

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

United States of America and the State of
California, *ex rel.* Steven Higgins,

Case No. 11-cv-2453 (JNE/SER)

Plaintiffs,

v.

ORDER

Boston Scientific Corporation,

Defendant.

Joy P. Clairmont, Daniel R. Miller, and William H. Ellerbe, Berger Montague PC, 1818 Market Street, Suite 3600, Philadelphia PA 19103, and E. Michelle Drake, Berger Montague PC, 43 Southeast Main Street, Suite 505, Minneapolis MN 55414 (for Relator Steven Higgins); and

Fredrick Robinson and Lesley Reynolds, Reed Smith LLP, 1301 K Street Northwest, Suite 1100 – East Tower, Washington DC 20005, and Allison M. Lange Garrison, Norton Rose Fulbright US LLP, 60 South Sixth Street, Suite 3100, Minneapolis MN 55402 (for Defendant Boston Scientific Corporation).

I. PROCEDURAL BACKGROUND

Relator Steven Higgins, MD, initiated this *qui tam* action on August 26, 2011 on behalf of the United States and the State of California under the False Claims Act (“FCA”) and the California False Claims Act (“CFCA”). (Compl. ¶ 1, ECF No. 1). Higgins alleged that Defendant Boston Scientific Corporation engaged in two distinct schemes: (1) selling defective cardiac defibrillator devices under the names Cognis and Teligen; and (2) providing kickbacks. (Compl. ¶ 2). The United States and the State of California

declined to intervene and, on May 6, 2016, Higgins was permitted to pursue this action on their behalf. (ECF Nos. 44, 47).

Higgins thereafter filed his Amended Complaint on October 7, 2016. (Am. Compl., ECF No. 61). The Amended Complaint alleged one fraudulent scheme: that Boston Scientific sought FDA approval and subsequently sold defective cardiac defibrillator devices under the names Cognis and Teligen. (Am. Compl. ¶ 2). Boston Scientific sought dismissal of Higgins' suit. (ECF No. 63). In deciding that motion, the Court first addressed whether the Court had subject matter jurisdiction with respect to the FCA's public disclosure bar, concluding it does. (Aug. 29, 2017 Order, at 5–8, ECF No. 97), *also available at United States ex rel. Higgins v. Boston Sci. Corp.*, 2017 WL 3732099, at *3–*4 (D. Minn.). The Court next found that while Higgins appeared to state a viable claim under Rule 12(b), he failed to satisfactorily plead his fraud claim with particularity as required by Rule 9(b). (Aug. 29, 2017 Order, at 8–21), *United States ex rel. Higgins v. Boston Sci. Corp.*, 2017 WL 3732099, at *4–*10. Higgins' Amended Complaint was dismissed. (Aug. 29, 2017 Order, at 21), *United States ex rel. Higgins v. Boston Sci. Corp.*, 2017 WL 3732099, at *10. Nevertheless, Higgins was permitted to amend his complaint to cure the Rule 9(b) pleading deficiencies. (Aug. 29, 2017 Order, at 21), *United States ex rel. Higgins v. Boston Sci. Corp.*, 2017 WL 3732099, at *10.

Higgins filed his Second Amended Complaint on September 19, 2017, alleging that Boston Scientific engaged in a fraudulent scheme whereby it sought FDA approval and subsequently sold defective cardiac defibrillator devices under the names Cognis and Teligen. (Sec. Am. Compl., ECF No. 98). Again, Boston Scientific sought dismissal of the

complaint, arguing that Higgins failed to plead his fraud claims with particularity. (ECF Nos. 103, 106). The Court rejected that argument, finding “Higgins has particularly pled fraud in how Boston Scientific allegedly misled the FDA.” (Dec. 13, 2017 Order, at 1, ECF No. 117), *also available at United States ex rel. Higgins v. Boston Sci. Corp.*, 2017 WL 6389671, at *1 (D. Minn.).

