United States District Court
Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

KIM HUDLOW, et al., Plaintiffs, v. EXTHERA MEDICAL CORPORATION, et al., Defendants.	Case No. 25-cv-02492-MMC **ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS**

Before the Court are four motions to dismiss plaintiffs' First Amended Complaint ("FAC"), filed by (1) John Preston ("Preston"); (2) Devon Quasha ("Dr. Quasha"); (3) ExThera Medical Corporation ("ExThera"); and (4) Quadrant Clinical Care LLC, Quadrant Management LLC, and Alan Quasha ("Mr. Quasha") (collectively, "Quadrant Defendants"). (See Doc. Nos. 87, 89, 90, & 91.) Plaintiffs[1] have filed a single opposition, to which defendants have filed separate replies. The Court, having read and considered the papers filed in support of and in opposition to the motions, hereby rules as follows.[2]

BACKGROUND[3]

ExThera is "a San Francisco Bay Area medical device company." (See FAC ¶ 5.) "The company developed a blood filter, known as the 'Seraph 100,'" that "capture[s]

[1] The patient plaintiffs are David Hudlow, Brian Withey, John Bowen, Kyle Chupp, Ricardo Salgado, and Ingrid Peri. The remaining individual plaintiffs, Kim Hudlow, Jaime Baskin, Stacey Bowen, Vanessa Chupp, Carla Vass-Salgado, and Ron Peri, are the spouses of those patient plaintiffs, respectively.

[2] By prior order, the Court took the matters under submission. (See Doc. No. 120.)

[3] The below facts are taken from the FAC.

viruses, bacteria, and fungi" by "work[ing] in tandem with a dialysis machine, which pumps blood out of a patient's body and into the device before returning it, filtered of pathogens, to the patient." (See id. ¶ 32.)

During the COVID-19 pandemic, ExThera's Seraph 100 filter "showed initial promise for treatment of COVID-19," and, "[i]n April 2020, the U.S. Food and Drug Administration granted ExThera Emergency Use Authorization for the treatment of severe COVID-19 disease with the Seraph filter." (See id. ¶ 33.)

Following the pandemic, ExThera, in September 2022, "announced that data from a preliminary in vitro study…demonstrated that the Seraph filter could remove circulating tumor cells," after which "ExThera announced plans to study the use of the Seraph filters as a treatment to prevent further metastasis in cancer patients." (See id. ¶ 34.)

In July 2023, "ExThera announced that it had received FDA investigational device exemption for use of the Seraph filter for the removal of circulating tumor cells (CTC)," and that it "would market this treatment under the trade name ONCObind." (See id. ¶ 35) (internal quotation omitted).

During "the fall of 2023," "ExThera's Chief Medical and Regulatory Officer, Dr. Sanja Ilic ("Dr. Ilic"), conducted a trial [of ONCObind] in Zagreb, Croatia" in which "between 8 and 12 patients with late-stage, metastatic disease" participated and for whom "ExThera provided Seraph 100 filters at no cost." (See id. ¶ 37.) "The results of the study were published in November 2024," which study "explain[ed] that the ExThera filters could remove pathogens and CTCs from the bloodstream," but "ma[de] no mention…that patients' health or overall cancer burden improved as a result." (See id.) (emphasis omitted).

In December 2023, Preston, "an ExThera board member and also an investment advisor" to "Alan Quasha's private equity firm, Quadrant Management, told Mr. Quasha about the Seraph 100 filters' new use in ONCObind." (See id. ¶ 39.) "Within days of…Preston's pitch on its behalf, ExThera shared 'results' from their Croatian trial with Mr. Quasha," who "then invested $3 million dollars in the company." (See id.)

Mr. Quasha's investment firm, Quadrant Management, "soon formed a clinical division known as Quadrant Clinical Care, which it incorporated on December 26, 2023," the purpose of which being "to establish a facility in an existing clinic on the Caribbean island of Antigua." (See id. ¶ 42.) "Quadrant Clinical Care then paid ExThera an additional $10 million to become ExThera's exclusive Caribbean distributor" of the Seraph 100 filters. (See id.) "Shortly after" the clinic was set up, Quadrant Clinical Care "hired Mr. Quasha's daughter, Dr. Devon Quasha…to oversee the clinic as its Chief Medical Officer." (See id. ¶ 47.)

Around "January and February 2024, [p]laintiffs]…began hearing about the ONCObind procedure that [d]efendants were administering in Antigua" (see id. ¶ 52) and "reached out to ExThera to learn more about the treatment" (see id. ¶ 53).

"[B]eginning in February 2024," plaintiffs spoke with Dr. Ilic and Preston and were told "that ONCObind had cured the cancer of multiple participants in a European trial," "that ONCObind would be approved by the FDA for U.S. trials soon," and that "individuals who received ONCObind in Antigua would have automatic and free access to the U.S. trials." (See id. ¶¶ 53-54.)

Also in February, Dr. Ilic, Preston, Dr. Quasha, and Mr. Quasha spoke "with certain physicians in the United States," including two with practices in Florida, "about the promise of the ONCObind procedure for treating all forms of metastatic cancer," with the expectation that such physicians "would refer patients to the Antigua clinic." (See id. ¶¶ 55-56.)

Thereafter, plaintiffs Mr. Hudlow, Mr. Withey, Mr. Bowen, Mr. Chupp, Mr. Salgado, and Ms. Peri each received the ONCObind treatment at the Antigua clinic at the cost of "$45,000 per round" (see id. ¶ 10), three of whom "died within days or weeks of leaving Antigua, and each surviving [plaintiff] became sicker and saw their cancer markers increase significantly following the procedure" (see id. ¶ 14). None "experienced the promised tumor reduction." (See id.)

Based on the above, plaintiffs assert the following eight Claims for Relief: (1) Civil

RICO, in violation of 18 U.S.C. § 1962(c) (see id. ¶¶ 258-281); (2) Civil RICO Conspiracy, in violation of 18 U.S.C. § 1962(d) (see id. ¶¶ 282-286); (3) Fraud (see id. ¶¶ 287-296); (4) Negligence (see id. ¶¶ 297-300); (5) Intentional Infliction of Emotional Distress (see id. ¶¶ 301-305); (6) Battery (see id. ¶¶ 306-311); (7) Product Liability (Failure to Warn) (see id. ¶¶ 312-319); and (8) Wrongful Death (see id. ¶¶ 320-324).

By the instant motions, Quadrant Defendants, Dr. Quasha, and Preston move to dismiss for lack of personal jurisdiction under Rule 12(b)(2) of the Federal Rules of Civil Procedure and failure to start a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure. ExThera moves to dismiss solely under Rule 12(b)(6).

LEGAL STANDARD

I. Rule 12(b)(2)

A motion to dismiss under Rule 12(b)(2) may be based on the face of the complaint and/or declarations of fact. See Doe v. Unocal Corp., 248 F.3d 915, 922 (9th Cir. 2001), abrogated on other grounds as recognized by Williams v. Yamaha Motor Co., 851 F.3d 1015 (9th Cir. 2017). Where a defendant challenges personal jurisdiction, the plaintiff bears the burden of establishing the forum court's personal jurisdiction over such defendant, see Mattel, Inc. v. Greiner & Hausser GmbH, 354 F.3d 857, 862 (9th Cir. 2003), and where the defendant's motion "is based on written materials rather than an evidentiary hearing, the plaintiff need only make a prima facie showing of jurisdictional facts," see CollegeSource, Inc. v. AcademyOne, Inc., 653 F.3d 1066, 1073 (9th Cir. 2011) (internal quotation and citation omitted). In that regard, "uncontroverted allegations in the complaint must be taken as true, see id. (internal quotation and citation omitted), "any evidentiary materials submitted on the motion are construed in the light most favorable to the plaintiff[,] and all doubts are resolved in [the plaintiff's] favor," see Ochoa v. J.B. Martin & Sons Farms, Inc., 287 F.3d 1182, 1187 (9th Cir. 2002) (internal quotation

and citation omitted).

II. Rule 12(b)(6)

Dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure "can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1990). Rule 8(a)(2), however, "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (quoting Fed. R. Civ. P. 8(a)(2)). Consequently, "a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." Id. Nonetheless, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than . . . a formulaic recitation of the elements of a cause of action." Id. (internal quotation, citation, and alteration omitted).

