



## **Munderloh et al v. Biegler GmbH et al**

2022 | Cited 0 times | D. Arizona | March 28, 2022

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Timothy Munderloh, et al.,

Plaintiffs, v. Biegler GmbH, et al.,

Defendants.

No. CV-21-08004-PCT-GMS ORDER

Dismiss Under 12(b)(2) and 12(b)(6) (Doc. 33). Also pending before the Court is Dr.

on for Leave to File a Surreply (Doc. 45). For the reasons below, both

Motions are denied.

**BACKGROUND** For the purposes of the Motion and unless otherwise noted the Court construes all facts alleged in the Complaint as true. Defendant Biegler manufactures the Stivax

Stivax device -acupuncture device for use in the practice of acupuncture by sale of the Stivax device in the United States as an acupuncture device. (Doc. 1 at 13.)

After receiving FDA approval, Defendant Biegler engaged Defendant Solace

Advancement as the importer and distributor of the Stivax device in the United States. (Doc. 1 at 14.) Both Defendants Biegler and Solace Advancement then contacted other distributors, including Doc Solutions, to market and sell the Stivax device. (Doc. 1 at 14.) Mark Kaiser hief Executive Officer, personally promoted, marketed, and sold the Stivax device throughout the United States to various medical providers, including Plaintiffs. (Doc. 1 at 15.) Although the FDA had classified the Stivax device as an electro-acupuncture device, Defendants, including Defendant Biegler, marketed the device to medical providers - by Medicare. (Doc. 1 at 4 5, 42.) Importantly, Defendant Biegler knew



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

that the Stivax device was not actually reimbursable. (Doc. 1 at 11 13, 41.) Despite this knowledge, Defendant Biegler collaborated with Defendant Solace Advancement to produce promotional materials, including a promotional video, that misrepresented that the Stivax device was implantable and usable by doctors. (Doc. 1 at 16 18, 40 42.) Acupuncture was not mentioned in any of these materials. (Doc. 1 at 17 18.) In addition to these promotional materials, Defendants Biegler and Solace Advancement created the would be marketed as reimbursable by Medicare as an implantable pain management

device. (Doc. 1 at 36, 42.) As part of this scheme, Mr. Kaiser personally visited Plaintiffs to induce them to purchase the Stivax device. As is the industry norm, Mr. Kaiser trained the purchasing medical providers on how to properly code and bill the Stivax device for reimbursement by Medicare. (Doc. 1 at 15 17, 26 28.) Mr. Kaiser instructed Plaintiffs that they should use a particular set of codes to bill for the Stivax device and explained that management device. (Doc. 1 at 26 the

promotional materials developed by Defendants Biegler and Solace Advancement,

Plaintiffs billed the Stivax device as they had been instructed by Mr. Kaiser, which resulted

in overpayments and audits by Medicare. (Doc. 1 at 33 37.) Based on the foregoing, Plaintiffs filed suit on behalf of themselves and all others similarly situated against Defendants Biegler, Solace Advancement, and others, alleging violations of the common-law fraud claims. (Doc. 1.) Defendant Biegler has moved to dismiss for lack of

personal jurisdiction and for failure to state a claim upon which relief can be granted. (Doc. 21c33.)

### DISCUSSION I. Personal Jurisdiction in Arizona

Defendant Biegler first argues that the Court cannot assert personal jurisdiction over it without violating due process. 1

(Doc. 33-1.) On a motion to dismiss for lack of personal

Schwarzenegger v. Fred Martin Motor Co., 374 F.3d 797, 800 (9th Cir. on written materials rather than an evidentiary Id. (quoting Sher v. Johnson, 911 F.2d 1357, 1361 (9th Cir. 1990)). Although the plaintiff cannot simply rest on the id. (quoting Amba Mktg. Sys., Glob. Commodities Trading Grp., Inc. v.

Beneficio de Arroz Choloma, S.A., 972 F.3d 1101, 1106 (9th Cir. 2020). Allegations that are contradicted by affidavit are not assumed as true, but factual disputes between affidavits CollegeSource, Inc. v. AcademyOne, Inc., 653 F.3d 1066, 1073 (9th Cir. 2011). The Court applies Arizona law to determine whether it may exercise jurisdiction over a defendant. Picot v. Weston



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

long-arm statute provides for personal jurisdiction co-extensive with the limits of federal 1 Plaintiff does not seem to contest that Arizona does not have general personal jurisdiction over Defendant Biegler. Therefore, the Court will only consider whether Arizona has specific personal jurisdiction.

Doe v. Am. Nat. Red Cross, 112 F.3d 1048, 1050 (9th Cir. 1997); Ariz. R. to comport with due process, Schwarzenegger, 374 F.3d at 801 (quoting Co. v. Washington, 326 U.S. 310, 316 (1945)).

