UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ET AL., EX REL. FRANK GARCIA ET AL. Plaintiffs, v. NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, AND GENENTECH, INC., Defendants.	)	CIVIL ACTION NO. 06-10465-WGY
UNITED STATES OF AMERICA ET AL., EX REL. STEPHEN FAUCI, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, GENENTECH, INC., AND ROCHE HOLDINGS, INC., Defendants.	)	CIVIL ACTION NO. 10-11728-WGY
UNITED STATES OF AMERICA ET AL., EX REL. ALLISON KELLY, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS CORPORATION, GENENTECH, INC., ROCHE HOLDINGS, INC., AND THE ROCHE GROUP, Defendants.	)	CIVIL ACTION NO. 12-10962-WGY

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MEMORANDUM AND ORDER

YOUNG, D.J. March 17, 2015

I. INTRODUCTION

In these qui tam actions, two former employees of Genentech, Inc. and a former employee of Novartis Pharmaceuticals Corporation brought lawsuits against their former employers alleging unlawful and fraudulent practices in the marketing of a drug called Xolair, in violation of the federal False Claims Act ("FCA") and individual states' qui tam statutes. Relators Frank Garcia ("Garcia") and Allison Kelly ("Kelly") (collectively, the "Relators"), as well as a third relator, Stephen Fauci ("Fauci"), filed complaints in the name of the United States and of individual states[1] against various pharmaceutical companies

[1] The Plaintiff states named in the action filed by Garcia are: California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, New Hampshire, New Mexico, Tennessee, Texas, the Commonwealths of Massachusetts and of Virginia, the District of Columbia, New York, and Georgia.

The Plaintiff states named in the action filed by Kelly are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode island, Tennessee, Texas, the Commonwealths of Massachusetts and of Virginia, and Wisconsin.

including Novartis Pharmaceuticals Corporation ("Novartis"),[2] Novartis AG, and Genentech, Inc. (collectively, the "Defendants") accusing them of causing health care providers to overbill federal and state health insurance programs.[3] Garcia Docket, Compl. ("Garcia Compl."), ECF No. 1, ¶ 2; Garcia Docket, First Am. Compl., ("Garcia Am. Compl.") ¶ 270, ECF No. 17; Kelly Docket, Compl. Damages, Civil Penalties, & Other Relief Under Qui Tam Provisions Federal Civil FCA & Similar State Statutes ("Kelly Compl.") ¶ 1 ECF No. 1; Fauci Docket, Pl.'s Compl.

The Plaintiff states named in the action filed by Fauci are: California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, Oklahoma, Rhode island, Tennessee, Texas, the Commonwealths of Massachusetts and of Virginia, Wisconsin, and the District of Columbia.

[2] Novartis is also a defendant in a currently pending case brought by a former Novartis sales manager in the Southern District of New York. There, the United States government and individual states have intervened. That case is based upon alleged kickback activities to induce pharmacies to purchase other Novartis drugs and to cause them to submit false or fraudulent statements or claims, in violation of the FCA. United States v. Novartis Pharms. Corp., No. 11-08196 (S.D.N.Y. filed Nov. 14, 2011).

[3] Garcia filed his complaint under Case No. 06-10465, which will be referred to as the "Garcia Docket." Fauci filed his complaint under Case No. 10-11728, which will be referred to as the "Fauci Docket." Kelly filed her complaint under Case No. 12-10962, which will be referred to as the "Kelly Docket."

Fed. FCA 31 U.S.C. §§ 3729 et seq. & Pendent St. FCA ("Fauci Compl.") ¶ 1, ECF No. 1.

On June 17, 2014, the Defendants filed a motion before the Court to dismiss the actions brought in 2006 by Garcia (the "First Action"), in 2012 by Kelly (the "Second Action"),[4] and in 2010 by Fauci ("Fauci's Action").[5] Garcia Docket, Defs.' Joint Mot. Dismiss Compls. Relators Garcia, Fauci, & Kelly ("Defs.' Mot. Dismiss"), ECF No. 123. The Defendants argue that the Relators, as well as Fauci, failed to plead fraud with sufficient particularity in accordance with Federal Rule of Civil Procedure 9(b). Garcia Docket, Defs.' Joint Mem. Law Support Mot. Dismiss Compls. Relators Garcia, Fauci, & Kelly ("Defs.' Mem. Dismiss") 2, 27-32, ECF No. 125. The Court holds that the Relators' pleadings do not meet the requirements of Rule 9(b) and therefore grants the Defendants' motion to dismiss.

