IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PERRY DiTOTO,	*	
Plaintiff,	*	
v.	*	Civil Action No. RDB-25-1388
NEVRO CORPORATION, GLOBUS MEDICAL, INC., and UNITED STATES FOOD AND DRUG ADMINISTRATION	*	
Defendants.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

In this products liability action, Plaintiff Perry DiToto ("Plaintiff" or "Mr. DiToto") sues Defendants Nevro Corporation, Globus Medical, Inc. (collectively with Nevro Corporation, "Nevro Defendants"),[1] and the United States Food and Drug Administration ("FDA") (collectively, "Defendants") in relation to alleged defects in the implanted medical device Senza II Spinal Cord Stimulation System ("Senza II SCS") distributed by Nevro. *See generally* (ECF No. 19). On October 27, 2020, Mr. DiToto underwent a procedure pursuant to which he was surgically implanted with this device. (*Id.* ¶ 74.) From that date until February 8, 2023, when the device was explanted, he alleges that he experienced painful shocks and related complications from the device beginning on May 4, 2022, and lasting until its removal on that date. *See* (*id.* ¶¶ 75–84). Plaintiff initiated this action on May 1, 2025, by filing a seven-count

[1] Plaintiff alleges that, on February 6, 2025, Globus Medical, Inc. acquired Nevro Corporation such that Nevro Corporation is "a wholly owned subsidiary of Globus." (ECF No. 19 ¶ 40.)

Complaint in this Court against Defendant Nevro Corporation. (ECF No. 1.) He alleged various products liability claims against Nevro, which moved to dismiss the Complaint, *see* (ECF No. 14).

On October 20, 2025, Plaintiff filed the operative, nine-count First Amended Complaint (ECF No. 19), in which he alleges product liability claims, other state common-law claims, and a claim for declaratory relief. The jurisdiction of this Court is predicated on diversity of citizenship. 28 U.S.C. § 1332. (*Id.* ¶¶ 38–41, 45.) In Counts I–VI and VIII–IX, Mr. DiToto alleges products liability and other state common-law tort claims against Nevro Defendants.[2] (*Id.*) Specifically, he alleges manufacturing defect—product liability on a theory of strict liability (Count I); breach of implied warranties (Count II); various forms of negligence, including manufacturing defect—product liability on a negligence theory (Count III); fraudulent misrepresentation (Count IV); breach of express warranties (Count V); negligence (Maryland statute or ordinance rule) (Count VI); a violation of Maryland's Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 *et seq.* (Count VIII); and negligent misrepresentation (Count IX). In Count VII, Mr. DiToto seeks a declaration that the FDA violated § 706 of the Administrative Procedures Act, 5 U.S.C. § 706, when it approved certain aspects of the Nevro Senza II SCS system (Count VII). As explained further

[2] Plaintiff does not clearly specify against which Defendants each Count is alleged. Rather, Plaintiff includes demands for relief in each Count that reference "Defendant," "Defendants," "Nevro," or "Nevro and Globus." *See generally* (ECF No. 19). As explained further below, Count VII is alleged against Defendant Food & Drug Administration (*Id.* ¶¶ 174–78.) Accordingly, the Court construes each Count as alleged against the party or parties named in the demand for relief. Where the demand for relief names only "Defendant," the Court construes the Count as alleged against Nevro Defendants. *See e.g.*, *Bell v. N.Y. State Dep't of Corr. & Cmty. Supervision*, 2019 WL 1305809, at *5 (N.D.N.Y. Mar. 22, 2019) (assuming, for purposes of addressing motion to dismiss, that counts for which plaintiff did not specify defendant were intended to be alleged against all defendants); *see also Elliott v. Oldcastle Lawn & Garden, Inc.*, 2016 WL 11190494, at *4 n.5 (D.S.C. Dec. 1, 2016) (noting that pleadings that do not specify to which defendant a cause of action applies "place[] a heavy burden on the Court and litigants to determine precisely what claims Plaintiff raises against whom").

below, in Count VII, Mr. DiToto seeks declaratory relief against the Food and Drug Administration.[3]

There are two motions currently pending before the Court: (1) Nevro Corporation's Motion to Dismiss (ECF No. 14) as to the original Complaint; and (2) Nevro Defendants' Motion to Dismiss Plaintiff's First Amended Complaint (ECF No. 29). These Defendants essentially argue that all Plaintiff's claims are preempted by federal statute. The parties' submissions have been reviewed, and no hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2025). While this Court has jurisdiction pursuant to 28 U.S.C. § 1332, the Court has federal question jurisdiction over Count VII, as that claim arises under § 706 of the Administrative Procedures Act, 5 U.S.C. § 706.[4] *See* 28 U.S.C. § 1331. For the reasons that follow, Nevro Corporation's original Motion to Dismiss (ECF No. 14) is DENIED AS MOOT. Nevro Defendants' Motion to Dismiss Plaintiff's First Amended Complaint (ECF No. 29) is GRANTED IN PART and DENIED IN PART. The Motion (ECF No. 29) is GRANTED as to Count II of the First Amended Complaint, alleging breach of implied warranties, which is DISMISSED. The Motion is DENIED as to Counts I, III, IV, V, VI, VIII, and IX.