Here, Defendant Biegler provided an affidavit from its President and CEO Ingeborg (Doc. 33-1 at 21 24.) In it, Mr. Biegler claims that Defendant Biegler is an Austrian corporation with its principal place of business in Austria; that Defendant Biegler does not conduct any business operations within the United States and has no physical presence in Arizona; that Defendant Biegler does not market, sell, or distribute products directly to Arizonans; and that Defendant Biegler has no control over where the product is marketed after it is given to the distributor, Defendant Solace Advancement. (Doc. 33-1 at 22 23.) Plaintiffs provide no rebuttal evidence of Defendant's, Plaintiffs reallege the allegations in the Complaint. 2 Cummings v. W. , 133 F. Supp. 2d 1144, 1154, 1158 (D. Ariz. 2001); see Data Disc., Inc. v. Sys. Tech. Assocs., Inc., 557 F.2d 1280, 1284 If only one side of the conflict was supported by affidavit, [the] task would be relatively easy, for [courts] may not assume the truth of allegations in a pleading which are contradicted by affidavit Plaintiffs have failed to meet their burden to show that Arizona courts may exercise specific jurisdiction over Defendant Biegler. II. Jurisdiction under Rule 4(k)(2) Plaintiffs argue that this Court may assert jurisdiction pursuant to Federal Rule of Civil Procedure 4(k)(2). (Doc. 43 at 7.) The Rule states, federal law, serving a summons or filing a waiver of service establishes personal

2 The Court has considered both the cited exhibits in the Complaint and the evidence in . Neither sufficiently demonstrates that Defendant Biegler committed an intentional act directly aimed at Arizona.

courts of general jurisdiction; and (B) exercising jurisdiction is consistent with the United (2). To assert jurisdiction under Rule 4(k)(2), the defendant must not be subject to the personal jurisdiction of any state court of general jurisdiction the federal court's exercise of personal jurisdiction must comport with due process. Holland Am. Line Inc. v. Wartsila N. Am., Inc., 485 F.3d 450, 461 (9th Cir. 2007). Plaintiffs clearly meet the first element because they allege two claims arising under federal law. 3

(Doc. 1 at 49 51.) With respect to the second requirement, if the defendant the federal court is entitled to use Rule 4(k)(2). Holland, 485 F.3d at 461. Defendant Biegler has named no such state. (Doc. 33-1.) Therefore, the only remaining issue is whether exercise of jurisdiction over Defendant Biegler comports with due process. The due

process analysis under Rule 4(k)(2) is nearly identical to traditional personal jurisdiction analysis with one significant difference: rather than considering contacts between Defendant Biegler and Arizona,



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

contacts with the nation as a whole. Holland, 485 F.3d at 462.

The Ninth Circuit uses a three-part test to determine whether specific jurisdiction -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, Glob. Commodities, 972 F.3d at 1107 (quoting Schwarzenegger must arise out of - Id. Id.

3 rly invokes Rule 4(k)(2), it can rely on pendent jurisdiction for its state law claims, so long as those claims arose under the same nucleus of operative Grayson v. Anderson, 816 F.3d 262, 271 (4th Cir. 2016)

Picot, 780 F.3 Schwarzenegger Id. Because RICO

claims are torts, the purposeful direction analysis is appropriate. See, e.g., Barantsevich v. VTB Bank, 954 F. Supp. 2d 972, 991 (C.D. Cal. May 29, 2013); Kayne v. Ho, LA CV09-06816 JAK (CWx), 2012 WL 12883918, at \*2 (C.D. Cal. Sept. 6, 2012). A. Purposeful Direction

an intentional act, (2) expressly aimed at the forum state, (3) causing harm that the

Picot, 780 F.3d at 1214 (quoting Schwarzenegger, 374 F.3d at 803). Walden v. Fiore, 571 U.S. 277, 290

Axiom Foods, Inc. v , 874 F.3d

1064, 1069 (9th Cir. 2017) (quoting Wash. Shoe Co. v. A-Z Sporting Goods Inc., 704 F.3d 668, 675 (9th Cir. 2012), abrogated by Walden, 571 U.S. at 290). 1. Intentional Act A defendant commits an intentional act when it acts Schwarzenegger, 374 F.3d at 806. Plaintiffs argue

siction: (i) FDA 510(k) applications for the Stivax device; (ii) interactive websites fulfilling Stivax device orders, specifically catered to medical providers in the United States; (iii) shipment of the Stivax device to the United States, specifically to [Defendant] Solace Advancement and/or Doc Solutions; and (iv) direction, coordination, and funding with respect to the marketing and sale of the Stivax device in the [United (Doc. 43 at 8.) Mr. Biegler specifically controve Case 3:21-cv-08004-GMS Document 52 Filed 03/28/22 Page 6 of 26 (Doc. 33-1 at 22 23.) own allegations corroborate that the Stivax website was maintained by Defendant Solace

Advancement, not Defendant Biegler, although website on the Stivax website. 4

(Doc. 1 at 40 41.) Therefore, the Court must determine

Defendant Biegler has not denied that it sought and received approval from the FDA to market the



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

Stivax device in the United States. 5

(Doc. 1 at 42); (Doc. 33-1.) That is clearly an intentional act. Plaintiffs have thus satisfied their burden as to this element. 2. Aimed at the Forum Defendant Biegler clearly aimed its conduct at the United States by seeking approval from a U.S. agency to market to a U.S. audience. (Doc. 1 at 14, 42.) Assuming for the FDA received such approval in 2016. (Doc. 1 at 14, 42.) *Lewis v. Mercedes-Benz USA, LLC*, 530 F. Supp. 3d 1183, 1212 (S.D. Fla. 2021); *Ayla, LLC v. Alya Skin Pty. Ltd.*, 11 F.4th 972, 982 (9th Cir. 2021); see also *Silver Ring Splint Co. v. Digisplint, Inc.*, 508 F. Supp. 2d 508, 515 (W.D. Va. 2007). 3. Causes Harm in the Forum Plaintiffs allege that Stivax marketing and sales agents represented that it was non-narcotic and was thus reimbursable by Medicare. (Doc. 1 at 4 5.) Based on that representation,

