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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* BROOKS WALLACE, ROBERT FARLEY and MANUEL FUENTES, *et al.*,	)	
Plaintiffs,	)	2:18-cv-01010-LSC
vs.	)	
EXACTECH, INC.,	)	
Defendant.	)	

MEMORANDUM OF OPINION

This is a *qui tam* action brought by Relators on behalf of the United States, 23 states, and themselves against Defendant Exactech, Inc. ("Exactech"), a medical device manufacturer. Relators accuse Exactech of violating and conspiring to violate the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and corresponding state FCAs by knowingly causing false claims to be submitted to federal and state healthcare programs for defective replacement knee devices surgically implanted by unsuspecting physicians and by using false statements material to those claims. Relators also allege that Exactech violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and the FCA by paying remuneration to physicians who suspected the defects in order to induce them to continue to buy Exactech products.

Before this Court is Exactech's Motion to Dismiss Relators' Amended Complaint. (Doc. 57.) The motion has been fully briefed and is now ripe for review. For the reasons stated below, Exactech's motion is due to be granted in part and denied in part.

I. BACKGROUND[1]

A. Factual Background

Exactech manufactures the Optetrak Total Knee Replacement ("TKR") system for use during knee replacement surgeries. The Optetrak TKR system involves implanting into the patient a "tibia tray," a component which is anchored to the patient's tibia and connects to the mechanical knee. A patient's first TKR surgery is called a Primary Knee Replacement or "Primary TKR." If such a patient experiences a problem with the Primary TKR device or procedure, the patient may be required to undergo a revision surgery called a "Revision TKR," which is more complex and involves a larger, heavier implant. One reason a Primary TKR device fails and requires a revision surgery is when the metal device inserted into the patient's tibia becomes loose and begins to wobble, known as "tibial loosening," causing pain and immobility. Until 2011, Exactech had only two options for tibia

[1] In evaluating a motion to dismiss, this Court "accept[s] the allegations in the complaint as true and construe[s] the facts in the light most favorable to the plaintiff." *Lanfear v. Home Depot, Inc.*, 679 F.3d 1267, 1275 (11th Cir. 2012). Therefore, the following facts are taken from Relators' Amended Complaint, and the Court makes no ruling on their veracity.

trays within their Opetrack product line: (1) the allegedly defective Finned Tibia Tray, used in Primary TKRs, and (2) the "Trapezoid" Tray, used in the revision system.

Relators Brooks Wallace ("Wallace") and Robert Farley ("Farley") became Exactech sales representatives in August 2011 and 2012, respectively. Relator Manuel Fuentes ("Fuentes") is a physician who was employed by Exactech from 2006 to 2011. Wallace and Farley marketed and sold the Finned Tibia Tray to multiple physicians and hospitals in Alabama and Northwest Florida, including Dr. James Floyd ("Dr. Floyd") and Dr. David Lemak ("Dr. Lemak") in Birmingham. Fuentes was involved in Exactech's internal investigation, described in further detail below, into potential causes of the Finned Tibia Tray's tibial loosening problems.

1. Exactech's Knowledge of Problems with the Finned Tibia Tray

No later than 2008, Exactech learned that the Finned Tibia Tray failed in approximately 30–35% of patients within the first three years of implantation. This failure rate is ten times the failure rate of comparable knee replacement devices and six times the failure rate at which a device should be voluntarily recalled. The Finned Tibia Tray failures involved tibial loosening, causing pain and immobility and necessitating a Revision TKR to remedy the failure. In 2007 and early 2008, Exactech learned that the Finned Tibia Tray failed at "alarming" rates, including

failures for 51 specific patients of Dr. Wayne Moody, an orthopedic surgeon in Auburn, Maine; 35 specific patients of Dr. Chris Hutchins, an orthopedic surgeon in New Haven, Connecticut; and numerous patients of surgeons in Florida and Georgia. Dr. Moody and Exactech Distributor Timothy O'Neill ("O'Neill") made a detailed presentation to Exactech regarding the device failures, and Exactech assured them that it would put together a "committee" to address them. Exactech also told them that Dr. Moody was the only surgeon from whom it was hearing of these device failures and that the problem was not with the Finned Tibia Tray but instead with one of Dr. Moody's surgical techniques. According to Relators, these statements to O'Neill and Dr. Moody were false because Exactech had already received reports from other physicians about tibial loosenings due to defective Finned Tibia Trays that required revision surgeries.

2. Exactech's Investigation and Alleged Cover Up

After receiving reports about the Finned Tibia Tray failures, Exactech hired Dr. Ivan Gradisar to audit patient outcomes and develop a better understanding of the tibial loosening problem. Dr. Gradisar reviewed patients from an Ohio hospital who had received a revision knee replacement surgery over a seventeen-month period and a fifteen-month period between 2004 and 2008. Dr. Gradisar was one of the primary designers of the Optetrack TKR and, as a result, he was viewed as a

"friend of the company" and also received significant income through royalties on Optetrack TKR sales. (Doc. 54 ¶ 73.) Relators allege that Exactech and Dr. Gradisar conspired to manipulate the outcome of the audit, minimize the extent of the known device failures, and "protect the company." (*Id.*) They further allege numerous flaws in Dr. Gradisar's audit methods and conclusions that were designed to manipulate the outcome, many details of which are not relevant to the Court's decision. Notwithstanding the alleged attempts to manipulate the outcome, Dr. Gradisar's audit stated that, out of 47 patients who received a TKR revision surgery between January 1, 2007, and March 31, 2008, 24 required revision due to tibial loosening from a failed Finned Tibia Tray implant. Relators describe this ratio—more than 50%—as "well outside the industry norm." (*Id.* ¶¶ 75, 79.) The audit further stated Dr. Gradisar's belief that there were "multiple" causes of the device failures, including the improper "cement technique" of the implanting surgeons. (*See id.* ¶ 77.) Relators allege that Dr. Gradisar's audit and report triggered an FDA reporting requirement regarding the device failures identified therein; however, Exactech did not submit such a report.

As a result of the reports of device failures, revision surgeries, and Dr. Gradisar's audit, Exactech conducted an internal investigation into the loosening problem, where its engineers identified several design engineering and

manufacturing flaws they believed contributed to the failures, all of which were introduced around mid-2006.[2] Exactech determined that these numerous defects created a "perfect storm" of issues, each contributing to the mounting device failures and necessitating revision surgeries. (*See* doc. 54 ¶ 88.) According to Relators, Exactech eventually stopped the investigation, replaced the device, and tried to cover up the problems. Relator Fuentes personally attended Exactech's investigatory committee meetings. During one meeting attended by "leading engineers, product managers and executives within Exactech," Exactech's Director of Marketing proposed that Exactech issue a recall, pull the Finned Tibia Tray inventory from the market, and replace it with the Revision TKR's "Trap Tray." (*Id.* ¶¶ 90–91.) Exactech's CFO responded that recalling the Finned Tibia Tray was not an option because it would be too financially detrimental, explaining that Exactech was "drowning in [Finned Tibia Tray] inventory" and the company could not afford to absorb the inventory cost. (*Id.* ¶ 92.) Additionally, the CFO's position

[2] The first of these flaws was a production process failure relating to Exactech's implementation of a new sizing tool that Relators allege violated federal "Current Good Manufacturing Practice" regulations ("cGMPs"). According to Relators, Exactech's previous sizer accurately measured patients' bones, while the post-2006 sizer did not, resulting in widespread tibial loosenings. Next, Relators allege that a change in the coating material used to cover the exterior of the Finned Tibia Tray also contributed to the mounting device failures and violated cGMPs. While the exterior of early Finned Tibia Trays was made "gritty" through a "sand-blasting" process, the post-2006 devices had a "shiny, polished, finish," contributing to loosening. (*See* Doc. 54 ¶ 84.) Exactech also identified a manufacturing defect which caused the device's forgings to be improperly shaped and a design defect relating to the device's "nose," both of which contributed to the loosenings. (*See id.* ¶ 86–87.)

was that "if Exactech adhered to its legal and ethical obligations and disclosed" the device failures, "the financial damage to [Exactech] would be too great and thus disclosure of any kind was not a viable financial option." (*Id.*) Exactech's Vice President of Regulatory and Clinical did not object to this plan. The Vice President further cautioned that, because the FDA requires each revision that may have been caused by the Finned Tibia Tray be reported, following these reporting requirements would suggest a device defect. Exactech decided not to issue a recall of the Finned Tibia Tray nor to disclose any problems related to the device to the FDA, Centers for Medicare or Medicaid, its surgeon customers, their patients, or the Department of Justice.

According to Relators, Exactech "sequestered" all information related to hundreds of device failures in order to hide them from physicians and patients and to avoid federal reporting obligations. Surgeons who were experienced with the device and gained independent knowledge of its defects, however, refused to purchase and implant it. And so, Exactech provided certain surgeons who experienced device failures with a different device and with consulting agreements in order to induce them to continue to use Exactech's products.

Thereafter, Relators say that Exactech falsely informed unsuspecting distributors and surgeons who lacked actual knowledge of the Finned Tibia Tray's

defects that the device was an industry leader in its survival rate. This representation was made even though Exactech knew that the failure rate was actually ten times the industry standard and six times the rate at which orthopedic devices should be voluntarily recalled. Exactech made and used numerous marketing materials, including the "Optetrak-A Comprehensive Knee System Main Brochure," that falsely touted the Finned Tibia Tray's survival rates. According to Relators, the marketing materials propounding the false survival rates relied upon studies that were outdated, unreliable, and related to a completely different device. *Id.*[3]

Through its marketing materials and through its employees Bob Purcell and Dave Petty, Exactech presented this false survival rate data to Relators Wallace and Farley and to Dr. Lemak and other unsuspecting orthopedic surgeons. Relators allege that, by selling a device based on false survival rate data and marketing materials, Exactech sold a device that was misbranded and, therefore, the charges were not payable by federal and state healthcare programs.