A pretrial scheduling conference was then set and the parties were directed to jointly prepare a Rule 26(f) report. (ECF No. 121). The parties disagreed on nearly every part of the discovery plan and schedule. (ECF No. 130 *passim*). Following the pretrial conference, this Court directed the parties to meet and confer further in an attempt to reach an agreement on a pretrial schedule that met all parties’ needs in lieu of a wholly court-imposed schedule. (ECF Nos. 134, 135). The parties complied and developed a pretrial schedule. (ECF No. 135). The parties also agreed that regular telephone status conferences would “keep discovery in this case moving forward efficiently.” (ECF No. 135, at 1). This Court incorporated the parties’ agreed-upon deadlines in a pretrial scheduling order and set monthly telephonic status conferences. (ECF Nos. 137, 138). Relevant here, July 31, 2018 was to serve as the deadline for motions seeking to amend the pleadings to add parties or claims. (ECF No. 137, at 1).¹

Higgins filed his instant Motion for Leave to File Third Amended Complaint on July 31, 2018. (ECF No. 145). Higgins seeks to add a claim under the California Insurance

¹ In response to a prompt in the Rule 26(f) report that asked whether the party had any plan to amend the pleadings, Higgins indicated that he had no intention to amend his complaint “to add any additional parties but reserves his right to amend.” (ECF No. 130, at 5). Boston Scientific made the same reservation in functionally identical language. (ECF No. 130, at 5).

Frauds Protection Act (“CIFPA”). Boston Scientific opposes the motion, arguing Higgins’ new claim under CIFPA is futile for three reasons: (1) Higgins did not file the proposed Third Amended Complaint under seal as CIFPA requires; (2) CIFPA’s statute of limitations bars Higgins’s claim; (3) and Higgins’s claim is not plead with particularity as required by Rule 9(b). Boston Scientific also argues it is unduly prejudiced by the proposed amendment. At the hearing on Higgins’ motion, Boston Scientific argued for the first time that the Court lacks jurisdiction over the proposed CIFPA claim. Specifically, Boston Scientific argued that Higgins’s CIFPA claim does not arise out of the same transaction or occurrence for the Court to exercise supplemental jurisdiction under the FCA. This Court ordered supplemental briefing on the jurisdictional issue. (ECF Nos. 164, 168, 169). For the reasons stated below, the motion is denied.

II. ANALYSIS

A. Legal Standard

A court should “freely give leave” to amend a pleading before trial when “justice so requires.” Fed. R. Civ. P. 15(a). Nonetheless, leave to amend should not be given when there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment[.]” *Foman v. Davis*, 371 U.S. 178, 182 (1962). “Delay alone is not enough to deny a motion to amend; prejudice to the nonmovant must also be shown.” *Bediako v. Stein Mart, Inc.*, 354 F.3d 835, 841 (8th Cir. 2004). Filing a motion to amend a pleading within the deadline established by a pretrial scheduling order “does not confine the district court’s

consideration of the merits of such [a] motion[] and does not preclude it from finding that an amendment would result in prejudice.” *Moses.com Sec., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1066 (8th Cir. 2005).

Courts may deny amendments that are futile. *See, e.g., Lunsford v. RBC Dain Rauscher, Inc.*, 590 F. Supp. 2d 1153, 1158 (D. Minn. 2008); *DeRoche v. All Am. Bottling Corp.*, 38 F. Supp. 2d 1102, 1106 (D. Minn. 1998). That is, “[d]enial of a motion for leave to amend on the basis of futility means the district court has reached the legal conclusion that the amended complaint could not withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure.” *Zutz v. Nelson*, 601 F.3d 842, 850 (8th Cir. 2010) (internal quotation marks omitted).

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal quotation marks and citations omitted).

B. Futility

1. CIFPA Filing Requirements

Under CIFPA, “[a]ny interested persons . . . may bring a civil action for a violation of [CIFPA] for the person and for the State of California.” CAL. INS. CODE § 1871.7(e)(1). The complaint “shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders.” CAL. INS. CODE

§ 1871.7(e)(2). This 60-day time period gives the State of California an opportunity to intervene. *See generally* CAL. INS. CODE § 1871.7(e).

Boston Scientific argues that Higgins failed to comply with this requirement in that his Third Amended Complaint was not filed under seal. This argument is unavailing because Higgins has not actually filed his Third Amended Complaint. Rather, he seeks permission from this Court to file it in the first instance.² Thus, Higgins has not even had the opportunity to run afoul of this CIFPA requirement, rendering Boston Scientific's argument premature.