BACKGROUND

In ruling on a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), this Court "accept[s] as true all well-pleaded facts in a complaint and construe[s] them in the

[3] Summons was issued to Defendant Food and Drug Administration on October 28, 2025. (ECF No. 25.) The docket in this case does not reflect completion of service of process or any response by the FDA. *See infra* p. 10 n.11.

[4] As to all other Counts, which arise under Maryland common law or statute, the Court has diversity jurisdiction pursuant to § 1332 because there is complete diversity of the parties and the amount in controversy exceeds $75,000. (ECF No. 19 ¶¶ 38–41, 45.) As to diversity of citizenship: Plaintiff is a citizen of Maryland; Defendant Nevro Corporation is incorporated in Delaware and has its principal place of business in California; and Defendant Globus Medical, Inc., is incorporated in Delaware and has its principal place of business in Pennsylvania. (*Id.* ¶¶ 38–40.)

light most favorable to the plaintiff." *Wikimedia Found. v. Nat'l Sec. Agency*, 857 F.3d 193, 208 (4th Cir. 2017) (citing *SD3, LLC v. Black & Decker (U.S.), Inc.*, 801 F.3d 412, 422 (4th Cir. 2015)). Except where otherwise indicated, the following facts are derived from Plaintiff's First Amended Complaint (ECF No. 19)[5] and accepted as true solely for the purpose of deciding the pending Motions to Dismiss (ECF Nos. 14, 29).

I. Factual History

a. Regulatory Framework for Medical Devices

Through the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c *et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA"), *id.* §§ 301 *et seq.*, Congress tasked the Food and Drug Administration with overseeing a "regime of detailed federal oversight" over medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The MDA divides medical devices into three categories for different levels of risk presented by each device. *Id.* at 316. As relevant here, Class III devices "include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators" and are subject to the highest level of scrutiny.[6] *Id.* at 317. A Class III device is "purported or represented to be for a use in supporting or sustaining human

[5] Local Rule 103.1(d) of the District of Maryland explicitly provides that "[p]leadings . . . shall not exceed forty (40) pages in length. In extraordinary circumstances, parties may seek leave of Court to amend or supplement the initial pleading with additional pages." Loc. R. 103.1(d) (D. Md. 2025); *see also Morris v. Mem'l Dev. Partners, LP*, JMC-23-1641, 2024 WL 811489, at *5 (D. Md. Feb. 23, 2024) (explaining court previously directed plaintiff to refile initial Complaint that violated Local Rule 103.1(d) and Federal Rule Civil Procedure 8(a)(2)); *Monster Invs., Inc. v. Avance Title, LLC*, ABA-24-767, 2025 WL 744197, at *3 (D. Md. Mar. 6, 2025) (explaining proposed amended complaint violated Local Rule 103.1(d) where it was fifty-two pages in length). Plaintiff's operative First Amended Complaint is sixty-two (62) pages, more than twenty pages longer than is permitted under Local Rule 103.1(d). Plaintiff has not sought leave for such a lengthy filing. The Court has reviewed Plaintiff's impermissibly lengthy filing and summarizes the facts relevant to the pending motions to dismiss.

[6] Class I devices include elastic bandages and examination gloves are subject to the lowest level of oversight, termed "general controls." *Riegel*, 552 U.S. at 316 (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices include powered wheelchairs and surgical drapes are subject to the general controls plus "special controls," such as "performance standards and postmarket surveillance measures." *Id.* at 316–17 (quoting § 360c(a)(1)(B)).

life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii).

Before a manufacturer may sell a Class III device, the company must seek and receive premarket approval ("PMA") from the FDA. *Riegel*, 552 U.S. at 317. "Premarket approval is a 'rigorous' process." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–76 (1996)). "To obtain premarket approval, a device manufacturer must submit to the FDA" a detailed application including, among many other components, "a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing." *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572–73 (4th Cir. 2012) (citing 21 U.S.C. § 360e(c)(1)). When premarket approval is granted, the device must be manufactured "with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323. Additionally, Class III devices are subject to reporting requirements, and the FDA retains the power to withdraw approval based on new data. *Id.* at 319–20.

b. Nevro Corporation's Senza II Spinal Cord Stimulator

Defendant Nevro Corporation designs, manufactures, and sells spinal cord stimulation ("SCS") devices. (ECF No. 19 ¶ 47.) A spinal cord stimulator is a surgically implanted device intended to treat chronic pain in the torso or limbs that is otherwise difficult to manage. *See* (*id.*); *see also* U.S. Food & Drug Admin., *Senza Spinal Cord Stimulation System – P130022/S039*, https://www.fda.gov/medical-devices/recently-approved-devices/senza-spinal-cord-stimulation-system-p130022s039 (last accessed May 18, 2026). The SCS device relevant to this case, Nevro's Senza II SCS device, is a multi-part system involving a rechargeable, implanted pulse generator and lead wires, which are secured to the patient's spinal cord. (*Id.* ¶¶ 47–49.)

After being implanted, the Senza II delivers electrical impulses to the patient's spinal cord for the purpose "of modulating the electrical pain signals which manifest in subjective patient pain." [7] (*Id.* ¶ 50.)