[3] Exactech represented that the Exactech Optetrak system has a survival rate of 99% at five years. This survival rate was based on a study by Dr. Raymond P. Robinson. This study, however, focused exclusively on the survival rate of the Exactech Optetrak Trapezoid Tibial Tray, a different (and functional) device. Exactech used the results of Dr. Robinson's study to claim that the entire Optetrak system had a 99% survival rate, even though no patient in the study received a Finned Tibia Tray. Exactech further represented that the Optetrak system has a 98.6% survival rate at 8.5 years. The 98.6% figure is based on an unpublished, non-peer-reviewed presentation by Dr. Gradisar, which was made in 2004 and thus surveyed pre-2006 devices, rather than the post-2006 Finned Tibia Tray.

3. Submission of False Claims

Relators allege that Exactech directly submitted false claims for Finned Tibia Trays to the Veterans Administration. Relators provide details for two Finned Tibia Trays that were sold to the VA under a "Firm Fixed Price Federal Contract Award." These details include the delivery order number, the amount the Government paid for the device, and the date on which it paid.

Relators additionally allege that (1) Exactech caused Dr. Lemak to submit at least 32 false claims to Medicare for Finned Tibia Tray implants, and that (2) Exactech caused Dr. Floyd to submit at least four false claims to Medicaid for Finned Tibia Tray implants. In 2012, Dr. Lemak performed 32 knee operations on Medicare patients at Trinity Hospital in Birmingham in which he implanted an Optetrak Finned Tibia Tray. Relator Wallace personally witnessed Dr. Lemak implant the Finned Tibia Tray for each operation. Subsequently, the hospital's billing department sent a claim to Medicare for each device. In 2013, Dr. Lemak performed 36 knee operations on Medicare patients in which he implanted an Optetrak Finned Tibia Tray. Subsequently, the billing department sent a claim to Medicare for each device. Each claim certified that it complied with all applicable Medicare and/or Medicaid laws and regulations, including the Anti-Kickback Statute.

In 2012, Dr. Floyd implanted numerous Finned Tibia Trays into Medicaid-insured patients at Cooper Green Mercy Hospital in Birmingham and then submitted claims for payment to Medicaid. Relators provide details for four of such claims, including the date of the surgery, the serial number of the Finned Tibia Tray, and the cost of the device to the Medicaid program. Relators also allege that the price of the device was specifically negotiated to allow for its purchase by the Medicaid program. Additionally, several of the patients implanted by Dr. Lemak at Trinity Hospital were also insured by Medicaid.

Each month, Relator Wallace sent Purchase Order Numbers, which corresponded to all Exactech component surgeries that had been performed and billed to Government healthcare programs the previous month, along with corresponding patient information, to Brittany Dinatelo, an Exactech employee. Relators also allege that Exactech negotiated pricing agreements with specific hospitals for which the Government reimbursement rate is a "well-known and primary factor" in determining the cost of Exactech's devices to these hospitals. (*See* doc. 54 ¶¶ 135–36). Further, Exactech was "acutely aware of federal health care program involvement in the purchasing and regulation of medical devices." (*Id.* ¶ 135). Finally, Exactech's accounting department—including employee Chris

Font—has records designating each Exactech device that was paid for by particular Government health care programs.

4. Kickbacks to Dr. Lemak

In 2014, Dr. Lemak saw multiple patients with tibial loosening problems following their Primary TKRs with the Finned Tibia Tray. By late 2017, Dr. Lemak had to perform 55 revision surgeries on patients who had been implanted with the Finned Tibia Tray. At various points spanning from 2014 through 2017, Dr. Lemak expressed to Exactech his dissatisfaction with the extent of the tibial loosenings and his concern that there was a problem with the Finned Tibia Tray. At one point, Dr. Lemak expressed that he was likely going to change devices. After Dr. Lemak had made clear his dissatisfaction with the Finned Tibia Tray and told Exactech that he was likely going to change devices, Exactech offered Dr. Lemak a "sham" consulting agreement in its "Sports Medicine Division," a division that did not even exist.[4] Specific Exactech employees, including Cary Christensen ("Christensen"), Exactech's Vice President of Sales for the Southeast region, were responsible for coordinating and providing Dr. Lemak with these agreements and payments. On

[4] Relators list 17 additional surgeons who Exactech alleges were provided illegal remuneration in the form of consulting agreements, but as Exactech correctly points out in its Motion to Dismiss, Relators provide no details with respect to these surgeons regarding the consulting agreements, the remuneration Exactech allegedly offered them, or that any of these surgeons submitted a single claim to the government as a result of these alleged consulting agreements. (*See* Doc. 54 ¶ 191.)

May 23, 2016, Relator Wallace forwarded Christensen a text from Dr. Lemak in which Dr. Lemak expressed his continued disappointment with the Finned Tibia Tray and the lack of meaningful response from Exactech. Christensen responded to Relator Wallace that she "had a long talk with Thien," an Exactech employee who facilitated consulting payments to Dr. Lemak, and that it was time to get Dr. Lemak "REALLY . . . involved with sports side." (*See* doc. 54 ¶ 198.) On October 10, 2016, Relator Wallace texted Christensen asking how to fill out Dr. Lemak's timesheet for payment under the consulting agreement, adding that Dr. Lemak "was complaining about tibial loosenings again this am. So wanted to stay on top of that for him." (*See id.* ¶ 199.) According to Relators, this message illustrates the connection between the tibial loosenings, which was the reason Dr. Lemak had threatened to change prosthesis, and the consulting payments. (*See id.*) Relators also describe the services performed by Dr. Lemak pursuant to the consulting agreement, explaining:

> Dr. Lemak met twice with Exactech representatives and talked about sports medicine generally for a few hours and was paid several hundred dollars per hour for doing so. No products were developed and no meaningful discussions that could lead to product development ever materialized. Dr. Lemak reported to Relator Wallace that the conversations were pointless.

(*See id.* ¶ 200.) Further, Exactech allegedly paid Dr. Lemak $5,400 in consulting fees in 2016. Additionally, Relators provide examples of twelve Medicare patients who received Exactech TKR devices at Grandview Hospital in Birmingham, where Dr.

Lemak began working in 2015, after Exactech paid remuneration to Dr. Lemak and for whom claims were then submitted to the Medicare program. Relators allege that Dr. Lemak was not offered a consulting agreement by Exactech prior to his threats to stop purchasing Exactech's devices, and that his consulting agreement was "swiftly terminated" after he stopped purchasing Exactech's devices. (*See id.* ¶ 195.)

B. Procedural Background

On December 20, 2019, Exactech filed its first Motion to Dismiss Relators' Complaint (doc. 37), arguing that Relators had failed to state a claim against him under Federal Rules of Civil Procedure 9(b) and 12(b)(6). In a Memorandum of Opinion (doc. 49), Judge Annemarie Axon *sua sponte* found that Relators' Complaint constituted an impermissible shotgun pleading. The Court reasoned that the first paragraph of each count incorporated by reference all preceding paragraphs of the Complaint and that the Complaint included a variety of irrelevant information which was improper to include. The Court then granted Relators leave to amend their Complaint in conformity with Federal Rules of Civil Procedure 8(a)(2), 9(b), and 10(b). On March 2, 2020, Relators filed their Amended Complaint (doc. 54), which sought to correct the deficiencies. Exactech responded with another Motion to Dismiss (doc. 57), now under consideration.

II. STANDARD OF REVIEW

A pleading that states a claim for relief must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, the facts alleged in the complaint must be specific enough that the claim raised is "plausible." *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.") A claim for relief is plausible on its face when the complaint's "factual content . . . allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Resnick v. AvMed, Inc.*, 693 F.3d 1317, 1325 (11th Cir. 2012) (quoting *Iqbal*, 556 U.S. at 678). Conclusory statements of law may "provide the framework of a complaint," but the plaintiff is required to support them with "factual allegations." *Iqbal*, 556 U.S. at 679.

The process for evaluating the sufficiency of a complaint has two steps. This Court "begin[s] by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* Conclusory statements and recitations of a claim's elements are thus disregarded for purposes of determining whether a plaintiff is entitled to survive a motion to dismiss. *Id.* at 678. Next, this Court "assume[s] [the] veracity" of "well-pleaded factual allegations"

and "determine[s] whether they plausibly give rise to an entitlement to relief." *Id.* at 679. A complaint's factual matter need not be detailed, but it "must . . . raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

In reviewing the complaint, this Court "draw[s] on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. Nonetheless, "[a] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of [the facts alleged] is improbable." *Twombly*, 550 U.S. at 556. This Court considers only "the face of the complaint and attachments thereto" in order to determine whether a plaintiff states a claim for relief. *Starship Enters. of Atlanta, Inc. v. Coweta Cty.*, 708 F.3d 1243, 1252 n.13 (11th Cir. 2013). Generally, the complaint should include "enough information regarding the material elements of a cause of action to support recovery under some 'viable legal theory.'" *Am. Fed'n of Labor & Cong. of Indus. Orgs v. City of Miami*, 637 F.3d 1178, 1186 (11th Cir. 2011) (quoting *Roe v. Aware Woman Ctr. for Choice, Inc.*, 253 F.3d 678, 683–84 (11th Cir. 2001)).

