

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

RITU BHAMBHANI, LLC d/b/a *
COMPLETE CARE OF MARYLAND, *
et al., *

Plaintiffs, *

v. *

Civil No. RDB-22-1732

NEURAXIS, INC. f/k/a INNOVATIVE *
HEALTH SOLUTIONS, INC., *
et al., *

Defendants. *

* * * * *

MEMORANDUM OPINION

This case features allegations of fraud, conspiracy, and related misconduct in the sale of the Neuro-Stim System, an electroacupuncture device designed to treat chronic pain. Plaintiffs, a collection of limited liability companies owned by Drs. Ritu Bhambhani and Sudhir Rao, allege that Defendants Neuraxis, Inc. (“Neuraxis”), Acclivity Medical LLC (“Acclivity”), and Joy Long (“Long”) “fraudulently sold and marketed the [Neuro-Stim] as a surgically implantable medical device, not just a tool for acupuncture,” and falsely assured prospective consumers that this device was billable to Medicare under a set of standardized billing codes. (Compl. ¶¶ 3, 6, ECF No. 1.) They bring claims for: (I) civil violations of the Racketeering Influenced and Corrupt Organizations Act (“RICO”), pursuant to 18 U.S.C. § 1962(c) (Count One); (II) conspiracy to violate RICO (Count Two), pursuant to 18 U.S.C. § 1962(d); (III) fraudulent misrepresentation (Count Three); (IV) intentional misrepresentation (Count Four); and (V) civil conspiracy (Count Five). (*Id.* ¶¶ 86–118.)

Three dispositive motions are now pending before this Court: (1) Defendant Neuraxis, Inc.’s Motion to Dismiss (ECF No. 23); (2) Defendant Acclivity Medical, LLC’s Motion to Dismiss (ECF No. 26); and (3) Defendant Joy Long’s Motion to Dismiss (ECF No. 31). Neuraxis, joined by its co-Defendants,¹ contends that Plaintiffs have failed to state a claim under Counts I and II, alleging civil violations of RICO, and argues in the alternative that all of Plaintiffs’ claims should be dismissed for failure to exhaust all available administrative remedies under the federal Medicare Act, 42 U.S.C. § 1935 *et seq.* (See Neuraxis Mem. Supp. Mot. Dismiss 3–20, ECF No. 23-1; Neuraxis Repl. Supp. Mot. Dismiss 2–9, ECF No. 32.) The parties’ submissions have been reviewed and no hearing is necessary. See Local Rule 105.6 (D. Md. 2021). For the reasons that follow, Defendants’ Motions to Dismiss (ECF Nos. 23, 26, 31) are **GRANTED** in part and **DENIED** in part. Specifically, Counts I and II, asserting civil claims under RICO, are dismissed with prejudice as to all Defendants. Defendants’ motions are **DENIED** with respect to Counts III, IV, and V, which remain pending.²

BACKGROUND

When evaluating a motion to dismiss, this Court must “accept as true all well-pleaded facts in a complaint and construe them in the 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*

¹ Defendants Acclivity and Long expressly adopt the arguments advanced by Neuraxis and present no additional reasoning of their own. (See Acclivity Mot. Dismiss 1, ECF No. 26; Long Mot. Dismiss 1, ECF No. 31.) Accordingly, the three pending motions will be addressed in tandem.

² Plaintiffs invoke two grounds for subject matter jurisdiction: diversity jurisdiction pursuant to 28 U.S.C. § 1332(a)(1), and federal question jurisdiction pursuant to 28 U.S.C. § 1331, on account of the RICO claims. (Compl. ¶¶ 12–13.) Despite the dismissal of the federal RICO claims, this Court retains jurisdiction on account of diversity of citizenship. Plaintiffs allege that they are citizens of Maryland, (*id.* ¶¶ 17–22), that the Defendants are based in Indiana and Kentucky, (*id.* ¶¶ 23–25), and the amount in controversy exceeds \$75,000.00, (*id.* ¶ 12). Accordingly, this Court retains subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1).

(*U.S. Inc.*, 801 F.3d 412, 422 (4th Cir. 2015)). The facts outlined below reflect the substance of Plaintiff's operative Complaint and will be accepted as true for the purpose of Defendant's Motion to Dismiss.

Defendant Neuraxis, Inc. (“Neuraxis”)³ is an Indiana-based corporation that produces medical devices. (Compl. ¶ 23, ECF No. 1.) Neuraxis manufactured and marketed the Neuro-Stim System (“Neuro-Stim”), an electro-acupuncture device designed to alleviate chronic pain by using electrode arrays to stimulate the peripheral and cranial nerves in the outer ear. (*Id.* ¶¶ 2, 23.) In 2011, the Centers for Medicare and Medicaid Services (“CMS”) determined that a substantially identical electroacupuncture device was ineligible for Medicare reimbursement, (*id.* ¶ 29), and in 2014, the Food and Drug Administration (“FDA”) only approved the Neuro-Stim for use in the practice of acupuncture, (*id.* ¶ 2). Plaintiffs allege that Defendants “fraudulently sold and marketed the [Neuro-Stim] as a surgically implantable medical device, not just a tool for acupuncture,” and falsely advertised that this device was “billable to third-party payers, including Medicare” under standardized Current Procedural Terminology (“CPT”) codes that are used across the medical industry. (*Id.* ¶¶ 3, 6.)⁴

I. Development and Marketing of the P-STIM and Neuro-Stim

³ Neuraxis was formerly known as Innovative Health Solutions, Inc. (“IHS”), and bore that designation at the time of many of the underlying events relevant to Plaintiffs’ allegations in this case. (*Id.* at 1.) For clarity, Neuraxis shall be referred to by its current name throughout this opinion.

⁴ Current Procedural Terminology (“CPT”) is a standardized coding and documentation system maintained by the American Medical Association and employed by medical providers to “document and report medical, surgical, radiology, anesthesiology, and evaluation and management services.” (*Id.* ¶ 6.) The use of the CPT is mandated by the Health Insurance Portability and Accountability Act of 1966 (“HIPAA”). (*Id.*) Consequently, medical providers nationwide use the CPT to determine whether their services are billable to Medicare, and to decide how much reimbursement a given service ought to receive. (*Id.*)

The Neuro-Stim was not the first electroacupuncture tool Neuraxis brought to market. Before developing the Neuro-Stim, Neuraxis was the FDA-registered primary distributor of the “P-STIM,” a device manufactured by Austrian company Biegler GmbH. (*Id.* ¶ 26.) According to the Complaint, Neuraxis “invested substantial sums” in the P-STIM—marketing the device throughout the United States and selling tens of thousands of units to healthcare providers. (*Id.*) Throughout this promotional campaign, Neuraxis assured its customers that the P-STIM was eligible for Medicare reimbursement. (*Id.* ¶¶ 27–28.) However, in 2011, CMS determined that electroacupuncture tools, including the P-STIM, were ineligible for Medicare coverage. (*Id.* ¶ 29.) Consequently, the P-STIM was no longer billable under the CPT codes that Neuraxis had previously advertised. (*Id.*)