The FDA granted Nevro premarket approval to sell the first iteration of the Senza SCS system on May 18, 2015.[8] (ECF No. 29-1 at 9.) It later granted supplemental premarket approval for the Senza II SCS on January 4, 2018. (*Id.*)

c. Mr. DiToto's Factual Allegations

Plaintiff Perry DiToto claims that he suffers from chronic back pain. (ECF No. 32 at 2.) He alleges that, in the summer of 2020, he was introduced to sales representatives of Nevro Corporation as part of an evaluation for spinal cord stimulation therapy. (ECF No. 19 ¶ 68.) In September 2020, he met again with Nevro sales representatives and underwent a trial procedure in which stimulator leads were implanted into his body and connected to an external pulse generator. (*Id.* ¶ 70.) One of the representatives consulted with Mr. DiToto and helped him to adjust the electrical pulse settings of the trial device. (*Id.*) He alleges that these sales representatives had no medical training or medical certification. (*Id.* ¶ 69.) When the trial period had ended, Mr. DiToto reported a significant improvement in his lower back pain.[9] (*Id.*)

Plaintiff alleges that, following that trial period, Nevro's sales representatives made numerous claims about a permanent SCS device, including: (1) that the pain relief from a

[7] Other factual allegations concerning the Nevro Senza II SCS system which are relevant to specific counts in the First Amended Complaint are listed as appropriate in this Court's Analysis section, *infra* p. 11.

[8] The Court takes judicial notice of this fact, which appears in an official government publication, as its accuracy cannot be reasonably be questioned. Fed. R. Evid. 201(b)(2); *see United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017).

[9] It is not clear from the First Amended Complaint how long this trial period lasted.

permanent pulse generator device would equal or better that achieved during the trial period; (2) that the permanent SCS device would permanently deliver substantial pain relief; (3) that he would be able to resume normal daily activities following implantation of the permanent device; (4) that Nevro representatives would be readily available to help him adjust device settings for optimal pain relief; (5) that the permanent SCS device was safe and would not cause damage to his spine, nerves, or nervous system function; and (6) that these representatives had sufficient medical knowledge and training to make purposeful, effective adjustments to the SCS device as necessary. (*Id.* ¶ 71.)

On or about October 27, 2020, Mr. DiToto underwent a procedure to have the Nevro Senza II SCS device implanted by Charles Simmons, MD.[10] (*Id.* ¶ 74.) Almost eighteen months later, on or about May 4, 2022, Plaintiff called Nevro Corporation to make an appointment with his alleged assigned representative to adjust his stimulator. (*Id.* ¶ 75.) He claims that during that call, a Nevro representative tried to help Mr. DiToto adjust his Senza II SCS device over the phone. (*Id.* ¶ 76.) He alleges that while attempting to reprogram the device at the representative's instruction, the Senza II SCS "delivered two strong and extremely painful electrical jolts to [his] right buttocks, down his right leg[,] and to his foot. (*Id.*) He claims that he later told a neurologist, unnamed in the First Amended Complaint, that the feeling was "like his leg was being blown off." (*Id.*) The First Amended Complaint also states that Nevro Corporation's "internal documentation maintained to track the performance of his specific Nevro Senza II [SCS] device [would] indicate that the behavior of the SCS fluctuated significantly on the day [he] was shocked." (*Id.* ¶ 77.) He claims that such fluctuation would

[10] Dr. Simmons is not a party to this action.

"correlate to the device outputting significantly more electricity than approved by the FDA or otherwise deviating from FDA imposed limitations on the device that [would] suggest a mechanical defect." (*Id.*) Finally, he claims that this event occurred "under the control and supervision of Nevro's sales representative." (*Id.* ¶ 78.)

Mr. DiToto next alleges that two days later, on May 6, 2022, he met with a Nevro Corporation representative for an in-person reprogramming of his Senza II SCS device. (*Id.* ¶ 79.) He avers that on May 10, 2022, his legs "fell out from under him" while at a physical therapy appointment. (*Id.*) On that same day, he called Nevro and still another representative suggested another reprogramming. (*Id.* ¶ 80.) Mr. DiToto alleges that, at that time, he was experiencing "extreme pain in both buttocks, legs[,] and feet." (*Id.*) He claims that he thought it would be best to "turn the [Senza II SCS] device off and plan for a removal." (*Id.*)

Plaintiff alleges that after the shocks he experienced on or about May 4, 2022, he "experienced constant and severe pain and weakness in his buttocks as well as both legs and feet," which then required him to use a cane to keep balance and a wheelchair for "all but the shortest walking distances." (*Id.* ¶ 81.) He asserts that he subsequently sought treatment from several "physician specialists," each of whom ran tests to rule out potential alternative causes of the pain and weakness outside of the shocks he experienced on or about May 4, 2022 from his Senza II SCS device. (*Id.* ¶ 82.) He alleges that these specialists recognized that his "immobility arose only after the shocking incident [of May 4, 2022,] and found no definitive explanation for his immobility beyond that event." (*Id.*) He also asserts that his condition "did not improve with prescribed medication therapy." (*Id.* ¶ 83.)

On February 8, 2023, Mr. DiToto had his Senza II SCS device removed from his body.