In addition to the standard discussed above, Rule 9(b) applies to claims brought under the False Claims Act. *See United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308–09 (11th Cir. 2002). Rule 9(b) provides that for a claim "alleging fraud or mistake, a party must state with particularity the

circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The particularity required by the rule is satisfied when the complaint sets forth:

> (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

Ziemba v. Cascade Int'l Inc., 256 F.3d 1194, 1202 (11th Cir. 2001) (quotation omitted). "Rule 9(b) must not be read to abrogate rule 8, however, and a court considering a motion to dismiss for failure to plead fraud with particularity should always be careful to harmonize the directives of rule 9(b) with the broader policy of notice pleading." *Friedlander v. Nims*, 755 F.2d 810, 813 n.3 (11th Cir. 1985), *abrogated on other grounds by Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) (en banc).

III. DISCUSSION

Exactech argues that the Amended Complaint is an impermissible shotgun pleading that should be dismissed with prejudice since Relators have already once failed to cure the complaint's deficiencies. Additionally, Exactech argues that Relators have failed to state a claim under Rule 9(b) and Rule 12(b)(6).

First, the Court will address Relators' concession that their claims under the state FCAs fail to state a claim upon which relief can be granted. The Amended Complaint contains no allegations that any false claims were presented to any State Medicaid or other state programs. In fact, factual allegations of any kind relating to any named state are scarce, and finding such allegations requires the reader to sift through the entire 91-page Amended Complaint. In their response brief, Relators "acknowledge that, although they are confident in their allegations that Exactech is well-aware that it has marketed and sold defective knee devices paid for by these state Medicaid programs, resulting in false claims," they are "**not themselves in position to identify the specific state Medicaid patients who have been harmed** (other than those specific Alabama Medicaid claims described herein). **If that inability means that the Court is inclined to dismiss Relators' state FCA claims at this stage, so be it**." (Doc. 61 at 56 n.21 (emphasis added).) Additionally, Relators state that if they "gain . . . information in discovery regarding Exactech's violation of state FCAs, they will petition the court for leave to re-file those claims." (*Id.*) Accordingly, the Court finds that Counts VII–XXIX of Relators' Amended Complaint are due to be dismissed without prejudice.

Before turning to the merits of the federal claims, the Court will address Exactech's shotgun pleading arguments.

A. Shotgun Pleading

A district court has the prerogative to "control its docket and ensure the prompt resolution of lawsuits, which in some circumstances includes the power to dismiss a complaint for failure to comply with Rule 8(a)(2) and Rule 10(b)." *Weiland v. Palm Beach Cty. Sheriff's Office*, 792 F.3d 1313, 1320 (11th Cir. 2015). A complaint that violates Rule 8(a)(2), Rule 10(b), or both, is often referred to by courts in the Eleventh Circuit as a "shotgun pleading." *Id.* The Eleventh Circuit has identified "four rough types or categories of shotgun pleadings," *id.* at 1321, but only the first two types are discussed by Exactech. The first, and most common, type of shotgun pleading is one that "contain[s] multiple counts where each count adopts the allegations of all preceding counts, causing each successive count to carry all that came before and the last count to be a combination of the entire complaint." *Id.* The second type of shotgun pleading is a complaint that is "replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action." *Id.* at 1321–22.[5]

[5] The third type of shotgun pleading is one that "fails to separate into a different count each cause of action or claim for relief." *Id.* at 1322–23. Finally, the fourth type is one that "asserts multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against." *Id.* at 1323.

The "unifying characteristic" of all shotgun pleadings, however, "is that they fail to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Id.* This does not mean a complaint must be flawless to survive dismissal on shotgun pleading grounds. Although it may not be "a model of efficiency or specificity," *id.* at 1325, a complaint should not be dismissed as a shotgun pleading unless it is "virtually impossible" to determine which allegations of fact were intended to support which claims for relief, *id.* (citation omitted). Nevertheless, "[c]ourts in the Eleventh Circuit have little tolerance for shotgun pleadings," *Vibe Micro, Inc. v. Shabanets*, 878 F.3d 1291, 1295 (11th Cir. 2018), as they "exact an intolerable toll on the trial court's docket . . . and impose unwarranted expense on the litigants [and] the court," *Cramer v. Florida*, 117 F.3d 1258, 1263 (11th Cir. 1997).

This Court struck without prejudice Relators' original Complaint as an impermissible shotgun pleading of the first and second types. For the reasons explained below, the Court finds that the Amended Complaint is not an impermissible shotgun pleading.

1. Shotgun pleading of the first type

The Amended Complaint cured the deficiencies which rendered the original Complaint a shotgun pleading of the first type. Relators' original Complaint was a

shotgun pleading of the first type because each of its 30 counts incorporated by reference the allegations in all preceding paragraphs, including all preceding *counts*. (*See* Doc. 1 ¶¶ 218–401.) In Relators' Amended Complaint, however, the allegations of each count are not "rolled into every successive count on down the line." *See Weiland*, 792 F.3d at 1324. Rather, each of its 29 counts incorporates by reference only the facts "specifically alleged in paragraphs 1-203 of this complaint," which are the factual allegations that precede the counts but none of the counts themselves. (*See* Doc. 54 ¶¶ 204–316.) *See also Weiland*, 792 F.3d at 1324 (finding that the plaintiff's re-allegation of paragraphs 1 through 49 at the beginning of each count of his complaint did not constitute a shotgun pleading of the first type, as the allegations of each count were not "rolled into every successive count on down the line").

However, Relators' Amended Complaint may still be a shotgun pleading of the first type if their "failure to more precisely parcel out and identify the facts relevant to each claim materially increase[s] the burden of understanding the factual allegations underlying each count." *Weiland*, 792 F.3d at 1324. The problem with shotgun pleadings of this type is that they force the court to guess what conduct the counts are referring to because "the answer is always everything that the plaintiff has previously mentioned anywhere in the complaint." *Estate of Bass v. Regions Bank, Inc.*, 947 F.3d 1352, 1356 n.5 (11th Cir. 2020).

While still "not a model of the careful drafter's art," *see Skinner v. Switzer*, 562 U.S. 521, 530 (2011), the Court finds that Relators' Amended Complaint provides Exactech "adequate notice of the [federal] claims against [it] and the factual allegations that support those claims," s*ee Weiland*, 792 F.3d at 1325. Specifically, Relators have added subsections in the Amended Complaint and changed the titles of others, "greatly simplif[ying]" the task of connecting the 203 factual paragraphs to Counts I–VI. *See id.* For example, in Relators' original complaint, the heading titled "Exactech's Fraudulent Schemes," included the facts allegedly giving rise to all 29 causes of action, and while they were further broken down into subsections, these subsections did not aid in connecting the factual allegations to the different counts. For example, some headings included "Dr. Lemak Continues to Raise Concerns as More Patients Experience Pre-Mature Device Failure," (doc. 1 at 67), and "Exactech Misled the FDA by Failing to Submit Adverse Event Reports Based on Information in Dr. Gradisar's Audit," (*id.* at 45). In the Amended Complaint, however, the subheadings within "Exactech's Fraudulent Schemes" make connecting factual allegations to causes of action a simpler task. For example, there is now a subheading labeled "Exactech Had Knowledge the Following False Claims Were Submitted to Medicare and Other Government Healthcare Programs." (Doc. 54 at 43.) This heading clearly relates to the FCA's scienter element. There is also a

subheading labeled "Exactech's Conspiratorial Investigation of the Tibial Loosening Issues," (*id.* at 21), which clearly relates to Relators' conspiracy claim.

In addition to better organizing the factual allegations, Relators have also improved the Amended Complaint by alleging specific facts within Counts I–VI that pertain to those particular counts. (*See id.* ¶¶ 204–27.) In each of the counts in their original Complaint, Relators incorporated by reference all preceding paragraphs and then merely stated legal conclusions mirroring the statutory language relevant to the particular count. The Amended Complaint, however, includes specific factual allegations under Counts I–VI which aid in connecting each Count to particular sections of allegations in the body of the Amended Complaint. Accordingly, the Court concludes that the Amended Complaint is not a shotgun pleading of the first type with respect to the federal claims.[6]

[6] Exactech's shotgun pleading arguments based on Relators' "new theories of liability" are not well-taken. Specifically, Exactech argues that Relators "now allege that Exactech violated Current Good Manufacturing Practices ('cGMP') and 'misbranded' the Finned Tibia Tray, . . . even though the term ["misbranding"] did not appear once in the initial complaint," and that "it is unclear whether Relators dropped other theories, such as the fraudulent-inducement and defective-device theories." (Doc. 58 at 13.) But Relators were permitted to add new theories of liability in their Amended Complaint and abandon others. That they did so cannot be a basis for striking the Amended Complaint. To the extent that Exactech finds confusing Relators' omission of explicit references to fraudulent-inducement and defective-device theories, this Court would instruct Exactech to focus their attention on the operative complaint in determining the claims against it and grounds on which they rest, rather than the initial complaint which this Court previously struck. Further, the Supreme Court itself has explained that "under the Federal Rules of Civil Procedure, a complaint need not pin plaintiff's claim for relief to a precise legal theory." *Skinner v. Switzer*, 562 U.S. 521, 530 (2011).

2. Shotgun pleading of the second type

This Court also found Relators' initial complaint to be a shotgun pleading of the second type in part because it was "replete with . . . immaterial facts." (*See* Doc. 49 at 3.) For example, Relators' original complaint spent three pages describing the particulars of Relators' professional backgrounds, (*see* doc. 1 at 13–15), going into such irrelevant detail as "Born and medically trained in Guatemala, Dr. Fuentes entered the orthopedic device field immediately after graduating and helped introduce modern Orthopedic devices . . . to Guatemala and throughout Central America." However admirable Dr. Fuentes' international triumphs, this information is wholly irrelevant to Relators' task at this stage: adequately pleading that Exactech defrauded United States healthcare programs. The Amended Complaint, on the other hand, omits these irrelevant details and includes only information such as when individuals were employed by Exactech, the length of time they worked for Exactech, and what they claim to have personal knowledge of with respect to the conduct giving rise to this suit.

