 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. <u>Abbott Spinal Cord Stimulator Litigation</u>

To date, fifteen lawsuits have been filed by four law firms against Abbott alleging injury caused by an Abbott spinal cord stimulator system. *See* Schedule of Actions. Each of these actions asserts virtually identical claims against Abbott, for similar injuries, caused by

an Abbott spinal cord stimulator system. The majority of plaintiffs in 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 seven different federal jurisdictions.

d. Many More Claims Anticipated

The currently filed cases represent only a small sample of the cases that will be filed against Abbott. While Movants do not know the exact number of stimulator systems Abbott has sold, the overall spinal cord stimulator market is very large. An estimated 50,000 spinal cord stimulators are implanted annually, and Abbott is a market leader in the spinal cord stimulator industry. *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. Abbott has not made any substantial safety or efficacy improvements to its spinal cord stimulators since 2020, though it has 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. In fact, approximately 150 individuals who were injured by an Abbott spinal cord stimulator system have retained the

undersigned law firm.

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. Questions common to all suits arise from the underlying facts and course of conduct alleged in each complaint. The JPML has already addressed many of the arguments that will be made below, as well as the arguments that will likely be made by Abbott if it chooses to oppose centralization. *See In re Boston Scientific Corporation Spinal Cord Stimulator Products Liability Litigation*, MDL No. 3181 (Dk. No. 76), June 5, 2026. Movants' actions and the related actions are comparably situated in terms of numerosity of cases, similarity of factual and legal issues, and diversity of venue and counsel to the Boston Scientific actions. The same factors that supported transfer of

MDL No. 3181 support transfer of these actions against Abbott.

Similar to the actions in MDL No. 3181, the Abbott cases share common issues relating to the design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of Abbott's spinal cord stimulator systems. Such common questions, many of which directly influence Abbott's defenses 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 failed to warn and/or adequately warn innocent consumers and physicians about the known risks of its spinal cord stimulator systems;

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

4) Whether Abbott 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 its spinal cord stimulator systems from physicians and patients;

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

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

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

Additionally, the Movants and the plaintiffs in the related cases all allege injury by an Abbott spinal cord stimulator marketed under the same PMA. As such, while there are differences among the specific models due to changes made by Abbott through

the PMA supplement process, the regulatory history of each model is the same.

Finally, all Movants allege similar injuries caused by an Abbott spinal cord 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 or differences among the case-specific injuries 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, Abbott's preemption defense and the Administrative Procedure Act claims against the FDA will be most efficiently and consistently litigated and decided in a coordinated proceeding. Specifically, Abbott will argue that the Movants' claims are all preempted by federal law due to the purported Class III status of their spinal cord stimulators. In fact, Abbott has 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).

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 Abbott's preemption defense or the FDA's defense to the Administrative Procedures Act claims. However, the risk of disparate rulings is real and imminent, as seen recently in similar cases filed against Boston Scientific and Nevro. Specifically, the District of Maryland recently denied Nevro's motion to dismiss in a spinal cord stimulator case, while the Western District of Michigan granted Boston Scientific's motion to dismiss in a similar, though differently pleaded case. *Compare Mark Dunham v. Boston Scientific Corp.*, 1:25-cv-00481 (W.D. Mich.) (granting motion to dismiss) with *Perry DiToto v. Nevro Corp.*, *et al*., 1:25-cv-01388-RDB (D. Md.) (denying motion to dismiss on all claims except implied warranty). 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 Abbott and FDA have filed motions in some of the related actions, none have been fully briefed or ruled upon. Further, 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 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, while § 1407 transfer is for pretrial proceedings only, § 1404 transfer requires a plaintiff to fully commit to the transferee venue. For many reasons, some plaintiffs may not be able or willing to commit the entire litigation of their case, including trial, to a venue outside their home state.

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. The Central District of California is an Ideal Transferee Forum

The Movants request that these cases be transferred to the Central District of California. 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).

The JPML recently transferred spinal cord stimulators pending against Boston Scientific to Judge Josephine Staton in the Central District of California. *In re Boston Scientific Corporation Spinal Cord Stimulator Products Liability Litigation*, MDL No. 3181 (Dk. No. 76), June 5, 2026. While the JPML's transfer order in MDL No. 3181 declined to create an industry-wide MDL, it did not foreclose the transfer of an Abbott-specific MDL to Judge Staton. As was argued by plaintiffs in the JPML proceedings in MDL No. 3181, there are significant similarities between the Abbott and Boston Scientific spinal cord stimulator cases. There will be substantial overlap in the plaintiffs' experts, regulatory issues, and the defendants' defenses. Transfer of the Abbott cases to Judge Staton will allow one Judge to handle the background work involved in addressing these issues, rather than requiring multiple judges to address similar issues, thereby promoting judicial economy. Additionally, many of the related actions also include APA claims against the FDA, and transfer to Judge Staton will ensure that all spinal cord stimulator APA claims to be presided over by one judge. Permitting one judge to preside over these cases will prevent disparate rulings on Abbott and Boston Scientific's preemption defenses, as well as on the APA claims.

Finally, the attorneys representing plaintiffs in the Abbott actions are the same as those representing plaintiffs in the Boston Scientific actions. Transferring the Abbott actions to a different court will unnecessarily burden plaintiffs' counsel with litigation in two different courts. While Abbott and Boston Scientific may prefer this outcome, it does not increase the "convenience of parties and witnesses" nor "promote the just and efficient conduct" of these actions. *See* 28 U.S.C. § 1407. This is especially true where much of the work required of plaintiffs' counsel in these MDLs will be the same or similar, regardless of the specific

manufacturer involved.

Therefore, under the Section 1407 criteria, the Central District of California 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 Spinal Cord Stimulator Product Liability cases to the Central District of California for coordinated and/or consolidated proceedings.

Dated: June 22, 2026

Respectfully submitted,

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