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CORPORATION

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

IN RE: BOSTON SCIENTIFIC CORPORATION SPINAL CORD STIMULATOR PRODUCTS LIABILITY LITIGATION This Document Relates to: ALL ACTIONS	Case No. 2:26-ml-03181-JLS-E **JOINT PRELIMINARY REPORT**

Pursuant to the Court's Pretrial Order No. 1: Setting Initial Scheduling Conference (ECF 2), Plaintiffs, by and through designated counsel Behram Parekh and Trevor Rockstad, and Defendants Boston Scientific Corporation and Boston Scientific Neuromodulation Corporation (collectively, "BSC") and the U.S. Food and Drug Administration ("FDA") (collectively, "the Parties") hereby submit this Preliminary Joint Report. The parties have met and conferred in an attempt to reach consensus on the issues addressed but have noted below where their positions diverge. As to any issue where FDA's position is not called out, the agency takes no position.

I. THE FACTS AND KEY LEGAL ISSUES

A. Plaintiffs' Statement:

The following generally summarizes the allegations in the various complaints currently on file in this MDL, but is not a comprehensive list of all factual allegations and legal theories raised therein. While both BSC and the FDA argue the merits of Plaintiffs' claims in their sections, Plaintiffs believe that should properly be addressed in the forthcoming motions.

1. The Product

Spinal Cord Stimulator ("SCS") devices are Class III implantable neuromodulation systems. Boston Scientific and other SCS manufacturers claim these devices treat chronic intractable pain by delivering electrical impulses to the dorsal columns of the spinal cord, purportedly "overriding" or "masking" the transmission of pain signals to the brain. An SCS system consists of an implantable pulse generator ("IPG"), one or more electrical leads placed in the epidural space, and external patient and clinician controllers for programming and adjusting stimulation parameters. Boston Scientific's SCS product line originates from PMA P030017, initially approved by the FDA on April 27, 2004 for its Precision Spinal Cord Stimulator System. Since the original approval, Boston Scientific has filed almost 400 supplements under PMA P030017. These supplements introduced successive device generations including the Precision Plus, Precision Spectra,

Precision Montage, Precision Novi, Spectra WaveWriter, WaveWriter Alpha, and WaveWriter Alpha Prime.

2. Injuries and Damages

In addition to the claim for general lack of efficacy of the device, leading to unnecessary risks of surgery and surgical site complications, the various injuries experienced by Plaintiffs arise from a few common mechanisms of injury. These complications can generally be divided into three categories that capture those mechanisms of injury: battery related failure, lead related failure and/or migration, and electrical malfunction leading to nerve injury, although there may be other forms of injury such as the inability to explant a device safely, programming, problems, etc. Plaintiffs claim battery failures have led to serious internal burns. Plaintiffs allege that lead fractures and/or migrations have driven the need for complex revision surgeries. Plaintiffs also allege that nerve injuries have resulted from electrical malfunctions and lead to conditions including but not limited to pain and burning sensations, lower limb numbness and paralysis, gastroparesis, fecal and urinary incontinence. Some plaintiffs have not experienced acute side effects but allege a lack of efficacy from the devices. Some also allege that they cannot safely undergo a device removal due to the nature of the spinal implantation of these products. These plaintiffs, therefore, are forced to live with an invasively implanted device that provides no therapeutic benefit.

Economic damages for these claims include lost wages, the cost of revision procedures, treatment for injuries and symptoms, and, in some cases, the cost of the implanting and explanting the permanent SCS device. Non-economic damages include pain, suffering, hedonic damages, and mental distress and anguish.

3. Causes of Action

a. Claims Against BSC

Causes of action for many of the plaintiffs include, but are not limited to Failure to Warn, Defective Design, Manufacturing Defect, Breach of Warranty,

Unauthorized Practice of Medicine, Violations of Consumer Fraud Protections and Deceptive Business Practices, Negligence, Corporate Negligence, Negligence Per Se, Negligent Supervision, Negligent Training, Negligent Retention, Vicarious Liability, Fraud, Fraudulent Concealment, Negligent Misrepresentation, and Punitive Damages.

Plaintiffs dispute that these devices reliably deliver on BCS' therapeutic promise and contend that the real-world complication and failure rates — including lead migration, lead fracture/breakage, IPG malfunction, lead-connection failure, and other device hardware-related complication rates as high as 38% — substantially undermine the safety and efficacy representations Boston Scientific makes to patients and physicians. Plaintiffs also note that published peer-reviewed literature documents real-world migration and fracture rates between 13.2% and 22.6% — rates Plaintiffs contend far exceed those disclosed in Boston Scientific's manufacturer-funded clinical trials and marketing materials.

Plaintiffs contend that the successive generations of products approved via PMA supplements incorporated significant modifications — including multi-waveform stimulation, Bluetooth-enabled programming, major revisions to battery architecture, and redesigned lead configurations — each of which affected the device's performance characteristics. Plaintiffs allege these modifications generated new safety risks that Boston Scientific failed to adequately evaluate, disclose, or communicate to physicians and patients.

Plaintiffs allege that Boston Scientific deviated from its FDA-approved manufacturing processes and Current Good Manufacturing Practice (cGMP") regulations. These violations caused the SCS device implanted in Plaintiff to deviate materially from Boston Scientific's FDA-approved design specifications, formula, and performance standards, including specifications governing lead structural integrity, insulation integrity, electrical performance, hermetic sealing, memory capacity and usage, software, and IPG/battery reliability.