Plaintiffs allegedly purchased Stivax devices and were later audited by Medicare and 4 Defendant Biegler controverted Plain at the direction of Defendant Biegler. (Doc. 33- [Defendant Solace Advancement] in Michigan, [Defendant] Biegler has no direction or control over where or how has not been rebutted by Plaintiffs. 5 Although Paul Dryden, a resident of Florida, submitted the official paperwork to the FDA, ed on the 510(k) summary as the official contact, Defendant Biegler was specifically identified in the 510(k) summary as Defendant Biegler was the addressee un approval letter. (Doc. 1-2); see 21 C.F.R. § 807.40.

denied coverage. (Doc. 1 at 4 6, 33 37.) Had Defendant Biegler not sought FDA approval, it presumably would not have been able to sell the Stivax device in the United States. Moreover, it is the very nature of that approval the classification of the device that is the alleged fraud in this lawsuit. (Doc. 1 at 4 5.) Because approval allowed it to be sold in the United States, where the classification was allegedly

misrepresented and caused harm, Plaintiffs have sufficiently shown purposeful direction. B. Arising Out of Forum Activities

The second requirement for specific, personal jurisdiction is that the claim asserted in the litigation arises out of the defendant s forum related activities. *Panavision Int l, L.P. v. Toeppen*, 141 F.3d 1316, 1322 (9th Cir. 1998) on a but for test to determine whether a particular claim arises out of forum-related activities and thereby satisfies the second requirement for specific jurisdiction. *Ballard v. Savage*, 65 F.3d 1495, 1500 (9th Cir. 1995).

Here, as explained above, Defendant Biegler would have been unable to sell the Stivax device, through its distributors, to Plaintiffs without FDA approval. The fact that the Stivax device was allegedly classified as an electro-acupuncture device as a non-narcotic implantable pain management medical device alleged contact seeking FDA approval is a but-for cause of the harm alleged. C. Reasonableness



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

Even if the first two requirements are met, in order to satisfy the Due Process Clause, the exercise of personal jurisdiction must be reasonable. *Ziegler v. Indian River Cnty.*, 64 F.3d 470, 474-75 (9th Cir. 1995). For jurisdiction to be reasonable, it must comport with *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985). If a defendant seeks to defeat jurisdiction, he must present a compelling case that the presence of the defendant in the forum is essential to the case. *Core Vent v. Nobel Indus. AB*, 11 F.3d 1482, 1487 (9th Cir. 1993).

In addressing reasonableness, courts consider seven factors: (1) the extent of a defendant's purposeful interjection; (2) the burden on the defendant in defending in the forum; (3) the extent of conflict with the sovereignty of the defendant's state; (4) the forum state's interest in adjudicating the dispute; (5) the most efficient judicial resolution of the controversy; (6) the importance of the forum to the plaintiff's interest in convenient and effective relief; and (7) the existence of an alternative forum. , 141 F.3d at 1323. No one factor is dispositive; a court must balance all seven. *Id.* 1. Degree of Interjection

Even though the Court has concluded that Defendant Biegler purposefully directed its activities at the United States, *Harris Rutsky & Co. Ins. Servs., Inc. v. Bell & Clements Ltd.*, 328 F.3d 1122, 1132 (9th Cir. 2003). purposeful interjection, the less is jurisdiction to be anticipated and the less reasonable is *Ins. Co. of N. Am. v. Marina Salina Cruz*, 649 F.2d 1266, 1271 (9th Cir. 1981).

To obtain FDA approval, Defendant Biegler filed a Section 510(k) premarket notification of intent to market the Stivax device. 21 C.F.R. § 807.81; (Doc. 1-2.). The and address. 6

§ 807.92; (Doc. 1-2.). The FDA found that, based on the information predicate devices marketed in interstate commerce . . . or to devices that have been

reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) Biegler could sell the Stivax device in the United States. (Doc. 1-2 at 2.) Although

Defendant Biegler provided information to the FDA, it did not have to undergo extensive FDA testing or trials. Its interjection, therefore, is moderate. 6 -2 at 5.)

2. Burden on the Defendant's burden in litigating in the forum is a factor in the assessment of whether the burden is so great as to constitute a deprivation of , 141 F.3d at 1323 (quoting *Caruth* , 59 F.3d

126, 128-29 (9th Cir.1995) communication and transportation have tended to diminish the burden of defense of a

*Marina Salina Cruz*, 649 F.2d 1266, 1271 (9th Cir. 1981); *Ballard*, 65 F.3d at 1501. Defendant Biegler is headquartered in Austria and thus would have to litigate this case across international borders, and



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

potentially across language barriers, if the Court found personal jurisdiction. However, because of developments made during the COVID- 19 pandemic, modern methods of communication alleviate this burden significantly. Thus,

is so great as to constitute a deprivation of due process, it will not overcome clear *Roth v. Garcia Marquez*, 942 F.2d 617, 623 (9th Cir. 1991) (quoting *Hirsch v. Blue Cross, Blue Shield*, 800 F.2d 1474, 1481 (9th Cir. 1986)). The Court does not find this factor dispositive. 3. Sovereignty

. . depends also in part upon the seriousness of *Marina Salina Cruz*, 649 F.2d at 1272. [L]itigation against an alien defendant creates a higher jurisdictional barrier than litigation against a citizen from a sister state. *Harris Rutsky*, 328 F.3d at 1133. Although this factor is important, it is not controlling. *Id.*

Because Defendant Biegler is a foreign company, exercising jurisdiction necessarily

The United States has an interest in providing redress to individuals who are harmed by the conduct of foreign companies. That is especially true in a case like this, in which Defendant Biegler is alleged to have specifically sought permission from the FDA to sell the Stivax device to U.S. providers for the use of U.S. patients. This factor weighs in

5. Efficient Judicial Resolution *Panavision* , 141 F.3d at 132 modern advances in communication and transportation. *Harris Rutsky*, 328 F.3d at 1133

(quoting , 141 F.3d at 1323).