The Amended Complaint also cuts in half the discussion of the process for replacing a knee and statistics relating to patients of knee replacements in the United States and healthcare programs. (*See id.* at 13–14.) Relators also slightly shortened their discussion of the operation of various healthcare statutes and regulations. (*See*

id. at 3–12.) While still spanning ten pages of the Amended Complaint, this discussion takes a very different course in the Amended Complaint than it did in the original Complaint because Relators added new theories of liability that stem from Exactech's alleged violation of additional healthcare regulations. This Court finds that while not "a model of efficiency or specificity," *Weiland*, 792 F.3d at 1325, this information is not so irrelevant as to warrant striking the Amended Complaint. Relators also substantially shortened their statement of the case, (*see* doc. 54 at 1), and the discussion of Exactech's devices and history, (*see id.* at 16). In sum, this Court finds that Relators have sufficiently cured the deficiencies in their Complaint as they relate to the inclusion of immaterial facts, and that the Amended Complaint is not a shotgun pleading of the second type.

B. Motion to Dismiss Under Rules 9(b) and 12(b)(6)

The False Claims Act "imposes significant penalties on those who defraud the Government." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016). It imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). It also imposes liability on any person who knowingly avoids or decreases an obligation to

pay money to the Government, known as a "reverse false claim," *see* § 3729(a)(1)(G), and on any person who conspires to violate subparagraphs (A), (B), or (G), *see* § 3729(a)(1)(C). The FCA authorizes private citizens to bring actions on behalf of the United States. *Id.* § 3730(b).

Relators here allege that Exactech caused false claims to be presented for payment from the Medicare, Medicaid, and VA programs in violation of 31 U.S.C. § 3729(a)(1)(A) (Counts I & II); that Exactech made false statements in connection with claims for payment in violation of § 3729(a)(1)(B) (Count III); that Exactech conspired with physicians and other individuals to submit false claims in violation of § 3729(a)(1)(C) (Count IV); that Exactech unlawfully withheld payments to federal healthcare programs in violation of § 3729(a)(1)(G) (Count V); and that Exactech paid illegal kickbacks to physicians in order to induce them to purchase Exactech's products in violation of 42 U.S.C. § 1320a-7b and 31 U.S.C. § 3729(a)(1)(A) (Count VI). Exactech argues that all claims are due to be dismissed for failure to state a claim under Rule 12(b)(6) and failure to allege fraud with particularity under Rule 9(b). The Court will address each argument.

1. Counts I & II – 31 U.S.C. § 3729(a)(1)(A)

For Relators to state a claim under 31 U.S.C. § 3729(a)(1)(A), they must sufficiently allege "(1) a false or fraudulent claim, (2) which was presented, or caused

to be presented, for payment or approval, (3) with the knowledge that the claim was false." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017) (citing § 3729(a)(1)(A)). A "claim" for purposes of the FCA includes both "direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Escobar*, 136 S. Ct. at 1996 (citing § 3729(b)(2)(A)).

Count I of Relators' Amended Complaint involves the latter type of "claim," alleging that Exactech indirectly caused third parties to present false claims for reimbursement to the Medicare and Medicaid programs. Count II, on the other hand, involves the former type of "claim," by alleging that Exactech directly presented false claims for payment to the Veterans Administration ("VA"). Under both Counts, Relators proceed under what has been coined the "false certification" theory of liability. "Under this theory, FCA liability may arise where a defendant falsely asserts or implies that it has complied with a statutory or regulatory requirement when, in actuality, it has not so complied." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1284 (11th Cir. 2019) (citing *Escobar*, 136 S. Ct. at 1999). Claims for government payment that make such assertions or implications are false within the meaning of the FCA. *See Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1272 (11th Cir. 2018). In addition to alleging (1) falsity of the claim, (2) knowledge,

and (3) direct or indirect presentment, relators proceeding under the false certification theory must also show that the false certification is *material* to the Government's payment decision. *See Escobar*, 136 S. Ct. at 1996, 2001–02. This materiality requirement ensures that the FCA does not become "an all-purpose antifraud statute," or "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (citation omitted). According to the Supreme Court, a claimant states a claim under the false certification theory "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. The Court will now consider falsity, presentment, causation, and materiality in turn.

i. Falsity

Liability under the false certification theory is not limited to false statements of compliance with laws that are "express conditions of payment." *Escobar*, 136 S. Ct. at 2001. The Supreme Court refused to adopt a "circumscribed view of what it means for a claim to be false or fraudulent" under a false certification theory. *Id.* at 2002 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270

(C.A.D.C. 2010)). Rather, "concerns about fair notice and open-ended liability" are instead "addressed through strict enforcement of the Act's materiality and scienter requirements." *Id.*

To show that claims submitted by Exactech were false, Relators allege problems with various certification statements within claims submitted by healthcare providers to government healthcare programs. By submitting these forms, healthcare providers certify compliance with the laws and regulations governing the provision of healthcare, that the information submitted is neither false nor misleading, and that all items and services billed for are "reasonable and necessary." As will be explained in further detail below, by plausibly alleging that Exactech's Finned Tibia Tray was "misbranded" and not "reasonable and necessary" in violation of governing healthcare laws, Relators sufficiently allege that claims for payment of the device were false under the FCA.

a. Misbranded

A "misbranded" medical device may not be sold in the United States. *See* 21 U.S.C § 331. One way a device becomes "misbranded" is if its manufacturer violates the FDA's requirements for reporting adverse events. *Id.* § 352(t). These requirements require manufacturers, *inter alia*, to investigate each adverse event, evaluate its causes, and furnish particular information to the FDA within 30 days of

receiving or otherwise becoming aware of information "from any source" that "reasonably suggests that a device" a manufacturer markets "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50. The FDA defines "caused or contributed" to mean

> that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure, (2) Malfunction, (3) Improper or inadequate design, (4) Manufacture, (5) Labeling, or (6) User error.

Id. § 803.3(c).

Relators alleged that Exactech violated these mandatory reporting requirements, thereby rendering the Finned Tibia Tray "misbranded" and not able to be sold in the United States. (*See* Doc. 54 ¶ 101.) Specifically, Relators allege that Exactech was aware of 51 revision surgeries by Dr. Moody,[7] 35 revision surgeries by Dr. Hutchins, other revisions by surgeon clients of Exactech distributors, and

[7] Exactech argues that any claims submitted before June 28, 2008, would be barred by the FCA's ten-year statute of limitations, as those claims would have been submitted more than ten years before Relators filed this action. *See* 31 U.S.C. § 3731(b). Thus, any actual claims that were presented to government healthcare programs by Dr. Moody before he notified Exactech of his mounting revisions in "2007 or early 2008," *see* Doc. 54 ¶ 61, are time barred. However, Exactech's failure to submit adverse event reports to the FDA relating to these mounting revisions would still render the device "misbranded" for purposes of future claims submitted to government healthcare programs during the limitations period, and also contributes to allegations of Exactech's knowledge of the device failures.

revision surgeries identified by Dr. Gradisar's audit and accompanying report. Because a "Revision TKR" necessitated by tibial loosening qualifies as a "serious injury," *see* 21 C.F.R. § 803.3(w), Relators argue that Exactech was required to submit adverse event reports for each of these revisions. Thus, because Exactech failed to do so, Relators argue that the Finned Tibia Tray became misbranded, making any subsequent claim for payment of the device false.

Through its internal investigation into the tibial loosening problem, Exactech found several defects in the Finned Tibia Tray's design and manufacturing process that Exactech believed created a "perfect storm" of issues, each contributing to the mounting device failures and necessitating revision surgeries. (*See id.* ¶ 88.) This allegation is sufficient to show that the Finned Tibia Tray "caused or contributed" to "serious injuries," namely, hundreds of revision surgeries. *See* 21 C.F.R. § 803.3. To be sure, Dr. Gradisar's audit and report indicated his belief that one of "multiple" causes of the failures was the improper "cement technique" of the implanting surgeons. (*See id.* ¶ 77.) Even if Dr. Gradisar's belief in "multiple" causes was genuine—a point Relators highly contest—this information is nonetheless arguably sufficient to trigger a mandatory adverse event report, as an improper

cement technique likely qualifies as "user error" within the reporting regulations.[8] *See* 21 C.F.R. § 803.3(c). Although it did comply with its responsibility to investigate the revisions and their causes, Exactech is hard-pressed in arguing that its discoveries did not obligate it to report to the FDA.[9] Accepting the Amended Complaint's factual allegations as true and viewing them in the light most favorable to Relators, *see Lanfear v. Home Depot, Inc.*, 679 F.3d 1267, 1275 (11th Cir. 2012), Relators sufficiently allege that Exactech violated its mandatory reporting obligations in violation of healthcare laws, rendering the Finned Tibia Tray misbranded and making any subsequent claim for payment of the device improper because such claims falsely certified compliance with governing healthcare laws.

b. Reasonable and Necessary

In addition to allegations of misbranding, Relators also allege that the Finned Tibia Tray is not "reasonable and necessary," in violation of Medicare and Medicaid laws. (*See* Doc. 54 ¶ 1.) Healthcare laws provide that "no payment may be

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[8] Relators further allege that Dr. Gradisar's report obligated Exactech to submit a "five-day report" under 21 C.F.R. § 803.53. The Court need not decide this issue, as Relators make a sufficient showing that Exactech failed to comply with "30-day" reporting requirements.