[4] The "First Action" and the "Second Action" are identified as such because of the first-to-file rule as it applies to these two actions. As to Fauci, since he voluntarily dismissed his case on June 16, 2014, the analysis will not focus on his action, which, therefore, can simply be identified as "Fauci's Action."

[5] On June 16, 2014, Fauci filed a notice of voluntary dismissal, which he corrected on June 17, 2014. Garcia Docket, Relator Fauci's Notice of Voluntary Dismissal, ECF No. 120; Garcia Docket, Relator Fauci's Corrected Notice Voluntary Dismissal, ECF Nos. 121, 122. The Relators proceeded with their actions against the Defendants.

A. Factual Background

Beginning in 2003, Novartis and Genentech, Inc. co-marketed Xolair in the United States. Garcia Compl. ¶ 6; Kelly Compl. ¶ 2. Xolair is the brand name for a medication approved by the Food and Drug Administration ("FDA") to treat moderate to severe, persistent allergic asthma in patients aged twelve and older whose symptoms are inadequately controlled with inhaled corticosteroids. Garcia Compl. ¶¶ 5, 27; Kelly Compl. ¶ 3. According to Kelly, the Defendants had hoped that the FDA would approve Xolair for "much wider use, including the treatment of mild asthma." Kelly Compl. ¶ 3.

Garcia worked as a Xolair sales representative at Genentech, Inc. in the New York area from June 2003 through May 2004. Garcia Compl. ¶ 23. Kelly worked as a Xolair sales representative for Novartis from 2003 until late 2006 in the Bronx and Westchester County, New York. Kelly Compl. ¶¶ 23, 52.

The Relators allege that the Defendants, in an effort to increase sales of Xolair and despite FDA's approval for limited uses, engaged in off-label marketing and kickback schemes to broaden their patient population and increase sales. Garcia Compl. ¶¶ 30-31, 38; Kelly Compl. ¶¶ 12-13, 15-18. Specifically, the Relators allege that the

Defendants' pharmaceutical representatives told health care providers ("HCPs") that Xolair was effective for "mild asthma," as well as for "allergy symptoms that may precede an asthma attack in patients suffering from 'allergic asthma,'" called "allergic cascade," and also for "other allergic conditions not associated with asthma, like peanut allergy." Kelly Compl. ¶¶ 9-10. According to the Relators, Defendants also instructed their Xolair sales managers and sales representatives to speak with HCPs about "active asthma," which "generally refers to patients who have been diagnosed with asthma, or experienced asthma symptoms to any extent, within the past year." Id. According to the Relators, the Defendants also urged HCPs to use Xolair on children. Garcia Compl. ¶ 35; Kelly Compl. ¶ 10. The Relators assert that the Defendants also provided kickbacks like free cash equivalents and expensive gifts, free medical and office equipment, and free services to HCPs in order to induce them to prescribe Xolair. Garcia Compl. ¶ 38; Kelly Compl. ¶ 18.

The Relators declare that the Defendants' campaign to boost Xolair sales was extremely successful. Kelly Compl. ¶ 20. In 2003, the year in which Xolair was launched, revenue was only about $25,000,000, whereas it increased to $187,000,000 in 2004 and $320,000,000 in 2005. Garcia

Compl. ¶ 26; Kelly Compl. ¶ 20. From 2003 through 2008, Xolair sales in the United States approximated $2,000,000,000. Kelly Compl. ¶ 21.