Building upon its success marketing the P-STIM, Neuraxis developed its own electroacupuncture device—the Neuro-Stim System. (*Id.* ¶¶ 27–28.) Plaintiffs allege that the Neuro-Stim was “‘substantially similar’ to the P-STIM both in functionality and outcomes.” (*Id.* ¶ 27.) In 2014, FDA approved the Neuro-Stim for use in acupuncture services only. (*Id.* ¶¶ 2, 28.) Thereafter, Neuraxis proceeded to market its new device through a series of “exclusive-rights” agreements with various “Sales Agents,” including Innovative Healthcare Solutions (“IHCS”) and Acclivity. (*Id.* ¶¶ 3–4, 28.)⁵ Neuraxis and its Sales Agents ran an extensive advertising campaign, promoting the Neuro-Stim in online and printed media, at trade shows, and through outreach to physicians. (*Id.* ¶¶ 3–4.) Collectively, they employed the same marketing strategies

⁵ Neuraxis also hired “Coding Agents” to help its Sales Agents secure purchases by providing physicians with prewritten coding, documentation, and reimbursement instructions. (*Id.* ¶ 32.)

they had used to sell the P-STIM, “focusing on representations . . . related to the billing, coding, and reimbursement of the device.” (*Id.* ¶ 28.)

Plaintiffs allege at length that Neuraxis misrepresented the nature of the Neuro-Stim and its eligibility for Medicare coverage. When CMS determined that the P-STIM was ineligible for reimbursement, Neuraxis contrasted the two devices, and assured medical providers that the Neuro-Stim would be highly profitable, billable to Medicare under a code that authorized “between \$4,800.00 and \$11,400.00 per patient in reimbursement for a procedure with little associated cost.” (*Id.* ¶¶ 7, 29.) To accomplish this, Defendants allegedly concealed the nature of the device and the limited scope of its FDA approval. For example, Neuraxis President Brian Carrico instructed the company’s Sales Agents, including IHCS and Acclivity, to market the device as “a peripheral neurostimulator,” and instructed them not to “ever use the word acupuncture or meridian point or anything like that.” (*Id.* ¶ 30.) Sales Agents assured medical providers they would receive “extraordinary reimbursement” for the Neuro-Stim, and that the Neuro-Stim “is clearly delineated from acupuncture and other neuro-stimulator treatments.” (*Id.* ¶¶ 33, 34, 36, 37, 42, 58.) Neuraxis provided its Sales Agents with promotional materials claiming that the Neuro-Stim was billable under CPT codes for implantable nerve stimulators and approved by the FDA to treat chronic and acute pain. (*Id.* ¶¶ 37–42.)

II. Plaintiffs are Solicited to Purchase the Neuro-Stim

Plaintiffs are a collection of Maryland-based limited liability companies owned by Ritu Bhambhani, M.D., and Sudhir Rao, M.D., two board-certified anesthesiologists practicing in

the State of Maryland. (*Id.* ¶¶ 17–22, ECF No. 1.)⁶ Bhambhani operates entity-Plaintiffs Ritu Bhambhani, LLC, and Box Hill Surgery Center, LLC (the “Bhambhani Practice Entities”) and is affiliated with several hospitals in the Abingdon, MD area. (*Id.* ¶ 19.) Rao operates entity-Plaintiffs Pain and Spine Specialists of Maryland LLC, and SimCare ASC LLC (the “Rao Practice Entities”) and is affiliated with practices in Maryland, Virginia, and Pennsylvania. (*Id.* ¶ 22.) Collectively, Plaintiffs allege that they relied on Defendants’ representations related to the Neuro-Stim’s billing and coding eligibility to purchase large quantities of the device for use in their anesthesiology and pain medicine practices. (*Id.* ¶¶ 36–67.)

IHCS marketed the Neuro-Stim to the Bhambhani Practice Entities. On August 17, 2015, Robert A. Smith, Vice President of Sales and Marketing for IHCS, sent Dr. Bhambhani an email describing the Neuro-Stim as a market-first, FDA-approved “nerve stimulator” that was approved to treat chronic and acute pain. (*Id.* ¶ 36, Ex. 7.) This email included an educational video and a powerpoint slideshow highlighting the “extraordinary reimbursement and high profit” available for physicians who used the Neuro-Stim in their practices. (*Id.* ¶ 42.) The presentation claimed that the Neuro-Stim was eligible for reimbursement by workers’ compensation, health insurance, and personal injury insurance, and instructed physicians to bill Neuro-Stim treatment under “CPT 64555, Percutaneous Implantation of Neurostimulator Electrodes at a Peripheral Nerve”—the same code that Neuraxis used to promote the P-STIM

⁶ Specifically, Plaintiffs include (1) Ritu Bhambhani, LLC d/b/a Complete Care of Maryland, a limited liability company registered at 496 Rutland Drive, Fallston, MD 21047, (*id.* ¶ 17); (2) Box Hill Surgery Center LLC, a limited liability company registered at 100 Walter Ward Boulevard, Suite 100, Abingdon, MD 21009, (*id.* ¶ 18); (3) Pain and Spine Specialists of Maryland LLC, a limited liability company registered at 2702 Back Acre Circle, Suite 290B, Mt. Airy, MD 21771, (*id.* ¶ 20); (4) SimCare ASC LLC, a limited liability company registered at 100 Walter Ward Boulevard, Suite 100, Abingdon, MD 21009, (*id.* ¶ 21).

until CMS limited its eligibility in 2011. (*Id.* ¶¶ 37–42.) Nowhere in this presentation did IHCS mention that the Neuro-Stim had been approved only for use in acupuncture. (*Id.* ¶ 43.)

Defendant Acclivity marketed the Neuro-Stim to the Rao Practice Entities. On August 15, 2015, Matthew Miller, a Distributor/Principal of Acclivity, contacted Dr. Rao to advertise the Neuro-Stim as a pain management treatment eligible for Medicare reimbursement. (*Id.* ¶¶ 54–56.) Miller shared many of the marketing documents prepared by Neuraxis—including fact sheets, brochures, and exemplar Explanation of Benefits statements—to demonstrate that the Neuro-Stim is billable under CPT 64555. (*Id.* ¶¶ 55–56.) He also placed Rao in touch with Defendant Joy Long, who provided a memorandum, procedure notes, and letters of necessity to explain the proper coding and billing procedures for the device. (*Id.* ¶ 57.) These documents characterized the Neuro-Stim as “clearly delineated from acupuncture,” and provided several foundational justifications for billing Neuro-Stim treatments under CPT 64555. (*Id.*) According to the Complaint, Long “specifically advised the Rao Practice Entities to conceal the name of the device” when submitting claims unless additional information was requested by the third-party payor. (*Id.* ¶ 57(j).) Neither Acclivity nor Long disclosed that the device had been cleared by FDA only for use in the practice of acupuncture. (*Id.* ¶ 58.)