Boston Scientific argues that Higgins' procedural error has "deprived [the State of California] of its statutory right to review the allegations" to decide whether to investigate and intervene. (ECF No. 150, at 5–6). Even if this Court were to construe Higgins' filing of his proposed Third Amended Complaint in conjunction with his motion to amend—which he was required to do under the Local Rules—as a filing sufficient to trigger this CIFPA requirement, and further assuming that Boston Scientific has standing to raise this statutory argument, Higgins' alleged failure to comply with the CIFPA filing requirement does not render the proposed amendments futile.

CFCA and CIFPA have identical procedural requirements. Under CFCA, "[a] complaint filed by a private person under [CFCA] shall be filed . . . in camera and may remain under seal for up to 60 days." CAL. GOV'T CODE § 12652(c)(2). CIFPA's requirement is the same. CAL. INS. CODE § 1871.7(e)(2) ("The complaint shall be filed in

² Under the Local Rules, Higgins was required to file alongside his motion to amend a copy of his proposed amended pleading. D. Minn. LR 15.1(b). Only once the motion is granted does the moving party file and serve the amended pleading. *Id.*

camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders.”). These 60-day provisions allow the State of California an opportunity to intervene. *See generally* CAL. INS. CODE § 1871.7(e); CAL. GOV’T CODE § 12652. Under both CFCA and CIFPA, California is obligated to notify the court whether it intends to proceed with the action. CAL. GOV’T CODE § 12652(b)(3)(B); CAL. INS. CODE § 1871.7(e)(4)(B).

With respect to Higgins’ CFCA claim, the State of California did not strictly comply with its statutory requirement to notify the Court that it declined to proceed with this action. Rather, that information was provided via a footnote to the United States’ own notice declining intervention, which stated: “The State of California has advised the United States that it also declines to intervene in this action.” (ECF No. 44, at 1 n.1). Instead of informing the Court as required, the State of California informed the United States. This Court will not enforce strict compliance with a California procedural requirement where the State of California itself has not strictly complied, and even less so where a private entity is attempting to enforce that requirement on the non-compliant State’s behalf.

Accordingly, this Court concludes Higgins’ public filing of his motion for leave to amend, which included as an attachment the proposed Third Amended Complaint as required by the Local Rules, does not render the proposed amendment futile.

2. Statute of Limitations and Relation Back

An amended pleading is futile if the claims are time-barred. *Ingrim v. State Farm Fire & Cas. Co.*, 249 F.3d 743, 745–46 (8th Cir. 2001); *Sentell v. RPM Mgmt. Co., Inc.*, 653 F. Supp. 2d 917, 919–22 (E.D. Ark. 2009); *see Foster v. Cerro Gordo Cty.*, 33 F. Supp.

3d 1052 (N.D. Iowa 2014). CIFPA provides that suits “may not be filed more than three years after the discovery of the facts constituting the grounds for commencing the action.” CAL. INS. CODE § 1871.7(l)(1). Notwithstanding this three-year statute of limitations, “no action may be filed . . . more than eight years after the commission of the act constituting a violation.” CAL. INS. CODE § 1871.7(l)(2). Boston Scientific argues that Higgins’ proposed new claim violates CIFPA’s statutes of limitations and repose, and that the proposed Third Amended Complaint does not relate back to Higgins’ previous pleadings.³

This Court need not consider statutes of limitations and repose arguments, however, if Higgin’s proposed Third Amended Complaint relates back to his previous complaints. Under Rule 15, an “amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading.” Fed. R. Civ. P. 15(c)(1)(B). “To arise out of the same conduct, transaction, or occurrence, the claims must be tied to a common core of operative facts.” *Taylor v. United States*, 792 F.3d 865, 869 (8th Cir. 2015) (quotation omitted). The purpose of relation back is “to balance the interests of the defendant protected by the statute of limitations with the preference expressed in the Federal Rules of Civil Procedure in general, and Rule 15 in particular, for resolving disputes on their merits.” *Krupski v. Costa Crociere S.p.A.*, 560 U.S. 538, 550 (2010).