The Relators contend that the Defendants have misbranded Xolair, "making it ineligible for reimbursement" under government healthcare programs, especially Medicare and Medicaid. Id. ¶ 15. They also allege that the Defendants have illegally induced HCPs to submit claims for reimbursement at improper rates by advising them to use improper medical codes, called "upcoding," for the administration of Xolair. Kelly Compl. ¶ 17, 280-92. The Relators allege that the Defendants have abused government health care programs such as Medicare, Medicaid, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"), the Veteran Health Administration, and the Federal Employees Health Benefits Program ("FEHBP"). Id. ¶¶ 27, 41. The Relators also cite legislation that prohibits or restricts the prescription of drugs and prohibits kickback activity in relation to payments made under a government health care program, such as the Federal Food, Drug and Cosmetic Act ("FDCA"), the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and the Medicare and Medicaid Anti-Kickback Act ("AKA"), as amended by the

Patent Protection and Affordable Care Act. Garcia Compl. ¶¶ 12-14, 21; Kelly Compl., ¶¶ 19, 46, 102-10.

B. Procedural Posture

These cases were first assigned to Judge Nancy Gertner on March 14, 2006. They were then transferred to Judge Joseph L. Tauro on September 23, 2011, and then again transferred to this session of the Court on March 13, 2014. Garcia Docket, Elec. Clerk's Notes, Sept. 23, 2011 & March 13, 2014, ECF No. 91.

1. The Relators

On March 14, 2006, the Relators jointly filed a qui tam action against the Defendants (the "Garcia Complaint"). Garcia Compl. The Relators amended the complaint on December 19, 2007 to add claims under New York's and Georgia's qui tam statutes. Garcia Am. Compl. ¶¶ 269-88.[6] The United States declined to intervene on January 18, 2011, Garcia Docket, Notice of Election to Decline Intervention by United States of America, ECF No. 38, and the individual states named in the Garcia Complaint declined to intervene on February 7, 2011, Garcia Docket, Notice of Election to Decline Intervention by States, ECF

[6] While the Relators filed the complaint and the amended complaint jointly, Kelly voluntarily dismissed the case on August 1, 2011, hence the names "Garcia Complaint" and "Garcia Amended Complaint."

No. 41. On January 19, 2011, Judge Gertner ordered that the file in the First Action remain under seal and not be made public. Garcia Docket, Order, ECF No. 39.

On August 1, 2011, Kelly moved voluntarily to dismiss herself from the First Action. Garcia Docket, Mot. Voluntary Dismissal, ECF No. 45. On August 2, 2011, Kelly filed a motion to keep her name under seal. Garcia Docket, Relator Mot. Keep Name Under Seal ("Kelly Mot. Keep Name Sealed"), ECF No. 49. Judge Gertner allowed this motion shortly thereafter. Garcia Docket, Order, ECF No. 50. On August 8, 2011, Judge Gertner ordered the dismissal of Kelly without prejudice and ordered Garcia "to file a complaint within [sixty] days" removing all references to Kelly. Garcia Docket, Order ("August 2011 Order"), ECF No. 51.

On August 19, 2011, Garcia asked for an additional thirty-day extension. Garcia Docket, Mot. Extension Time, ECF No. 53. Judge Tauro denied the extension on October 3, 2011. Garcia Docket, Order, ECF No. 54. Garcia was granted additional time to obtain counsel on March 6, 2012. Garcia Docket, Order, ECF No. 56.

At an April 24, 2012, status conference, Judge Tauro ordered that the "Relators have until May 31, 2012, to file a complaint in a new case." Garcia Docket, Order ("April

2012 Order"), ECF No. 64. On May 31, 2012, Judge Tauro allowed the Relators an extension of time to file a complaint. Garcia Docket, Order ("May 2012 Order"), ECF No. 67.

On June 6, 2012, Kelly brought the Second Action by filing a complaint against the Defendants as well as against Novartis Corporation, Roche Holdings, Inc., and the Roche Group (the "Kelly Complaint"). Kelly Compl. Novartis Corporation and Roche Holdings, Inc. are parent holding companies that do not develop, manufacture, sell, or market any pharmaceuticals or other products.[7] Garcia Docket, Joint Mem. Law Supp. Novartis Corp.'s & Roche Holdings, Inc.'s Mot. Dismiss Compls. Relators Fauci & Kelly ("Novartis & Roche Mem. Dismiss") 2, ECF No. 126.