Relying on these alleged representations, Plaintiffs purchased a substantial number of Neuro-Stims for use in their anesthesiology and pain medicine practices. (*Id.* ¶¶ 46, 62.) Between September 2015 and June 2016, the Bhambhani Practice Entities purchased 420 units for approximately \$264,000.00, (*id.* ¶ 49), and between September 2015 and October 2016, the Rao Practice Entities purchased 90 units for the price of \$45,194.00, (*id.* ¶ 62). Both sets of Plaintiffs continued to communicate with representatives of the Defendants, and received

additional advice regarding billing and reimbursement procedures. (*See id.* ¶¶ 44–49, 59–62.) However, in 2016 and 2017, various Medicare providers decided to audit the Bhambhani and Rao Practice Entities on the suspicion that they were improperly billing electroacupuncture services to the Medicare program. (*Id.* ¶¶ 50–51, 63–64.) Shortly thereafter, these providers issued refund demands, seeking over \$1,000,000 from the Bhambhani Practice Entities, and \$750,000 from the Rao Practice Entities. (*Id.* ¶¶ 53, 65–67.) Plaintiffs spent thousands of dollars defending the Medicare audits and pursued unsuccessful administrative appeals of the repayment requests. (*Id.* ¶¶ 53, 67.)⁷

III. Procedural History

On February 6, 2019, Drs. Bhambhani and Rao, in their individual capacity, filed a putative class action against Defendants in this Court, captioned *Ritu Bhambhani, M.D., et al. v. Innovative Health Solutions, Inc., et al.* (“*Bhambhani P*”). Initially, this Court granted in part and denied in part Defendants’ motion to dismiss, concluding that plaintiffs had sufficiently alleged claims for fraudulent misrepresentation, intentional misrepresentation, and civil conspiracy under Maryland law. *See Bhambhani v. Innovative Health Sols., Inc.*, No. RDB-19-0355, 2020 WL 673180, at *8 (D. Md. Feb. 11, 2020). However, this Court ultimately granted summary judgment to the Defendants on the basis that Drs. Bhambhani and Rao lacked standing as individuals, as only the practice entities had purchased the Neuro-Stim and suffered an injury

⁷ Plaintiffs submitted their appeals to the Office of Medicare Hearings and Appeals, identified in the Complaint as the “Office of Administrative Law.” (Compl. ¶¶ 53, 67; Pls.’ Resp. Opp. 7, ECF No. 30.) According to Plaintiffs’ Response in Opposition, the Rao Practice Entities received an adverse decision from an Administrative Law Judge (“ALJ”) on April 12, 2018, and the Bhambhani Practice Entities received an adverse decision from an ALJ on June 23, 2022. (Pls.’ Resp. Opp. 7, 10.) However, Plaintiffs declined to pursue these appeals further. (*Id.*)

in fact. *See Bhambhani v. Innovative Health Sols., Inc.*, No. LKG-19-0355, 2022 WL 2133906, at *6 (D. Md. Jun. 14, 2022).⁸

On July 14, 2022, one month after this Court granted summary judgment in the predecessor case, the Rao and Bhambhani Practice Entities filed suit on their own behalf, tolling the statute of limitations as of the commencement of the predecessor case. (Compl. ¶¶ 16, ECF No. 1.) *See Am. Pipe and Construction Co. v. Utah*, 414 U.S. 538, 554 (1974) (“[T]he commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action.”). Defendants Neuraxis, Acclivity, and Long have moved to dismiss this case. (*See* ECF Nos. 23, 26, 31.) These motions are ripe for review.

STANDARD OF REVIEW

Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, 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. Fed. R. Civ. P. 12(b)(6). The purpose of Rule 12(b)(6) is “to test the sufficiency of a complaint and not to resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.” *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)) (internal quotation marks omitted).

⁸ The predecessor case was initially assigned to the undersigned Judge but was transferred to Judge Lydia J. Griggsby of this Court prior to the entry of summary judgment.

To survive a motion under Fed. R. Civ. P. 12(b)(6), a complaint must contain facts sufficient to “state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl., Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Under the 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.” *Twombly*, 550 U.S. at 555. A complaint 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 that a recovery is very remote and unlikely.” *Id.* at 556 (internal quotations omitted). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678; see *A Soc’y Without a Name v. Virginia*, 655 F.3d 342, 346 (4th Cir. 2011).

When the gravamen of a complaint entails allegations of fraud, Rule 9(b) requires that “the circumstances constituting fraud be stated with particularity.” *Adams v. NVR Homes, Inc.*, 193 F.R.D. 243, 250 (D. Md. 2000). The rule “does not require the elucidation of every detail of the alleged fraud, but does require more than a bare assertion that such a cause of action exists.” *Mylan Labs., Inc. v. Akzo, N.V.*, 770 F. Supp. 1053, 1074 (D. Md. 1991). To satisfy the rule, the plaintiff must “identify with some precision the date, place and time of active misrepresentations or the circumstances of active concealments.” *Johnson v. Wheeler*, 492 F. Supp. 2d 492, 509 (D. Md. 2007). A court “should hesitate to dismiss a complaint under Rule 9(b) if [it] is satisfied (1) that the defendant has been made aware of the particular circumstances for which [it] will have to prepare a defense at trial, and (2) that [the] plaintiff

has substantial pre-discovery evidence of those facts.” *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999).

ANALYSIS

Plaintiffs claim that Defendants misrepresented the nature of the Neuro-Stim device, the scope of its FDA approval, and its eligibility for Medicare coverage. In the operative five-count Complaint, Plaintiffs bring claims for: (I) civil violations of the Racketeering Influenced and Corrupt Organizations Act (“RICO”), pursuant to 18 U.S.C. § 1962(c) (Count One); (II) conspiracy to violate RICO (Count Two); (III) fraudulent misrepresentation (Count Three); (IV) intentional misrepresentation (Count Four); and (V) civil conspiracy (Count Five). (Compl. ¶¶ 86–118.) Defendants argue that Plaintiffs fail to state a claim under Counts 1 and 2, alleging civil violations of RICO, and argue in the alternative that *all* of Plaintiffs’ claims should be dismissed for failure to exhaust administrative remedies under the Medicare Act. (Neuraxis Mem. Supp. 3–20, ECF No. 23.)⁹ For the reasons that follow, Defendants’ Motions to Dismiss (ECF Nos. 23, 26, 31) are **GRANTED** with respect to Counts 1 and 2, alleging civil violations of RICO, and **DENIED** with respect to all other Counts.

I. Counts I and II – Civil RICO Claims

First, Defendants challenge the sufficiency of Counts I and II, alleging violations of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1961–1968.