Plaintiffs allege that the clinical and sales representatives employed and deployed by BSC to actively participate in the selection, implantation, programming, and post-operative management of its SCS devices acted beyond the permissible scope. These representatives were not licensed physicians or healthcare providers but nevertheless routinely:

- Attended and directed intraoperative programming during the implantation procedure;
- Made real-time clinical decisions about stimulation parameters, waveforms, amplitude, and frequency, substituting their judgment for that of the licensed treating physicians;
- Reprogrammed devices on post-operative occasions, including occasions when patient's treating physician was not present;
- Made affirmative representations to Plaintiffs about expected therapeutic outcomes, the significance of complications, and the anticipated results of reprogramming; and
- Advised Plaintiffs to delay or decline device removal after complications arose, attributing plaintiffs' symptoms to sub-optimal device settings rather than device failure.

These activities not only exceed the permissible scope of activity, but also induce plaintiffs to reasonably rely upon the representatives' misrepresentations regarding the safety and efficacy of the devices. This includes misleading plaintiffs as to the source of their injury as those plaintiffs attempted to investigate their injuries in due diligence. These direct-to-patient misrepresentations also contradict the FDA-approved warnings included in the device labeling.

Plaintiffs allege that Boston Scientific exercised functional control over the administration of the SCS system by actively participating in implantation, intraoperatively programming the device, pushing firmware updates and stimulation programming changes remotely after implantation, designing and controlling preset

therapy "profiles" that physicians could not override without manufacturer approval, and altering battery behavior, stimulation amplitude, and system responsiveness without physician direction or real-time medical oversight. Plaintiffs allege this conduct constituted the unauthorized practice of medicine.

b. Claims Against the FDA

Several Plaintiffs bring claims under the Administrative Procedures Act, alleging that the FDA failed to comply with its own rules and was arbitrary and capricious in the manner it granted approvals of BSC's SCS products. The allegations focus on the evidence required for initial PMA approval and the use of PMA supplements instead of new PMA applications. These plaintiffs seek declaratory relief that, due to the failure to undergo the proper regulatory approval process, the Medical Device Amendments to the Federal Food, Drug, & Cosmetic Act do not preempt any claims against BSC. It is unclear at this time whether these claims will continue to be pursued in the manner in which they are currently pled, or whether they will be separated out into a separate complaint.

Plaintiffs' Statement of Legal Issues:

A central threshold legal issue in this litigation will be federal preemption under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k(a). Plaintiffs' position is that each claim survives preemption as it is premised on state-law duties that are genuinely parallel to, and do not exceed, the specific federal requirements imposed by the FDA through PMA P030017 and its implementing regulations. Plaintiffs further argue that implied preemption under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), does not bar claims grounded in independent state-law duties, as opposed to claims that exist solely by virtue of federal law.

Plaintiffs also highlight that the greater weight of plaintiffs' claims are premised primarily on independent state-law duties and common law and therefore not preempted by any federal device regulation. These include the claims for corporate negligence, negligent supervision, negligent training, negligent retention,

fraud, negligent misrepresentation, consumer protection statutes, and the unauthorized practice of medicine.

The permissible scope of activity for a medical device company's sales and clinical representatives will be another central issue as part of the claims for unauthorized practice of medicine. Plaintiff's theory that programming, reprogramming, and making clinical recommendations constitute the unauthorized practice of medicine raises novel questions about the line between permissible technical support and the practice of medicine. Plaintiffs further assert that BSC is vicariously liable for the unauthorized practice of medicine committed by its employees and agents in the scope of their employment.

Finally, another issue in this litigation will be standing to bring APA claims against the FDA pursuant to Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq.

Plaintiffs also note that while one court has granted a motion to dismiss by BSC in a spinal cord stimulator case in which FDA was not a defendant, two other courts have ruled on motions to dismiss by other manufacturers in similar cases with virtually identical legal issues, both of which have denied the motions, either in full or in part, on the basis of a lack of express or implied preemption. *See Dunham v. Boston Scientific Corp.*, 821 F. Supp. 3d 879 (W.D. Mich. 2026); *c.f. Perry DiToto v. Nevro Corp. et al.*, Case No. RDB-25-1388, 2026 WL 1425041 (D. Md. May 21, 2026); *Cathryn Keys v. Medtronic, Inc.*, et al., Case No. 25-CV-1966 (PJS/ECW), 2026 WL 2030069 (D. Minn. July 14, 2026).

B. **BSC's Statement:**

Factual Background. The BSC spinal cord stimulator devices ("SCS") at issue in this litigation are Class III medical devices that obtained premarket approval ("PMA") from the U.S. Food and Drug Administration ("FDA") prior to sale. PMA approval constitutes a finding that the devices are safe and effective for the indicated uses. In general, BSC SCS devices are indicated as an aid in the management of

chronic intractable pain of the trunk and/or limbs associated with various conditions, including failed back surgery syndrome, Complex Regional Pain Syndrome, intractable low back or leg pain, Diabetic Peripheral Neuropathy of the lower extremities, degenerative disc disease, and multiple back surgeries. There have been a number of different BSC SCS systems since 2004, including the Precision™ System, Precision Spectra™ System, Precision Novi™ System, Precision Montage™ System, Spectra WaveWriter™ System, WaveWriter Alpha™ System, and WaveWriter Alpha™ Prime System. Each system includes an implantable pulse generator ("IPG"), implanted leads that are placed by the surgeon in proximity to selected spinal nerves, and external controllers (*e.g.*, remote controls and/or apps). But the technology and capabilities of each device differ, and the particular components, configurations, and other choices by the implanter (including, most prominently, type of leads and lead placement) will differ from patient to patient. Some models are compatible with MRIs and others are not. The electrical stimulation waveforms and patterns can be different in different models, including paresthesia-based therapy, subperception therapy, and different types of burst stimulation. Batteries can be rechargeable or nonrechargeable.