[9] Exactech argues that because tibial loosening can also be caused by "factors unique to an individual patient, such as a patient's lifestyle, age, and body mass index," it did not violate reporting requirements. (*See* Doc. 58 at 32.) But the existence of additional potential causes does not eliminate the possibility that the device "may have contributed" to an injury, particularly where, as here, multiple other identified causes were alleged to be attributable to such device.

made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A);[10] *see also AseraCare*, 938 F.3d at 1284. An item or service is "reasonable and necessary" if it is "'safe' and 'effective' . . . that is, . . . [if it] has been proven safe and effective based on authoritative evidence, or alternatively, . . . is generally accepted in the medical community as safe and effective for the condition for which it is used." 54 Fed. Reg. 4302-04. Current Good Manufacturing Practice regulations ("cGMPs") "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). cGMPs are intended to assure that devices are "safe and effective." *Id.* A device that does not comply with cGMPs is considered "adulterated" and cannot be sold in the United States. *See* 21 U.S.C. § 331.

Relators here argue that, because 30–35% of Finned Tibia Trays fail within three years of implantation—a failure rate ten times greater than the industry standard, *see* Doc. 54 ¶ 60—the Finned Tibia Tray is not reasonable and necessary

[10] While this statute refers specifically to the Medicare program, most state laws similarly define medical necessity for Medicaid purposes. *See, e.g.*, Florida Administrative Code (Rule 59G-1.010).

under relevant healthcare laws. According to Relators, this high failure rate is a result of flaws in Exactech's manufacturing and engineering design process that rendered the device "adulterated." (*See id.* ¶ 80-89.) These flaws also allegedly caused the defective device to be materially different than the device originally approved by the FDA. (*See id.*) Relators allege that Exactech introduced several manufacturing and engineering process flaws into the Finned Tibia Tray: (1) a production process failure relating to a new sizing tool; (2) a change in the coating material for the device's exterior; (3) a manufacturing defect causing the device's forgings to be improperly shaped; and (4) a design defect with the device's "nose." According to Relators, these flaws violated cGMPs, contributed to the mounting revisions, and were identified by Exactech during its internal investigation. (*See id.*) Relators argue that by not addressing, remediating, or disclosing these problems, Exactech violated cGMP regulations as well as mandatory reporting requirements, rendering the device "adulterated" and "misbranded." *See* 21 U.S.C. § 360j(f); 21 C.F.R. § 803.53; 21 C.F.R. § 820.70.

Relying on case law from the Fourth Circuit, Exactech argues that payment requests for medical devices and services are not considered false or fraudulent "on the sole basis that [they] ha[ve] been adulterated as a result of having been processed in violation of FDA safety regulations." *United States ex rel. Rostholder v. Omnicare,*

Inc., 745 F.3d 694, 702 (4th Cir. 2014). Rather, relators must allege "actual fraudulent conduct." *Id.* For example, the *Omnicare* court rejected the relator's FCA claim based on "adulterated drugs" because the relator "failed to identif[y] any false statement or other fraudulent misrepresentation by the Defendant." *Id.* The *Omincare* decision is not binding on this Court, and even assuming the Court found it persuasive, the present case is distinguishable. Beyond mere regulatory violations, Relators allege that Exactech's changes in the manufacturing and engineering process also rendered the post-2006 Finned Tibia Tray a "materially different" device than the device originally approved by the FDA in 1994. (*See* Doc. 54 ¶ 84-85.) The First Circuit in *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 37 (1st Cir. 2017), found that such an allegation—that the defendant device manufacturer "got FDA approval for a device and then palmed off a defective version of that device both directly on the government itself and on unsuspecting doctors and patients, who then submitted claims for payment to unsuspecting government payors"—is an actionable theory under both § 3729(a)(1)(A) and § 3729(a)(1)(B), provided it is pled with sufficient particularity. It appears that the Eleventh Circuit has not considered this particular issue, and this Court is persuaded by the First Circuit's reasoning that, by palming off a different device as being the same as a previously approved, non-defective device, a defendant makes specific

misrepresentations about the device, thereby rendering false claims for payment of the device. *See id.*[11]

Due to the manufacturing process flaws, as alleged by Relators, the Finned Tibia Tray was "adulterated" and a "materially different device" than that approved by the FDA. These allegations are sufficient to demonstrate that the Finned Tibia Tray was not "reasonable and necessary," making claims for government payment for the device false because such claims falsely certified compliance with governing healthcare laws.

ii. Presentment of a false claim

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[11] As Exactech points out, the relator in *Nargol* also advanced a separate design-defect theory which relied on allegations of false statements made by defendant to the FDA and physicians in order to secure FDA approval of a device. The court rejected this particular claim, holding that "the FDA's failure actually to withdraw its approval of [the device at issue] in the face of [the relator's] allegations precludes [the relator] from resting his claims on a contention that *the FDA's approval was fraudulently obtained*." *Nargol*, 865 F.3d 29 at 34 (emphasis added) (quoting *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016)). Thus, Exactech argues that this Court should similarly reject Relators' allegation that the Finned Tibia Tray suffered from design defects that contributed to rendering it not "reasonable and necessary." Regarding alleged design defects, however, the facts in *Nargol* are distinguishable from the present case. Relators here make no allegation that Exactech fraudulently secured approval from the FDA originally to market the device. Rather, Relators claim that the originally approved device was materially different from the defective device Exactech has been fraudulently palming off as the original. This is the precise theory that was held to state an FCA claim in *Nargol*. *Nargol*, 865 F.3d 29 at 31.

Even aside from Relators' "palmed off" device allegations, that a device is FDA-approved does not necessarily render it "reasonable and necessary" for purpose of securing government payment. *See Nargol*, 865 F.3d 29 at 35; *see also United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 905 (9th Cir. 2017). "[J]ust as it is not the purpose of the False Claims Act to ensure regulatory compliance, it is not the FDA's purpose to prevent fraud on the government's fisc." *Campie*, 862 F.3d at 905.

Alleging statutory or regulatory noncompliance is insufficient to state an FCA claim absent allegations that an actual false claim was presented for payment. *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002). "Liability under the False Claims Act arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal policies." *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005). Because the submission of a false claim is "the sine qua non of a False Claims Act violation," *Clausen*, 290 F.3d at 1311, "that submission must be pleaded with particularly and not inferred from the circumstances." *Corsello*, 428 F.3d at 1013. Rather, for presentment allegations to pass muster under Rule 9(b), "some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government." *Clausen*, 290 F.3d at 1311.

An FCA claimant can satisfy the indicia of reliability requirement "by alleging the details of false claims by providing specific billing information—such as dates, times, and amounts of actual false claims or copies of bills." *United States v. HPC Healthcare, Inc.*, 723 F. App'x 783, 788–89 (11th Cir. 2018) (citing *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1326 (11th Cir. 2009)); *see also Clausen*, 290 F.3d at 1312 n.21. But since the Eleventh Circuit evaluates indicia of reliability on a "case-by-case basis," *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358 (11th Cir. 2006),

it is not necessary that a claimant allege all of these details for each claim, or even all of these details for a single claim, *Clausen*, 290 F.3d at 1312 n.21. Rather, the claimant need only allege "some of this information for at least some of the claims . . . in order to satisfy Rule 9(b)." *Clausen*, 290 F.3d at 1312 n.21.

As explained in further detail below, Relators here allege with sufficient particularity that Exactech indirectly caused the presentment of false claims to Medicare and Medicaid and directly presented false claims to the VA.[12]

a. Indirect Presentment to the Medicare and Medicaid Programs

Relators list six examples of specific Medicare-insured patients of Dr. Lemak who were implanted with the Finned Tibia Tray which failed prematurely and whose claims were submitted to Medicare. (*See* Doc. 54 ¶ 146.) The most detailed of these examples includes the following information: the name of the implanting surgeon, the hospital where the device was implanted, the date of surgery, the serial numbers of the devices, the dollar amount that Exactech received for the devices, the date of the revision surgery, the surgeon who performed revision surgery, and the amount that Exactech billed Medicare for the defective device. (*See id.*)

[12] Relators allege in passing that Exactech also caused the submission of false claims for payment to the Tricare program, but as Exactech correctly points out in its Motion to Dismiss, Relators have alleged no facts to show that any claims were submitted to Tricare.

Although Relators do not allege the "actual date" that reimbursement claims were submitted, they do allege that they were submitted "shortly after the surgery and subsequent to Relator Wallace personally providing the signed implant sheet to the billing department, and before Relator Wallace received the end-of-the-month purchase order number corresponding to each surgery." (Doc. 54 ¶ 141). Because the Amended Complaint also alleges specific dates of particular surgeries, *see id.* ¶ 146, Relators provide a particular time frame during which claims were submitted. They allege that Dr. Lemak billed Medicare for 32 Primary TKR surgeries he performed in 2012 and that Relator Wallace personally witnessed Dr. Lemak implant the Finned Tibia Tray for each of these 32 operations. (*See* Doc. 54 ¶ 140.) To be sure, even "highly-compelling statistical analysis" cannot suffice to show the actual submission of a false claim. *Hopper*, 588 F.3d at 1322. But Relators also allege "second-hand information about billing practices," *Carrel*, 898 F.3d at 1276, as well as "specific persons" and "entities" "that participated in . . . that process," *Hopper*, 588 F.3d at 1322, for these 32 surgeries. In particular, Relators allege that after each surgery, Relator Wallace brought a form to be signed by a Trinity Hospital employee. The form provided for the billing responsibility to be turned over to the hospital. Relator Wallace then delivered a copy of the form to a hospital billing department employee, often Molly Kirk. As a courtesy to patients, the hospital billed Medicare

on the patients' behalf. After Relator Wallace provided the Exactech implant form to the billing department, the billing department then submitted the claim for payment to Medicare. Although merely alleging "without any stated reason for [the] belief" that false claims "must have been submitted" is insufficient, *Clausen*, 290 F.3d at 1311, Relators here provide sufficient reasons for their belief that false claims must have been submitted within a particular timeframe.