Plaintiffs are seeking class certification to represent not only themselves but other medical providers who purchased the Stivax device. (Doc. 1 at 46.) Class members could very well be found throughout the United States. The named Plaintiffs are from Arizona. (Doc. 1 at 7 8.) Defendant Solace Advancement is a Michigan LLC, and Defendants Titan Medical Compliance and Dr. Timothy Warren are residents of Kansas. (Doc. 1 at 8 9.) evidence and witnesses are likely in the United States. Although there may be some

evidence in Austria, Plaintiff allegation that Defendant Biegler directed its American evidence that originated with Defendant Biegler is likely now in the hands of other

Defendants in the United States. (Doc. 1 at 14, 36, 40 42.) Moreover, to the extent that there are witnesses in Austria that may need to be deposed, the Court finds that modern technology alleviates much of

6. Plaintiffs Interest in Convenient and Effective Relief *Cas. Co. v. Burns & Wilcox Ltd.*, No. CV-19-04854-PHX-DWL, 2020 WL 4039119, at



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

\*10 (D. Ariz. July 17, 2020). This factor weighs most strongly in favor of the plaintiff if

the chosen forum presents the only means of litigating a claim, or if refusing to exercise jurisdiction would force the plaintiff to pursue the case in multiple locations. Id.

If the Court found that the United States lacked jurisdiction over Defendant Biegler, Plaintiffs would likely have to prosecute two cases in two different forums: one against Defendant Biegler in Austria, if cognizable, and the other against the rest of Defendants in ver, the Court recognizes that this factor should not weigh heavily in the reasonableness analysis. Although this factor

7. Existence of Alternative Forum availability of an alternative Harris Rutsky, 328 F.3d at 1133 34. Plaintiffs have provided no such argument in this case. Although the Court assumes that Austria would provide Plaintiffs a forum in which they could pursue relief, whether the forum would be adequate is impossible to say Ballard, 65 F.3d at 1502. This factor weighs in Defendant

8. Balancing the Factors compelling case exercise of jurisdiction would violate due process. Factors 2 and 3 weigh squarely in Defendant factors 4 and 5 to

be most persuasive. Absent compelling circumstances, it would be unjust to allow a foreign defendant to avail itself of the U.S. market and regulatory scheme yet avoid U.S. laws because of the inconvenience of litigating in a foreign forum that it intentionally targeted. The rest of the Defendants are located in the United States, as is the majority of evidence and witnesses, and Plaintiffs should not have to litigate in Austria under these facts. There is therefore specific personal jurisdiction under Federal Rule of Civil Procedure 4(k)(2).

III. Dismissal for Failure to State a Claim To survive dismissal for failure to state a claim pursuant to Federal Rule of Civil se a right

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555

fact are taken as true and construed in the light most favorable to

7 Smith v. Jackson, 84 F.3d 1213, 1217 (9th Cir. 1996). However, legal conclusions couched allegations of law and unwarranted inferences are not sufficient to defeat a motion to

Pareto v. F.D.I.C., 139 F.3d 696, 699 (9th Cir. 1998).

Unlike the plausibility standard applied to other claims, fraud claims are subject to a heightened pleading standard. Federal Rule of Civil Procedure 9(b) requires that fraud be pleaded with particularity. alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. . . . Malice, intent, knowledge, and other conditions of a person may be



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

alleged g Fed. R. Civ. P. 9(b). Schreiber Distrib. Co. v.

Serv Well Furniture Co., 806 F.2d 1393, 1400 (9th Cir. 1986) (quoting Bosse v. Crowell Collier & Macmillan, 565 F.2d 602, 611 (9th Cir. 1977)). time, place, and specific content of the false representations as well as the identities of the

parties to the misrepres Id. at 1401. Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003) (quoting Cooper v. Pickett, 137 F.3d 616, 627 (9th Cir. 7

declaration when deciding its 12(b)(6) Motion without converting the Motion into one for summary judgment. Townsend v. Columbia Operations, 667 F.2d 844, 849 (9th Cir. 1982) the pleadings are considered by the court, a Rule 12(b)(6) motion considered.

Id. (quoting Decker v. GlenFed, Inc. (In re GlenFed, Inc. Sec. Litig.), 42 F.3d 1541, 1548 (9th Cir. 1994)).

A. RICO Claim Defendant Biegler failure to state a claim. (Doc. 33-1 at 10 11.) 18 U.S.C. § for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise s affairs through a pattern of racketeering activity. person injured in his

Plaintiffs allege that the Stivax caused them to pay an inflated price for the Stivax device, in violation of § 1962. (Doc. 1.)

Defendant Biegler now moves to dismiss the claim because Plaintiffs have failed to establish standing and have failed to sufficiently plead the RICO and fraud claims. (Doc. 33-1 at 10 11.)