Spinal cord stimulators have been on the market for decades, and the decision whether a particular patient may benefit from the device and whether its benefits outweigh the risks for that patient is one made between the patient and their learned intermediary medical provider. BSC's SCS devices have been extensively studied, including in a number of clinical studies following the initial PMA approval by FDA in 2004. The risks are well-understood and reflected in the FDA-approved labeling. These include:

- Lead migration resulting in undesirable changes in stimulation and reduction in pain relief;

- System failure, including due to battery leakage, device failure, lead breakage, hardware malfunctions, loose connections, electrical problems, etc. resulting in ineffective pain control;
- Tissue reaction to the materials or devices, including formation of reactive tissue around the lead in the epidural space, which can lead to neurological/sensory deficit, including paralysis;
- Skin thinning or tenderness, including formation of a seroma, at the implant location;
- Spinal fluid leaks, hematoma, seroma, epidural hemorrhage or paralysis, as well as temporary pain or infection post-surgery;
- Undesirable stimulation over time due to cellular changes in tissue, change in electrode position, loose electrical connections, and/or lead failure;
- Migration of the implant from its original position; and
- Weakness, clumsiness, numbness or pain below the level of implantation.

Plaintiffs' alleged injuries typically fall within these categories of already-warned-about potential risks that are accordingly non-actionable on any kind of failure-to warn claim.

BSC's field representatives work closely and in tandem with the medical provider learned intermediaries who prescribe and implant these devices. The SCS systems are initially programmed in the operating room with technical support of field representatives. Following implantation, reprogramming or adjustments are often necessary to try to optimize the pain relief provided. BSC provides the mySCS™ Go Therapy Controller App that allows the patient to turn therapy on or off, adjust stimulation strength, and activate or modify programs and schedules. Field representatives typically work with the patient to teach them how to adjust the programming or settings on their own, and may also work with the patient to change

programming or settings if the patient is having difficulties. This is not the unauthorized practice of medicine under the laws of any state.

The initial PMA approval for what was then called the Precision Spinal Cord Stimulation (SCS) System was granted by FDA in 2004. Over the more than two decades since then, Boston Scientific has continued to evolve and improve its SCS products, and FDA has approved nearly 400 PMA supplements, submitted as federal law requires, involving changes large and small to many aspects of BSC's processes, suppliers, labeling, manufacturing, and designs. There is no basis in law or fact for Plaintiffs' claims that BSC misused the regulatory process or misled FDA in any way when it obtained approvals via PMA supplements for changes to its SCS devices. Indeed, BSC's PMA supplements were fully compliant with federal law and regulations.

Plaintiffs' manufacturing defect claims are vague, conclusory, and unfounded. Most of the complaints include only bald statements that BSC violated certain federal Current Good Manufacturing Practices ("cGMPs"), which are broad guidelines that cannot provide the basis for a manufacturing defect claim nor do Plaintiffs adequately plead any connection between alleged manufacturing defects and their alleged injuries. Indeed, their claim that the SCS systems as a category simply do not provide the relief promised is inconsistent with any manufacturing defect claim.

BSC's Statement of Legal Issues: Because the SCS is a Class III, PMA-approved product, claims under state law that would impose additional or different requirements from those applicable under federal law are expressly preempted. *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008). In addition, any claims premised on purported fraud on the FDA or that rely entirely on alleged violations of federal law are preempted under *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 342 (2001). In order to avoid preemption, plaintiffs must allege a specific violation of a specific federal requirement and a parallel state law claim, which their complaints fail to do.

Plaintiffs have alleged a novel theory to try to avoid preemption, specifically

asserting that regulatory noncompliance by BSC and/or improper approvals of the PMA and PMA supplements by FDA somehow invalidates prior PMA approvals and retroactively strips SCS devices sold years ago from any claim to protection based on preemption. This approach is both factually and legally meritless, but will need to be addressed by the Court early in the MDL. *See Keys, et al. v. Medtronic, Inc. and U.S. Food and Drug Administration*, 2026 WL 2030069 (D. Minn. July 14, 2026).

In addition, Plaintiffs' complaints fail to state a claim under Rule 8 and 9(b) in that, among other things, they fail to plead any particular defect in the SCS systems, fail to allege plausibly pleaded facts, are conclusory, or are otherwise deficient. BSC has five fully-briefed, pending motions to dismiss existing complaints and, if necessary, intends to file a motion to dismiss any master complaint on similar legal grounds. In addition, BSC expects to move to intervene and to address Plaintiffs' Administrative Procedure Act claim against FDA based, *e.g.*, on plaintiffs' lack of standing, failure to exhaust administrative remedies, and failure adequately to plead a viable APA claim. BSC believes that the standing and other issues involved in the APA claim need to be addressed early in the litigation. *See Keys*, 2026 WL 2030069, at *4.