In analyzing a motion to dismiss, a district court must accept as true all material allegations in the complaint and construe them in the light most favorable to the nonmoving party. See NL Indus., Inc. v. Kaplan, 792 F.2d 896, 898 (9th Cir. 1986). "To survive a motion to dismiss," however, "a complaint must contain sufficient factual material, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). "Factual allegations must be enough to raise a right to relief above the speculative level," Twombly, 550 U.S. at 555, and courts "are not bound to accept as true a legal conclusion couched as a factual allegation," Iqbal, 556 U.S. at 678 (internal quotation and citation omitted).

Generally, a district court, in ruling on a Rule 12(b)(6) motion, may not consider any material beyond the complaint. See Hal Roach Studios, Inc. v. Richard Feiner & Co., Inc., 896 F.2d 1542, 1555 n.19 (9th Cir. 1990). Documents whose contents are alleged

in the complaint, and whose authenticity no party questions, but which are not physically attached to the pleading, however, may be considered. See Branch v. Tunnell, 14 F.3d 449, 454 (9th Cir. 1994). In addition, a district court may consider any document "the authenticity of which is not contested, and upon which the plaintiff's complaint necessarily relies," regardless of whether the document is referenced in the complaint. Parrino v. FHP, Inc., 146 F.3d 699, 706 (9th Cir. 1998). Finally, the Court may consider matters that are subject to judicial notice. See Mack v. South Bay Beer Distribs., Inc., 798 F.2d 1279, 1282 (9th Cir. 1986).

DISCUSSION

I. Personal Jurisdiction

As noted, Quadrant Defendants, Dr. Quasha, and Preston move to dismiss under Rule 12(b)(2) of the Federal Rules of Civil Procedure for lack of personal jurisdiction.

A. Nationwide Jurisdiction – 18 U.S.C. § 1965(b)

Plaintiffs allege that Quadrant Defendants, Dr. Quasha, and Preston are subject to personal jurisdiction under 18 U.S.C. § 1965, on the asserted ground that "[t]here is no other single district in which all [d]efendants are subject to jurisdiction, and the ends of justice in this multi-state, international conspiracy to commit wire fraud require the trial of this case in a single forum." (See FAC ¶ 29.)

"In any action under section 1964 of [Chapter 96][4] in any district court of the United States in which it is shown that the ends of justice require that other parties residing in any other district be brought before the court, the court may cause such parties to be summoned, and process for that purpose may be served in any judicial

[4] Chapter 96 is titled "Racketeer Influenced and Corrupt Organizations"; § 1962 sets forth prohibited activities thereunder, and § 1964 provides district courts with jurisdiction over civil cases brought for violations of § 1962.

district of the United States by the marshal thereof." See 18 U.S.C. § 1965(b).

"In section 1965(b), Congress provided for service of process upon RICO defendants residing outside the federal court's district when it is shown that 'the ends of justice' require it," Butcher's Union Local No. 498, United Food and Commercial Workers v. SDC Investment, Inc., 788 F.2d 535, 538 (9th Cir. 1986), thereby "enabl[ing] plaintiffs to bring all members of a nationwide RICO conspiracy before a court in a single trial," id. at 539.

"For nationwide service to be imposed under section 1965(b)," (1) the court must "have personal jurisdiction over at least one of the participants in the alleged multidistrict conspiracy," (2) the plaintiff must "show that there is no other district in which a court will have personal jurisdiction over all of the alleged co-conspirators," and (3) the plaintiff must "allege a single nationwide RICO conspiracy." See id.; see also Limcaco v. Wynn, 2023 WL 154965, at *1 (9th Cir. 2023) (holding "[n]ationwide service under § 1965(b) requires [1] a court to have personal jurisdiction over at least one of the participants, [2] no other district to be able to assert personal jurisdiction over all the alleged co-conspirators, and [3] facts showing the existence of a multidistrict conspiracy encompassing defendants").

1. Personal Jurisdiction Over At Least One Defendant

As to the first requirement of § 1965(b), that the Court "have have personal jurisdiction over at least one of the participants in the alleged multidistrict conspiracy," see Butcher's Union, 788 F.2d at 539, there is no dispute that ExThera "is headquartered in Martinez, California" (see FAC ¶ 30), and, consequently, "is subject to general personal jurisdiction in this judicial district" (see id.); see also Ford Motor Co. v. Montana Eighth Judicial District Court, 592 U.S. 351, 358-59 (2021) (holding corporation is subject to general personal jurisdiction in "its place of incorporation and principal place of

business"); Hertz Corp. v. Friend, 559 U.S. 77, 92-93 (holding corporation's "principal place of business" is "where the corporation maintains its headquarters").

Accordingly, the first requirement of § 1965(b) is satisfied.

2. No Other District with Personal Jurisdiction Over All Defendants

As to the second requirement of § 1965(b), that "that there is no other district in which a court will have personal jurisdiction over all of the alleged co-conspirators," see Butcher's Union, 788 F.2d at 539, plaintiffs allege that "Quadrant Management LLC is incorporated in Delaware with its headquarters in New York"; that "Quadrant Clinical Care LLC is incorporated in Delaware, and, on information and belief, is a fully owned subsidiary of Quadrant Management and is operated as an arm of Quadrant Management without observing the corporate formalities necessary to maintain a separate identity"; that "Alan Quasha… resid[es] in Colorado"; that "Devon Quasha… resid[es] in Massachusetts"; and that "John Preston resid[es] in Massachusetts." (See FAC ¶¶ 22-26.)

By such allegations, plaintiffs appear to have made a sufficient showing that there is no other district in which a court will have general personal jurisdiction over all of the defendants. See Ford Motor Co., 592 U.S. at 358-59. As defendants point out, however, plaintiffs have not made a sufficient showing that there is no district in which a court would have specific personal jurisdiction over all of the defendants. See MSP Recovery Claims, Series LLC v. Actelion Pharmaceuticals US, Inc., 2024 WL 3408221, at *4 (N.D. Cal. July 12, 2024) (finding lack of personal jurisdiction under § 1965(b); noting "[w]hile [p]laintiffs may have demonstrated there is no district in which a [c]ourt would have general jurisdiction over all [d]efendants, [p]laintiffs have failed to establish there is no district in which a [c]ourt has specific personal jurisdiction over all the [d]efendants").

Specific personal jurisdiction exists where, inter alia, a non-resident defendant "purposefully direct[s] his activities" at the forum or "purposefully avails himself of the privilege of conducting activities in the forum," the claim "arises out of or relates to the defendant's forum-related activities," and the exercise of jurisdiction is "reasonable." See Davis v. Cranfield Aerospace Solutions, Limited, 71 F.4th 1154, 1161-62 (9th Cir. 2023) (internal quotation and citation omitted). The "purposeful direction test typically applies to tort claims," and requires the defendant to "have allegedly (1) committed an intentional act, (2) expressly aimed at the forum state, (3) causing harm that the defendant knows is likely to be suffered in the forum state." See id. at 1162-63 (internal quotation and citation omitted).

Here, to the extent plaintiffs argue "there are no facts suggesting one district court, aside from the Northern District of California, would have specific jurisdiction over all [p]laintiffs anywhere in the country," and that "[w]here such facts are not alleged, [p]laintiffs have made their showing" (see Opp. at 104:1-3), the Court disagrees.

First, to meet their burden of demonstrating a lack of specific personal jurisdiction, plaintiffs must "proffer[]…evidence regarding defendants' contacts with other districts." See Barantsevich v. VTB Bank, 954 F.Supp.2d 972, 989-90 (C.D. Cal. 2013); see also Huntair, Inc. v. Gladstone, 774 F.Supp.2d 1035, 1039-40 (N.D. Cal. Feb. 16, 2011) (characterizing as "conclusory" and "insufficient" plaintiffs' allegation that "they are not aware of any other district in which a court would have personal jurisdiction over all of the defendants") (internal quotation and citation omitted). Moreover, in this instance, the FAC includes facts suggesting there is, in fact, another district in which a court will have personal jurisdiction over all of the alleged co-conspirators, namely, the state of Florida, in that plaintiffs allege all of the defendants purposefully directed to physicians in Florida statements that were essentially misleading as to the benefits of ONCObind. (See FAC

¶¶ 55-59, 177-178, 188, 247, 262.)