⁹ In the predecessor case, this Court concluded that Drs. Bhambhani and Rao had adequately pled claims for fraudulent misrepresentation, intentional misrepresentation, and civil conspiracy under Maryland law. *See Bhambhani v. Innovative Health Sols., Inc.* (“*Bhambhani P*”), No. RDB-19-0355, 2020 WL 673180, at *8 (D. Md. Feb. 11, 2020). Counts 3, 4, and 5 of the instant Complaint feature substantially identical fraud and conspiracy claims, (*see* Compl. ¶¶ 101–18), and Defendants do not contend that these counts are inadequately pled.

RICO prohibits “any person employed by or associated with any enterprise” from conducting “such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.” 18 U.S.C. § 1962(c). This provision grants “a private civil right of action to [a]ny person injured in his business or property by reason of a violation of the RICO provisions.” *ESAB Grp., Inc. v. Centricut, Inc.*, 126 F.3d 617, 626 (4th Cir. 1997) (alteration in original). As this Court has previously noted, to state a civil claim under RICO, a plaintiff must allege: “(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity and (5) a resulting injury in his business or property (6) by reason of the RICO violation.” *Fidelity & Guar. Life Ins. Co. v. Sharma*, No. RDB-17-1508, 2019 WL 1430100, at *7 (D. Md. Mar. 29, 2019) (quoting *Kun Lee v. PMG 1001, LLC*, RDB-09-1514, 2010 WL 148323, at *3 (D. Md. Jan. 11, 2010)).

Importantly, a civil RICO claim “is a unique cause of action that is concerned with eradicating organized, long-term, habitual criminal activity,” and imposes ““drastic”” penalties, including “not only costs and attorney’s fees, but also *treble* damages.” *United States Airline Pilots Ass’n v. Awappa, LLC*, 615 F.3d 312, 317 (4th Cir. 2010) (quoting *Gamboa v. Velez*, 457 F.3d 703, 705 (7th Cir. 2006); *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 233 (1989)). In *United States Airline Pilots Association v. Awappa, LLC*, the United States Court of Appeals for the Fourth Circuit instructed courts to

exercise caution “to ensure that RICO’s extraordinary remedy does not threaten the ordinary run of commercial transactions; that treble damage suits are not brought against isolated offenders for their harassment and settlement value; and that the multiple state and federal laws bearing on transactions . . . are not eclipsed or preempted.”

615 F.3d at 317 (quoting *Menasco, Inc. v. Wasserman*, 886 F.2d 681, 683 (4th Cir. 1989)).

Consequently, there is a “distinction between ordinary or garden-variety fraud claims better

prosecuted under state law and cases involving a more serious scope of activity.” *Al-Abood ex rel. Al-Abood v. El-Shamari*, 217 F.3d 225, 238 (4th Cir. 2000). RICO is concerned only with “ongoing unlawful activities whose scope and persistence pose a special threat to social well-being.” *Menasco, Inc.*, 886 F.2d at 683 (quoting *Int’l Data Bank, Ltd. v. Zepkin*, 812 F.2d 149, 155 (4th Cir. 1987)); accord *Flip Mortg. Corp. v. McElhone*, 841 F.2d 531, 538 (4th Cir. 1988) (“[T]his circuit will not lightly permit ordinary business contract or fraud disputes to be transformed into federal RICO claims.”); *HMK Corp. v. Walsey*, 828 F.2d 1071, 1074 (4th Cir. 1987) (“[T]he heightened civil and criminal penalties of RICO are reserved for schemes whose scope and persistence set them above the routine.”).

In support of their motions to dismiss, Defendants argue that Plaintiffs fail to allege two necessary elements of a civil RICO claim: (1) the existence of an actionable “enterprise,” whose conduct may be the predicate of a RICO violation; and (2) “continuity,” as required to demonstrate a “pattern of racketeering activity.” (Neuraxis Mot. Dismiss 8.)¹⁰ After carefully considering the Complaint, this Court finds that Plaintiffs’ allegations amount only to ordinary commercial fraud, and do not resemble the persistent, widespread, organized criminal activity that RICO was designed to curtail. Plaintiffs have not plausibly alleged the existence of an “enterprise” distinct from Neuraxis; and the “pattern of racketeering activity” that they allege is not sufficiently prolonged or serious to sustain a civil RICO claim.

¹⁰ Additionally, Defendants appear to argue that Long’s statements cannot be the basis of a fraud claim, as she “repeatedly and thoroughly informed the Rao Practice Entities that there were differing opinions and that it was the medical practice entities’ obligation to only bill and code for the medical procedures that its physicians were performing.” (Neuraxis Mem. Supp. 15–16.) As these statements form only a part of the Complaint and must be viewed in the light most favorable to the Plaintiffs, this Court expresses no opinion as to their effect on the surviving claims at this time.

A. Existence of an Enterprise

To state a RICO claim, Plaintiffs must allege that the defendants were conducting the affairs of an “enterprise,” broadly defined to include “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4).¹¹ This element requires a plaintiff to plead “(1) an ongoing organization; (2) associates functioning as a continuing unit; and (3) [that] the enterprise is an entity ‘separate and apart from the pattern of activity in which it engages.’” *Mitchell Tracy v. First Am. Title Ins. Co.*, 935 F. Supp. 2d 826, 842 (D. Md. 2013) (quoting *Proctor v. Metro Money Store Corp.*, 645 F. Supp. 2d 464, 477–78 (D. Md. 2009)); *see also Turkette*, 452 U.S. at 583. “To satisfy § 1962(c)’s ‘distinctiveness’ requirement, the Plaintiffs must further allege that the RICO ‘enterprise’ is distinct from the defendant ‘person’ alleged to have violated RICO.” *Id.* (quoting *Levine v. First Am. Title Ins. Co.*, 682 F. Supp. 2d 442, 457 (E.D. Pa. 2010)). Accordingly, “to establish liability under § 1962(c) one must allege and prove the existence of two distinct entities: (1) a ‘person’; and (2) an ‘enterprise’ that is not simply the same ‘person’ referred to by a different name.” *Cedric Kushner Productions, Ltd. v. King*, 533 U.S. 158, 161 (2001).

Plaintiffs’ allegations in support of this element fall short in two critical respects. First, the enterprise that they allege cannot be separated from the pattern of activities it orchestrated. As noted above, RICO is concerned with long-term, organized, widespread criminal activity.

¹¹ A RICO enterprise need not be formally incorporated or have a distinct legal identity. *See United States v. Tillet*, 763 F.2d 628, 631 n.2 (4th Cir. 1985) (“[A]n associated-in-fact enterprise is one type of enterprise defined in § 1961(4).”); *see also Boyle v. United States*, 556 U.S. 938, 948 (2009) (“Such a group need not have a hierarchical structure or a ‘chain of command’”); *United States v. Turkette*, 452 U.S. 576, 583 (1981) (“The enterprise is . . . a group of persons associated together for a common purpose of engaging in a course of conduct.”)