(*Id.* ¶ 84.) He alleges that he never "abuse[d] or misuse[d] his SCS [device] or its component parts." (*Id.* ¶ 85.) He further alleges that he always "complied with the directives and instructions associated with the use of the device, namely, those set forth in the patient user manual and the instructions provided by Nevro personnel." (*Id.* ¶ 86.) He claims that, even after the SCS device was removed from his body, he continued to experience "significant lower extremity weakness, pain[,] and immobility that rendered him dependent on the use of wheelchairs and canes." (*Id.* ¶ 87.) Mr. DiToto alleges that he was able to improve, but not fully fix, his condition only by "long-term therapeutic intervention." (*Id.* ¶ 88.) Finally, he claims that he continues to experience a "significantly reduced quality of life," specifically because of his alleged mobility issues. (*Id.* ¶ 89.)

II. Procedural History

On May 1, 2025, Mr. DiToto filed his original complaint in this Court, alleging seven counts of state law claims against Defendant Nevro Corporation. *See generally* (ECF No. 1). Nevro Corporation moved to dismiss the original complaint on September 29, 2025. (ECF No. 14.) On October 10, 2025, Plaintiff filed the operative nine-Count First Amended Complaint. (ECF No. 19.) In Counts I–VI and VIII–IX, Mr. DiToto alleges products liability and other state law tort claims against Nevro Defendants. (*Id.*) Specifically, he alleges strict product liability—manufacturing defect (Count I); breach of implied warranties (Count II); negligence, including manufacturing defect—product liability on a negligence theory (Count III); fraudulent misrepresentation (Count IV); breach of express warranties (Count V); negligence (Maryland statute or ordinance rule) (Count VI); a violation of Maryland's Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 *et seq.* (Count VIII); and

negligent misrepresentation (Count IX). In Count VII, Mr. DiToto seeks a declaration that the FDA violated § 706 of the Administrative Procedures Act, 5 U.S.C. § 706, when it approved certain aspects of the Nevro Senza II SCS system (Count VII). Count VII is not presently before this Court.[11]

On January 9, 2026, Nevro Defendants filed the pending Motion to Dismiss the First Amended Complaint. (ECF No. 29.) As of the date of filing this Memorandum Opinion, Defendant Food and Drug Administration has not filed an answer or other responsive pleading to Count VII, nor has any attorney entered an appearance on the FDA's behalf. The pending Motions to Dismiss (ECF Nos. 14, 29) are fully briefed.

STANDARD OF REVIEW

A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Rule 12(b)(6) of the Federal Rules of Civil Procedure authorizes the dismissal of a complaint if it fails to state a claim upon which relief can be granted. "A Rule 12(b)(6) motion tests the sufficiency of a complaint; it does not, however, 'resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.'" *King v. Rubenstein*, 825 F.3d 206, 214 (4th Cir. 2016) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)). To survive such a motion, a complaint must

[11] Nevro Defendants note in their Motion to Dismiss the First Amended Complaint that they are not parties to Count VII. (ECF No. 29-1 at 7 n.1.) They also note that they intend on moving to intervene as defendants in that Count. (*Id.*) As of the date of filing this Memorandum Opinion, which comes more than five months after Nevro Defendants filed the pending Motion to Dismiss (ECF No. 29), they have not so moved. Nevertheless, while acknowledging that they are not parties to Count VII, Defendants preview their arguments as to the merits of that claim. (ECF No. 29-1 at 24.) They specifically state that "Plaintiff's APA claim is a transparent, albeit misguided, attempt to avoid preemption." (*Id.*) Given that Nevro Defendants lack a "direct stake in the outcome" of an "adversary argument . . . embracing conflicting and demanding interests," such argumentative previews are of no moment. *Diamond v. Charles*, 476 U.S. 54, 62 (1986) (first quote); *Flast v. Cohen*, 392 U.S. 83, 95 (1968) (second quote).

contain facts sufficient to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) (quoting *Bell Atl., Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Under this plausibility standard, a complaint must contain "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555; *see Painter's Mill Grille, LLC v. Brown*, 716 F.3d 342, 350 (4th Cir. 2013). A complaint need not include "detailed factual allegations." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). It must, however, set forth "enough factual matter (taken as true) to suggest" a cognizable cause of action, "even if . . . [the] actual proof of those facts is improbable and . . . recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (internal quotations omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to plead a claim. *Iqbal*, 556 U.S. at 678; *see A Soc'y Without a Name v. Virginia*, 655 F.3d 342, 346 (4th. Cir. 2011). In other words, the factual allegations in the complaint, taken as true, must "permit the court to infer more than the mere possibility of misconduct" by the defendant. *Iqbal*, 556 U.S. at 679.

ANALYSIS

I. Nevro Corporation's Motion to Dismiss (ECF No. 14)

"Ordinarily, an amended complaint supersedes those that came before it." *Goodman v. Diggs*, 986 F.3d 493, 498 (4th Cir. 2021). This Court has held that the filing of an Amended Complaint renders moot pending motions to dismiss the original complaint so long as the Amended Complaint addresses the issues raised in the prior motion to dismiss. *See Howard v. Ocwen Loan Servicing, Inc.*, RDB-18-3296, 2019 WL 4750333, at *2 (D. Md. Sept. 30, 2019); *Verderamo v. Mayor & City Council of Balt.*, 4 F. Supp. 3d 722, 724 n.3 (D. Md. 2014). In this

case, Plaintiff's First Amended Complaint (ECF No. 19) has added two defendants and added two additional claims. Nevro Defendants' pending Motion to Dismiss the First Amended Complaint fully briefs the arguments of Nevro Corporation and Globus Medical, Inc., for the dismissal of each of the nine Counts alleged against them in the First Amended Complaint. Accordingly, Nevro Corporation's Motion to Dismiss (ECF No. 14) as to the original Complaint (ECF No. 1) is DENIED AS MOOT.