On October 10, 2012, Garcia filed a motion to amend his Complaint and consolidate it with the Kelly Complaint. Garcia Docket, Relators' Unopposed & Ex Parte Mot. Am. & Consol. FCA Compl. With Proposed Attach. Consol. First Am. Compl. in Civil Action No. 12-CV-10962-JLT ("Relators' Mot. Am."), ECF No. 70. Fauci jointly sought to amend and consolidate his complaint filed on October 8, 2010 (the

[7] Novartis Corporation and Roche Holdings, Inc. assert that Roche Group is a trade name and is not a legal entity. Novartis & Roche Mem. Dismiss 2 n.1. The Relators do not challenge this.

"Fauci Complaint"), Fauci Compl., with the Kelly Complaint. Id.

On May 14, 2013, Judge Tauro ordered the Kelly Complaint "be unsealed and served upon the defendants" by Kelly. Kelly Docket, Order 1, ECF No. 6. In this order, it also appears that the United States and all of the individual states, except Indiana, declined to intervene in the Second Action, just as they had in the First Action. Id.

On June 13, 2013, Judge Tauro closed the First Action without entry of judgment and further ordered that the action might be reopened upon motion. Garcia Docket, Order, ECF No. 83. On January 14, 2014, the United States moved to reopen the First Action to alert the Defendants about a potential issue in the Second Action regarding the "first-to-file" rule in qui tam actions under 31 U.S.C. § 3730(b)(5). Garcia Docket, United States Mot. Reopen Case and Partial Seal Lift, ECF No. 85. The "first-to-file" rule prevents a person from bringing an action based on the same allegations of fraud as alleged in an earlier or pending action. Id. On January 23, 2014, Judge Tauro reopened the First Action and unsealed the contents of the file. Garcia Docket, Order, ECF No. 88.

On March 7, 2014, following Garcia and Fauci's October 2012 motion to amend their complaints and consolidate them with the Kelly Complaint, the Relators and Fauci filed a consolidated first amended complaint. Garcia Docket, Consol. First Am. Compl. For Damages, Civil Penalties, & Other Relief Under Qui Tam Provisions Federal Civil FCA & Similar State Statutes, ECF No. 90. On April 17, 2014, the Defendants opposed Garcia and Fauci's October 2012 motion to amend. Garcia Docket, Defs.' Opp'n Relators' Mot. Amend & Consol., ECF No. 113. On April 18, 2014, this Court denied the motion to amend and struck from the docket the consolidated first amended complaint. Garcia Docket, Order ("April 2014 Order"), ECF No. 114; Fauci Docket, Order, ECF No. 27; Kelly Docket, Order, ECF No. 33. That same day, the Court consolidated the First and the Second Actions, as well as Fauci's Action, for pre-trial and administrative purposes only. Id.

On June 12, 2014, the Relators and Fauci, together with the Defendants, Novartis Corporation and Roche Holdings, Inc., jointly moved: (1) to request leave for Novartis Corporation and Roche Holdings, Inc. to file two consolidated memoranda of law in support of the motions they intended to file to dismiss Garcia's, Kelly's and Fauci's complaints; (2) to extend Novartis AG's time to

file a motion to dismiss; and (3) to extend the Relators' time to reply to the motions to dismiss. Garcia Docket, Joint Mot. Consol. Defs.' Mem. Law Support Mot. to Dismiss & Extend Novartis AG's and Relators' Time Resp., ECF No. 118. The Court granted this joint motion the next day. Garcia Docket, Elec. Order, ECF No. 119.