Accordingly, the second requirement of § 1965(b) is not satisfied, and, consequently, plaintiffs have failed to establish personal jurisdiction under § 1965(b).

B. Traditional Bases of Personal Jurisdiction

Plaintiffs next allege that defendants are subject to personal jurisdiction "[i]ndependent of jurisdiction under 18 U.S.C. § 1965(b)." (See FAC ¶ 31.)

With respect to non-resident defendants such as Quadrant Defendants, the Ninth Circuit "uses a three-part test to determine whether specific jurisdiction exists:

> (1) The non-resident defendant must purposefully direct his activities or consummate some transaction with the forum or resident thereof; or perform some act by which he purposefully avails himself of the privilege of conducting activities in the forum, thereby invoking the benefits and protections of its laws;
>
> (2) the claim must be one which arises out of or relates to the defendant's forum-related activities; and
>
> (3) the exercise of jurisdiction must comport with fair play and substantial justice, i.e. it must be reasonable.

See Davis, 71 F.4th at 1161-62.

1. ExThera

As noted, ExThera does not challenge the FAC on grounds of personal jurisdiction.

2. Quadrant Defendants

Plaintiffs assert Quadrant Defendants are subject to specific personal jurisdiction in this district, relying on their allegations that "Quadrant Management is a significant investor in ExThera," and that "Quadrant Management and Quadrant Clinical Care are major purchasers and distributors of the ExThera Seraph 100 filters designed and shipped from California, and in at least one case, exported the filters from California to Antigua." (See FAC ¶ 31.)

Plaintiffs' claims, however, do not arise out of or relate to Quadrant Defendants'

purchases of the Seraph 100 filters, but, rather, to the manner by which defendants obtained their consent to be treated with the filters and the harm they suffered as a result of such treatment. Further, none of that conduct is alleged to have been directed to anyone in California, nor is any of the harm alleged to have been suffered in California. See Davis, 71 F.4th 1154. at 1163 (holding "[h]arm suffered in the forum state is a necessary element in establishing purposeful direction") (internal quotation and citation omitted).

Accordingly, plaintiffs have failed to establish personal jurisdiction as to Quadrant Defendants.

3. Dr. Quasha and Preston

To establish personal jurisdiction over Dr. Quasha and Preston, plaintiffs rely solely on § 1965(b). (See Opp. at 102:15-19.)

Accordingly, plaintiffs have failed to establish personal jurisdiction as to Dr. Quasha and Preston.

C. Conclusion: Personal Jurisdiction

In sum, plaintiffs have established personal jurisdiction as to ExThera, but have failed to establish personal jurisdiction as to Quadrant Defendants, Dr. Quasha, or Preston.

Accordingly, to the extent plaintiffs' claims are brought against Quadrant Defendants, Dr. Quasha, and Preston, the FAC is subject to dismissal, and the Court evaluates plaintiffs' claims only as asserted against ExThera.

II. Civil RICO – 18 U.S.C. § 1962(c)

The First Claim for Relief alleges a violation of 18 U.S.C. § 1962(c), which section makes it "unlawful for any person employed by or associated with any enterprise…to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." See 18 U.S.C. § 1962(c).

"The elements of a civil RICO claim are as follows: (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity (known as 'predicate acts') (5) causing injury to plaintiff's 'business or property.'" Living Designs, Inc. v. E.I. Dupont de Nemours and Co., 431 F.3d 353, 361 (9th Cir. 2005) (internal quotation and citation omitted).

Plaintiffs allege that "ExThera Medical Corporation, Quadrant Management LLC, Quadrant Clinical Care LLC, Alan Quasha, John Preston, and Devon Quasha together constituted an association-in-fact enterprise," referred to in the FAC as the "ONCObind RICO Enterprise." (See FAC ¶ 261.) "The ONCObind RICO Enterprise," according to plaintiffs, "was an ongoing, continuing group or unit of persons and entities associated together for the common purpose of perpetuating fraud, in particular to maximize profits at offshore 'medical' clinics by promoting to cancer patients the ONCObind procedure as a safe and effective cancer treatment, when in fact the ONCObind RICO Enterprise knew such claims were false and/or unsupported by evidence." (See id. ¶ 263.)

A civil RICO claim under § 1962(c) requires, as noted above, a "pattern of racketeering activity." See 18 U.S.C. § 1962(c).

The specified criminal acts that satisfy the "racketeering activity" element are described in 18 U.S.C. § 1961(1), and encompass "mail fraud" in violation of 18 U.S.C. § 1341 and "wire fraud" in violation of § 1343. See 18 U.S.C. § 1961(1). Here, plaintiffs allege, "[d]efendants' systematic scheme to fraudulently promote the ONCObind procedure as a safe and effective cancer treatment to maximize profits at offshore 'medical' clinics…was facilitated by the use of the United States mail and wires," which schemes, plaintiffs allege, "constitute 'racketeering activity.'" (See FAC ¶ 267; see also id. ¶¶ 269-271.)

Next, the "pattern" element "requires the showing of a relationship between the predicates and…the threat of continuing activity." See Howard v. America Online Inc.,

208 F.3d 741, 749 (9th Cir. 2000) (internal quotation and citation omitted). Such "continuity requirement focuses on whether the associates' behavior was ongoing rather than isolated activity." See Odom v. Microsoft Corp., 486 F.3d 541, 553 (9th Cir. 2007).

"To satisfy the continuity requirement, [p]laintiffs must prove either a series of related predicates extending over a substantial period of time, i.e., closed-ended continuity, or past conduct that by its nature projects into the future with a threat of repetition, i.e., open-ended continuity." Howard, 208 F.3d at 750 (internal quotation and citation omitted).

A. Closed-Ended Continuity

"Closed-ended continuity refers to a closed period of repeated conduct," and "is established by showing that the predicate acts occurred over a substantial period of time." See Allwaste, Inc. v. Hecht, 65 F.3d 1523, 1526 (9th Cir. 1995). Here, as discussed below, the alleged pattern of racketeering activity is insufficient to establish closed-ended continuity.

According to the FAC, the alleged predicate acts of mail and wire fraud committed by ExThera took place over the span of only a few months, specifically, from January 2024, when the initial "three participants"[5] are alleged to have received the ONCObind treatment at the Antigua clinic (see FAC ¶ 43) to May 2024, when the last alleged predicate act is alleged to have been committed, namely, an alleged act of wire fraud by Preston (see id. ¶ 247).

As the Supreme Court has explained, "[p]redicate acts extending over a few weeks or months and threatening no future criminal conduct do not satisfy [the continuity]

[5] These three individuals are not further identified in the FAC.

requirement." See H.J. Inc. v. Northwestern Bell Telephone Co., 492 U.S. 229, 242 (1989); see also Religious Technology Center v. Wollersheim, 971 F.2d 364, 366-67 (9th Cir. 1992) (holding "[a] pattern of activity lasting only a few months does not reflect the long term criminal conduct to which RICO was intended to apply"; noting "[w]e have found no case in which a court has held the requirement to be satisfied by a pattern of activity lasting less than a year") (internal quotation and citation omitted); Howard, 208 F.3d at 750 (holding "[a]ctivity that lasts only a few months is not sufficiently continuous").

Plaintiffs argue closed-end continuity is established because the alleged predicate acts took place "over at least an eight month period," from December 2023, when defendants established Quadrant Clinical Care in December 2023, until July 2024, "when Quadrant Clinical Care informed Ms. Baskin that they would retain Ms. Baskin's payment for the third, unused filtration and would use those funds to pay for the clinic Quadrant Clinical Care operated for Mr. Withey's stay in the 'ICU.'" (See Opp. at 32:16-27.) Neither the establishment of Quadrant Clinical Care nor Quadrant Clinical Care's statement as to payment, however, is alleged to be an act of mail or wire fraud, and, even assuming, arguendo, such acts constitute predicate acts, eight months nonetheless falls short of the requisite period of time. See Kan-Di-Ki v. Sorenson, 723 Fed.Appx. 432, 434 (9th Cir. 2018) (holding "alleged scheme" over a ten month period "was too limited and short in duration to sufficiently establish closed-ended continuity").