Awappa, LLC, 615 F.3d at 317. Consequently, a RICO plaintiff must show “evidence of an ongoing organization, formal or informal, and . . . evidence that the various associates function as a continuing unit.” *Boyle v. United States*, 556 U.S. 938, 945 (2009) (quoting *Turkette*, 452 U.S. at 583). To satisfy this element, plaintiffs must establish the existence of “an entity ‘separate and apart from the pattern of activity in which it engages.’” *Mitchell Tracy*, 935 F. Supp. 2d at 842 (quoting *Proctor*, 645 F. Supp. 2d at 480); *Turkette*, 452 U.S. at 583 (“The ‘enterprise’ is not the ‘pattern of racketeering activity.’”). If “the entity cannot be separated from the pattern of conduct in which it engaged,” the evidence does not support the existence of a distinct enterprise. *First Guar. Mortg. Corp. v. Bryant*, No. WDQ-03-3259, 2007 WL 9780442, at *2–3 (D. Md. Jun. 7, 2007) (Quarles, J.); *Proctor*, 645 F. Supp. 2d at 480.

The enterprise alleged in this case is coextensive with the activities in which it engaged. Plaintiffs allege that Defendants acted to conduct the affairs of an “NSS Enterprise.” (Compl. ¶¶ 68–75.) They define this enterprise as an association-in-fact between Neuraxis, its Sales and Coding Agents, and their employees, (*id.* ¶ 70), and allege that its express purpose was to sell the Neuro-Stim to medical providers, (*id.* ¶ 71). They also delimit this enterprise by the dates Defendants were selling the Neuro-Stim, alleging that:

The NSS Enterprise maintained its existence from at least October 2014 (when the NSS first received FDA-clearance, see Exhibit 1) through October 2016 (the date of the Rao Practice Entities’ last purchase of an NSS from IHS through Acclivity, see Exhibit 18), and upon information and belief for years beyond October 2016 as the NSS Enterprise continues to market the NSS to this day.

(*Id.* ¶ 73.) Construing the Complaint in Plaintiffs’ favor, it is transparent that this enterprise “cannot be separated” from the fraudulent marketing scheme alleged in this litigation. *Bryant*, 2007 WL 9780442, at *3. The sole function of this enterprise was to market the Neuro-Stim,

and its existence was bounded by the dates that this fraudulent scheme allegedly took place. Nothing in the Complaint suggests that it had any separate existence or any separate function. Consequently, the “NSS Enterprise” is nothing more than the Neuro-Stim marketing scheme, dressed in different clothes. If the alleged “pattern of racketeering activity” was “removed from the equation,” this enterprise would cease to exist. *Cf. Crest Const. II, Inc. v. Doe*, 660 F.3d 346, 354–55 (8th Cir. 2011) (quoting *Handeen v. Lemaire*, 112 F.3d 1339, 1352 (8th Cir. 1997)).

Second, Plaintiffs fail to plead distinctiveness. To satisfy this element, Plaintiffs must allege the existence of “an ‘enterprise’ that is not simply the same ‘person’ referred to by a different name.” *Cedric Kushner*, 533 U.S. at 161. As Judge Boardman of this Court summarized, “the ‘person’ alleged to have violated RICO must be separate and distinct from the ‘enterprise’ or tool through which the RICO violation occurred.” *AMA Systems, LLC v. 3B Tech, Inc.*, DLB-21-1472, 2022 WL 2133905, at *4 (D. Md. June 14, 2022) (citing *Chambers v. King Buick GMC, LLC*, 43 F. Supp. 3d 575, 588 (D. Md. 2014); *Mitchell Tracey*, 935 F. Supp. 2d at 842). Thus, a RICO “‘enterprise’ was meant to refer to a being different from, not the same as or part of, the person whose behavior the act was designed to prohibit.” *Id.* at *5 (quoting *United States v. Computer Scis. Corp.*, 689 F.2d 1181, 1190–91 (4th Cir. 1987), *overruled on other grounds by Busby v. Crown Supply, Inc.*, 896 F.2d 833 (4th Cir. 1990)).

To whatever extent the “NSS Enterprise” has an existence or identity broader than the pattern of racketeering it allegedly orchestrated, it is also the “person” alleged to have violated RICO—Neuraxis, the manufacturer and distributor of the Neuro-Stim. (Compl. ¶¶ 28–35.) In describing the alleged “NSS Enterprise,” Plaintiffs explain that Neuraxis manufactured the Neuro-Stim, (*id.* ¶ 71), designed the alleged coding scheme, (*id.* ¶ 72(c)), provided information

and instructions for its Sales Agents to market the device, (*id.* ¶¶ 72(d), (e)), entered exclusive distributorship agreements with those Sales Agents to distribute the device on its behalf, (*id.* ¶ 72(f)), and “profited from . . . each [device] its Sales Agents sold,” (*id.* ¶ 71). These are the actions of a corporation furthering its own interests, not the interests of a distinct enterprise. *Cf. Cedric Kushner*, 533 U.S. at 163 (“[L]iability ‘depends on showing that the defendants conducted or participated in the conduct of the *enterprise’s* affairs, not just their *own* affairs.” (quoting *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993))).

The Complaint asserts that Neuraxis is distinct from the “NSS Enterprise” because it contracted with Sales Agents and leveraged those relationships to insulate itself from liability. (Compl. ¶ 74.) But it is axiomatic that a corporation may not be liable under RICO “for associating in an alleged enterprise that consists only of its own employees, agents, subdivisions, subsidiaries, franchises, or members.” *AMA Systems*, 2022 WL 2133905, at *5; *Tronsgard v. FBL Fin. Grp., Inc.*, 312 F. Supp.3d 982, 998 (D. Kan. 2018) (“The Complaint contains no allegations that Farm Bureau carried out its fraudulent scheme by working with a business or entity separate from Farm Bureau itself, its affiliates, or its agents.”). This is because the actions of an agent may be attributed to the principal, who directs and controls the agent’s activities for the principal’s benefit. *See Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 659–60 (4th Cir. 2019). Plaintiffs allege that Neuraxis entered exclusive rights agreements with the Sales Agents and specifically controlled many aspects of their marketing strategies—such as by furnishing specific documents for them to distribute and providing them with messaging instructions. (*See, e.g.*, Compl. ¶ 3 (“[Neuraxis] engaged in this fraudulent scheme through a series of exclusive-rights sales-agent distributors.”); *id.* ¶ 33 (“The coding

information being conveyed to potential [Neuro-Stim] purchasers by Sales Agents and Coding Agents very clearly originated from [Neuraxis].”); *id.* ¶ 72(e) (“[Neuraxis] controlled all messaging associated with marketing and selling the devices”).) Accordingly, while the Sales Agents had legal identities distinct from Neuraxis, Plaintiffs allege that they were functioning as Neuraxis’ agents—marketing the Neuro-Stim at Neuraxis’ direction, subject to its control. Or, contrasting the words of Judge Boardman, they were “the arms and legs of a single player,” not “members of a team.” *AMA Systems*, 2022 WL 2133905, at *7.