On June 17, 2014, the Defendants filed a motion to dismiss the First and Second Actions, as well as Fauci's Action. Defs.' Mot. Dismiss. Novartis Corporation and Roche Holdings, Inc., which are defendants only in the Second Action and Fauci's Action, filed a motion to dismiss both of those actions. Garcia Docket, Notice Novartis Corp.'s and Roche Holdings, Inc.'s Joint Mot. Dismiss Compls. Relators Fauci and Kelly, ECF No. 124. Novartis AG, however, never filed a motion to dismiss. On August 5, 2014, the Relators opposed the Defendants' motion to dismiss. Garcia Docket, Opp'n Defs.' Mot. Dismiss ("Relators' Opp'n Defs.' Mot. Dismiss"), ECF No. 141. On September 10, 2014, the Defendants, together with Novartis Corporation and Roche Holdings, Inc., filed a consolidated reply memorandum in support of the Defendants' motion to dismiss and Novartis Corporation's and Roche Holdings, Inc.'s motion to dismiss. Garcia Docket, Defs.' Consol.

Reply Mem. Supp. Mot. Dismiss Relators' Compls. ("Reply"), ECF No. 147.

During a motion session held on September 19, 2014, the Court addressed the motions to dismiss filed by the Defendants and by Novartis Corporation and Roche Holdings, Inc. and took the motions under advisement. Garcia Docket, Elec. Clerk's Notes Mot. Hr'g, Sept. 19, 2014, ECF No. 148.

2. Fauci

On October 8, 2010, Fauci filed his complaint against Novartis, Genentech, Inc., and Roche Holdings, Inc. in the name of the United States pursuant to 31 U.S.C. §§ 3729 et seq. and a number of individual states under those individual states' qui tam statutes provisions. Fauci Compl. At the United States' request, on November 4, 2010, Judge Gertner administratively consolidated Fauci's Action with the First Action. Garcia Docket, Order, ECF No. 37; Fauci Docket, Order, ECF No. 7. The June 17, 2014, motions to dismiss filed by the Defendants as well as by Novartis Corporation and Roche Holdings, Inc. applied both to Fauci's Action, as well as to the First and the Second Actions. Defs.' Mem. Dismiss 1; Novartis & Roche Mem. Dismiss 2.

On June 16, 2014, corrected on June 17, 2014, Fauci filed a notice of voluntary dismissal of all claims raised

in his complaint. Garcia Docket, Relator Fauci's Notice of Voluntary Dismissal, ECF No. 120; Garcia Docket, Relator Fauci's Corrected Notice Voluntary Dismissal. Fauci sought to dismiss the case with prejudice as to himself and without prejudice as to the United States and the individual states named in the Fauci Complaint. Fauci Corrected Notice Dismissal. Garcia, Novartis, Genentech, Inc., and Roche Holdings, Inc. stipulated to Fauci's dismissal of his action. Id. On July 1, 2014, the United States consented to Fauci's dismissal of his action. Garcia Docket, United States Notice Consent Relator Fauci's Notice Voluntary Dismissal, ECF No. 130. On July 18, 2014, amended on July 21, 2014, Fauci notified the Court that the individual states named in his Complaint had provided written consent to the dismissal with prejudice as to him but without prejudice as to them. Garcia Docket, Notice State Consent Relator's Mot. Dismissal, ECF No. 134; Garcia Docket, Am. Notice State Consent Relator's Notice Voluntary Dismissal and Request Entry Final Order Closing Case, ECF No. 135.

C. The Relators' Claims and the Defendants' Motion To Dismiss

The Relators sued the Defendants, first, for violations of 31 U.S.C. § 3729(a)(1) and (2); second, for

conspiracy to defraud pursuant to 31 U.S.C. § 3729(a)(3); third, for reverse false claims violations pursuant to 31 U.S.C. § 3729(a)(7);[8] and fourth, for violations of the individual states' equivalent qui tam provisions. Garcia Compl. ¶¶ 15-20, 46-268; Kelly Compl. ¶¶ 325-819. Novartis Corporation and Roche Holdings, Inc. are also targeted in the Kelly Complaint. Kelly Compl. ¶¶ 325-819.