Accordingly, to the extent plaintiffs rely on closed-ended continuity, plaintiffs have not satisfied the "pattern" element of § 1962(c).

B. Open-Ended Continuity

"If closed-ended continuity cannot be established, plaintiffs may plead open-ended continuity." Allwaste, 65 F.3d at 1526. "Open-ended continuity refers to past conduct that by its nature indicates a threat of future criminal conduct" or "projects into the future with

a threat of repetition." See H.J., 492 U.S. at 241. In other words. "[o]pen-ended continuity is the threat that criminal conduct will continue into the future." See Allwaste, 65 F.3d at 1527 (internal quotation and citation omitted). "It is established by showing either that the predicate acts include a specific threat of repetition extending indefinitely into the future or that the predicate acts were part of an ongoing entity's regular way of doing business." Id. (internal quotation and citation omitted). Here, as set forth below, plaintiffs fail to allege facts sufficient to support a finding of open-ended continuity.

Plaintiffs allege that "[d]efendants' acts…present a threat of continued racketeering activity, including…the fact that the ONCObind RICO Enterprise…continues to offer the procedure and [d]efendants…remain associated and financially involved with one another." (See FAC ¶ 281.) In the absence of factual support, however, such conclusory allegation is unavailing. See, e.g., Howard, 208 F.3d at 750 (finding allegation "that [defendant's] improper activities continue even at the present" failed to demonstrate continuity where plaintiffs "gave no factual support for acts after [any particular]" date). Moreover, the offering of the ONCObind procedure, by itself, i.e., without any misrepresentation, constitutes neither mail nor wire fraud; similarly, plaintiffs' assertion that "ExThera Medical continues to highlight the ONCObind treatment on its website" (see Opp. at 30:5-6), even if pleaded in the FAC, fails to meet the requisite showing of fraud.

Accordingly, to the extent plaintiffs rely on open-ended continuity, plaintiffs have not satisfied the "pattern" element of § 1962(c).

C. Conclusion: Civil RICO – 18 U.S.C. § 1962(c)

Plaintiffs' First Claim for Relief is subject to dismissal.

III. Civil RICO Conspiracy – 18 U.S.C. § 1962(d)

The Second Claim for Relief alleges a violation of 18 U.S.C. § 1962(d), which subsection makes it "unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c)." See 18 U.S.C. § 1962(d).

"[S]ection 1962(d) makes it unlawful to conspire to conduct or participate in the conduct of an enterprise's affairs, where its affairs are conducted through a pattern of racketeering activity." U.S. v. Tille, 729 F.2d 615, 619 (9th Cir. 1984). The Ninth Circuit has held, however, that the failure to adequately plead a substantive RICO claim under § 1962(c) precludes a RICO conspiracy claim under § 1962(d). See Howard, 208 F.3d at 751 (holding "[p]laintiffs cannot claim that a conspiracy to violate RICO existed if they do not adequately plead a substantive violation of RICO"; noting "[e]ven if [p]laintiffs properly claimed that the defendants agreed to be a part of an enterprise, the failure to allege substantive violations precludes their claim that there was a conspiracy to violate RICO"); see also Religious Technology Center, 971 F.2d at 367 n.8 (finding "conspiracy cause of action cannot stand" where plaintiff "has failed to allege the requisite substantive elements of RICO").

Here, given plaintiffs' failure to plausibly allege a civil RICO claim under § 1962(c), plaintiffs likewise fail to allege a civil RICO conspiracy claim under § 1962(d).

Accordingly, plaintiffs' Second Claim for Relief is subject to dismissal.

IV. Fraud

The Third Claim for Relief asserts a claim of fraud, based on "both affirmative misrepresentations about the clinical promise of ONCObind and material omissions of fact about the risks of ONCObind." (See FAC ¶ 288.)

Under California law, the "necessary elements of fraud are: (1) misrepresentation

(false representation, concealment, or nondisclosure); (2) knowledge of falsity (scienter); (3) intent to defraud (i.e., to induce reliance); (4) justifiable reliance; and (5) resulting damage." See Alliance Mortgage Co. v. Rothwell, 10 Cal.4th 1226, 1239 (Cal. 1995) (internal quotation and citation omitted). Additionally, allegations of fraud are subject to Rule 9(b)'s heightened pleading standard. See Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1103, 1106 (9th Cir. 2003) (holding, to meet Rule 9(b)'s particularity requirement, "[a]verments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged").

Here, in alleging a fraud claim against ExThera, plaintiffs rely on misrepresentations made to patients by Preston as a member of ExThera's Board of Directors, and by Dr. Ilic as ExThera's Chief Regulatory Officer and Vice President of Clinical, Regulatory and Medical Affairs. The Court next considers the alleged misrepresentations made by Preston and Dr. Ilic.[6]

A. Preston

Plaintiffs allege Preston made to plaintiffs various fraudulent misrepresentations, either directly or by omission, that (1) the results of the Croatian trial demonstrated high efficacy of the ONCObind procedure in treating tumors (see FAC ¶¶ 53, 68, 69, 70, 178, 222, 240); (2) the ONCObind procedure was safe (see id. ¶¶ 67, 69, 71, 224); (3)

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[6] To the extent plaintiffs, based on a conspiracy theory, rely on alleged misrepresentations made by other defendants (see FAC ¶ 253 (alleging "[a]ll defendants engaged in a civil conspiracy and are liable for any of the torts committed by the other [d]efendants"), plaintiffs fail to plead the two defining elements of such a conspiracy, namely, "the formation of a group of two or more persons who agreed to a common plan or design to commit a tortious act," and "a wrongful act committed pursuant to the agreement," see City of Industry v. City of Fillmore, 198 Cal.App.4th 191, 212 (2011); see also Kidron v. Movie Acquisition Corp., 40 Cal.App.4th 1571, 1582 (1995) (holding "[m]ere association does not make a conspiracy").

plaintiffs should forego chemotherapy and radiation treatments in order to experience the benefits of the ONCObind procedure (see id. ¶¶ 69, 54, 182); (4) patients who received the ONCObind procedure in Quadrant Clinical Care's Antigua clinic would receive ONCObind for free in future American clinical trials (see id. ¶¶ 54, 75); and (5) adverse clinical test results and symptoms following the ONCObind procedure, such as increased cancer biomarkers, constituted evidence of the procedure's effectiveness in treating cancer (see id. ¶¶ 98, 247).

ExThera argues it is not liable for any alleged false statements by Preston because the FAC "contains no factual allegations that…Preston made any alleged false statements pursuant to any authority granted by ExThera's Board." (See ExThera Motion at 13:22-14:7.)

Under California law, "a corporation is liable for the acts of its officers and directors so long as they are acting within the scope of their agency for the corporation." See Bakst v. Community Memorial Health System, Inc., 2011 WL 13214315, at *4 (C.D. Cal. March 7, 2011); see also Von Beltz v. Stuntman, Inc., 207 Cal.App.3d 1467, 1488 (1989) (holding "a private corporation is generally liable under the doctrine of respondeat superior for torts of its agents or employees committed while they are acting within the scope of their employment"). Consequently, a corporation can be held liable "for a misleading statement made by an employee or other agent who has actual or apparent authority" to so speak. See Hollinger v. Titan Capital Corp., 914 F.2d 1564, 1577 n.28 (9th Cir. 1990); see also Von Schrader v. Milton, 96 Cal.App. 192, 202 (1929) (holding "[a] corporation is liable for the fraud and deceit of its officers and agents, acting in the apparent course of their employment").[7]

[7] Although ExThera cites to Delaware agency law (see ExThera Motion at 13:24),

"[A]ctual authority…may be implied as well as express." See Unite Here Retirement Fund v. City of San Jose, 2023 WL 5181633, at *5 (N.D. Cal. Aug. 11, 2023) (internal quotation and citation omitted). "Express actual authority derives from an act specifically mentioned to be done." See N.L.R.B. v. District Council of Iron Workers of the State of Cal. and Vicinity, 124 F.3d 1094, 1098 (9th Cir. 1997). "Implied actual authority comes from a general statement of what the agent is supposed to do; an agent is said to have the implied authority to do acts consistent with that direction." Id.