³ Higgins’ initial complaint was filed in August 2011. He filed his Amended Complaint on October 7, 2016. Following the Court’s ruling on Boston Scientific’s motion to dismiss, Higgins filed his Second Amended Complaint on September 19, 2017. The conduct at issue in all complaints dates between 2008 and 2009.

Higgins' proposed Third Amended Complaint spans 333 paragraphs. Of those 333 paragraphs, 278 are repeated from the Second Amended Complaint, one is a new introductory paragraph, and the remaining 54 are additions that describe Higgins' proposed CIFPA claim. Higgins alleges: "In addition to the false claims that Defendant caused to be submitted to Medicaid and Medicare that form the basis of Relator's claims under the federal False Claims Act and California False Claims Act, Defendant likewise caused the submission of false claims to private insurers in California." (Proposed Third Am. Compl. ¶ 280, ECF No. 145-1). Higgins then describes the legal framework of CIFPA. (Proposed Third Am. Compl. ¶¶ 282–89).

Higgins next alleges that insurance companies in California generally reimburse providers for implantation of cardiac defibrillators, estimating from "firsthand experience" that "approximately one-third of his patients who received a Cognis or Teligen device in California were covered by private insurance carriers, such as Aetna, Anthem, Blue Cross, Blue Shield, Cigna, Humana and UnitedHealth." (Proposed Third Am. Compl. ¶¶ 290–92, 301, 305, 309, 314). Higgins estimates he implanted Boston Scientific devices in approximately 90 patients in California covered by private insurance carriers. (Proposed Third Am. Compl. ¶ 293). "Based on his experience, [Higgins] knows that these private insurance carriers provided reimbursement for the implantation of Cognis and Teligen and related services," typically "in the range of \$40,000 or more." (Proposed Third Am. Compl. ¶¶ 294–95).

Higgins alleges that insurance companies in California only provide coverage for medically necessary and FDA-approved medical devices. (Proposed Third Am. Compl.

¶¶ 296–317). Private insurance carriers’ coverage policies and provider agreements “are similar to the federal requirement that Medicare only cover medically reasonable and necessary services.” (Proposed Third Am. Compl. ¶ 315) (citation omitted). Allegedly, Boston Scientific caused providers to submit false claims to private insurance carriers “[f]or the same reasons described . . . with respect to [his] claims related to Medicare and Medicaid fraud,” including reimbursement for defective devices and medically unnecessary services, all of which occurred due to “fraudulently induced FDA approval.” (Proposed Third Am. Compl. ¶¶ 318–21).⁴ These false claims to private insurance carriers were then reimbursed, but coverage would have been denied had Boston Scientific not fraudulently obtained FDA approval for defective devices. (Proposed Third Am. Compl. ¶¶ 321–28).

Boston Scientific attempts to differentiate Higgins’ CIFPA claims from his FCA and CFCA claims through the different processes used for medical claim reimbursements. Boston Scientific asserts that the claim submissions processes are so different between government-operated health insurance programs and private insurance carriers that Higgins’ new CIFPA claim cannot relate back. This Court disagrees. The essence of the conduct at issue is not the specific details of remuneration, but rather the allegation that Boston Scientific misled the FDA in bringing defective defibrillator devices to market.

⁴ Higgins’ addition of “medically unnecessary services” in his CIFPA claim does not appear to fully overlap with his previous pleadings in that Higgins only references medical services in his FCA and CFCA claims when noting “any services which are incident to medically unnecessary care are not reimbursable.” (Proposed Third Am. Compl. ¶ 190). Because Boston Scientific does not argue this point and this Court does not discuss it further.

Who paid for those devices and how—whether private or public health insurance—is merely the final step in what Higgins asserts was a fraudulent scheme many months in the making. Ultimately, which entity paid Boston Scientific for its defibrillator devices is immaterial to the question that need be answered in this litigation: whether Boston Scientific acted with impropriety when bringing their devices to market. The FDA approval process, not the remuneration process, is the common core of operative facts under which all of Higgins’ claims arise. Thus, this Court concludes Higgins’ new CIFPA claim, as found in his proposed Third Amended Complaint, relates back to his previous timely pleadings.