Additionally, many of the cases filed to date appear to involve statute of limitations or statute of repose issues that should result in dismissal. This includes two of the five cases with fully-briefed motions to dismiss. There is nothing unfair to these Plaintiffs in deciding these issues now. Indeed, it is unfair to BSC for facially time-barred claims to be allowed to remain in the MDL and require resources that would not need to be devoted to them if these issues are addressed early on, nor would the facts change in any master complaint so there is no need to await one.

Claims relating to the unauthorized practice of medicine should also be able to be addressed early on (as the recent *Keys* ruling demonstrates). Each of the five pending motions to dismiss addresses these claims and argues for their dismissal on the pleadings.

C. **FDA's Statement:**

FDA is not a proper party to this MDL, which overwhelmingly concerns state law product liability claims between Plaintiffs and BSC. Any claims against FDA should be severed and dismissed at the earliest possible opportunity. As BSC notes above, the inclusion of an APA claim by some Plaintiffs may be a strategic attempt to avoid the manufacturer's expected preemption defenses. This is a novel approach—to the best of FDA's knowledge, it has not previously been named as a Defendant in a product liability MDL.

Plaintiffs seek damages from BSC for injuries allegedly caused by BSC's spinal cord stimulator devices (SCS). A typical member case, like the earliest-filed one in this district, raises nine state law claims against BSC, ranging from negligence to failure to warn to breach of warranty. See Compl. ¶¶ 85–165, ECF No. 1, *Grainger v. Boston Sci. Corp.*, No. 2:25-cv-06515 (C.D. Cal.). Only some member cases, however, name FDA as a Defendant. When FDA is named, such cases have only raised a single claim under the Administrative Procedure Act, alleging, for example, that FDA's failure to require a new PMA was arbitrary and capricious, an abuse of discretion, and contrary to law, id. ¶ 171, or that the processing of mandatory safety submissions was unreasonably delayed, see Compl. ¶ 54, ECF No. 1, *Neal v. Boston Sci. Corp.*, No. 2:26-cv-03543 (C.D. Cal.). As relief, such cases have sought, for example, "declaratory relief that . . . FDA's actions regarding the PMA supplements . . . were arbitrary, capricious, an abuse of discretion, and contrary to law." Grainger Compl. ¶ 179, "injunctive relief requiring the FDA to reconsider and, if necessary, rescind or suspend the PMA approvals," id. ¶ 180, and an order to "compel completion" of the "administrative processing" of safety submissions, Neal Compl. ¶ 48.

Plaintiffs' APA claims are not viable and should be dismissed for a number of reasons—most clearly for lack of standing. Put simply, the relief that these Plaintiffs seek against FDA, which is purely prospective, would not remedy the injuries they

have suffered from allegedly defective SCS. Some Plaintiffs appear to have recognized as much. Of the 39 member or related cases listed in Attachment A, 23 never raised claims against FDA at all. In four others, the claim against FDA was voluntarily dismissed in response to a motion to dismiss. And in a set of four similar cases against Medtronic, another SCS manufacturer, the U.S. District Court for the District of Minnesota recently dismissed the APA claims against FDA for lack of standing. *See Keys v. Medtronic*, No. 25-cv-1966, 2026 WL 2030069, at *4 (D. Minn. July 14, 2026). FDA will likewise move to dismiss any remaining APA claims against it here and respectfully submits that its motion should be heard at the earliest possible opportunity. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998) (the "first and fundamental question is that of jurisdiction," for without it, "the court cannot proceed at all in any cause").

Even if an APA claim against FDA could survive a motion to dismiss, it would be in a fundamentally different procedural posture than the state law product liability claims against BSC that comprise the bulk of this MDL. APA cases are ordinarily resolved based on the administrative record compiled by the agency. Accordingly, discovery in APA cases is generally inappropriate, and they are exempt from Rule 26's ordinary requirement to confer and develop a proposed discovery plan. If such cases survive a motion to dismiss, they are generally decided on cross-motions for summary judgment, following production of the administrative record. And it is black-letter law that discovery in APA cases is rarely appropriate. *See, e.g., Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971) (requiring "a strong showing of bad faith or improper behavior" before extra-record discovery is permitted). Instead, if the challenged action "is not sustainable on the administrative record made, then the . . . decision must be vacated and the matter remanded to [the agency] for further consideration." *Camp v. Pitts*, 411 U.S. 138, 143 (1973) (per curiam).

Given these unique procedural requirements, many typical MDL procedures, which generally focus on streamlining discovery, are inapplicable to the APA claims raised in a subset of the member cases here. FDA thus respectfully proposes that those claims be severed under Federal Rule of Civil Procedure 21 and consolidated under Federal Rule of Civil Procedure 42, at which point FDA would move to dismiss them. This approach would have the benefit of placing the APA claims on a different track, appropriately recognizing their fundamentally different procedural posture. And if FDA's motion to dismiss were granted and Plaintiffs wished to appeal, the separate track would facilitate quicker appellate review of an issue that all parties appear to agree would benefit from early resolution, especially given the prospect of more MDLs concerning manufacturers of other SCS products. Regardless, however, of whether the APA claims are severed or addressed within the MDL, FDA respectfully requests that their motion to dismiss be decided promptly, so that further litigation can focus on the proper parties.