Apparent authority, on the other hand, "is created, and its scope defined, by the acts of the principal in placing the agent in such a position that he appears to have the authority which he claims or exercises." See Blanton v. Womancare, Inc., 38 Cal.3d 396, 406 (1985). "Apparent authority arises from the principal's manifestations to a third party that supplies a reasonable basis for that party to believe that the principal has authorized the alleged agent to do the act in question." See N.L.R.B., 124 F.3d at 1099. Apparent authority, however, "cannot be established by the representations or conduct of the purported agent"; "the statements or acts of the principal must be such as to cause the belief the agency exists." See J.L. v. Children's Institute, Inc., 177 Cal.App.4th 388, 404 (2009). In particular, apparent authority is created by "some intentional conduct or neglect on the part of the alleged principal creating a belief in the minds of third persons that an agency exists, and a reasonable reliance thereon by such third persons." See Young v. Horizon West, Inc., 220 Cal.App.4th 1122, 1133 (2013) (internal quotation and citation omitted).

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and plaintiffs, while "not conced[ing] that Delaware law governs" (see Opp. at 37 n.12), respond with citations to Delaware cases, neither party submits any authority suggesting Delaware law, rather than the law of the forum state, governs the determination of whether Preston, in the commission of the alleged fraud, acted as ExThera's agent.

"[W]here a plaintiff alleges that a defendant is liable for fraud under an agency theory," whether as an "agent or apparent agent," Rule 9(b) requires that the existence of the agency relationship be pled with particularity." See Jackson v. Fischer, 931 F.Supp.2d 1049, 1061 (N.D. Cal. 2013).

Here, plaintiffs have not alleged facts demonstrating that Preston, in making the above-discussed allegedly fraudulent statements to plaintiffs, acted within the scope of his agency as a member of ExThera's Board of Directors. In particular, plaintiffs have not alleged any facts suggesting ExThera expressly directed Preston to recruit patients for Quadrant Clinical Care's Antigua clinic, or that the recruitment of patients was incidental to his duties as a board member, nor have plaintiffs alleged any facts suggesting ExThera put Preston in the position of leading plaintiffs to believe he was speaking for ExThera when he engaged in such conduct.

Although implied authority can "arise out of the duties…assumed by [a corporate officer] and acquiesced in by the corporation," see Butler v. Solano Land Co., 46 Cal.App. 171, 174 (1920), plaintiffs' argument that such acquiescence has been demonstrated because "Preston's statements were made as a representative of ExThera for multiple months, including while other ExThera officers made extremely similar representations," is unavailing, as the paragraphs of the FAC to which plaintiffs cite include no facts as to representations made by anyone for multiple months or ExThera's knowledge thereof. (See Opp. at 37:6-14 (citing FAC ¶¶ 67, 68, 254).)[8]

Accordingly, to the extent plaintiffs' Third Claim for Relief is based on Preston's

[8] The case to which plaintiffs cite for the proposition that they "are not required to provide facts to support the elements of an agency relationship" (see Opp. at 37:15-26) is distinguishable, in that the claim asserted therein was not fraud. See Dion LLC v. Infotek Wireless, Inc., 2007 WL 3231738, at *1 (N.D. Cal. Oct 30, 2007).

allegedly fraudulent statements, such claim is subject to dismissal.

B. Dr. Ilic

Plaintiffs allege that Dr. Ilic, ExThera's Chief Regulatory Officer and Vice President of Clinical, Regulatory, and Medical Affairs, made to plaintiffs various fraudulent misrepresentations, either directly or by omission, that (1) the results of the Croatian trial demonstrated high efficacy of the ONCObind procedure in treating tumors (see FAC ¶¶ 37, 53, 64, 65, 100, 103, 137); (2) the ONCObind procedure had the ability to boost patients' immune systems; (3) the ONCObind procedure was safe (see id. ¶¶ 65, 73); (4) plaintiffs should forego chemotherapy and radiation treatments in order to experience the benefits of the ONCObind procedure (see id. ¶¶ 44, 54, 65); (5) ExThera was beginning clinical trials in the United States and that patients who received the ONCObind procedure in Quadrant Clinical Care's Antigua clinic would receive ONCObind for free in such future trials (see id. ¶¶ 54, 75, 99, 103, 123, 153); and (6) adverse clinical test results and symptoms after the ONCObind procedure, such as increased cancer biomarkers, constituted evidence of the procedure's effectiveness in treating cancer, and that patients needed further ONCObind treatment following such symptoms (see id. ¶¶ 98, 99, 100).

There is no dispute that the above-listed alleged misrepresentations were made by Dr. Ilic as an agent of ExThera. The Court next considers the allegedly fraudulent statements made by Dr. Ilic.

1. Statements Regarding the Croatian Trial and ONCObind's Efficacy

First, plaintiffs allege that Dr. Ilic made fraudulent misrepresentations to plaintiffs regarding the results of ExThera's Croatian trial and ONCObind's efficacy in treating cancer.

In particular, plaintiffs allege that "on or around February 8, 2024," Dr. Ilic "spoke on the phone with Ms. Hudlow and Ms. Baskin" ("February 8 phone call"), during which call Dr. Ilic represented that, of the patients who received the ONCObind treatment in the Croatian trial, "nearly all of them had positive results after filtration," that "several of the patients had no evidence of cancer after treatment, [that] the lowest reduction in primary tumor size was 49%," and that the only patient who had passed away after the trial died "because the patient had undergone a lot of chemotherapy after the filtration and had gotten additional chemotherapy after the filtration." (See FAC ¶ 65.) Plaintiffs allege such statements were false because "[n]o data had been published corroborating that the Croatian study reduced participants' primary tumor sizes, reduced pain, or rendered cancer undetectable." (See id. ¶ 270(i).)

ExThera argues "the absence of data does not make Dr. Ilic's statements untrue," and, in any event, that "[p]laintiffs fail to allege any facts that Dr. Ilic knew that any statements about the Croatian study were false." (See ExThera Mot. at 15:16-20.)

Plaintiffs, however, have alleged that Dr. Ilic organized and conducted the Croatian trial (see FAC ¶ 37), that the Croatian trial did not yield the results that Dr. Ilic represented to Ms. Hudlow and Ms. Baskin over the phone (see id. ¶¶ 37-38), and that the article she published regarding the results of the trial did not make claims regarding the size of patients' tumor reductions or that the participants in the trial had no evidence of cancer following participation in the trial (see id. ¶ 37 n.10). Such factual allegations are sufficient to support a finding of falsity and that Dr. Ilic either "had actual knowledge of the untruth" of the above-referenced statements or "that the statements were carelessly and recklessly made." See Watt v. Peterson, 125 Cal.App.2d 788, 792 (1954) (setting forth showing necessary to plead fraud).

Further, although not challenged, plaintiffs have adequately pleaded reliance (see

FAC ¶ 294) and resulting damage, namely, loss of money (see id. ¶ 296).[9]

Accordingly, to the extent the Third Claim for Relief is based on the above-referenced statements regarding the Croatian trial and ONCObind's efficacy, such claim is not subject to dismissal.

2. Statements Regarding ONCObind's Ability to Boost Patients' Immune Systems

Second, plaintiffs allege multiple defendants represented that, "[b]y filtering the blood, ONCObind supercharges the immune system, harnessing it to attack primary tumors themselves," whereas, according to plaintiffs, "[t]here is no evidence that ONCObind supercharges the immune system and allows the body to attack primary tumors themselves." (See FAC ¶ 270(ii).)

The statements attributed to Dr. Ilic regarding the filters, however, namely, that in the February 8 phone call she "explained how the filters utilized heparin sulfate to bind circulating tumor cells and remove them from the bloodstream," and that, of the patients who participated in the Croatian trial, "the lowest reduction in primary tumor size was 49%" (see id. ¶¶ 270(ii) (citing id. ¶ 65)) do not include any reference to the immune system, let alone a representation as to "supercharg[ing] the immune system" (see id. ¶ 270(ii)).

Accordingly, to the extent the Third Claim for Relief is based on the above-referenced statements regarding ONCObind's ability to boost patients' immune systems, such claim is subject to dismissal.

[9] To the extent plaintiffs allege additional resulting damages, including worsening medical conditions and death, plaintiffs fail to make the requisite showing of a causal connection between the above-discussed misrepresentations and such additional damages.