3. Rule 9(b) Particularity Requirements

Under Rule 9(b), a party that alleges fraud or mistake “must state with particularity the circumstances constituting fraud or mistake,” although “[m]alice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). To satisfy the rule, “the complaint must plead such facts as the time, place, and content of the defendant’s false representations, as well as the details of the defendant’s fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.” *United States ex rel. Joshi v. St. Luke’s Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006) (citations omitted). “In other words, ‘the complaint must identify the who, what, where, when, and how of the alleged fraud.’” *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016) (quoting *Joshi*, 441 F.3d at 556).

Higgins’ Second Amended Complaint meets this requirement. (Dec. 13, 2017 Order, at 1), *United States ex rel. Higgins v. Boston Sci. Corp.*, 2017 WL 6389671, at *1.

Higgins' proposed Third Amended Complaint does not disturb any of the underlying facts related to the FDA approval process. As noted already, the same set of operative facts underpins Higgins' FCA, CFCA, and CIFPA claims. It follows that the underlying fraud alleged—misleading the FDA in the approval process—is plead with particularity under Rule 9(b).

4. Supplemental Jurisdiction

Higgins' Second Amended Complaint, raising a claim under the False Claims Act, is properly in federal court. 28 U.S.C. § 1331 (“The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.”); 28 U.S.C. § 1345 (“Except as otherwise provided by Act of Congress, the district courts shall have original jurisdiction of all civil actions, suits or proceedings commenced by the United States, or by any agency or officer thereof expressly authorized to sue by Act of Congress.”); *see also* 31 U.S.C. § 3732(a) (“Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred.”). Moreover, Higgins' claim under the California False Claims Act is also appropriately in federal court, as the False Claims Act grants “jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.” 31 U.S.C. § 3732(b). The question Boston Scientific raises, however, is whether the Court has jurisdiction over Higgins' proposed CIFPA claim.

Higgins' CIFPA claim seeks funds paid by private insurance companies, not a state or local government, thereby removing it from the FCA's jurisdictional provisions. The remaining vehicle for jurisdiction, then, is the Court's supplemental jurisdiction under 28 U.S.C. § 1367(a). Under Section 1367, courts "shall have supplemental jurisdiction over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution." 28 U.S.C. § 1367(a); *Wong v. Minn. Dep't of Human Servs.*, 820 F.3d 922, 932 (8th Cir. 2016) ("[F]ederal law affords a federal court the power to exercise supplemental jurisdiction over a state-law claim if it 'derives from a common nucleus of operative fact' as a claim otherwise within the court's jurisdiction.") (quoting *City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 165 (1997)). Courts

may decline to exercise supplemental jurisdiction over a claim . . . if—

- (1) the claim raises a novel or complex issue of State law,
- (2) the claim substantially predominates over the claim or claims over which the district court has original jurisdiction,
- (3) the district court has dismissed all claims over which it has original jurisdiction, or
- (4) in exceptional circumstances, there are other compelling reasons for declining jurisdiction.

28 U.S.C. § 1367(c).

Boston Scientific argues that the factors found in Section 1367(c) militate a finding that the Court should not exercise supplemental jurisdiction, rendering Higgins' proposed Third Amended Complaint futile. As Section 1367 makes clear, courts "*shall* have supplemental jurisdiction" over claims related to claims that otherwise provide jurisdiction. 28 U.S.C. § 1367(a) (emphasis added). This Court already concluded that Higgins' CIFPA

claim arises from the same core of operative facts as his FCA and CFCA claims, meaning all of Higgins' claims are related. If a court has supplemental jurisdiction over a matter, it “*may decline*” to exercise it in certain circumstances. 28 U.S.C. § 1367(c) (emphasis added). Given the permissive nature of this determination, this Court rejects the conclusion that Higgins' proposed Third Amended Complaint is futile merely because the Court *could* decline to exercise its supplemental jurisdiction.⁵

C. Prejudice

Boston Scientific asserts that Higgins exhibited undue delay in asserting his CIFPA claim. This Court agrees. When questioned at the hearing as to why he waited until the final day under the scheduling order before seeking leave to amend, Higgins proffered no explanation other than he was permitted to do so under the scheduling order and rules. Simply filing a timely motion to amend does not preclude a finding that the non-moving party would be prejudiced. *Moses.com Sec., Inc.*, 406 F.3d at 1066. Put differently, a timely motion together with the liberal standard under Rule 15 does not mean that amendment is automatic. *United States ex rel. Lee v. Fairview Health Sys.*, 413 F.3d 748, 749 (8th Cir. 2005) (“Although leave to amend shall be freely given when justice so requires, plaintiffs do not have an absolute or automatic right to amend.”) (quotation and citations omitted)