B. Pattern of Racketeering Activity

Second, to state a RICO claim, Plaintiffs must allege a “pattern of racketeering activity,” requiring at least two predicate acts committed in ten years of each other. 18 U.S.C. § 1961(5). This element requires a plaintiff to establish “that the racketeering predicates are related, and that they amount to or pose a threat of continued criminal activity.” *H.J. Inc.*, 492 U.S. at 239. Predicate acts are “related” if they “have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events.” *United States v. Mathis*, 932 F.3d 242, 259 (4th Cir. 2019) (quoting *H.J. Inc.*, 492 U.S. at 240). To plead “continuity,” the plaintiff must allege either “a closed period of repeated conduct,” or open, ongoing conduct that “projects into the future with a threat of repetition.” *ePlus Tech., Inc. v. Aboud*, 313 F.3d 166, 182 (4th Cir. 2002) (quoting *H.J. Inc.*, 492 U.S. at 241). As the Complaint clearly alleges that all predicate acts were “related” to Defendants’ objective of selling the Neuro-Stim to medical providers, only the “continuity” element is at issue in this case.

The Fourth Circuit applies a “flexible” approach to the “continuity” inquiry, directing courts to engage in “a case-by-case analysis that ‘looks to the criminal dimension and degree of the alleged misconduct.’” *Capital Lighting and Supply, LLC v. Wirtz*, No. JKB-17-3765, 2018 WL 3970469, at *6 (D. Md. Aug. 20, 2018) (quoting *Brandenburg v. Seidel*, 859 F.2d 1179, 1185 (4th Cir. 1988), *overruled on other grounds by Quackenbush v. Allstate Ins. Co.*, 517 U.S. 706 (1996); *HMK Corp.*, 828 F.2d at 1073); *accord Zepkin*, 812 F.2d at 155 (“[N]o mechanical test can determine the existence of a RICO pattern.”); *Menasco, Inc.*, 886 F.2d at 683 (“[T]he test is commonsensical, not formulaic”). “Facts relevant to this inquiry include the number and variety of predicate acts and the length of time over which they were committed, the number of putative victims, the presence of separate schemes, and the potential for multiple distinct inquiries.” *Brandenburg*, 859 F.2d at 1185; *Parcoil Corp. v. Newsco Well Serv., Ltd.*, 887 F.2d 502, 504 (4th Cir. 1989). The gravity and extent of the misconduct must reflect that it is “part of a prolonged criminal endeavor.” *Menasco, Inc.*, 886 F.2d at 683–84; *accord HMK Corp.*, 828 F.2d at 1074 (noting that RICO applies only to “schemes whose scope and persistence set them above the routine”).

Plaintiffs allege that the Defendants operated an enterprise consisting of Neuraxis, its Coding Agents, its Sales Agents, and various employees named in the Complaint. (Compl. ¶¶ 68–73.) They claim that the common purpose of this enterprise was to sell the Neuro-Stim to medical providers while insulating Neuraxis from liability for its misrepresentations. (*Id.* ¶ 71.) To achieve this, Neuraxis coordinated the messaging of its nationwide marketing campaign—furnishing its affiliates with documentation related to the Neuro-Stim; providing them with instructions on the Neuro-Stim’s billing and coding protocols; and instructing them never to

inform customers that the device was only to be used in the practice of electroacupuncture. (*Id.* ¶ 72.) Plaintiffs claim that this putative enterprise existed between October 2014, when FDA approved the Neuro-Stim for use in acupuncture, and at least October 2016, the date of Plaintiffs’ last purchase. (*Id.* ¶ 73.) However, they also claim “on information and belief” that the enterprise has continued to this day. (*Id.*)

First, viewing the Complaint in the light most favorable to Plaintiffs, the alleged Neuro-Stim scheme has insufficient scope and reach to be “part of a prolonged criminal endeavor.” *Menasco, Inc.*, 886 F.2d at 684. The Complaint alleges that Defendants orchestrated this scheme between October 2014 and October 2016. (Compl. ¶ 73.) This two-year period does not present “the type of persistent, long-term fraudulent conduct” required to establish closed-ended continuity.¹² *GE Inv. Private Placement Partners II v. Parker*, 247 F.3d 543, 550 (4th Cir. 2001) (duration of two years insufficient); *see also United States v. Pinson*, 860 F.3d 152, 163 (4th Cir. 2017) (duration of two and a half years insufficient); *Becker v. Noe*, No. ELH-18-00931, 2019 WL 1415483, at *20 (D. Md. Mar. 27, 2019); *Kiddie Academy Domestic Franchising, LLC v. Wonder World Learning, LLC*, No. ELH-17-3420, 2019 WL 1441812, at *32 (D. Md. Mar. 31, 2019). Moreover, despite seven years, two cases, and multiple rounds of pleadings, motions practice, and discovery, Plaintiffs have not identified any other victims of the alleged scheme. While the Complaint discusses prior efforts to market the P-STIM, there is no indication that Neuraxis committed racketeering violations during that prior marketing campaign. And while

¹² Although the Complaint alleges “upon information and belief” that the scheme continues to this day, (Compl. ¶ 73), such allegations are plainly insufficient to satisfy Rule 9(b), which requires that all claims grounded in fraud be pled with particularity. Additionally, Plaintiffs acknowledge that “plausibly alleging ‘open-ended continuity’ . . . is unrealistic,” and concede that their RICO claims rest on a theory of closed-ended continuity only. (Pls.’ Resp. Opp. 23.)

the Complaint alleges in general terms that both devices were marketed and sold nationwide, it does not identify any other parties who claim to have been injured by Defendants' putative misrepresentations.

To bolster these allegations, Plaintiffs describe sixteen False Claims Act settlements across the country in which providers agreed to reimburse the government for thousands of dollars in improper Medicare reimbursements they obtained for electroacupuncture services. (Pls.' Resp. Opp. 32–34.) As an initial matter, Plaintiffs cannot amend their Complaint through their opposition to a motion to dismiss. *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984) (“[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.” (citing *Jacobson v. Peat, Marwick, Mitchell & Co.*, 445 F. Supp. 518, 526 (S.D.N.Y. 1977))). Even if they could, Plaintiffs fail to connect these settlements with the fraudulent scheme alleged in this specific case, against these specific Defendants. These settlements may suggest that the government has sought and obtained refunds from other practitioners who attempted to bill electroacupuncture treatments to Medicare. However, this case is concerned only with the conduct of Neuraxis and its Sales Agents—not with other Defendants in other electroacupuncture fraud cases before other courts.