II. Nevro Defendants' Motion to Dismiss Plaintiff's First Amended Complaint (ECF No. 29)

As noted, Mr. DiToto's First Amended Complaint contains nine counts. *See* (ECF No. 19). Nevro Defendants seek dismissal of Counts I, III, IV, V, VI, VIII, and IX. *See* (ECF No. 29-1 at 7). They argue, in essence, that each of these state law claims is preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360c *et seq.* (ECF No. 29-1 at 7.) The Court proceeds by providing a background on the preemption framework as it applies to this case. The Court then applies that framework to Mr. DiToto's claims. As set out below, several of the Counts may be considered together.

a. Preemption Background

There are two types of preemption relevant to this case. First, the Food, Drug, and Cosmetic Act specifies that any action "for the enforcement, or to restrain violations" of that statute must be brought "by and in the name of the United States." 21 U.S.C. § 337(a). In other words, private plaintiffs do not have a federal cause of action under the FDCA or its amendments (*i.e.*, the MDA). To that end, the Supreme Court has long held that § 337(a) impliedly preempts private plaintiffs bringing *state* law claims against medical device manufacturers merely for failing to satisfy their *federal* regulatory obligations. *See Buckman Co.*

v. Plaintiffs' Legal Comm., 541 U.S. 341, 348 (2001). Second, the MDA includes a provision expressly preempting any state regulation of medical devices "which is different from, or in addition to" any MDA requirement. 21 U.S.C. § 360k(a); *see also Walker v. Medtronic, Inc.*, 670 F.3d 559, 572 (4th Cir. 2012).

Nevertheless, the Supreme Court has explained that state claims that are "parallel" to federal claims are *not* preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). Specifically, the Supreme Court in *Riegel* recognized that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495). As Judges of this Court have previously recognized, to state a parallel claim, a plaintiff must (1) allege that the manufacturer failed to comply with a specific federal requirement applicable to the device, and (2) explain how that federal violation also violated state law. *See Chiapello v. Corin USA Ltd.*, SAG-23-3149, 2024 WL 3548726, at *4 (D. Md. July 23, 2024) (*Ellis v. Smith & Nephew, Inc.*, TMC-15-545, 2016 WL 7319397, at *3 (D.S.C. Feb. 16, 2016)); *Diodato v. Mentor Worldwide LLC*, JKB-20-762, 2020 WL 3402296, at *2 (D. Md. June 19, 2020) (quoting *Winkler v. Medtronic, Inc.*, PX-18-00865, 2018 WL 6271055, at *4 (D. Md. Nov. 29, 2018)).

Finally, as Mr. DiToto notes in his Response (ECF No. 32), the Supreme Court has repeatedly recognized, including in the context of the Medical Device Amendments, that there is a presumption against preemption. *Lohr*, 518 U.S. at 485 ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action."); *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008);

Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) ("[W]e . . . have a duty to accept the reading [of a statute] that disfavors pre-emption."); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995) (citation omitted).

b. Counts I and III: Product Liability—Manufacturing Defect

The First Amended Complaint contains two product liability—manufacturing defect claims. In Count I, that claim arises pursuant to a strict liability theory. (ECF No. 19 ¶¶ 185–95.) In Count III, Mr. DiToto alleges the a manufacturing defect but on a negligence theory. As noted above, to state a non-preempted parallel claim, each count must allege that Nevro Defendants failed to comply with a specific federal requirement applicable to the Senza II SCS and explain how that federal violation also amounted to a state law violation. *See Chiapello*, 2024 WL 3548726, at *4. The First Amended Complaint alleges that Mr. DiToto's Senza II SCS device was in a defective condition at the time of sale and that it reached him in that defective condition. (ECF No. 19 ¶¶ 186–87.) Specifically, he claims that the device was defective in that it did not comply with the FDA-imposed limitation on maximum impedance supplied to a patient's spinal cord. (*Id.* ¶ 13.) He further alleges that the device was not the one "approved by the FDA as it deviated from specifications" provided during the premarket approval process." (*Id.* ¶ 190.) Finally, he alleges that Nevro had "parallel duties under state and federal law . . . to exercise reasonable care in manufacturing [the Senza II SCS device] without deviations and defects." (*Id.* ¶ 193.)