Higgins has not pointed this Court to any reason, other than his own whim, as to why he could not or did not bring his CIFPA claim in the previous three iterations of his complaint—the initial complaint filed on August 26, 2011; the Amended Complaint filed

⁵ While this Court will not engage in a preemptive supplemental jurisdiction analysis in determining whether Higgins' proposed Third Amended Complaint is futile, it will discuss these factors when considering the prejudice faced by Boston Scientific should amendment be permitted.

on October 7, 2016; or the Second Amended Complaint filed on September 19, 2017. As this Court has already concluded, the CIFPA claim relates back and relies upon the same allegations set forth in Higgins' previous pleadings. The critical conduct at issue is not the specific details of remuneration, but rather the allegation that Boston Scientific misled the FDA in bringing defective defibrillator devices to market. It should be no surprise that private insurance carriers would likewise receive claims for coverage alongside those received by the public health insurance programs. As Higgins' himself declares, he "was familiar with [his] own patients and their forms of insurance" in August 2008 through July 2009, including "many patients who were insured by private insurance companies in California." (July 30, 2018 Decl. of Steven Higgins, MD ¶ 8, ECF No. 145-1, at Ex. 32). To put it bluntly, Higgins provides no reason why he has waited until what would be his fourth complaint in this action to bring the proposed CIFPA claim despite the obvious reality that some claims would have been submitted to private insurance carriers; this Court will not generate or speculate about a reason to justify this inexplicable and needless delay.

This delay imposes tremendous burden upon Boston Scientific. As discussed above, CIFPA permits the State of California an opportunity to intervene. CAL. INS. CODE § 1871.7(e). To conduct an appropriate investigation into the claims asserted, the State of California may ask for additional time before it decides whether to intervene. *Id.* While the State of California has declined to intervene with respect to the CFCA claim, it must be newly presented with the opportunity to intervene on Higgins' CIFPA claim. This required pause in proceedings could have been wholly avoided had Higgins put forth the full set of

his claims against Boston Scientific in the first instance, allowing the State of California to review a comprehensive grouping of Higgins' claims.

With respect to Boston Scientific's supplemental jurisdiction arguments, this Court finds them compelling. Courts may decline to exercise supplemental jurisdiction where the state law claim "substantially predominates over the claim or claims over which the district court has original jurisdiction." 28 U.S.C. § 1367(c)(2). Under CIFPA, Higgins must prove that Boston Scientific intended to defraud when presenting its false claim. *See, e.g., People ex rel. Gov't Emps. Ins. Co. v. Cruz*, 198 Cal. Rptr. 3d 566, 574 (Cal. Ct. App. 2016). This requirement is not mirrored in the False Claims Act, where "[n]o proof of specific intent to defraud the government is required." *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002) (citing 31 U.S.C. § 3729(b)). This difference injects a significant additional element into this action, requiring Higgins to now prove that Boston Scientific not only submitted false claims, but did so with the intent to defraud. While Higgins' proposed Third Amended Complaint names seven private insurance carriers, and Higgins agreed at the hearing to limit his CIFPA claims to the "largest" private insurers, injecting the intent to defraud element into this litigation changes the complexion of this litigation.

Admittedly, the critical conduct at issue is not the specific details of remuneration, but rather the allegation that Boston Scientific misled the FDA in bringing defective defibrillator devices to market; nonetheless, the CIFPA claim would upset this reality. The *scienter* element will lead the CIFPA claim to dominate this litigation, dwarfing the FCA and CFCA claims involving the two public healthcare systems. The added CIFPA claim