Second, the predicate acts that form the basis of the alleged racketeering pattern are ordinary, run-of-the-mill commercial fraud. *Cf. HMK Corp.*, 828 F.2d at 1074 (“The existence of a pattern . . . depends on context, particularly on the nature of the underlying offenses.”). The Fourth Circuit has been reticent to allow RICO claims to proceed based only on predicate acts of ordinary mail and wire fraud “because it will be the unusual fraud that does not enlist the mails and wires in its service at least twice.” *GE Investment*, 247 F.3d at 549 (quoting *Al-*

Abood, 217 F.3d at 238). Although the Complaint alleges “multiple acts of mail fraud” and “multiple acts of wire fraud,” (Compl. ¶ 91), and offers several particularized examples of putative misrepresentations attributable to the Defendants, (*see, e.g., id.* ¶¶ 28–42, 54–58), the types of misrepresentations they allege are present in nearly every commercial fraud dispute. Characterizing this case as anything more “would transform ‘every such dispute . . . [into] a cause of action under RICO.’” *McElbone*, 841 F.2d at 538 (quoting *HMK*, 828 F.2d at 1074).¹³

Ultimately, Plaintiffs offer nothing to bring this case “sufficiently outside the heartland of fraud cases to warrant RICO treatment.” *Al-Abood*, 217 F.3d at 238. The crux of their Complaint is that Neuraxis sought to increase its profits by marketing the Neuro-Stim as a nerve stimulator, not an electroacupuncture tool, and falsely assuring practitioners that it was billable under Medicare codes that do not apply. This is garden-variety commercial fraud. Thousands of consumers bring claims in every state challenging misrepresentations made by the sellers of products in their marketing campaigns. While such fraud may be serious, it is not “the sort of extended, widespread, or particularly dangerous pattern of racketeering which Congress intended to combat with federal penalties.” *McElbone*, 841 F.2d at 538. Accordingly, Plaintiffs fail to state a claim under RICO. Defendants’ motion is accordingly **GRANTED** with respect to Counts I and II,¹⁴ and these counts are dismissed with prejudice.

¹³ Plaintiffs argue in their Response in Opposition that this case “pose[s] a special threat to social well-being.” *GE Investment*, 247 F.3d at 543, 551 (quoting *Menasco*, 886 F.2d at 684), as the alleged scheme “resulted in a taxpayer-funded health benefit program for the elderly being defrauded of at least \$1.7 million.” (Pls.’ Resp. Opp. 26.) In so arguing, they overstate the significance of this case. Plaintiffs seek to recoup their private losses incurred from purchasing the Neuro-Stim and billing the device in accordance with Defendants’ instructions. This case does not vindicate the rights of the elderly or the financial losses incurred by the Medicare program.

¹⁴ Plaintiffs’ failure to state a substantive RICO claim is dispositive of their RICO conspiracy claim under 18 U.S.C. § 1962(d). “A conspiracy claim under section 1962(d) may survive a *factfinder’s* conclusion that there is insufficient evidence to prove a RICO violation, but if the pleadings do not

II. Administrative Exhaustion

Second, Defendants allege that the Complaint should be dismissed for failure to exhaust the remedies prescribed by the Medicare Act. (*See* Neuraxis Mem. Supp. 17–20; Neuraxis Repl. Supp. 2–9.) Ordinarily, federal courts “have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. However, 42 U.S.C. § 405(h) provides that:

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

This provision, made applicable to Medicare by 42 U.S.C. § 1395ii and § 1395ff, curtails federal question jurisdiction by providing that the administrative process set forth in § 405(g), “to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all ‘claim[s] arising under’ the Medicare Act.” *Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984) (quoting *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975)). In turn, “Section 405(g) provides that an individual may obtain judicial review of a claim arising under the Medicare Act only after receipt of a ‘final decision’ by the Secretary of HHS.” *Accident, Inj. & Rehab., PC v. Azar*, 943 F.3d 195, 197, 200 (4th Cir. 2019) (quoting 42 U.S.C. § 405(g)).

state a substantive RICO claim upon which relief may be granted, then the conspiracy claim also fails.” *Efron v. Embassy Suites (Puerto Rico), Inc.*, 223 F.3d 12, 21 (1st Cir. 2000) (citing *Howard v. Am. Online, Inc.*, 208 F.3d 741, 751 (9th Cir. 2000), *cert. denied*, 121 S. Ct. 77 (2000)). This is because “[a] conspirator must intend to further an endeavor which, if completed, would satisfy all of the elements of a substantive criminal offense.” *Salinas v. United States*, 522 U.S. 52, 65 (1997). Thus, as “the pleadings do not state a substantive RICO claim under § 1962(c), Plaintiffs’ RICO conspiracy claim fails as well.” *GE Investment*, 247 F.3d at 551 n.2.

Accordingly, claimants must exhaust all administrative remedies before the federal courts may exercise jurisdiction over any claim “arising under” the Medicare Act.¹⁵ *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 5 (2000); accord *Buckner v. Heckler*, 804 F.2d 258, 259 (4th Cir. 1986); *Hopewell Nursing Home, Inc. v. Heckler*, 784 F.2d 554, 557–58 (4th Cir. 1986). A claim arises under the Medicare Act, and must be exhausted, if the Medicare Act “furnishes ‘both the standing and substantive basis for the presentation’ of the claim,” *Buckner*, 804 F.2d at 259 (quoting *Ringer*, 466 U.S. at 615), or the claim is “inextricably intertwined” with a claim for benefits, *Ringer*, 466 U.S. at 614. These principles apply to “[c]laims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy.” *Shalala*, 529 U.S. at 14.¹⁶ The purpose of this requirement is to “give the administrative process the first opportunity to resolve disputes over eligibility or the amount of benefits awarded

¹⁵ The administrative review process for Medicare benefits decisions is “comprehensive and specific,” and “begins with the submission of a claim for reimbursement, continues through a detailed and multistep administrative process, and concludes with the provision for judicial review.” *Cumberland Cnty. Hosp. Sys., Inc. v. Burnwell*, 816 F.3d 48, 52–53 (4th Cir. 2016). First, claimants must submit their claim for benefits to a Medicare Administrative Contractor for an initial benefits determination. *See id.* at 53 (citing 42 U.S.C. §§ 1395ff(a), 1395kk-1(a)). Second, claimants who are dissatisfied with the initial benefits decision may seek a redetermination from the original contractor, followed by reconsideration from a Qualified Independent Contractor (“QIC”). *Id.* (citing 42 U.S.C. §§ 1395ff(a)(3), 1395ff(c)). Third, the claimant may appeal the QIC’s decision to an Administrative Law Judge (“ALJ”). *Id.* (citing 42 U.S.C. § 1395ff(d)(1)). Fourth, the claimant may appeal the ALJ’s ruling to the Departmental Appeals Board. *Id.* (citing 42 U.S.C. § 1395ff(d)(2)). The decision of the Departmental Appeals Board constitutes the final decision of the Secretary and is subject to judicial review. *Id.* (citing 42 U.S.C. § 1395ff(b)(1)(A)); *see also Smith v. Berryhill*, 139 S. Ct. 1765, 1779 (2019).