Mr. DiToto argues that these allegations sufficiently state a violation of federal requirements. Specifically, he argues that "[b]ecause the device at issue in this case deviated from the device parameters set by the FDA, such a deviation would also violate the federal

requirements in the [premarket approval] Order [of the Senza II SCS system]." (ECF No. 32 at 6 (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010); *Gomez v. St. Jude Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006)).) In *Lohr*, 518 U.S. at 481, 494–95, the Supreme Court first considered the "limited scope" of the preemption provision in § 360k. *See Bausch*, 630 F.3d at 550 (using the term "limited scope" and discussing the Supreme Court's holding in *Lohr*). As the United States Court of Appeals for the Seventh Circuit explained in its *Bausch* opinion, the Supreme Court's decision in *Lohr* held that "lawsuits brought under state law against medical device manufacturers who submit 'premarket notification' to the FDA . . . are not preempted by [§ 360k] when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture, assembly, and sale." *Id.* (citing *Lohr*, 518 U.S. at 481, 494–95).

Nevro Defendants argue that Mr. DiToto has failed to state a parallel state law claim because, as they read the First Amended Complaint, he alleges that his device failed on May 4, 2022. (ECF No. 29-1 at 13.) As they note, a plaintiff cannot simply assert that a device failed on a given day. (*Id.* (quoting *Smith v. St. Judge Cardiac Rhythm Mgmt. Div.*, CCB-12-1746, 2013 WL 1104427, at *4 (D. Md. Mar. 13, 2013).) The First Amended Complaint does not merely allege that Mr. DiToto's Senza II SCS device failed on a given date, however. Instead, Mr. DiToto alleges that the device was manufactured as defective, with the evidence of that defect being the fact that the device failed. At the motion-to-dismiss stage, that is sufficient to plead a plausible violation of FDA requirements following premarket approval. *See Bausch*, 630 F.3d at 550; *see also Twombly*, 550 U.S. at 556; *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 104 (D. Conn. 2014).

The First Amended Complaint also sufficiently explains how that federal violation also amounted to a state law violation. *See Chiapello*, 2024 WL 3548726, at *4; *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 743 (D. Md. 2015). Maryland law creates strict liability for unreasonably dangerous products sold in a defective condition. *Phipps v. Gen. Motors Corp.*, 363 A.2d 955, 958 (Md. 1976). A plaintiff alleges a viable product defect claim by alleging a deficiency in manufacturing. *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 407 (D. Md. 2001) (citation omitted). "A negligence theory of products liability, in contrast, focuses upon the reasonableness of the manufacturer's acts and omissions, including the reasonableness of any warning, rather than upon the existence of a defect in the product itself." *Id.* (citing *Phipps,* 363 A.2d at 958). "'The elements of proof are the same whether the claim [is] characterized as one for strict liability or negligence . . . or breach of warranty." *Id.* (quoting *Watson v. Sunbeam Corp.,* 816 F.Supp. 384, 387 n. 3 (D.Md.1993)).

In *Williams*, Judge Blake of this Court ruled that a manufacturing defect claim was not preempted by § 360k because the FDA had approved a specific design—"and *only* that design"—and so "any such deviation would also violate the federal requirements outlined in the FDA's premarket approval order. 123 F. Supp. 3d at 743 (emphasis in original) (citation omitted). In this case, the First Amended Complaint alleges that Mr. DiToto's Senza II SCS was manufactured such that it was defective when sold. His theory is that the system, as manufactured by Nevro Defendants, deviated from its intended design, and such deviation caused him harm. As pleaded, he has stated a plausible violation of the FDA requirements for that device. He has also shown that such a violation, if true, would also amount to a violation of Maryland law that is parallel to the federal claim. Accordingly, Nevro Defendants' Motion

to Dismiss (ECF No. 29) is DENIED as to the product liability—manufacturing defect claims in Counts I and III.

c. Count II: Breach of Implied Warranties

In Count II, Mr. DiToto alleges that Nevro Defendants breached the implied warranties of merchantability and fitness for a particular purpose. (ECF No. 19 ¶¶ 196–205.) Nevro Defendants argue that this Count is expressly preempted by § 360k of the Medical Device Amendments. (ECF No. 29-1 at 15–16.) In his Opposition (ECF No. 32), Mr. DiToto fails to respond to this argument. Indeed, Mr. DiToto does not mention Count II anywhere in his Opposition. He has therefore not shown how any alleged violation of federal law also violates state law requirements. *See Chiapello*, 2024 WL 3548726, at *4; *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) ("Without a freestanding basis in state law, [a plaintiff's alleged parallel claims] are impliedly preempted."). Accordingly, Nevro Defendants' Motion to Dismiss is GRANTED as to Count II of the First Amended Complaint. That Count will be DISMISSED.

d. Count III: Negligence

Count III of Mr. DiToto's First Amended Complaint alleges a claim of product liability on a theory of negligence, discussed above. (ECF No. 19 ¶ 209.) It also alleges breach by Nevro Defendants of multiple other common law duties recognized by Maryland law. (*Id.*) Specifically, Mr. DiToto alleges that Nevro Defendants (1) failed to warn potential patients about the risks associated with the device, (2) failed to report and investigate adverse events, (3) failed to adequately train company representatives, and (4) failed to develop proper processes to determine settings of the Nevro II SCS device. (*Id.*) Again, as noted above, to

state a non-preempted, parallel state law claim, Mr. DiToto must allege a violation of some federal requirement and explain how such violation also violated state law. *See Chiapello*, 2024 WL 3548726, at *4.

i. Failure to Warn & Failure to Report

For the reasons stated above, Mr. DiToto's First Amended Complaint has plausibly stated federal violations. Additionally, it alleges that federal regulations, specifically, 21 C.F.R. § 803.32(b)(5), require Nevro Defendants to truthfully report the circumstances of an adverse event,[12] including whether and how a medical device was involved in such an event, to the FDA. (ECF No. 19 ¶ 167.) It alleges that Nevro Defendants consistently mis-report adverse events to the FDA, allegedly doing so more than 1,900 times from 2015 to 2020. (*Id.* ¶ 168.) Finally, it alleges Plaintiff, not Nevro Defendants, informed the FDA of the adverse event he experienced on May 4, 2022. (*Id.* ¶ 169 n.7.) Thus, Mr. DiToto sufficiently alleges violations of federal law.