1. Statutory Standing Defendant Biegler first argues that Plaintiffs lack standing to bring a RICO claim. (Doc. 33-1 at 10.) iness or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate Mendoza v. Zirkle Fruit Co., 301 F.3d 1163, 1168 (9th Cir. 2002) (quoting 18 U.S.C. § 1964(c) § 1964(c), a civil RICO plaintiff must show: (1) that his alleged harm qualifies as injury to

requires the plaintiff to establish proximate causation. Canyon Cnty. v. Syngenta Seeds, Inc., 519 F.3d 969, 972 (9th Cir. 2008) (quoting Holmes v. Sec. Inv. Prot. Corp., 503 U.S. 258, 268 (1992)). a. Injury that they paid more for the Stivax device than they would

have had they known it was not reimbursable by Medicare, is a cognizable injury under RICO. (Doc. 33-1 at 10.) granting standing of anything forbidden in the antitrust laws, and consequently the two have been interpreted

in tandem. Mendoza, 301 F.3d at 1168 (citation omitted) (quoting 15 U.S.C. § 15(a)).



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

The Supreme Court interpreted § 15 in *Reiter v. Sonotone Corp.*, 442 U.S. 330 (1979), 8

where it Id.

at 339. Th Id.

Here, as alleged in the Complaint, Plaintiffs relied on a misrepresentation, made by Stivax sales agents, that the Stivax device was reimbursable by Medicare. (Doc. 1.) Although Defendant Biegler is not alleged to have directly made this misrepresentation to Plaintiffs, it is alleged to have developed the Stivax Coding Scheme, in which it directed its distributors and sales agents to make this misrepresentation to American consumers. (Doc. 1 at 40 42.) Plaintiffs allege that they relied on this misrepresentation when they 37.) Thus, Plaintiffs

first element of RICO standing. 9 8 The Supreme Court refers to 15 U.S.C. § Reiter, 442 U.S. at 337. 9 To the extent Defendant Biegler argues that Plaintiffs lack Article III standing, that argument is likewise erroneous. (Doc. 33-1 at 10.) Article III standing requires a concrete, particularized, and actual or imminent injury. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Here, Plaintiffs were allegedly fraudulently induced to purchase a product for an inflated price, which caused them economic injury. (Doc. 1 at 37 38, 40.) Clearly, economic injury is sufficient to establish an Article III injury. *San Diego Cnty. Gun Rts. Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir. 1996) In re LinkedIn User Privacy Litig., 932 F. Supp. 2d 1089, 1093 94 (N.D. Cal. Mar. 6, 2013) (acknowledging that plaintiffs will have standing if they cf. *Humana Inc. v. Mallinckrodt ARD LLC*, No. CV 19-06926 DSF (MRW), 2020 WL 3041309, at \*16 (C.D. Cal. Mar. 9, 2020).

b. Causation Defendant Biegler also argues that Plaintiffs have failed to show that their injury was p - that the defendant violated §

ment in § Canyon Cnty., 519 F.3d at 981 (quoting *Holmes*, 503 U.S. at 265 66). Id.

Id. (quoting *Holmes*, 503 U.S. at 268). Plaintiffs allege that they relied on the misleading promotional material as well as the misrepresentations made by Mr. Kaiser when they decided to purchase the Stivax device. (Doc. 1 at 6, 15 18, 29.) Plaintiffs also allege that Defendant Biegler collaborated with Defendant Solace Advancement to create the misleading marketing material, and that Defendant Biegler Mr. Kaiser and Defendant Solace Advancement to market the Stivax device as reimbursable by Medicare. (Doc. 1 at 14 15; 42 43.) These actions are sufficient, if established, to satisfy both but-for and proximate causation. Had Defendant Biegler not created the misleading promotional material and controlled the misleading marketing by Defendants Solace Advancement and Mr. Kaiser, Plaintiffs would not have received either the material or the misrepresentations made by Mr. Kaiser to have relied upon. Moreover, Defendant Biegler cannot escape liability because of proximate causation merely because it is not alleged to have itself made any material misrepresentation to Plaintiffs. Because Plaintiffs as potential purchasers of the Stivax device concocted, they have



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

sufficiently established statutory standing under RICO. See *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co.*, 943 F.3d 1243 (9th Cir. 2019) (holding that patients and third-party payor could sue drug manufacturer under RICO even though the misrepresentations were made by doctors instead of

defendants); *Postpichal v. Cricket Wireless, LLC*, No. C 19 07270 WHA, 2021 WL 3403146 (N.D. Cal. Aug. 4, 2021) (holding that customers who relied on misleading marketing could sue telecommunications company under RICO despite *Humana Inc. v. Mallinckrodt*

*ARD LLC*, CV 19-06926 DSF (MRW), 2020 WL 3041309 (C.D. Cal. Mar. 9, 2020) (holding that third-party payor could sue drug manufacturer under RICO despite do intervening, illegal conduct).

2. Racketeering Activity Defendant Biegler next argues that Plaintiffs have failed to allege with sufficient particularity that Defendant Biegler engaged in racketeering activity. (Doc. 33-1 at 11.) A RICO violat *Howard v. Am. Online Inc.*, 208 F.3d 741, 746 (9th

Cir. 2000) (quoting *Sedima S.P.R.L. v. Imrex Corp.*, 473 U.S. 479, 496 (1985)). , wire fraud, and interstate transport of stolen property. 18 U.S.C. § 1961(1) (citing §§ 1341, 1343, 2314); (Doc. 1 at 50.)

raud must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007) (quoting *Bly Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)). here is no absolute

requirement that where several defendants are sued in connection with an alleged fraudulent scheme, the complaint must identify false statements made by each and every defendant *Id.* On the other hand, Rule 9(b) does not allow a complaint to merely lump multiple defendants together but require[s] plaintiffs to differentiate their allegations when suing more than one defendant . . . and inform each defendant separately of the allegations surrounding his alleged participation in the fraud. *Id.* (quoting *Haskin v. R.J. Reynolds Tobacco Co.*, 995 F. Supp. 1437, 1439 (M.D. Fla. 1998)) In the context of a fraud suit

involving multiple defendants, a plaintiff must, at a minimum, identify] the role of [each] defendant[ ] in the alleged fraudulent scheme. *Id.* (quoting *Moore v. Kayport Package Express, Inc.*, 885 F.2d 531, 541 (9th Cir.1989)).