In light of the foregoing, this Court finds the totality of Relators' allegations to be sufficient to show that Exactech caused the actual submission of claims for reimbursement to the Medicare program.[13] Because the Court concludes that Relators has sufficiently stated a claim for indirect presentment of false claims to the Medicare program, it need not consider whether Relators have also stated a claim for indirect presentment of false claims to Medicaid.[14]

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[13] Regarding the indirect claims under Count I, Relators must also show that Exactech proximately caused the presentment of the false claims. *See Ruckh v. Salus Rehabilitation, LLC*, 963 F.3d 1089, 1107 (11th Cir. 2020) (holding that proximate causation is "the appropriate standard by which to determine whether there is a sufficient nexus between the defendant's conduct and the submission of a false claim"). Relators allege that Exactech concealed the Finned Tibia Tray's defects, and that such concealment caused unsuspecting surgeons and hospitals to submit claims to the government for Finned Tibia Trays they would have otherwise refused to implant and submit claims on. According to Relators, two surgeons refused to continue implanting the device upon learning of its failures. Exactech does not challenge the sufficiency of Relators' causation allegations. Even if it had, Relators allegations sufficiently show that Exactech's concealment of device defects was "a substantial factor in inducing providers to submit claims for reimbursement" and that the submission of claims was "reasonably foreseeable . . . as a natural consequence" of Exactech's concealment. *Id.* (citation omitted).

[14] If the Court were to consider the issue on the merits, it would reach a similar conclusion that Relators sufficiently stated a claim for indirect presentment of false claims to Medicaid.

b. Direct Presentment to the VA

Relators also sufficiently allege that Exactech directly submitted false claims to the VA. Relators provide, among other information, two specific examples of Finned Tibia Trays that were sold to the VA under a "Firm Fixed Price Federal Contract Award." (*See* doc. 54 ¶ 161). These examples include the delivery order number, the amount the government paid for the device, and the date on which it paid. (*See id.* ¶ 161.) Applying the same legal principles discussed above in subpart a, this specific billing information provides sufficient indicia of reliability that Exactech caused the actual submission of false claims to the VA.

iii. Materiality

When proceeding under the false certification theory, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be

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Relators allege that all patients implanted with Exactech's devices by Dr. Floyd at Cooper Green Mercy Hospital in Birmingham were insured by Medicaid. Relators also list four specific examples of patients who received a Finned Tibia Tray implanted by Dr. Floyd at Cooper Green. Each of these examples includes the date of the surgery, the serial number of the specific Finned Tibia Tray, and the cost of the device to the Medicaid program. Relators also allege that the price of the device was specifically negotiated to allow for its purchase by the Medicaid program. Additionally, several of the patients implanted by Dr. Lemak at Trinity Hospital were also insured by Medicaid. Thus, the "second-hand information about billing practices," *Carrel*, 898 F.3d at 1276, and "specific persons" and "entities" "that participated in . . . that process," *Hopper*, 588 F.3d at 1322, alleged with respect to Trinity Hospital apply to these dual-insured patients as well. Applying the same legal principles discussed above in subpart *a* regarding Medicare, Relators likely alleged sufficient indicia of reliability that Exactech caused the actual submission of false claims to the Medicaid program.

material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 2002. The Supreme Court has emphasized that the materiality requirement is "demanding" and "rigorous," and that materiality must be plead with particularity under Rule 9(b). *Id.* at 2004 n.6.

The Supreme Court in *Escobar* declined to answer whether § 3729(a)(1)(A)'s judicially-imposed materiality requirement is derived from § 3729(b)(4)[15] or directly from the common law, but explained that "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (internal citation and brackets omitted). The Court explained that, under tort law principles, something is material only "if a reasonable man would attach importance to it in determining his choice of action," or "if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action." *Id.* at 2002–03 (internal citations and brackets omitted). The Court further explained that "[m]ateriality in contract law is substantially similar." *Id.* at 2003.

[15] Section 3729(b)(4) defines "material," for purposes of § 3729(a)(1)(B) and (G), as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

The Court then gave a non-exhaustive list of factors relevant to the materiality analysis. *See id.* at 2003–04. Courts should consider whether noncompliance is "minor or insubstantial" and amounts to "garden-variety breaches of contract or regulatory violations." *Id.* at 2003. Additionally, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* It is strong evidence that certain requirements are not material "if the Government pays a particular claim in full despite its actual knowledge that [those] requirements were violated," or "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position." *Id.* at 2003–04.

Relators' strongest allegation with respect to materiality is that the requirement that all items and services billed for must be "reasonable and necessary" is an express condition of payment under Medicare and Medicaid laws. This allegation, while relevant, is not sufficient on its own to establish materiality. *Escobar*, 136 S. Ct. at 2003. Relators also allege that, during an Exactech investigatory committee meeting, the Exactech Executive charged with regulatory compliance pointed out that if Exactech were to comply with its reporting obligations, the mounting revisions could be problematic because they would be indicative of device failure. This allegation suggests that Exactech "knew or had reason to know that the

recipient of the representation attaches importance to the specific matter in determining his choice of action." *Escobar*, 136 S. Ct. at 2003. Additionally, Exactech failed to disclose hundreds of Finned Tibia Tray failures reported by multiple doctors, which helped conceal the true failure rate of up to 35%—ten times greater than the industry standard. These allegations suggest more than "minor or insubstantial" noncompliance. Moreover, it is plausible that the Government "would have attached importance to the violation[s] in determining whether to pay" for devices that fail in over 3 out of 10 patients and at a rate ten times greater than the industry standard. *See Carrel*, 898 F.3d at 1272. Another allegation that speaks to the effect on the likely or actual behavior of the Government is that the Australian government declined to pay for the Finned Tibia Tray upon determining that the Optetrak knee devices had the worst failure rate of any implant sold in the country. (*See* Doc. 54 ¶ 54.) This allegation shows that another government, when made aware of the device's high failure rate, chose not to reimburse for claims for the device, demonstrating that misrepresentations or omissions about the device's failure rate were material to its decision. *See Escobar*, 136 S. Ct. at 2002.

The Court is not persuaded by Exactech's arguments, relying on the First Circuit's decision in *Nargol*, that (a) because Relators failed to allege that the Government has rejected a single claim for reimbursement even after being made

aware of Relators' allegations in this action, Exactech's alleged misrepresentations are not material to the Government's reimbursement decisions, or (b) Relators' failure to allege that the FDA used any of its "full array of tools" to punish Exactech for selling the defective Finned Tibia Tray demonstrates that the Government does not consider the alleged misrepresentations material. These arguments fail because they require the Court to draw inferences in favor of Exactech rather than Relators, which the Court cannot do when evaluating a motion to dismiss, *see Lanfear*, 679 F.3d at 1275, and also because this portion of *Nargol* is distinguishable from the present case and is therefore not persuasive.[16] This is so particularly in light of Relators' allegations that the FDA was not aware of the device defects because Exactech actively concealed them by avoiding its reporting requirements and by palming off the defective device as the originally approved one. The FDA's inaction

[16] The relators in *Nargol* claimed that the defendant device manufacturer made false statements about a device's failure rate in order to obtain FDA approval of a defective device and subsequently caused false claims to be submitted to the government for the device. *See Nargol*, 865 F.3d at 34. After relators told the FDA about the alleged defects, however, the FDA still allowed the device to remain on the market. *Id.* at 35. The First Circuit thus rejected relators' FCA claim, explaining that when the FDA "is told what Relators have to say, yet sees no reason to change its position . . . it is not plausible that the conduct of the manufacturer *in securing FDA approval* constituted a material falsehood." *Id.* (emphasis added). Again, *Nargol* is not binding authority, and this Court also finds this portion of its reasoning inapplicable to the present case because Relators here do not allege that approval for the original Finned Tibia Tray was fraudulently obtained. And unlike in *Nargol*, Relators here do not allege that they had previously told the FDA about problems with the device. Additionally, the FDA had no actual knowledge of the device's defects because, according to Relators, Exactech actively concealed the failures by avoiding its reporting requirements and by palming off the defective device as the originally approved one.

does not warrant the inference that the Government would not consider regulatory violations material where, as here, it is alleged that the FDA was unaware of any reason to act. And Relators' failure to allege the Government's rejection of a claim after learning of the Finned Tibia Tray's failures is not significant, particularly because Relators do not allege that any claims were *submitted* after the Government learned of the failures.

For the foregoing reasons, Relators have sufficiently alleged that Exactech's noncompliance with healthcare laws was material to the government's decision to pay for the Finned Tibia Tray.

iv. Knowledge

The FCA defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA's scienter requirement, like its materiality requirement, is "rigorous." *Escobar*, 136 S. Ct. at 2002. While § 3729(b)(1) does not require a "specific intent to defraud," relators proceeding under the false certification theory must allege that the defendant knew or should have known that its conduct violated regulations or statutes, *see Phalp*, 857 F.3d at

1154–55, and that such violation was material to the government's payment decision, *see United States ex rel. Marsteller v. Tilton*, 880 F.3d 1302, 1312 (11th Cir. 2018).