Mr. DiToto has also sufficiently alleged how such federal violations may also amount to state law violations. As Mr. DiToto notes in his Opposition, Maryland law recognizes that "a duty to warn can undergird a negligence case in . . . a product liability action." (ECF No. 32 at 7 (quoting *Williams*, 123 F. Supp. 3d at 742).) This duty sometimes "entail[s] a warning to a third party such as the FDA." *Williams*, 123 F. Supp. 3d at 742. As this Court has previously explained, breaching these state law duties to warn and report could also amount to breaching "several federal duties imposed by the [premarket approval for a Class III device] including,

[12] The FDA defines an adverse event as "any undesirable experience associated with the use of a medical product in a patient." Food & Drug Admin., *What is a Serious Adverse Event?*, https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event (last accessed May 18, 2026).

for example, the duty to provide the FDA with 'Adverse Reaction' and 'Device Defect' reports." *Id.* (citation omitted). As such, a state-law claim for failure to warn or failure to report is not preempted by § 360k. *See Williams*, 123 F. Supp. 3d at 743 (citing *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011)).

ii. Failure to Train & Develop Adequate Processes to Determine Device Settings

For the same reasons that the failure to warn and report claims in Count III are not preempted, Mr. DiToto's claims of failure to train and develop adequate processes to determine device settings are likewise not preempted by § 360k. In short, under *Lohr*, state law claims are not preempted by § 360k when premised on the theory that a manufacturer subject to premarket approval "failed to use reasonable care in the device's design, manufacture, assembly, and sale." *Bausch*, 630 F.3d at 550. These claims are, in essence, allegations that Nevro Defendants failed to use reasonable care in the sale of their Senza II SCS system. Accordingly, these claims are not preempted by § 360k.

In sum, Nevro Defendants' Motion to Dismiss (ECF No. 29) as to Count III of the First Amended Complaint is DENIED.

e. Count IV: Fraudulent Misrepresentation; Count VIII: Violation of Maryland Consumer Protection Act; *and* Count IX: Negligent Misrepresentation

In Count IV, Mr. DiToto alleges that Nevro Defendants made multiple fraudulent misrepresentations of fact in marketing the Senza II SCS system to him, in violation of Maryland law. (ECF No. 19 ¶¶ 217–30.) To state a claim for fraudulent misrepresentation under Maryland law, a plaintiff must allege that: "(1) the defendant made a false representation to the plaintiff, (2) the falsity of the representation was either known to the defendant or the

representation was made with reckless indifference to its truth, (3) the misrepresentation was made for the purpose of defrauding the plaintiff, (4) the plaintiff relied on the misrepresentation and had the right to rely on it, and (5) the plaintiff suffered compensable injury as a result of the misrepresentation." *Tate v. Am. Gen. Life Ins. Co.*, 627 F. Supp. 3d 480, 494 (D. Md. 2022) (citing *White v. Kennedy Krieger Inst., Inc.*, 221 Md. App. 601, 635, 110 A.3d 724 (2015)). Count VIII of the First Amended Complaint alleges that Nevro Defendants violated the Maryland Consumer Protection Act, Com. Law §§ 13-101 *et seq.*, in the way he alleges that they marketed and sold the Senza II SCS system to him. (ECF No. 19 ¶¶ 217–26.[13]) Count IX alleges negligent misrepresentation arising out of the same alleged conduct. (*Id.* ¶¶ 227–33.)

These three claims may be considered together for the purposes of preemption because each addresses the manner in which Nevro Defendants allegedly marketed and sold the Senza II SCS device to Mr. DiToto. The Court notes again that the question presented at this stage is whether these claims are preempted by federal law, specifically § 360k of the MDA. A state law claim is parallel to federal law, and therefore not preempted, when it alleges that a manufacturer subject to premarket approval of the FDA failed to use reasonable care in the device's design, manufacture, assembly, and, as relevant to this count, sale. *See Bausch*, 630 F.3d at 550. Quite simply, the allegations in Counts IV, VIII, and IX of the First Amended Complaint are that Nevro Defendants failed to use reasonable care in the sale of the Senza II

[13] The Court notes that the numbered paragraphs in the First Amended Complaint are not sequential throughout the entirety of the Complaint. At one point, the numbering of the paragraphs changes by almost eighty digits and then continue, such that many numbers appear twice. For the efficiency of the Court, however, this Memorandum Opinion uses the paragraph numbers as listed in the First Amended Complaint. The paragraph numbers for Counts VIII and IX go from 217 through 233. *See* (ECF No. 19).