will become the “real body” of this case, to which the FCA and CFCA would constitute only “appendages.” *United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 727 (1966). The CIFPA claims will overshadow the claims which initiated this action, changing it from a False Claims Act suit to a private insurance fraud suit. *Id.* at 726–27 (“[I]f it appears that the state issues substantially predominate, whether in terms of proof, of the scope of the issues raised, or of the comprehensiveness of the remedy sought, the state claims may be dismissed without prejudice and left for resolution to state tribunals.”). Such a shift in the litigation, particularly where the parties have only finally—after several fits and starts—embarked on discovery to address the merits of Higgins’ FCA and CFCA claims, places an undue burden on Boston Scientific. *See Bell v. Allstate Life Ins. Co.*, 160 F.3d 452, 454 (8th Cir. 1998) (“[W]hen late tendered amendments involve new theories of recovery and impose additional discovery requirements, courts are less likely to find an abuse of discretion due to the prejudice involved.”).

As discussed, there is nothing new about Higgins’ CIFPA claim that prevented him from asserting it in his previous pleadings, let alone putting Boston Scientific on notice by referencing it in his portion of the Rule 26(f) report, during the pretrial scheduling conference, or during a monthly status conference. This Courts finds troubling the fact that Higgins participated in a protracted negotiation with Boston Scientific concerning various discovery parameters without revealing that he was considering amending his complaint to add the CIFPA claim. This Court entered a scheduling order based on the parties’ agreements following that negotiation; agreements that were reached with only the FCA and CFCA claims in mind. Higgins’ proposed amendment is made all the more surprising

considering it was not discussed whatsoever prior to the motion to amend being filed: not in the Rule 26(f) report where the parties' specifically contemplated motions to amend; not at the monthly telephonic conferences; and not in the parties' pre-conference submissions. (See ECF Nos. 122, 130, 139, 141–43). The parties were made well aware that this Court is not enamored with the beleaguered and lethargic pace of the parties' litigation to date, as well as the fact that any delays will not be countenanced.

While this Court is well aware of the possibility to alleviate some of the burden imposed by CIFPA-related discovery by enacting reasonable modifications to the scheduling order and discovery parameters, *see Dennis v. Dillard Dep't Stores, Inc.*, 207 F.3d 523, 526 (8th Cir. 2000) (“[A]n ‘adverse party’s burden of undertaking discovery, standing alone, does not suffice to warrant denial of a motion to amend a pleading.’”) (quoting *United States v. Continental Ill. Nat’l Bank & Trust Co.*, 889 F.2d 1248, 1255 (2d Cir. 1989)), the burden of additional discovery does not stand alone such that it could be ameliorated through an extended pre-trial process. The discovery on the CIFPA claim, particularly the intent to defraud element, would become all-consuming and take control of this litigation from its stated purpose of remedying false claims to the government. This grim prospect, combined with the other prejudicial results should the proposed amendment be granted, requires denial of Higgins’ motion.

D. Summary

Higgins new CIFPA claim does not run afoul of the CIFPA filing requirements. The new CIFPA claim relates back to Higgins’ previous pleadings as it rests on the same core of operative facts. Higgins’ new claim, which mirrors his previous claims, meets the Rule

9(b) particularity requirements as it relates to the same allegedly fraudulent scheme found in his existing claims that have already withstood a Rule 9(b) challenge.

Where Rule 15(a) commands courts to “freely give leave” to amend a pleading before trial, it also limits that freedom to instances where “justice so requires.” Fed. R. Civ. P. 15(a). Justice does not require Higgins’ amendment. As this Court has concluded, Boston Scientific would be unduly prejudiced if Higgins is permitted to add his proposed CIFPA claim. There is nothing new or unexpected about the proposed CIFPA claim to remedy Higgins eleventh-hour request to amend, particularly where he tendered the proposed claim after three previous opportunities. While Higgins’ proposed CIFPA claim is not futile, the exercise of supplemental jurisdiction is problematic given its predominance over the FCA and CFCA claims. For all these reasons, this Court finds Boston Scientific would be unduly prejudiced should the motion be granted. Accordingly, it is denied.

III. CONCLUSION

Based on all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Relator Steven Higgins’s Motion for Leave to File Third Amended Complaint on July 31, 2018, (ECF No. 145), is **DENIED**.

Dated: October 30, 2018

s/ Steven E. Rau
STEVEN E. RAU
United States Magistrate Judge
District of Minnesota

Higgins v. Boston Scientific
Case No. 11-cv-2453 (JNE/SER)