II. CONSOLIDATED OR MASTER COMPLAINT AND PENDING MOTIONS TO DISMISS

The parties agree that if a master complaint is adopted, it should be subject to a motion to dismiss. The parties further agree that all responses to existing complaints should continue to be stayed pending the parties' submission and the Court's adoption of a case management order to govern this process.

However, the parties disagree on some aspects of how a master complaint should be structured and utilized or whether the APA claim should be severed prior to the adoption of a master complaint, and also disagree on treatment of the pending motions to dismiss, as follows.

A. Plaintiffs' Position:

Master Complaint and Answers: Plaintiffs submit that a master complaint and individual short form complaints make the most sense for this litigation. A master complaint will help streamline allegations and counts for the Plaintiffs in this case

while also allowing individual counsel to make any additional allegations they believe are necessary. While differing state laws may impact different cases, the allegations necessary to a choice of law analysis can be included in short form complaints and general allegations of state law can be included in the master complaint. Numerous MDLs have followed this process where plaintiffs in the underlying cases alleged state law claims from multiple states. *See*, *e.g.*, master complaints filed in In re Uber Techs., Inc., Passenger Sexual Assault Litigation, No. 3:23-MD-03084-CRB (N.D. Cal. Feb. 15, 2024), In re Valsartan, Losartan, and Irbesartan Products Liability Litigation, No. 1:19-ms-02875-TBK-SAK (D.N.J. Apr. 12, 2021), In re Baby Food Products Liability Litigation, No. 3:24-md-03101-JSC (N.D. Cal. July 15, 2024), In re Juul Labs, Inc. Marketing, Sales Practices, and Products Liability Litigation, No. 3:19-md-02913-WHO (N.D. Cal. Mar. 11, 2020).

Pending Motions to Dismiss: With a master complaint to govern all actions consolidated in this MDL, moving forward on the pending motions to dismiss in select cases would unfairly prejudice those individual plaintiffs and treat them differently than all other plaintiffs in this MDL. Unlike all other plaintiffs in the MDL, these individual plaintiffs would be deprived of the opportunity to have their claims considered as pled in the master complaint. Considering the pending motions to dismiss would also undercut a core purpose of this MDL consolidation by introducing unnecessary inefficiency and consumption of judicial resources, as this Court will then repeat the exercise again with respect to the master complaint. Deciding these individual motions will provide no benefit to the MDL, as these decisions will achieve no global progress. This is true whether the Court grants or denies the motions, or alternatively grants these plaintiffs' leave to amend their complaints which is asked for in every opposition to the motion.

Although Defendants argue that considerable work has gone into the briefing of these motions, if Defendants are correct that these motions encompass issues that will need to be decided on a global basis, that work will not go to waste and can be

reused in the briefing on the proposed master complaint. Accordingly, Plaintiffs respectfully request that the Court deny the pending Motions to Dismiss without prejudice to ensure fair and equitable treatment of all plaintiffs and efficient use of judicial resources.

B. BSC's Position:

Pending Motions to Dismiss: BSC submits that the Court should decide the five fully-briefed and pending motions to dismiss in the cases listed in Section V.A. below. These cases were brought by Plaintiffs' designated counsel Behram Parekh and Trevor Rockstad on behalf of five plaintiffs from different states (Virginia, Mississippi, California, and New Jersey). Their implants (to the extent identified) include the WaveWriter Alpha and Spectra WaveWriter SCS Systems, and the implantation dates span from early 2020 to the latter part of 2023. The alleged injuries in these five cases include: ineffective pain relief, shocking sensations, lead migration, battery flipping, pain, revision surgeries, neuropathy, numbness, gastroparesis, urinary incontinence, nerve pain, muscle weakness, paraplegia, and infection. As such, they are representative of the claims and allegations in the cases filed to date. In addition, they tee up the critical legal issues that the Court needs to address early on, particularly preemption of Plaintiffs' claims. Considerable effort has gone into fully briefing these motions, the resolution of which would help to streamline the litigation so that any master complaint that may follow for the remainder of the cases will be limited to claims that survive the initial rulings.

Master Complaint: After resolution of the pending motions, BSC does not oppose filing of a master complaint, but believes that any such complaint should constitute the operative pleading with respect to all allegations and causes of action asserted therein, and should include allegations as to all state's laws under which claims are being asserted. Any ruling on the master complaint should apply to all actions in this MDL. If that motion is not granted in full, BSC would expect the parties and the Court to address whether it should file an answer to the master complaint

and/or to any later-filed short form complaints. If a master complaint is filed, BSC agrees that individual plaintiffs should be required to direct-file short form complaints in a form agreed by the parties and consistent with a future Case Management Order on Direct Filing and Service of Process that the parties will negotiate and submit for the Court's approval. The short form complaints would provide required information about each Plaintiff's claims and adopt the allegations in the master complaint. Any short form complaints should be individually filed by each plaintiff (i.e., no multiple-plaintiff short form complaints should be permitted). The Court should stay any requirement for BSC to respond to individual short form complaints. Finally, if a separate track or master complaint as to the APA claim is established, BSC should be permitted to move to dismiss or otherwise address that claim for the reasons stated in its motions to intervene filed in the *Grainger* case and other cases referenced in Section V.