Plaintiffs are not required to show that each RICO defendant including [Defendant Biegler] personally committed at least two acts of mail or wire fraud to establish a pattern of racketeering. In re *JUUL Labs, Inc., Mktg., Sales Pracs., & Prod. Liab. Litig.*, 533 F. Supp. 3d 858, 871 (N.D. Cal. 2021). Instead, they need only demonstrate that Defendant was (1) a knowing participant in a scheme to defraud, (2) that [Defendant Biegler] participated in the scheme with the intent to defraud, and (3)



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

that a co-schemer's acts of mail and wire fraud occurred during participation in the scheme and were within the scope of the scheme. *In re Volkswagen Clean Diesel Mktg., Sales Pracs., & Prod. Liab. Litig.*, No. MDL 2672 CRB (JSC), 2017 WL 4890594, at \*13 (N.D. Cal. Oct. 30, 2017).

a. Co- Plaintiffs allege that Defendants committed a pattern of mail and wire fraud, which underlies the RICO claim. (Doc. 1 at 50.) The elements of mail fraud and wire fraud are (1) a scheme to defraud, (2) the use of the mails or wires to further that scheme, and (3) the specific intent to defraud. *In re JUUL Labs*, 497 F. Supp. 3d at 595.

As to Defendant Biegler specifically, Plaintiffs allege that Defendant Biegler developed promotional material that misrepresented that the Stivax device was an implantable medical device used by doctors instead of an electro-acupuncture device used by acupuncturists. (Doc. 1 at 14 16, 39 42.) It then allegedly provided this material to its distributors and agents. (Doc. 1 at 39 42.) Mr. Kaiser is alleged to have forwarded that promotional material to Plaintiffs by email. (Doc. 1 at 17 18.) Plaintiffs also generally allege,

Defendants invested substantial sums in advertising and marketing the Stivax device throughout the United States as a reimbursable non-narcotic implantable medical device rather than an electro-acupuncture device that is not reimbursable by Medicare on websites, at trade shows, in brochures,

in newsletters, in videos, on teleconferences and phone calls, and in on-site presentations at physician offices and ambulatory surgery centers. (Doc. 1 at 3 4.) In reliance on these misrepresentations, Plaintiffs purchased Stivax devices by filling out ord distributors, who then mailed the device to fulfill the orders. (Doc. 1 at 29 30.) These

allegations are sufficient to plead a pattern of Defendants consistently using the mail or wires to perpetuate their fraud for purposes of RICO. Because the alleged scope of the scheme specifically contemplated the misrepresentation of the Stivax device, and because Defendant Biegler is alleged to have specifically participated in the marketing and sale of the device, (Doc. 1 at 2 6, 14, 39 42), Plaintiffs have sufficiently stated the first element of holding Defendant Biegler liable for the fraud of other Defendants. b. Knowing Participant and Intent to Defraud Plaintiffs have sufficiently alleged Defendant Biegler was a knowing participant in a scheme to defraud. Defendant Biegler was allegedly aware that the Centers for Medicare - not reimbursable by Medicare. (Doc. 1 at 12); (Doc. 1-6 at 30.) 10

Even though the FDA found that the Stivax device as - at 13), Defendant Biegler nevertheless device, through its distributors and sales agents, as Medicare-reimbursable. (Doc. 1 at 14,

17, 22 23, 39 43.) These allegations sufficiently state that (1) Defendant Biegler knew or reasonably would have known that the Stivax device was not reimbursable, and (2) despite this knowledge,



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

Defendant Biegler nevertheless marketed the device otherwise. (Doc. 1 at 14, 39 43.) Moreover, as described above, Defendant Biegler allegedly developed misleading promotional materials, including that 10 [E]vidence outside the pleadings . . . cannot normally be considered in deciding a *Cervantes v. City of San Diego* court may, however, consider certain materials documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003); see Fed. R. Civ. P. 12(d). Complaint (Doc. 1) cites and references several exhibits attached to the Complaint. The Court considers these in full.

contain[ed] the same misinformation, concealment, and misrepresentations about the (Doc. 1 at 13, 22 23, 28, 40 42.) Plaintiffs have adequately alleged that despite Defendant non-reimbursability, it nevertheless instructed its sales

agents to lie about or conceal that fact. This is sufficient to plead knowing participation in a scheme to defraud.