3. Statements Regarding Safety of ONCObind Procedure

Third, plaintiffs allege multiple defendants represented that "there are no serious risks to the ONCObind procedure," whereas, according to plaintiffs, their "experiences…illustrate that ONCObind was not risk free." (See FAC ¶ 270(iv).)

The only statement attributed to Dr. Ilic, however, makes no reference to risk. (See id. ¶¶ 270(iv) (citing id. ¶ 65).)[10]

Further, to the extent plaintiffs contend that Dr. Ilic, "in addition to" making affirmative misrepresentations, "concealed or failed to disclose" that "at least one person had died after the Croatian trial" (see Opp. at 78:8-17), such contention is contradicted by their allegations in the FAC (see FAC ¶ 65 (alleging Dr. Ilic, in the February 8 phone call, "mentioned a single patient who passed away after filtration").

Accordingly, to the extent the Third Claim for Relief is based on the above-referenced statements regarding the safety of the ONCObind procedure, such claim is subject to dismissal.

4. Statements Regarding Advisability of Foregoing Chemotherapy and Radiation Treatments

Fourth, plaintiffs allege multiple defendants represented that "[t]he only obstacle to success is continued chemotherapy or radiation treatment and therefore patients should stop such treatment before receiving ONCObind and for some time afterwards," whereas, according to plaintiffs, "[t]here is no evidence that discontinuing or refraining from

[10] Although not cross-referenced in ¶ 270(iv) of the FAC, to the extent plaintiffs may be relying on their allegation that "Dr. Ilic and Mr. Preston made it clear to Ms. Hudlow and Ms. Baskin that ONCObind had no adverse effects, so long as the patient receiving the filtration did not receive chemotherapy too close to the treatment" (see FAC ¶ 73), such allegation fails to meet the requirements of Rule 9(b). See Vess, 317 F.3d at 1106 (holding "[a]verments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged").

undergoing chemotherapy or radiation was advisable." (See FAC ¶ 270(v).)

The only statement attributed to Dr. Ilic regarding chemotherapy, however, namely, that Dr. Ilic, in the February 8 phone call, "mentioned a single patient who passed away after filtration, but…insisted it was because the patient had undergone a lot of chemotherapy before the filtration and had gotten additional chemotherapy after the filtration" (see id. ¶ 270(v) (citing id. ¶ 65)), does not constitute a recommendation to any plaintiff that he/she cease chemotherapy or radiation treatments.

Accordingly, to the extent the Third Claim for Relief is based on the above-referenced statements regarding the advisability of foregoing chemotherapy and radiation treatments, such claim is subject to dismissal.

5. Statements Regarding Clinical Trials in the U.S.

Fifth, plaintiffs allege that, on multiple occasions, Dr. Ilic made false statements to Ms. Hudlow, Ms. Baskin, and Ms. Bowen regarding impending clinical trials of ONCObind in the United States, and that patients who received the ONCObind treatment at the Antigua clinic would have the opportunity to enroll for free in the clinical trials (see FAC ¶¶ 75, 99, 123, 153), whereas, according to plaintiffs, the purported clinical trials were "actually a single trial for a particular type of pancreatic cancer that no [p]laintiff participant had and appears to have only enrolled five participants" (see id. ¶ 270(viii)).

Plaintiffs allege that Dr. Ilic, during February, March, and April 2024, represented to plaintiffs that ONCObind clinical trials "would soon be available in the United States to treat all kinds of cancer" (see FAC ¶ 75), and, in particular, that two such trials were beginning, one at the "University of Oklahoma" (see id. ¶¶ 99, 123, 153) and one at the "MD Anderson Cancer Center in Texas" (see id. ¶¶ 99, 123), and that Antigua ONCObind recipients would be eligible to participate in such trials for free (see id. ¶¶ 75, 153). The only factual allegation as to the falsity of those statements, however, is that, as of the

time of the filing of the FAC, the sole clinical trial to have begun in the United States was at the University of Oklahoma and "limited to testing the procedure on a specific kind of pancreatic cancer" (see id. ¶ 99), which none of the plaintiffs is alleged to have had. Such allegation does not suffice to support a finding that, at the time the statements were made, approximately a year earlier, no other trials were anticipated. Further, plaintiffs have not alleged they agreed to receive treatment at the Antigua clinic in reliance on any of the above statements regarding clinical trials in the United States.

Accordingly, to the extent the Third Claim for Relief is based on the above-referenced statements regarding clinical trials in the United States, such claim is subject to dismissal.

6. Statements Regarding ONCObind's Adverse Effects and the Need for Further ONCObind Treatment

Sixth, plaintiffs allege multiple defendants represented that, following ONCObind treatment, "[a]ny negative test results or adverse events are proof that ONCObind is working and that further filtrations are needed," whereas, according to plaintiffs, "[p]laintiff participants' negative test results and adverse events were confirmation that ONCObind was harming them, in some cases leading to death." (See FAC ¶ 270(ix) (citing id. ¶¶ 99, 103, 137-138).)

As evidence of the falsity of such statements, plaintiffs allege that, after experiencing pain following the ONCObind treatment, Mr. Hudlow's condition did not improve, but, rather, "significantly worse[ned]," including the sudden appearance of "growths…on Mr. Hudlow's head and body," and "dramatic increase in circulating tumor DNA in Mr. Hudlow's blood," which results "never returned to the levels they were before he went to Antigua" (see FAC ¶¶ 95-98), all culminating in his death "12 days after his last ONCObind filtration" (see id. ¶ 117). The FAC contains no allegation, however, that

at the time the above-referenced statements were made, Dr. Ilic, either as a medical professional or otherwise, knew those statements were false or that she made them with reckless disregard for their truth.

Accordingly, to the extent the Third Claim for Relief is based on the above-referenced statements regarding ONCObind's adverse effects and the need for further ONCObind treatment, such claim is subject to dismissal.

V. Negligence

The Fourth Claim for Relief asserts a claim for negligence. (See FAC ¶¶ 297.)

Under California law, "[t]he elements of a negligence cause of action are: (1) a legal duty to use due care; (2) a breach of that duty; (3) the breach was the proximate or legal cause of the resulting injury; and (4) actual loss or damage resulting from the breach of the duty of care." See Brown v. Ransweiler, 171 Cal.App.4th 516, 534 (2009).

A. Duty

Plaintiffs assert "ExThera (through Dr. Ilic) had a special duty of care…because of the physician-patient relationship" with Mr. Hudlow and Mr. Withey. (See Opp. at 85:9-86:2.)[11]

"A physician's duty of care to a patient does not arise until a physician-patient relationship is established." See McCurry v. Singh, 104 Cal.App.5th 1170, 1176 (2024).

"The relationship…comes into existence when the patient, or someone acting for the patient, solicits the practitioner's services and the latter knowingly consents to, and begins consensually to act for, the benefit of the patient." Id. at 1176-77 (internal

[11] Plaintiffs' assertion that ExThera breached the ordinary duty of care is based on representations by Preston, who, as discussed above, has not been shown to have acted as ExThera's agent.

quotation and citation omitted). "The relationship does not arise when the physician does not affirmatively treat or directly advise the patient." Id. at 1176 (internal quotation and citation omitted).

Here, ExThera argues "the FAC fails to allege that…any ExThera employee acted as a treating physician to any [p]laintiff, or that ExThera treated any patients," and that plaintiffs improperly "lump[] 'Dr. Ilic and Dr. Quasha' together." (See ExThera Reply at 13:23-26.)