The Relators allege that the Defendants engaged in unlawful and fraudulent practices such as: 1) illegal off-

[8] These provisions have been amended and renumbered by the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, 123 Stat. 1617. FERA Section 4(f) stipulates that the amendments shall take effect on the date of enactment of FERA and shall apply to conduct on or after this date. Id. at 1621. FERA took effect on May 20, 2009, id. at 1631, after the period that Relators were employed by the Defendants. See Defs.' Mem. Dismiss 5 n.8. Therefore, the amended provisions do not apply to this case. United States ex rel. Loughren v. Unum Group, 613 F.3d 300, 306 n.7 (1st Cir. 2010). There is an exception in FERA as to the amended section 3729 (a)(2), which was made retroactive to June 7, 2008, applicable to "all claims under the False Claims Act . . . that [were] pending on or after that date." FERA § 4(f)(1), 123 Stat. 1621. Circuit courts disagree as to the meaning of "claims" and as to whether Congress intended the amended section 3729(a)(2) to apply retroactively to pending "actions," or rather to pending requests or demands for money. The First Circuit has not taken a position. Loughren, 613 F.3d at 306 n.7; United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 381 n.3 (1st Cir. 2011). Under the prior definition, the amended section 3729(a)(2) would apply to the Second Action; under the latter definition, the former version would apply. See Loughren, 613 F.3d at 306 n.7. This Court need not address this issue here because neither party in the Second Action alleges the application of the amended section 3729(a)(2) or argues that the amendment is relevant to this case. See Hutcheson, 647 F.3d at 381 n.3.

label marketing of Xolair for unapproved indications; 2) encouraging, aiding, abetting, and causing HCPs to falsely represent facts on Statement of Medical Necessity ("SMN") forms for Xolair; 3) offering and paying illegal kickbacks to HCPs if they promoted Xolair; 4) illegally and misleadingly instructing HCPs to use improper medical codes, or "upcoding," for the administration of Xolair; and 5) improperly targeting Disproportionate Share Hospitals ("DSHs") and other hospitals receiving federal funds, all to increase reimbursement for Xolair from governmental health insurance programs. Id. ¶ 1.

The Relators seek damages for joint liability, including but not limited to, treble damages and civil penalties in favor of the United States. Garcia asks for $11,000 per false claim and Kelly for $5,500 to $11,000 per false claim. Garcia Compl. 70-71; Kelly Compl. ¶ 820. The Relators also request damages and civil penalties in their favor and in favor of the individual states, as well as the payment of attorneys' fees, costs, expenses and interest. Garcia Compl. 70-72; Kelly Compl. ¶ 820.

In their motion to dismiss, the Defendants argue, first, that the Court lacks jurisdiction over the Second Action because it is barred by the first-to-file rule; second, that the Court lacks jurisdiction over both actions

under the public disclosure bar; third, that the Relators failed to plead fraud with particularity in accordance with Rule 9(b); fourth, that the Relators failed to state claims of conspiracy and reverse false claims violations under Federal Rule of Civil Procedure 12(b)(6); fifth, that both actions ought be dismissed with prejudice; and sixth, that the Court ought dismiss, or in the alternative, decline to exercise jurisdiction over, the Relators' state qui tam claims. Defs.' Mem. Dismiss 1-2, 35-36. The Defendants also briefly suggest that insufficient service of process is an additional ground for dismissing the Kelly Complaint. Id. 11 n.11.

Novartis Corporation's and Roche Holdings, Inc.'s motion to dismiss incorporates "all of the reasons for dismissal" set forth in the Defendants' motion to dismiss and adds additional bases for dismissal: first, under Rule 12(b)(6) for failure to state a plausible claim for relief as to them; and second, under Rule 9(b) for failure to plead fraud with particularity as to them. Novartis & Roche Mem. Dismiss 1.

On September 19, 2014, after hearing oral arguments, the Court from the bench granted Novartis Corporation's and Roche Holdings, Inc.'s motion to dismiss. Consequently, all claims asserted in the Kelly Complaint against Novartis

Corporation, Roche Holdings, Inc., and Roche Group are dismissed with prejudice as to Kelly. Elec. Clerk's Notes Mot. Hr'g, ECF No. 148. The Court specifies here that these claims are dismissed without prejudice as to the United States and to the individual states named in the Kelly Complaint.