SCS. Though the legal bases for putative liability are different, the preemption question is essentially the same: whether these claims impute to Nevro Defendants state law requirements that are "different from, or in addition to, any requirement" created by federal law. 21 U.S.C. § 360k. As alleged by Plaintiff, Counts IV, VIII, and IX are not alleged to impose any additional duties. Nevro Defendants' Motion to Dismiss (ECF No. 29) is DENIED as to Counts IV, VIII, and IX.

f. Count V: Breach of Express Warranties

In Count V, Mr. DiToto alleges that Nevro Defendants breached express warranties in marketing and selling the Senza II SCS device to him. (ECF No. 19 ¶¶ 231–42.) Specifically, Mr. DiToto alleges that Nevro Defendants warranted that: (1) the pain relief from an implantable pulse generator such as the Senza II SCS device would equal or outperform the trial device; (2) "the permanent device would permanently deliver substantial pain relief"; (3) he would be able to resume normal daily activities following implantation of the device; (4) Nevro's sales representatives would be available to help him with adjusting the device; and (5) Nevro's sales representatives had the medical knowledge and training necessary to effectively adjust the device. (*Id.* ¶ 233.) As this Court explained in *Williams*, an allegation of breach of express warranties is not preempted when it rests on communications voluntarily made with the medical profession or the public. *See* 123 F. Supp. 3d at 743 (citing *McCormick v. Medtronic, Inc.*, 101 A.3d 467, 492 (Md. Ct. Spec. App. 2014)). Federal law already requires Nevro Defendants to ensure that "any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law." *Id.* (citation and quotations omitted).

Viewed in the light most favorable to Mr. DiToto, Count V plausibly alleges that Nevro Defendants' sales representatives made the warranties noted above for the purpose of selling the Senza II SCS device. Accordingly, Count V, as pleaded, alleges a non-preempted state law claim. Nevro Defendants' Motion to Dismiss (ECF No. 29) is DENIED as to that Count.

g. Count VI: Negligence (Statute or Ordinance Rule)

As the Court has previously noted, throughout his First Amended Complaint, Mr. DiToto alleges that Nevro Defendants violated federal law. (ECF No. 19.) In Count VI of the First Amended Complaint, Mr. DiToto alleges, in part, that those violations of federal law mean that Nevro Defendants were negligent under the Maryland "statute or ordinance rule." (*Id.* ¶¶ 243–54.)

It is well-settled that to state a negligence claim requires a plaintiff to allege a duty owed to him by the defendant, the defendant's breach of that duty, causation between the breach and the harm suffered, and damages to the plaintiff. *Jacques v. First Nat. Bank of Md.*, 515 A.2d 756, 758 (Md. 1986) (citations omitted). Under Maryland law, a defendant's violation of a statute or ordinance may provide a basis for a claim of negligence when the plaintiff alleges that: (1) the statute or ordinance was designed to protect a class of persons of which he is part and (2) the violation proximately caused his injury. *Walton v. Premier Soccer Club, Inc.*, 334 A.3d 784, 788 (Md. 2025).

As Mr. DiToto notes in his Opposition (ECF No. 32 at 13), his allegation in Count VI is "a creature of Maryland state law." (*Id.*) As the Supreme Court clearly explained in *Lohr*, "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at

495. That is because "[§] 360k provides immunity for manufacturers of . . . Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law." *Bausch*, 630 F.3d at 553. While the United States of Appeals for the Fourth Circuit has not specifically addressed the effect of § 360k and Supreme Court precedent on statute or ordinance negligence claims, the Seventh Circuit in *Bausch* considered a claim of negligence pursuant to Illinois's statute or ordinance negligence rule. 630 F.3d at 553. The *Bausch* court ruled that Illinois's version of the statute and ordinance rule, which is identical to Maryland's (as explained in *Walton*), was not preempted by § 360k. *Id.* Following *Lohr*, the *Bausch* court ruled that if the plaintiff were successful in proving allegations of harm caused by the defendant's violations of federal law, then her claims under state law would not "impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law." *Id.* (quoting 21 U.S.C. § 360k).

The same analysis applies in Mr. DiToto's claim of statute or ordinance negligence under Maryland law. As already noted, he has plausibly alleged violations of federal law, including, for example, that his Senza II SCS deviated from the FDA's premarket approval when it was manufactured and later when it was sold to him. Thus, his claim of statute or ordinance negligence under Maryland law is parallel to that claim. It is not preempted by § 360k. Nevro Defendants' Motion to Dismiss (ECF No. 29) is DENIED as to Count VI.

CONCLUSION

For the reasons stated above, Nevro Corporation's Motion to Dismiss the original Complaint (ECF No. 14) is DENIED AS MOOT. Nevro Defendants' Motion to Dismiss the First Amended Complaint (ECF No. 29) is GRANTED IN PART and DENIED IN PART. Specifically, the Motion (ECF No. 29) is GRANTED as to Count II of the First Amended Complaint, which is DISMISSED. The Motion is DENIED as to Counts I, III, IV, V, VI, VIII, and IX.

A separate Order follows.

Date: May 21, 2026

/s/
Richard D. Bennett
United States Senior District Judge