Relators sufficiently allege that Exactech knew the Finned Tibia Tray was defective. According to Relators, in 2007 or early 2008, Mr. O'Neill and Dr. Moody informed Exactech of Dr. Moody's 51 tibial loosenings with Finned Tibia Tray devices, an amount Dr. Moody described to Exactech as "unprecedented" in his experience. (*See* doc. 54 ¶ 61.) He and Mr. O'Neill also made a presentation to Exactech addressing these loosenings. During this same time period, other doctors reported to Exactech an unusually large number of Finned Tibia Tray revisions, including 35 revision surgeries by Dr. Chris Hutchins and additional revisions by surgeon clients of Exactech distributors. Additionally, Dr. Gradisar's audit informed Exactech that, out of 47 patients who received a TKR revision surgery between January 1, 2007, and March 31, 2008, 24 Finned Tibia Trays failed due to tibial loosening and required a revision. Relators describe this ratio—more than 50%—as "well outside the industry norm." (*See* doc. 54 ¶¶ 75, 79.) Thereafter, Exactech conducted an internal investigation into the loosening problem, where its engineers allegedly identified several design engineering and manufacturing flaws that they believed contributed to the failures. The fact that several of these identified flaws

were eliminated in Exactech's replacement device further suggests that Exactech had knowledge of these issues.[17]

Second, Relators sufficiently allege that Exactech had knowledge that the defective Finned Tibia Tray was being implanted in patients covered by Government healthcare programs. Relators allege that Relator Wallace sent monthly Purchase Order Numbers, which corresponded to all Exactech component surgeries that had been performed and billed to government healthcare programs the previous month, along with corresponding patient information, to Brittany Dinatelo, an Exactech employee. Moreover, Relators allege that Exactech negotiated pricing agreements with specific hospitals for which the government reimbursement rate is a "well-known and primary factor" in determining the cost of Exactech's devices to these hospitals, and also that Exactech is "acutely aware of federal health care program involvement in the purchasing and regulation of medical devices." (*See* doc. 54 ¶¶ 135–36). Finally, Exactech's accounting department—including employee Chris Font—has records designating each Exactech device that was paid for by particular government health care programs.

[17] While Exactech is correct that "a device cannot be called defective for purposes of establishing *falsity* in a qui tam case just because new versions contain design improvements," (*see* doc. 58 at 33 (emphasis added)), design improvement can nevertheless aid in establishing Exactech's *knowledge* that such defects existed in a prior version.

Finally, Exactech's VP of Regulatory and Clinical explained in a committee meeting attended by "leading engineers, product managers, and executives within Exactech" that the FDA requires that each revision that may have been caused by the Finned Tibia Tray be reported, and that following these reporting requirements would suggest a device defect. (*See id.* ¶¶ 93–94.) These statements not only plausibly show that Exactech was aware that its conduct violated reporting requirements but also that Exactech "knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action." *Escobar*, 136 S. Ct. at 2003. Accordingly, it is plausible that Exactech knew or should have known that its conduct violated regulations or statutes and that such violation was material to the Government's payment decision.

For the reasons explained above, Relators have sufficiently alleged that Exactech knowingly submitted and caused to be submitted false claims to federal healthcare programs.

2. Count III - 31 U.S.C. § 3729(a)(1)(B)

For Relators to state a claim under § 3729(a)(1)(B), they must sufficiently allege that: "(1) the defendant made (or caused to be made) a false statement, (2) the

defendant knew it to be false, and (3) the statement was material to a false claim." *Phalp*, 857 F.3d at 1154 (citing 31 U.S.C. § 3729(a)(1)(B)).[18]

i. False Statements

To plead with particularity that Exactech made or caused to be made a false statement, Relators must "identify the particular document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result." *Matheny*, 671 F.3d at 1225.

Relators sufficiently allege that Exactech made or caused to be made multiple false statements. One allegedly false statement is Exactech's representations that the Finned Tibia Tray has a superior failure rate. Relators' allegations plausibly demonstrate that the statements regarding the failure rate are false because the

[18] These elements are consistent with the current version of the statute, which "omit[s] any intent or payment requirement." *United States ex rel. Patel v. GE Heathcare, Inc.*, 8:14-cv-120-T-33TGW, 2017 WL 4310263, at *8 (M.D. Fla. 2017). Exactech relies on the pre-FERA version of the FCA in asserting that § 3729(a)(1)(B) requires Relators to show that Exactech made those statements or records "for the purpose of getting a false claim paid," and that Exactech's false statements "caused the government to actually pay a false claim." (*See* Doc. 58 at 33.) The pre-FERA version of 31 U.S.C. § 3729(a)(1)(B)—which was codified at 31 U.S.C. § 3729(a)(2)—created liability for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2) (2008). Under this version of the statute, a relator is required to allege that "(1) the defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government; and (2) the defendant's false record or statement caused the government to actually pay a false claim." *Hopper*, 588 F.3d at 1327. "In contrast to § 3729(a)(2), the current version omits any reference to payment or intent." *Patel*, 2017 WL 4310263, at *8.

And although the pre-FERA version applies to claims for payment submitted before June 7, 2008, Exactech's alleged false statements and records do not qualify as "claims for payment."

studies upon which they rely do not relate to the Finned Tibia Tray, and because, according to Relators, the true failure rate of the Finned Tibia Tray is 30–35% in three years. Exactech made additional false statements when it shared this failure rate data with Relators Wallace and Farley, in 2011 and 2012 respectively, both through verbal statements by Exactech employee Bob Purcell and through its marketing materials. Exactech also presented this false information directly to Dr. Lemak. Additionally, Relators allege that Exactech made false statements and omissions within the eighteen Adverse Event Reports it submitted to the FDA in 2008. "[H]alf-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations" under the FCA. *Escobar*, 136 S. Ct. at 2000. According to Relators, these reports falsely stated that the adverse event was not a "Product Problem Report," and in one particular report, Relators allege that Exactech did not provide an answer to the question "Was Device Evaluated by Manufacturer?," in violation of reporting regulations, *see* 21 C.F.R. § 803.50(b)(3). This omission is misleading, as Exactech already knew the results of Dr. Gradisar's audit and report, which indicated an unusually high failure rate and multiple reportable causes. Exactech also made false statements directly to multiple surgeons who complained of mounting revisions by falsely telling them that Exactech was unaware of any other surgeon experiencing a high revision rate.

In conclusion, Relators' allegations describe the particular documents containing false statements (Optetrak Main Brochure, the underlying studies, and the eighteen adverse event reports); the statements that were false (that the Finned Tibia Tray had a survival rate of 98.6% at 8.5 years and 99% at five years, and that the adverse events were not "Product Problem Reports"); when those documents were provided (in August 2011, on October 12, 2011, in August 2012, on August 15, 2008, on November 14, 2008, and on November 21, 2008); who at Exactech provided those false statements (Bob Purcell and David Petty); to whom those false statements were provided (Relator Wallace, Relator Farley, Dr. Lemak, other physicians who read Exactech's official marketing materials, and the FDA); how the statement was false (it provided device survival data related to a completely different device and falsely stated that adverse events were not "Product Problem Reports" when they were); and what Exactech obtained as a result (payments for the defective device). These factual allegations are sufficient to show that Exactech made or caused to be made a false statement. *See Matheny*, 671 F.3d at 1225.

ii. Materiality

For the reasons explained above with respect to Counts I and II, Relators sufficiently allege that the false statements made, or caused to be made, by Exactech to Relators, surgeons, and the FDA were material to false claims. Although

materiality in Counts I and II was analyzed according to the standard set forth in *Escobar*, the Court concludes that the allegations also satisfy the standard set forth in § 3729(a)(1)(B) for Count III. Thus, Relators have sufficiently alleged materiality for Count III under § 3729(a)(1)(B).

iii. Knowledge

For the reasons explained above with respect to Counts I and II, Relators sufficiently allege that Exactech knew or should have known that its conduct violated regulations or statutes and that such violation was material to the Government's payment decision. Thus, Relators have sufficiently alleged Exactech's knowledge for Count III under § 3729(a)(1)(B).

3. Count VI – Federal False Claims Based on Anti-Kickback Statute 31 U.S.C. § 3729(a)(1)(A); 42 U.S.C. § 1320a-7b

The Anti–Kickback Statute ("AKS"), 42 U.S.C. § 1320a7b, prohibits "knowingly offering or providing remuneration for the purpose of inducing the recipient to purchase a good or service for which payment may be made under a federal health care program." *United States ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 808 (11th Cir. 2015). Under the AKS, "a claim that includes items and services resulting from a violation of [that statute] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). "Merely alleging a violation of [the AKS] does not sufficiently state a claim under the FCA. It is the *submission* and

payment of a *false . . . claim* [to a federal health care program] and false certification of compliance with the law that creates FCA liability." *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 706 (11th Cir. 2014).

For the reasons explained above, Relators have sufficiently alleged the falsity, knowledge, and materiality required to establish FCA liability. In addition, the Court finds that Relators have sufficiently alleged that Exactech paid remuneration to Dr. Lemak in order to induce him to purchase Exactech's products or services for which payment may be made under a federal health care program. *See Osheroff*, 776 F.3d at 808. Specifically, Relators sufficiently plead that the purpose of Exactech's consulting payments to Dr. Lemak was to induce him to continue purchasing Exactech products. This purpose is shown through Relators' allegations that Dr. Lemak was not offered a consulting agreement until he threatened to stop purchasing Exactech's products, and that his consulting agreement was terminated after he stopped using its products. This allegation, along with Dr. Lemak's opinion that the consultations "were pointless" as well as the conversations between Relator Wallace and Christensen connecting Dr. Lemak's complaints to Exactech's offer of remuneration, make it plausible that the purpose of the consulting agreements was to induce Dr. Lemak to continue to purchase Exactech products.