Plaintiffs have also adequately alleged intent to defraud. U constituting fraud or mistake[,] [m]alice, intent, knowledge, and other conditions of a

person s mind may be alleged generally. As explained above, Plaintiffs have alleged that Defendant Biegler knew that the Stivax device was not reimbursable but marketed it as reimbursable. These allegations sufficiently state both knowledge and intent to defraud at the pleading stage. Because Plaintiffs have sufficiently alleged that Defendant Biegler was a knowing participant in a scheme to defraud and actually intended to defraud, Defendant Biegler is at this point an appropriate defendant for the mail and wire fraud of its alleged co-conspirators. See *In re JUUL Labs*, 497 F. Supp. 3d at 595; *United States v. Stapleton*, 293 F.3d 1111, 1117 (9th Cir. 2002). B. RICO Conspiracy Defendant Biegler also argues that Plaintiffs fail to state a claim for RICO conspiracy. (Doc. 33-1 at 12.) 18 U.S.C. § 1962(d) makes it unlawful for any person conduct or participate, directly or indirectly, in the conduct of such enterprise s affairs through a pattern of racketeering activity 1962(c) (d). To be liable for a RICO conspiracy, the *Baumer v. Pacht*, 8 F.3d 1341,

1346 (9th Cir. 1993) (quoting *United States v. Neapolitan*, 791 F.2d 489, 499 (7th Cir. 1986)). personally committed at *In re JUUL Labs, Inc.*,

533 F. Supp. 3d at 871 72. In addition to the two agreements, conspiracy to violate RICO requires a showing that defendant was aware of the essential nature and scope of the enterprise and intended to participate in it. *Baumer*, 8 F.3d at 1346 (quoting *United States v. Muskovsky*, 863 F.2d 1319, 1324 (7th Cir. 1988)). express as long as its existence can be inferred from the words, actions, or interdependence

*Oki Semiconductor Co. v. Wells Fargo Bank, Nat. Ass n*, 298 F.3d 768, 775 (9th Cir. 2002) s Biegler and Solace Advancement



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

This material is alleged to have contained misrepresentations. (Doc. 1 at 17-18.) Plaintiffs also allege that Defendant Biegler required Defendant Solace Advancement, who maintained the Stivax website, to provide website, both of which contained misrepresentations about the Stivax device. (Doc. 1 at 41.) As explained above, the Complaint sufficiently alleges that Defendant Biegler knew or reasonably would have known that the Stivax device was not reimbursable by Medicare and was to be used by acupuncturists, not by doctors as a medical pain management device. But it nevertheless created promotional materials that allegedly misrepresented that fact. Defendant Biegler thus is alleged to have had knowledge that the promotional material it was producing, in collaboration with Defendant Solace Advancement, was fraudulent, or at least misleading. By allegedly working with Defendant Solace Advancement to misrepresent the Stivax device, with knowledge that Defendant Solace Advancement would use the promotional materials to conduct a misleading marketing campaign in the United States, Defendant Biegler would have agreed that Defendant Solace Advancement should commit fraud.

Biegler and Biegler as a sales agent and made misrepresentations in that capacity, allegedly at the direction of Defendant Biegler. (Doc. 1 at 15, 26, 38-42.) As alleged, therefore, Defendant, (Doc. 33-1 at 13), but rather affirmatively collaborated with co-conspirators to commit fraud, which is sufficient to plead a RICO conspiracy. *Reves v. Ernst & Young*, 507 U.S. 170 In order to participate, directly or indirectly, in the conduct of such enterprise's affairs, one must have some part in directing those affairs. . . . [O]ne must participate in the operation or management of the enterprise itself. C. State Tort Claims -law claims are barred by the economic loss doctrine. (Doc. 33-1 at 16.) It also alleges that the Complaint fails to meet the heightened pleading standard required to plead state-law fraud claims. (Doc. 33-1 at 15.) 1. Economic Loss Doctrine

The economic loss doctrine unless a *All., Inc.*, 223 Ariz. 320, 323, 223 P.3d 664, 667 (2010) (quoting *Carstens v. City of*

*Phoenix*, 206 Ariz. 123, 125, 75 P.3d 1081, 1083 (Ct. App. 2003)). The doctrine limit[s] a contracting party to contractual remedies for the recovery of economic losses unaccompanied by physical injury to persons or other property *Id.* Arizona courts generally apply the doctrine in product liability and construction defect cases, *Arimilli v. Rezendes*, No. CV-21-00345-PHX-GMS, 2021 WL 3406332, at \*4 (D. Ariz. Aug. 4, 2021), but the Arizona Supreme Court has not determined whether the doctrine bars fraud claims. *Jes Solar Co. v. Matinee Energy, Inc.*, No. CV 12-626 TUC DCB, 2015 WL 10943562, at \*4 (D. Ariz. Nov. 2, 2015). s highest court has not decided an issue, the *Ticknor v. Choice Hotels Intern., Inc.*, 265 F.3d 931, 939 (9th Cir. 2001). [A]bsent controlling

authority, federal courts look to existing state law but refrain from predicting potential changes in that law. *Barrett-Jackson Auction Co. v. Mountain Sports Int'l Inc.*, No. CV-20-00892-PHX-SRB, 2020 WL 9349176, at \*3 (D. Ariz. Sept. 9, 2020) (quoting *Ticknor*, 265 F.3d at 939).

Two Arizona Court of Appeals cases have addressed the applicability of the economic loss doctrine



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

in fraud cases. In *Cook v. Orkin Exterminating Co.*, 227 Ariz. 331, 258 P.3d 149 (Ct. App. 2011), the Court of Appeals held that the economic loss doctrine, which included claims for fraud and misrepresentation. *Cook*, 227 Ariz. at 335, 258 P.3d at 153. However, as noted by the Court of Appeals in the second case, *Shaw v. CTVT Motors, Inc.*, 232 Ariz. 30, 300 P.3d 907 (Ct. App. 2013), *Cook* not explicitly address the viability of a claim for fraudulent inducement under the economic

loss rule. The facts of that case, contractual remedies were sufficient. *Shaw*, 232 Ariz. at 32, 300 P.3d at 909. Notably, the *Shaw* court expressed about applying the economic loss rule . . . to any claim of fraud in the inducement because the economic loss economic relationships and to uphold the expectations. *Id.* at 33 n.4, 300 P.3d at 910

n.4 (quoting *Flagstaff*, 223 Ariz. at 327, 223 P.3d at 671). Federal courts have found similarly, holding that the economic loss doctrine should not apply to claims for fraudulent inducement because doing so would not further the policy behind the doctrine. See *Barrett-Jackson*, 2020 WL 9349176, at \*4 (collecting cases).