Contrary to ExThera's arguments, however, plaintiffs have alleged facts sufficient to support a finding that a physician-patient relationship was established between Dr. Ilic and both Mr. Hudlow and Mr. Withey. In particular, plaintiffs allege that Dr. Ilic, on various occasions, spoke with someone acting for Mr. Hudlow and Mr. Withey, namely, their spouses, Ms. Hudlow and Ms. Baskin, to discuss the ONCObind treatment's efficacy and safety and recommended the ONCObind treatment (see, e.g., FAC ¶¶ 65, 73, 99, 100, 103), assisted plaintiffs in enlisting in the treatment program (id. ¶¶ 66, 74, 81), evaluated plaintiffs' symptoms and responses to the procedure (id. ¶¶ 100, 103, 104, 137), offered to enroll plaintiffs in upcoming clinical trials (id. ¶ 99, 103, 123), referred plaintiffs to treating physicians, and informed those physicians about the ONCObind procedure (id. ¶¶ 58, 76).[12]

Given the above allegations, the Court finds plaintiffs have sufficiently pleaded a duty of care based on a physician-patient relationship between Dr. Ilic and Mr. Hudlow

[12] Although plaintiffs have alleged Dr. Ilic, on one occasion, communicated with Ms. Bowen regarding Mr. Bowen's ability to enroll in an upcoming trial of ONCObind in the United States (see FAC ¶ 153), and, on another occasion, assisted Mr. Chupp's physician in preparing paperwork for the purpose of administering ONCObind to Mr. Chupp in Canada (see id. ¶ 210), such allegations are insufficient to establish a physician-patient relationship between Dr. Ilic and either Mr. Bowen or Mr. Chupp.

and Mr. Withey.

B. Breach

"[T]he standard of care for physicians is the reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of the medical profession under similar circumstances." Avivi v. Centro Medico Urgente Medical Center, 159 Cal.App.4th 463, 470 (2008) (emphasis omitted). The "duty of care applies not only to the physician's actual performance or administration of treatment, but also to his choice of which courses of treatment to recommend (or not recommend) to a patient." See Flores v. Liu, 60 Cal.App.5th 278, 290 (2021).

Here, plaintiffs assert Dr. Ilic "breached [her] duty of care by encouraging [p]laintiffs to cease proven treatment methods…and to instead undergo an experimental procedure while misrepresenting the actual risks and lack of evidence." (See Opp. at 86:26-28.)

"A physician violates his duty of care to a patient if he recommends a course of treatment" when that treatment "is one that no reasonable physician using such skill, prudence and diligence as other members of the relevant medical community would have recommended." See Flores, 60 Cal.App.5th at 291. "Because, as noted above, the duty of care for recommending courses of treatment is pegged to what reasonable physicians using such skill, prudence and diligence as other members in the relevant medical community would do, whether that duty was breached in a particular case is generally a question for experts except where the matter...is...within the common knowledge of laymen." Id. at 292 (internal quotation and citation omitted).

Here, as noted, plaintiffs allege Dr. Ilic, in recommending plaintiffs undergo a course of treatment, markedly misstated the results of a study she herself conducted. Under such circumstances, the Court finds plaintiffs need not allege an expert opinion in

order to plead breach.

C. Causation

As noted, one of the elements of a negligence claim is that "the breach was the proximate or legal cause of the resulting injury." See Brown, 171 Cal.App.4th at 534. Defendants argue plaintiffs have failed to plead the requisite element of causation.

In response, plaintiffs cite to their allegations of "worsening disease, death, and emotional trauma." (See Opp. at 87:11-15.) Plaintiffs fail, however, to make the requisite causal connection between Dr. Ilic's recommendations and plaintiffs' worsening medical conditions. Plaintiffs have not alleged, for example, facts showing plaintiffs would not have suffered such worsening conditions had they followed a different course of treatment or had not received the alleged inadequate medical care at the Antigua clinic.

Under such circumstances, plaintiffs' Fourth Claim for Relief is subject to dismissal.

VI. Intentional Infliction of Emotional Distress

The Fifth Claim for Relief asserts a claim for intentional infliction of emotional distress. (See FAC ¶¶ 301-305.)

Under California law, "[t]he elements of the tort of intentional infliction of emotional distress are: (1) extreme and outrageous conduct by the defendant with the intention of causing, or reckless disregard of the probability of causing, emotional distress; (2) the plaintiff's suffering severe or extreme emotional distress; and (3) actual and proximate causation of the emotional distress by the defendant's outrageous conduct." See Christensen v. Superior Court, 54 Cal.3d 868, 903 (1991) (internal quotation and citation omitted). "Conduct to be outrageous must be so extreme as to exceed all bounds of that usually tolerated in a civilized community," and the defendant must have engaged in such conduct with the "inten[t] to inflict injury or…with the realization that injury will result." See

id. (internal quotation and citation omitted).

At the outset, ExThera argues, the "Estate of David Hudlow, Estate of John Bowen, and Estate of Kyle Chupp cannot assert an [intentional infliction of emotional distress] claim because emotional distress damages do not survive the death of the person who suffered them." (See ExThera Mot. at 21:14-16) (internal quotation and citation omitted). As plaintiffs point out, however, a cause of action for a decedent's pre-death pain and suffering survives and may be brought by the "decedent's personal representative or successor in interest on the decedent's cause of action" if the lawsuit was, as here, "filed on or after January 1, 2022, and before January 1, 2026." See Cal. Code Civ. P. § 377.34(b).

Further, as to the merits of such claim, plaintiffs, as discussed above, have adequately pleaded a fraud claim based on Dr. Ilic's alleged misrepresentations to seriously ill cancer patients in an effort to encourage them to participate in an allegedly inappropriate treatment protocol. Such conduct is sufficient to support a claim for IIED. See, e.g., Berkley v. Dowds, 152 Cal.App.4th 518, 534 (2007) (holding medical treatment advice can support a finding of outrageous conduct if that advice is "false and given in bad faith").

Accordingly, to the extent the Fifth Claim for Relief is based on the first of the above-discussed allegedly fraudulent statements, such claim is not subject to dismissal.

VII. Battery

In the Sixth Claim for Relief, plaintiffs assert a claim for battery, alleging "[d]efendants' touching of [p]laintiff[s]…through the use of ONCObind—was extremely offensive because [d]efendants misrepresented what the medical procedure was" and "did not disclose that the procedure amounted to human experimentation for which there was no clinical proof of efficacy at treating cancer and for which substantial risks existed."

(See FAC ¶ 308.)

Under California law, a plaintiff can assert a claim for "medical battery" either (1) "when a physician obtains the patient's consent to perform one type of treatment, but performs a substantially different treatment for which the plaintiff gave no consent," or (2) "when a physician performs the treatment for which consent was obtained and an infrequent complication occurs that the physician failed to disclose when obtaining the patient's consent." See Larson v. UHS of Rancho Springs, Inc., 230 Cal.App.4th 336, 349 (2014).

Here, plaintiffs have not alleged that, in the course of their medical care at Quadrant Clinical Care's Antigua clinic any ExThera physician or agent performed any treatment or medical procedure on any plaintiff. Rather, plaintiffs consistently allege that treatment was performed by Quadrant Clinical Care's Chief Medical Officer, namely, Dr. Quasha (see FAC ¶¶ 23, 47, 48, 60, 74, 81, 83, 97, 101, 125, 126, 150, 152, 155, 265), the clinic's attending physician, namely, Dr. Joseph John (see id. ¶¶ 85, 87, 105, 126, 151, 157, 208, 244, 252, 265), and other Quadrant Clinical Care staff (see id. ¶¶ 13, 15-20, 23, 85, 109, 130, 179, 229, 275).[13]

Accordingly, plaintiffs' Sixth Claim for Relief is subject to dismissal.

VIII. Product Liability (Failure to Warn)

The Seventh Claim for Relief asserts a claim for strict product liability for failure to warn of the risks presented by ExThera's Seraph 100 filters, namely, the risk of clogging, causing significant blood loss, and the risk of pain and worsening symptoms

[13] As with their claims of fraud, plaintiffs have failed to plead facts sufficient to show ExThera can, on a conspiracy theory, be held liable for the conduct of other defendants.

from their use in the filtration procedure. (See FAC ¶¶ 312-319; see also Opp. at 99:3.)

"In California, a defendant manufacturer can be held strictly liable for failure to warn if the plaintiff proves the following: (1) the defendant manufactured, distributed, or sold the product; (2) the product had potential risks that were known or knowable at the time of manufacture or distribution, or sale; (3) that the potential risks presented a substantial danger to users of the product; (4) that ordinary consumers would not have recognized the potential risks; (5) that the defendant failed to adequately warn of the potential risks; (6) that the plaintiff was harmed while using the product in a reasonably foreseeable way; (7) and that the lack of sufficient warnings was a substantial factor in causing the plaintiff's harm." Jian Wu v. Ean Holdings, LLC, 2014 WL 117338, at *3 (N.D. Cal. Jan. 10, 2014) (citing Judicial Council of Cal. Civil Jury Inst. No. 1205) (internal quotation and citation omitted).