¹⁶ This exhaustion requirement is quite broad, and extends to “all aspects” of a such a claim, even when the relief sought is nonmonetary in nature, *Ringer*, 466 U.S. at 621–22. *See, e.g., N.C. Ins. Guar. Assoc. v. Becerra*, 55 F.4th 428, 430 (4th Cir. 2022) (advisory opinion on reimbursement issue *Greater Carolina Ear Nose & Throat, P.A. v. Azar*, 334 F. Supp. 3d 739, 741 (E.D.N.C. 2018) (injunction against CMS “from recoupment of plaintiff’s Medicare reimbursement payments prior to the completion of the administrative process”); *Collins v. Wellcare Healthcare Plans, Inc.*, 73 F. Supp. 3d 653, 662 (E.D. La. 2014) (declaratory judgment that Medicare provider was not entitled to refund); *Kostenko v. U.S. Dep’t of Health & Human Servs.*, 916 F. Supp. 2d 661, 669 (S.D.W. Va. 2013) (challenge to exclusion from federal insurance participation).

under the Act,” *Grice v. Colvin*, 97 F. Supp. 3d 684, 698 (D. Md. 2015) (quoting *United States v. Blue Cross and Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1103 (11th Cir. 1998)), and to prevent plaintiffs from circumventing that process by prematurely litigating “[c]leverly concealed claims for benefits,” *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1141 (9th Cir. 2010) (quoting *Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1112 (9th Cir. 2003)); accord *Hopewell*, 784 F.2d at 557–58 (cautioning against “premature interference with the agency process”).

None of these concerns is implicated here. First, it is doubtful that the exhaustion requirement applies at all. The component of § 405(h) that requires exhaustion of claims that “arise from” the Medicare Act applies only to claims “against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof.” 42 U.S.C. § 405(h). Distinct from nearly every case invoking this provision, Plaintiffs do not challenge an adverse benefits decision by the Secretary of Health and Human Services, the Centers for Medicare Services, or an official Medicare provider. *Cf. Ringer*, 466 U.S. at 615; *Shalala*, 529 U.S. at 14; *Weinberger*, 422 U.S. at 765; *N.C. Ins. Guar. Assoc.*, 55 F.4th at 430 (request for advisory opinion by Secretary of HHS); *Grice*, 97 F. Supp. 3d at 685 (lawsuit against acting Secretary of HHS); *Greater Carolina Ear Nose & Throat*, 334 F. Supp. at 741 (claim seeking injunction against CMS). Instead, they bring this action against a medical device manufacturer and its agents for alleged fraud in a nationwide marketing campaign. There is no indication that Congress intended to strip the federal courts of jurisdiction to address this issue, or that run-of-the-mill fraud claims could be ameliorated through the administrative process.

Even if the exhaustion requirement applies, the “standing and substantive basis” for Plaintiffs’ claims is the common law of Maryland, not the Medicare Act. *Cf. Ringer*, 466 U.S. at

615. Plaintiffs invoke this Court’s diversity jurisdiction over their surviving fraud and conspiracy claims, which they bring under Maryland law. (Compl. ¶¶ 12–16.) *See* 28 U.S.C. § 1332(a)(1). If Plaintiffs have standing, it is due to Defendants’ alleged misrepresentations that induced Plaintiffs to purchase the Neuro-Stim for use in their medical practices, and the substantial amount that they expended to defend Medicare audits and refund Medicare reimbursements when the device was not billable as advertised. While the denial of benefits provides context for these claims, their outcome will depend on the substantive elements of the torts they allege—negligent misrepresentation, intentional misrepresentation, and civil conspiracy. Accordingly, this Court will have no need to interpret the substantive requirements of the Medicare Act to decide this case. *Cf. Baker v. HM Health Ins. Co.*, No. 5:15-CV-104, 2015 WL 6159482, at *4 (N.D.W. Va. Oct. 20, 2015) (finding that a claim that defendants “fraudulently deceived and lied to the plaintiff” to receive Medicare benefits did not arise under the Medicare Act).

Second, Plaintiffs do not ask this Court to review or overturn CMS’s determination that the Neuro-Stim is ineligible for reimbursement. In addition to the jurisdiction-stripping language discussed above, § 405(h) prohibits “any person, tribunal, or government agency” from reviewing any “findings of fact or decision of the [Secretary of Health and Human Services]” except as provided by § 405(g). Defendants argue that “[t]he gravamen of Plaintiffs’ Complaint is . . . whether Medicare should reimburse Plaintiffs for the device and related procedures.” (Neuraxis Repl. Supp. 3.)¹⁷ They note that Plaintiffs could not succeed on any of

¹⁷ Defendants cite the predecessor case discussed above for the notion that “[t]he appropriate administrative body must apply its expertise concerning the billing eligibility of medical devices before this Court addresses the issue,” and that “any attempt to determine the eligibility of the Neuro-Stim

their fraud claims if the NeuroStim was eligible for Medicare reimbursement as advertised—and that Plaintiffs will have suffered no damages if the Secretary overturns the audits they defended and the refunds they were forced to pay.¹⁸ (*Id.* at 3–5; Neuraxis Repl. Supp. 17–21.) However, while the *fact* of that denial is relevant to Plaintiffs’ claims, its *validity* is not at issue. Plaintiffs do not challenge the agency’s determination that the Neuro-Stim is not eligible for Medicare reimbursement. Rather, they accept the denial of benefits as an uncontested fact. As this proceeding does not ask this Court to “review” any findings of fact made by CMS, it does not implicate the second sentence of 42 U.S.C. § 405(h).

Ultimately, this is a fraud case, not a Medicare case. Plaintiffs bring claims against the manufacturer and distributor of a medical device for putative fraud committed in a marketing campaign. They do not bring suit “against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof,” and they do not seek to overturn CMS’s determination that the Neuro-Stim is ineligible for reimbursement. 42 U.S.C. § 405(h). While the denial of benefits is a factual backdrop for the Plaintiffs’ allegations, it is the common law of Maryland, not the Medicare Act, that provides “the standing and substantive basis” for

would be premature” in the absence of a final decision by the Secretary of Health and Human Services. *Bhambhani I*, 2020 WL 673180, at *8. Although these propositions remain true, they are irrelevant here. The plaintiffs in *Bhambhani I* requested a declaratory judgment that “the [Neuro-Stim] device is . . . not properly billable to health insurers and other third-party payers under CPT 64555.” *Id.* Issuing the requested declaration would have required this Court to intrude directly into the regulatory process and prematurely determine the billing eligibility of the Neuro-Stim. *Id.* No such request has been made in this case.

¹⁸ Notably, Plaintiffs allege potential sources of damages that are distinct from these refunds. The Complaint provides, for example, the cost of the Neuro-Stim devices that Plaintiffs purchased in reliance on Defendants’ putative fraud, (*see, e.g.*, Compl. ¶¶ 46, 49, 62), the “tens of thousands in legal fees and other related expenses relative to defending the Medicare audits,” and the manner in which disputed refunds were offset against payments that Plaintiffs would already have received for other medical services, (*see, e.g.*, Compl. ¶¶ 53, 67).

these claims. *Heckler*, 466 U.S. at 615. These distinctions bring this case outside the parameters of Medicare’s administrative exhaustion requirement. Accordingly, Defendants’ Motion to Dismiss is **DENIED** as to Counts III, IV, and V.

Date: May 25, 2023

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