This Court agrees with the reasoning in *Barrett-Jackson* and *Shaw* that the public policy behind the economic loss doctrine is not furthered when the underlying contract is procured by fraud, like it is alleged to be in this case. If the primary function of the doctrine is to encourage private ordering of economic relationships and to uphold the expectations of the parties, then certainly it would seem inapposite to hold innocent parties to limited contractual remedies when those contractual remedies were based on intentional misrepresentations made by the other party. *Id.* at \*3 (quoting *Flagstaff*, 223 Ariz. at 327,

223 P.3d at [], case- rather than using it as a categorical bar the Court will not apply it to the facts of this case. *Flagstaff*, 223 Ariz. at 323-24, 223 P.3d at 667-68. **2. Fraudulent Misrepresentation** Defendant Biegler next argues that Plaintiffs have failed to state a claim for fraudulent misrepresentation and fraudulent concealment. (Doc. 33-1 at 15.) To make a claim for fraudulent misrepresentation, a plaintiff must show (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) the speaker's intent that it be acted upon by the recipient in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) the listener's reliance on its truth; (8) the right to rely on it; and (9) his consequent and proximate injury. *Wells Fargo Credit Corp. v. Smith*, 166 Ariz. 489, 494, 803 P.2d 900, 905 (Ct. App. 1990). In contrast, Arizona also recognizes the tort of fraudulent concealment. One party to a transaction who by concealment or other action intentionally prevents the other from acquiring material information is subject to the same liability to the other, for pecuniary loss as though he had stated the nonexistence of the matter that the other was thus prevented from discovering. *Wells Fargo Bank v. Ariz. Laborers, Teamsters & Cement Masons Loc. No. 395 Pension Tr. Fund*, 201 Ariz. 474, 496, 38 P.3d 12, 34 (2002). Where failure to disclose a material fact is calculated to induce a false belief, the distinction between concealment and affirmative misrepresentation is tenuous. *Id.* (quoting *Schock v. Jacka*, 105 Ariz. 131, 133, 460 P.2d 185, 187 (1969)). even unknown, committed in



## Munderloh et al v. Biegler GmbH et al

2022 | Cited 0 times | D. Arizona | March 28, 2022

furtherance of the conspiracy, including acts not personally committed. Baker ex rel. Hall Brake Supply, Inc. v. Stewart Title & Tr. of Phx., Inc., 197 Ariz. 535, 542, 5 P.3d 249, 256 (Ct. App. 2000).

Vess, 317 F.3d at 1106. Between 2016 and 2019, Defendant Biegler allegedly conspired with Defendant Solace Advancement to

fraudulently market the Stivax device in the United States as reimbursable by Medicare. (Doc. 1 at 14, 17, 22 23, 39 40, 43.) Although Defendant Biegler itself may not have made the fraudulent statements directly to Plaintiffs, the alleged agreement with Defendant Solace Advancement (and other defendants) to fraudulently induce sales of Stivax devices would demonstrate that Defendant Biegler may be held liable for Mr. Kaiser and other sales a 11

as to the misrepresentation and concealment claims. 3. Civil Conspiracy Defendant Biegler finally argues that Plaintiffs have failed to plead a claim for civil conspiracy. (Doc. 33-1 at 15 civil conspiracy to occur[,] two or more persons must agree to accomplish an unlawful purpose or to accomplish a lawful object by unlawful Rowland v. Union Hills Country Club, 157 Ariz. 301, 306, 757 P.2d 105, 110 (Ct. App. 1988). Here, Defendant Biegler is alleged to have intended to accomplish a lawful object sale of the Stivax device by fraud, an unlawful means. As explained above, Plaintiffs adequately alleged that Defendant Biegler directed its distributors and sales agents to market the Stivax device as reimbursable by Medicare. See supra Part III.A.2, III.B, III.C.2. conspiracy claim is denied.

CONCLUSION The Court has personal jurisdiction over Defendant Biegler under Rule 4(k)(2) 11 As noted by the Arizona Supreme Court, the distinction between fraudulent concealment and fraudulent misrepresentation in this case is tenuous. Schock, 105 Ariz. at 133, 460 P.2d at 187. Mr. should be used to receive reimbursement; in much the same way, through those statements, Mr. Kaiser actively concealed that the Stivax device was not actually reimbursable by Medicare. Moreover, the promotional material affirmatively represented that the Stivax device was usable by doctors while also concealing the fact that it was intended for use by acupuncturists. Regardless ,

because it sought and received approval from the FDA to market the Stivax device in the United States and engaged a U.S. distributor to so market. Defendant Biegler cannot avail itself of the U.S. market and regulatory scheme without subjecting itself courts. Moreover, Plaintiffs have adequately pleaded claims under RICO and Arizona law.

All motions are denied. IT IS HEREBY ORDERED Under Rules 12(b)(2) and 12(b)(6) (Doc. 33) is DENIED.

IT IS FURTHER ORDERED (Doc. 45) is DENIED as moot.

Dated this 28th day of March, 2022.