C. FDA's Position:

Pending Motions to Dismiss: FDA previously filed motions to dismiss in three member cases: *Grainger v. Boston Sci. Corp*., No. 2:25-cv-6515 (C.D. Cal.); *Smith v. Boston Sci. Corp*., No. 2:25-cv-8821 (C.D. Cal.); *Guthrie v. Boston Sci. Corp*., No. 2:25-cv-11508 (C.D. Cal.). In each, the Plaintiff responded by voluntarily dismissing its APA claim against FDA under Rule 41(a)(1)(A), and the Court denied FDA's motion to dismiss as moot. FDA has not filed motions to dismiss in the remaining member cases, as they have not yet been served or the answer deadline has been stayed in light of the MDL.

Master Complaint: As discussed above, FDA proposes that the APA claims brought by a subset of Plaintiffs be severed and consolidated on a separate track from the MDL. If the Court instead determines to resolve them without severing, FDA does not object to the filing of a master complaint, so long as it is not merely an administrative summary of claims brought by individual Plaintiffs, but instead the legally operative complaint, superseding prior individual pleadings. Either way, FDA

would plan to file a single, consolidated motion to dismiss. Because the APA claims would be unaffected by varying state law or injuries unique to individual Plaintiffs, there would seem to be no need for short-form complaints against FDA.

III. ESTIMATE OF TOTAL NUMBER OF CASES AND BEST PRACTICES FOR DOCKET MANAGEMENT

A. Estimated Number of Cases

Designated Counsel estimate, based on the informal poll that they have conducted of Plaintiffs' counsels' retained cases, is that the total number of cases likely to be added to this MDL will reach over two thousand.

BSC notes that the earliest similar cases to the ones now in this MDL were filed in late April or early May 2025, and after more than 14 months, the total number of filed cases against BSC is still only 39 (with a total of 47 plaintiffs due to several multiple-plaintiff cases). BSC thinks it would be beneficial and would facilitate planning by the Court and the parties to have a better census of known cases early on.

B. Docket Management Best Practices

Regarding best practices for docket management, the parties have discussed the following topics:

1. **Filing on the master docket**.

Plaintiffs' Position: Plaintiffs' position is that due to the likelihood of a large number of filings in this MDL, Plaintiffs believe best practices would be to maintain both a master docket and for individual plaintiffs to file cases and individual case specific documents in individual dockets. Documents that pertain to all cases or which impact MDL wide issues should be filed on the master docket. Counsel should file a Notice of Appearance in the Master Docket once to receive Master Docket notices, but no individual complaints should be filed in the Master Docket. All case-specific filings should be filed in the respective individual dockets with proper service completed on Defendants' counsel. This reduces the amount of docket

pollution and preserves the Master Docket for the most important filings. This also prevents counsel from missing important filings because they are not potentially receiving tens or even hundreds of notifications when a large number of complaints are filed or when case specific filings are required. As an example, the Roundup MDL, which adopted BSC's proposed position, has over 22,000 docket entries in the master docket, whereas the Valsartan MDL, which began slightly prior the Roundup MDL but adopted Plaintiffs' proposed position, has approximately 3200 docket entries in the master docket. Plaintiffs believe the parties can negotiate specific procedures and propose an order to the Court to mitigate any notice or other issues.

BSC's Position: BSC's position is that individual short form complaints and all other filings should be made on the master docket and spread to the individual case(s) to which they apply. BSC is concerned about having to enter appearances in and keep abreast of filings in a large number of individual dockets. If Defendants do not enter an appearance in each individual docket, they will not receive ECF notices of filings in those dockets. Filing all documents in the master docket and spreading to the appropriate individual cases avoids this problem. However, BSC appreciates that the Court and Clerk's Office may have a preference on how filings are managed, and BSC will be glad to do whatever the Court prefers.

2. **Best practices for transfer of cases filed in this District prior to Master Complaint/Short Form process**. The parties would like the Court's guidance on how to efficiently identify and transfer in cases to the MDL that are filed in this District.

3. **Service of process**. The Plaintiffs submit that streamlined service would be most effective in this case. Whether that is electronic service by email or through a third-party vendor site, the Parties can work together and propose an order to the Court.

BSC has had preliminary discussions with Plaintiffs about service of process but is undecided as to how service on both BSC entities should be accomplished. BSC

will continue to discuss this with Plaintiffs' leadership and will advise the Court at a later date. BSC notes that some cases in this MDL have not yet been served (as shown on Exhibit A), but do need to be served on BSC's agents for service of process until any alternative has been put in place.

FDA notes that Federal Rule of Civil Procedure 4(i)(2) sets out the requirements for service of process on the United States and federal agencies, and FDA does not waive those requirements.

IV. LIST OF ALL KNOWN RELATED CASES IN STATE OR FEDERAL COURT AND STATUS OF SAME

The following cases are pending in this Court but not yet transferred to this MDL:

Angela Kiakis v. BSC, No. 2:26-cv-7709-PA-DSR

Tygeras Parker v. BSC, et al., No. 2:26-cv-07060-SPG-CTS

Katherine Van Liew, et al. v. BSC, et al., No. 2:26-cv-06949-AH-E

Lillie Mae Williams v. BSC, et al., No. 2:26-cv-06673-JLS-E

In addition, per CTO-3 (finalized by the JPML on July 21, 2026), *Bridgette Venturi v. BSC*, No. 1:26-cv-13178 (D. Mass.) is in the process of being transferred to this Court.