A. Causation

1. Blood Loss from Clogged Seraph 100 Filters

ExThera asserts the Seraph 100 filters did not cause plaintiffs' injuries, citing an article plaintiffs reference in the FAC (see FAC at 1 n.1; 15 n.12), which reference, according to ExThera, was for the purpose of "attribut[ing] their injuries to the alleged incompetence or absence of [Quadrant Clinical Care] staff." (See ExThera Motion at 23:22-23.) In particular, ExThera argues, "any alleged clogging was due to [Quadrant Clinical Care's] failure to properly administer the treatment, not because the filters themselves were defective." (See ExThera Reply at 15:7-8.) Although the article does mention one occasion on which Quadrant Clinical Care's improper administration caused the filter to clog (see Doc. No. 102-1 ("Coppola Decl.") Ex. 1 at 20), the FAC contains factual allegations sufficient to support a finding that, on multiple occasions, the Seraph 100 filters clogged when used in a manner intended by ExThera. (See FAC ¶¶ 129-131,

163, 243.)

2. ONCObind Procedure

Plaintiffs allege that, even where the Seraph 100 filters did not clog and functioned as intended, the ONCObind procedure caused plaintiffs "significant harm, including, but not limited to, severe emotional distress, extreme pain[14], loss of blood, tumor lysis syndrome[15], kidney failure, rapid progression of cancer metastasis, and, in three cases, death." (See FAC ¶ 319.)

As to tumor lysis syndrome, plaintiffs have alleged facts sufficient to show causation. (See FAC ¶¶ 65, 90, 200-202.) As to all of the other conditions, the above-quoted conclusory allegation, given the absence of factual support, is insufficient. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (holding "conclusory statements…do not suffice" to state plausible claim).

B. Learned Intermediary Doctrine

ExThera contends that, "even if the alleged harm was attributable to ExThera's filters," ExThera cannot be held liable for plaintiffs' failure to warn claim due to California's "learned intermediary doctrine." (See ExThera Motion at 24:2-4.)

"The learned intermediary doctrine provides that manufacturers have a duty to warn physicians, but not the physicians' patients, about certain risks accompanying use of their…medical devices." See Himes v. Somatics LLC, 16 Cal.5th 209, 221 (2024) (holding "the manufacturer is required to warn physicians of any non-negligible risks that

[14] There is no allegation that any plaintiff suffered extreme pain during and by reason of the administration of the treatment.

[15] According to the FAC, tumor lysis syndrome "occurs when many tumor cells are killed and the body struggles to process them as they are released into the bloodstream." (See FAC ¶ 90.)

are generally unknown to the medical community"). "Pursuant to the doctrine, the manufacturer fulfills its general duty of care owed to the patient by providing an adequate warning to the patient's physician." Id. at 222. "The patient cannot sue the manufacturer for failing to warn him or her directly." Id. at 221. "As long as the manufacturer has adequately warned the patient's physician of the non-negligible risks of its prescription drug or medical device, the manufacturer has fulfilled its duty to warn." Id.

"Moreover, the manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his or her duty to transmit these warnings to the patient." Id. at 222 (internal quotation and citation omitted). "The physician thus acts as a learned intermediary between the manufacturer and the patient by recommending a course of treatment based not only on the warnings relayed by the manufacturer, but also on the physician's own medical training and experience as well as the patient's particular needs and risk factors." Id. (internal quotation and citation omitted).

Here, ExThera argues, "[p]laintiffs do not allege ExThera failed to train [Quadrant Clinical Care's] physicians" to use the Seraph 100 filters, and that "[p]laintiffs admit ExThera sent employees to Antigua" to train the clinic's staff "on the use of the filters." (See ExThera Motion at 24:6-10.) As plaintiffs point out, however, their allegation that ExThera instructed staff at Quadrant Clinical Care's Antigua clinic on the administration of the ONCObind procedure (see, e.g., FAC ¶ 43) does not suggest ExThera warned of the risks presented by the Seraph 100 filters or the procedure in which they were used (see Opp. at 97:27-98:2), nor does it show ExThera warned any physicians who referred plaintiffs to the Antigua clinic.

C. Conclusion: Product Liability

To the extent plaintiffs' Seventh Claim for Relief is based on a failure to warn as to the risks of clogging and tumor lysis syndrome, such claim is not subject to dismissal. To

the extent the Seventh Claim for Relief is based on a failure to warn as to other risks, such claim is subject to dismissal.

IX. Wrongful Death

The Eighth Claim for Relief, brought by plaintiffs Kim Hudlow, Stacey Bowen, and Vanessa Chupp, and the Estates of David Hudlow, John Bowen, and Kyle Chupp,[16] asserts a claim for wrongful death. (See FAC ¶¶ 320-324.)

Under California law, the elements of a cause of action for wrongful death are (1) the commission of a "tort (negligence or other wrongful act)," (2) the "resulting death," and (3) "damages, consisting of the pecuniary loss suffered by the heirs." See Quiroz v. Seventh Ave. Center, 140 Cal.App.4th 1256, 1263 (2006) (internal quotation and citation omitted) (emphasis omitted).

As to the first element, as discussed above, plaintiffs have adequately pleaded a fraud and intentional infliction claim by Mr. Hudlow, and failure to warn claims by Mr. Bowen and Mr. Chupp.[17] As to the second element, however, plaintiffs have not, as discussed above, pleaded "a resulting death." See Quiroz, 140 Cal.App.4th at 1263.

Accordingly, plaintiffs' Eighth Claim for Relief is subject to dismissal.

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[16] To the extent the wrongful death cause of action is brought by the Estates of David Hudlow, John Bowen, and Kyle Chupp, such claim is subject to dismissal. See California Code of Civil Procedure § 377.60 (listing persons with standing to assert wrongful death cause of action); see also Horwich v. Superior Court, 21 Cal.4th 272, 283 (1999) (holding "Code of Civil Procedure section 377.60 "creates a new cause of action in favor of the heirs as beneficiaries…distinct from any the deceased might have maintained had he survived") (emphasis omitted) (internal quotation and citation omitted).

[17] ExThera's argument that plaintiffs' wrongful death claim fails because "California law does not recognize a claim for wrongful death where the decedent had a less than fifty percent chance of survival" is unavailing. (See ExThera Mot. at 24:16-17.) As plaintiffs point out, the case on which ExThera relies, Bromme v. Pavitt, 5 Cal.App.4th 1487 (1992), concerns alleged "failure[s] to diagnose and treat a potentially terminal condition," a claim not brought here. See id., 5 Cal.App.4th at 1493.

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CONCLUSION

For the reasons stated above, defendants' motions to dismiss are hereby GRANTED IN PART and DENIED IN PART as follows:

1. As to Quadrant Defendants', Dr. Quasha's, and Preston's motions to dismiss for lack of personal jurisdiction, said motions are hereby GRANTED, and all claims alleged against said defendants are hereby DISMISSED with leave to amend.
2. As to ExThera's motion to dismiss the First (Civil RICO), Second (Civil RICO Conspiracy), Fourth (Negligence), Sixth (Battery), and Eighth (Wrongful Death) Claims for Relief, the motion is hereby GRANTED, said claims are hereby DISMISSED with leave to amend.
3. As to ExThera's motion to dismiss the Third Claim for Relief (Fraud) and Fifth Claim for Relief (Intentional Infliction of Emotional Distress), to the extent said claims are based on statements regarding the Croatian trial and ONCObind's efficacy, the motion is hereby DENIED, and in all other respects is hereby GRANTED with leave to amend.
4. As to ExThera's motion to dismiss the Seventh Claim for Relief (Product Liability), to the extent the claim is based on failure to warn of the risks of clogging and tumor lysis syndrome, the motion is hereby DENIED, and in all other respects is hereby GRANTED with leave to amend.
5. If plaintiffs elect to amend, plaintiffs' Second Amended Complaint shall be filed no later than June 30, 2026.

IT IS SO ORDERED.

Dated: May 28, 2026

MAXINE M. CHESNEY
United States District Judge