To establish FCA liability based on an AKS violation, some courts further require a showing of causation, or some "link" between the payment of remuneration and the submission of false claims. *See, e.g.*, *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) ("[D]rawing on the 'resulting from' language of the 2010 amendment [to the AKS], if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA."); *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95–99 (3d Cir. 2018); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-CV-10601-IT, 2018 WL 1996829, at *6 (D. Mass. Apr. 27, 2018). Both parties agree that there must be some "link" but dispute what that link requires. Relators argue that they need not show that the remuneration "actually caused" false claims but only that "at least one of [Defendant]'s claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment)." (*See* Doc. 61 at 50–51) (quoting *Greenfield*, 880 F.3d at 98). Exactech argues that Relators must show that "at least one false claim *resulted from* an improper consulting agreement." (*See* Doc. 58 at 54–55 (emphasis added).) Courts requiring such a "link" differ on the extent of the connection required. *Compare Bawduniak*, 2018 WL 1996829, at *11 (citing *Greenfield*, 880 F.3d at 96) (holding that a complaint "need not show that a

quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks," finding it "sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, even if the physician would have prescribed those drugs absent the kickback") *and Greenfield*, 880 F.3d at 98 (finding that some "link" is required, but actual causation is not), *with United States ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 372 (5th Cir. 2017) (finding relator's complaint failed to allege details of the kickback scheme with sufficient particularity because it merely included "a single, vague paragraph [about] the alleged kickback scheme," which included no facts showing that doctors who received alleged kickbacks from the defendant caused the hospital to use defendant's products).[19]

Here, Relators have sufficiently alleged a causal connection between the illegal payments to Dr. Lemak and false claims submitted to Medicare. This Court need not decide the extent of the "link" that Relators must allege, as the Court finds that they satisfy the more stringent standard of showing that Exactech's provision of illegal remuneration "actually caused" the submission of false claims to the Government.

[19] Although both *Greenfield* and *King* are not binding on this Court and both were ruling at the summary judgment stage, this Court finds their analysis relevant to the present case.

Relators allege that false claims were actually submitted by Dr. Lemak subsequent to Exactech's provision of illegal kickbacks. They provide examples of twelve Medicare-insured patients who received Exactech devices from Dr. Lemak at Grandview Hospital in Birmingham, all of which occurred after Dr. Lemak's receipt of illegal kickbacks. Thus, it is plausible that actual claims were submitted to Medicare by Dr. Lemak as a result of being provided illegal remuneration by Exactech to induce him to continue purchasing Exactech products. For the foregoing reasons, Relators have sufficiently alleged violations of the FCA based on Exactech's violation of the AKS.

4. Count IV – Conspiracy Under 31 U.S.C. § 3729(a)(1)(C)

To state a claim of conspiracy to violate the FCA, Relators must allege (1) an unlawful agreement between two or more persons or entities to get a false claim paid by the United States, (2) an act performed in furtherance of the conspiracy by at least one of the conspirators, and (3) that the United States suffered damages as a result. *See Corsello*, 428 F.3d at 1014.[20] A conspiracy rarely can be established by showing "an explicit agreement; most conspiracies are inferred from the behavior of the

[20] *Corsello* interpreted the pre-FERA version of the statute. *See* 428 F.3d at 1014. The Eleventh Circuit has since said that "[i]t is not clear whether damages remain a required element of the new conspiracy provision following the 2009 amendments." *HPC Healthcare, Inc.*, 723 F. App'x at 791.

alleged conspirators[] and from other circumstantial evidence." *City of Tuscaloosa v. Harcros Chems., Inc.*, 148 F.3d 548, 569 (11th Cir. 1998) (citation omitted).

Relators have sufficiently alleged a plausible FCA conspiracy claim. Beginning in 2014, Dr. Lemak communicated to Exactech his dissatisfaction with the extent of the tibial loosenings and his concern that there was a problem with the Finned Tibia Tray. Exactech then offered Dr. Lemak a consulting agreement and made payments to him under said agreement. These payments qualify as acts performed in furtherance of the conspiracy. *See Corsello*, 428 F.3d at 1014. Moreover, as described in detail above, it is reasonable to infer that Exactech made such payments to Dr. Lemak in order to induce him to continue buying Exactech's products. After receiving such payments and despite his knowledge of prior device failures in his patients, it is alleged that Dr. Lemak continued to purchase the Finned Tibia Tray, implant it into his patients, and submit claims to the Government for payment. Considering the entirety of the Amended Complaint's allegations about the behavior of the alleged conspirators, it is plausible to infer that Exactech and Dr. Lemak agreed to get false claims paid by the Government. *See Harcros Chems., Inc.*, 148 F.3d at 569. The United States was damaged in that it paid for the defective Finned Tibia Trays through its federal healthcare programs. Accordingly, Relators have sufficiently alleged a conspiracy to violate the FCA.

5. Count V – Reverse False Claims Under 31 U.S.C. § 3729(a)(1)(G)

While a claim under § 3729(a)(1)(A) or § 3729(a)(1)(B) creates liability for false claims requesting money from the Government, a "reverse false claim" under 31 U.S.C. § 3729(a)(1)(G) creates liability for conduct that "results in no payment to the government when a payment is obligated." *United States ex rel. Bain v. Ga. Gulf Corp.*, 386 F.3d 648, 653 (5th Cir. 2004). Liability attaches under § 3729(a)(1)(G) when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals . . . an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). An obligation is defined as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, *or from the retention of any overpayment*." 31 U.S.C. § 3729(b)(3) (emphasis added). The Patient Protection and Affordable Care Act ("ACA") defines "overpayment" as "any funds that a person receives or retains under subchapter XVIII [Medicare] or XIX [Medicaid] to which the person . . . is not entitled under such subchapter." 42 U.S.C. § 1320a-7k(d)(4)(B).

As explained in further detail above, Relators sufficiently allege that Dr. Lemak and Grandview were reimbursed for false claims to Medicare and Medicaid. Because those reimbursement claims were false, and Exactech had knowledge of their falsity, Dr. Lemak and Grandview were not entitled to those reimbursements, making them "overpayments." *See* 42 U.S.C. § 1320a-7k(d)(4)(B). And because Dr. Lemak and Grandview allegedly have not returned these overpayments, they are obligations for reverse false claim purposes. Additionally, Relators allege that Exactech falsely told surgeons, including Dr. Lemak, that the Finned Tibia Tray was safe and concealed its long history of failures. Through such false statements, Exactech prevented surgeons from learning that they had submitted false claims for payment and therefore had an obligation to repay Medicare or Medicaid for the false claims. Accordingly, Relators have sufficiently alleged that Exactech knowingly concealed an obligation to return money to the Government. *See* 31 U.S.C. § 3729(a)(1)(G).

Exactech argues Relators must allege that Exactech itself— rather than "some third-party surgeons," (*see* doc. 58 at 52-53), owed an obligation to the government. But Exactech's interpretation is not supported by the plain language of the statute or by any binding Eleventh Circuit authority. Additionally, other courts allow liability for such indirect reverse false claims where a defendant knowingly makes a

false statement that it knows could cause a third party to impair its obligation to the government. *See, e.g.*, *United States v. Caremark, Inc.,* 634 F.3d 808, 817 (5th Cir. 2011). As the Fifth Circuit has recognized, the language of § 3729(a)(1)(G) "does not require that the [false] statement impair the defendant's obligation; instead, it requires that the statement impair '*an* obligation to pay or transmit money or property to the Government.'" *Id.* at 817. This Court is persuaded by the Fifth Circuit's reasoning and finds that such indirect reverse false claims may give rise to liability.

Exactech also argues that Relators' claim for relief under 31 U.S.C. § 3729(a)(1)(G) must be dismissed because it is "redundant" of their claims under § 3729(a)(1)(A) and § 3729(a)(1)(B). According to Exactech, Relators "rely on the same facts and allegations—that Exactech sold defective devices to physicians and thus caused the submission of false claims—to allege liability under the reverse-false-claim provision." (Doc. 58 at 50–51.) Several courts, including those in the Eleventh Circuit, have found that in order for the concealment of an obligation to be actionable under the reverse false claim provision, the obligation must arise independent of the affirmative false claims that are actionable under the other FCA provisions. *See United States ex rel. Schaengold v. Mem'l Health, Inc.*, No. 4:11-CV-58, 2014 WL 6908856, at *15–21 (S.D. Ga. Dec. 8, 2014); *see also Pencheng Si v. Laogai Research*

Found., 71 F. Supp. 3d 73, 97 (D.D.C. 2014) (rejecting relator's argument that defendants' concealment of their fraudulent activity resulted in reverse false claim liability because "by this logic, just about *any* traditional false statement or presentment action would give rise to a reverse false claim action; after all, presumably any false statement action under sections 3729(a)(1)(A) or 3729(a)(1)(B) could theoretically trigger an obligation to repay the fraudulently obtained money").

However, district courts should be "reluctant to dismiss on the basis of the pleadings when the asserted theory of liability is novel," because "it is important that new legal theories be explored and assayed in the light of actual facts rather than a pleader's suppositions." 5B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1357 (3d ed. 2020). The facts can be ascertained through pretrial discovery, "and by motion for summary judgment (or other suitable device), the [Court] can determine whether as a matter of law there is any right of recovery on those facts." *Shull v. Pilot Life Ins. Co.*, 313 F.2d 445, 447 (5th Cir. 1963).[21] While it appears that Relators' claim under 31 U.S.C. § 3729(a)(1)(G) may be redundant of the affirmative false claims, this Court concludes that the claim would best be

[21] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down before October 1, 1981.

assessed after factual development. Accordingly, Exactech's motion to dismiss Count V is due to be denied.

IV. CONCLUSION

For the reasons stated above, Exactech's motion (doc. 57) is GRANTED IN PART to the extent that Relators' claims under the state FCAs (Counts VII–XXIX) are DISMISSED WITHOUT PREJUDICE. The motion is DENIED IN PART as to the federal claims (Counts I–VI).

DONE and **ORDERED** on August 5, 2020.

L. Scott Coogler
United States District Judge

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