A list of cases known to the parties that are or should be in this MDL can be found at Exhibit A. Two of these cases also allege claims against other defendants.

In addition, BSC identifies one state court case that may be related:

Barone v. Rancho Mirage Surgery Center, Dr. Hazmer Cassim, Boston Scientific Corp., Boston Scientific Neuromodulation Corp., and Does 1-25 inclusive, Case No. CVPS2601008 (Cal. Super. Ct. Riverside Cty.) (assigned to Judge Harold Hopp). This is a medical negligence case that also includes allegations against BSC similar to those made in many of the federal court cases.

V. LIST OF PENDING MOTIONS

BSC's Motions to Dismiss are fully briefed and pending in:

Grainger v. BSC, 2:25-cv-06515-JLS-E

Wilson v. BSC, 2:25-cv-09958-JLS-E

Weisman v. BSC, 2:25-cv-08919-JLS-E

Smith v. BSC, 2:25-cv-08821-JLS-E

Guthrie v. BSC, 2:25-cv-11508-JLS-E

VI. LIST OF ADJUDICATED MOTIONS IN BSC CASES

In four member cases, this Court denied as moot pending motions to dismiss the APA claim against FDA after the Plaintiff in each case voluntarily dismissed that claim. See *Grainger v. Boston Sci. Corp*., No. 2:25-cv-6515 (C.D. Cal.); *Smith v. Boston Sci. Corp*., No. 2:25-cv-8821 (C.D. Cal.); *Guthrie v. Boston Sci. Corp.*, No. 2:25-cv-11508 (C.D. Cal.); *Wilson v. Boston Scientific*, 2:25-cv-9958 (C.D. Cal.). Outside this District, BSC's motion to dismiss was granted in *Dunham v. Boston Scientific Corp.*, 821 F. Supp. 3d 879 (W.D. Mich. 2026), a case included as part of the JPML Motion to Transfer. Plaintiffs note that the *Dunham* action was decided prior to creation of this MDL and that plaintiffs' counsel in that case has not filed any cases in this MDL.

VII. LIST OF ALL OUTSTANDING DISCOVERY

There is no outstanding discovery in any of the cases now in the MDL, nor has any discovery yet been served or conducted in any of the cases.

VIII. LIST OF PARENTS, SUBSIDIARIES, AND AFFILIATES AND LIST OF ALL COUNSEL

1. Parents, Subsidiaries, and Affiliates of BSC and BSNC:

a. Boston Scientific Neuromodulation Corporation is a wholly-owned subsidiary of Boston Scientific Corporation, a publicly traded corporation. Boston Scientific Corporation has no parent company or publicly traded subsidiaries or affiliates. If the Court requires information about non-publicly traded subsidiaries or affiliates of BSC, a recent list can be found in BSC's SEC filing at

https://www.sec.gov/Archives/edgar/data/885725/000088572525000011/exhibit21-listofsubsidiari.htm?utm.

2. List of Counsel: A list of all counsel in the cases in this MDL is attached as Exhibit B.

IX. NEED FOR SPECIAL MASTER OR INDEPENDENT SCIENTIFIC EXPERT

The parties do not see the need for an independent scientific expert for the Court at this time. Regarding a special master:

A. Plaintiffs' Position:

As discussed below, Plaintiffs believe that limited discovery as to regulatory files and manufacturing processes is appropriate at this time. Accordingly, Plaintiffs anticipate there will be a need to address discovery disputes prior to resolution of motions to dismiss. Plaintiffs would defer to the Court's wishes with respect to whether the Court prefers the appointment of a special master versus utilizing Magistrate Judge Eick for purposes of resolving discovery disputes.

B. BSC's Position:

As discussed below, BSC believes that discovery should be stayed pending filing of a master complaint by Plaintiffs' leadership and resolution of motions to dismiss. Thus, there is no immediate likelihood of discovery disputes. When discovery is active, BSC is willing to discuss a possible special master with Plaintiffs or having Magistrate Judge Eick address any disputes, and will also defer to the Court's wishes on this issue.

C. FDA's Position:

FDA does not believe that appointing a special master would facilitate the resolution of their motion to dismiss, which will focus on threshold legal issues, such as standing. Moreover, as noted above, discovery in APA cases is generally impermissible, whether before or after a motion to dismiss. Plaintiffs fall well short of meeting their heavy burden to show that an exception to that principle applies here.

X. TECHNICAL TUTORIAL FOR THE COURT

The Plaintiffs and BSC agree that a technical tutorial would be helpful for the Court at a time to be decided. Plaintiffs believe an initial abbreviated technical tutorial may be helpful to the Court prior to a decision on preliminary motions, particularly with regard to regulatory issues, whether presented solely by counsel or with the participation of expert witnesses. BSC does not believe a tutorial is necessary to understand the issues involved in preliminary motions, including Rule 12(b)(6) motions, but would be happy to participate in a technical tutorial whenever the Court desires.

XI. ADDITIONAL TOPICS

1. Discovery

Plaintiffs' Position: Plaintiffs submit that limited discovery as to administrative record, regulatory files, and manufacturing processes is appropriate at this time. The discrete nature of these files that must be separately maintained in an organized manner by Defendants pursuant to federal regulations, which are readily identifiable, and which will not require the negotiation of search terms and custodians, nor relevance or privilege review, will result in an efficient and expeditious discovery process. The production of these discrete documents presents no meaningful burden on Defendants while providing discovery directly relevant to preliminary issues in the case, including the anticipated dispositive motions. This limited and targeted approach appropriately balances the needs of the litigation with minimal burden on Defendants.

BSC's discussion of the ruling in *Keys* is premature to discuss in detail, however, Plaintiffs simply state that they disagree with parts of the rationale and underlying interpretations made by Judge Schiltz in his ruling on the APA claim therein, as well as believing that other issues raised therein are both distinguishable and can be surmounted by amended pleadings. Further, Defendants ignore that despite Judge Schiltz ruling that against the APA claim, he continued on to rule that the

parallel manufacturing defect-claims related to the plaintiff's spinal cord stimulator survived the motion to dismiss and were not preempted.

BSC's Position: BSC believes that all discovery should be stayed pending filing of a master complaint and initial motions to dismiss. Since BSC believes that many claims will be dismissed on motion, pursuing discovery without knowing what remains in the case will likely result in unnecessary expense and undue burden. BSC specifically opposes Plaintiffs' intention to seek discovery of "regulatory files and manufacturing processes" with unclear timing but presumably in advance of dispositive motions. BSC believes that the regulatory claims are likely to be dismissed on early motion (including on the five pending, fully-briefed motions to dismiss), and do not require discovery of any sort for their resolution. First, Plaintiffs' theory that preemption does not apply to their claims because of alleged regulatory improprieties either by BSC, FDA, or both, has no merit. Chief Judge Patrick Schiltz in similar cases brought against Medtronic recently ruled accordingly, and BSC will ask this Court to follow suit. *See Keys,* 2026 WL 2030069, at *8–11. Thus, discovery into the regulatory history of the SCS devices at issue is not necessary to resolution of preliminary motions (against either BSC or FDA). Second, permitting regulatory discovery to proceed initially will only result in delays and unnecessary burden and expense. Since the preliminary motions raise legal issues that can and should be decided without need of discovery, and because discovery of the regulatory history (with unknown parameters) going back more than two decades will undoubtedly take many months to accomplish, BSC will be required to expend significant resources on discovery that is unnecessary and will delay resolution of key issues that should significantly affect (and narrow) the scope of this MDL.

Discovery of "manufacturing processes" similarly is premature. BSC is entitled to challenge the adequacy of any pleading(s) on this issue before discovery takes place. It is improper for plaintiffs to make vague and unsupported claims about alleged manufacturing defects and then seek discovery in hopes of finding something

to support them. In addition, "manufacturing processes" without any defined defect(s), identification of the products and components at issue (since only 41 plaintiffs have filed claims but supposedly thousands more are expected), and the timeframe at issue would render any such discovery a fishing expedition likely unnecessary once dispositive motions are resolved.

Following resolution of preliminary motions, BSC will confer with Plaintiffs' leadership on appropriate phasing or other handling of discovery in order to ensure it remains proportional, reasonably necessary to address the remaining issues in the case, and not unduly burdensome.

FDA's Position:

As noted above, discovery in APA cases is generally impermissible, and Plaintiffs fall well short of meeting their heavy burden to show that an exception to that principle applies here. Moreover, any discovery would be irrelevant to FDA's motion to dismiss, which will focus on threshold legal issues, such as standing. And even if Plaintiffs' APA claims were to survive a motion to dismiss, review would be limited to the administrative record.

The administrative record in this case is likely voluminous—Plaintiffs assert that BSC's first SCS device was approved in 2004 and has since been the subject of nearly 400 PMA amendments. FDA should not be required to undertake the cost and expense of compiling the administrative record unless and until any APA claim survives a motion to dismiss. But in any event, there is no reason to think that the administrative record would be insufficient to resolve such a claim. Indeed, as noted earlier, individual Plaintiffs have thus far repeatedly dismissed FDA as a Defendant rather than respond to a motion to dismiss.

2. **Preservation Obligations**

The parties are cognizant of their obligations under the Federal Rules and relevant case law. The parties are acting in good faith to ensure that their preservation obligations are met and will meet and confer on these issues as the litigation proceeds.

3. Status Conferences

The Plaintiffs and BSC agree that monthly status conferences should be held, and that the first few should be held in person to facilitate engagement among the parties and the Court. Thereafter, Plaintiffs and BSC suggest alternating monthly between in-person and remote conferences, and that a joint report and agenda setting forth the parties' agreements and positions should be submitted at least three (3) court days prior to each conference. Plaintiffs and BSC further suggest that they be permitted jointly to request cancellation of any conference upon at least ten (10) court days' notice if they believe there is no need for a conference that month.

As noted above, FDA does not believe it is a proper Defendant here, and proposes that any APA claims against it be heard on a separate track and dismissed early. FDA further anticipates that many of the issues to be discussed at monthly status conferences will not be applicable to the claims against the agency. FDA therefore requests that, if the claims against it are not severed, its counsel be excused from attending such conferences. In the alternative, given that FDA is represented by Department of Justice counsel located in Washington, DC, it requests permission for counsel to attend such conferences remotely.

Respectfully submitted,

Dated: July 24, 2026

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CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2026, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system and thereby served it on all counsel of record.

/s/ *Monee Takla Hanna*
Monee Takla Hanna