During the same motion session, the Court also dismissed the Relators' claims of conspiracy and of reverse false claims violations for failure to state a claim under Rule 12(b)(6). Id. As a consequence, the claims of conspiracy and of reverse false claims violations alleged by the Relators against the Defendants pursuant to 31 U.S.C. § 3729(a)(3) and (7) are dismissed with prejudice as to the Relators. Id. The Court specifies that these claims are dismissed without prejudice as to the United States and to the individual states named in the Garcia Complaint, the Garcia Amended Complaint, and the Kelly Complaint.

Accordingly, the remaining issues before the Court concern the Defendants' motion to dismiss the Second Action because of the first-to-file jurisdictional bar, the First and Second Actions because of the public disclosure jurisdictional bar, and the First and Second Actions for failure to plead fraud with particularity in accordance

with Rule (9)(b) in the claims alleged pursuant to 31 U.S.C. § 3729(a)(1) and (2).

II. ANALYSIS

A. Legal Standards

1. Motion to Dismiss for Lack of Subject Matter Jurisdiction

The Relators assert that the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Garcia Compl. ¶ 1; Kelly Compl. ¶ 47. In their motion to dismiss, the Defendants dispute subject matter jurisdiction by raising two jurisdictional bars based upon the first-to-file rule and public disclosure.

Federal Rule of Civil Procedure 12(b)(1) permits a defendant to move for dismissal when a court lacks subject matter jurisdiction to entertain a matter under consideration. Fed. R. Civ. P. 12(b)(1). "Whether a relator is qualified to bring a qui tam action under the FCA is a question of subject matter jurisdiction." United States ex rel. Nowak v. Medtronic, Inc., 806 F. Supp. 2d 310, 326 (D. Mass. 2011) (Woodlock, J.) (citing Rockwell Int'l Corp. v. United States, 549 U.S. 457, 468 (2007)).

The party invoking the jurisdiction of a federal court has the burden of proving jurisdiction exists. Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995). The relators, "as the proponent[s] of federal jurisdiction, bear[] the burden of proving its existence by a preponderance of the evidence." United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 109 (1st Cir. 2010) ("Poteet I"). Amorphous or conclusory allegations that federal jurisdiction exists are not sufficient to survive a motion to dismiss. United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 28 (1st Cir. 2009) ("Duxbury I"). Since subject matter jurisdiction is based on allegations contained in the Fauci Complaint and the Kelly Complaint, the Court takes "as true all well-pleaded facts in the [complaints], scrutinize[s] them in the light most hospitable to the plaintiffs' theory of liability, and draw[s] all reasonable inferences therefrom in the plaintiffs' favor." Id. at 20 (quoting Fothergill v. United States, 566 F. 3d 248, 251 (1st Cir. 2009)).

2. Motion to Dismiss for Failure to Plead Fraud Adequately

The Defendants move to dismiss the Relators' claims under 31 U.S.C. § 3729(a)(1) and (2) for failure to plead fraud with particularity under Rule 9(b).

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). FCA allegations under federal law and their state counterparts are subject to the heightened pleading standards of Rule 9(b). Nowak, 806 F. Supp. 2d at 351 (citing United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 731 (1st Cir. 2007), abrogated on other grounds by Allison Engine Co., Inc., v. United States ex rel. Sanders, 553 U.S. 662 (2008)). According to the standard of Rule 9(b), "a complaint must specify the 'time, place, and content of an alleged false representation.'" Rost, 507 F.3d at 731 (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996)).

B. Insufficient Service of Process

In their motion to dismiss, the Defendants also briefly challenge the sufficiency of process of the Kelly Complaint. Under Federal Rule of Civil Procedure 12(b)(5), a party may assert insufficient service of process as a ground for dismissing a complaint. Fed. R. Civ. P. 12(b)(5). When a defendant files a motion to dismiss under Rule 12(b)(5) challenging the sufficiency of process, "the plaintiff bears the burden of proving its adequacy."

Beatie and Osborn LLP v. Patriotic Sci. Corp., 431 F. Supp. 2d 367, 384 (S.D.N.Y. 2006).

According to Federal Rule of Civil Procedure 4(b), "after filing the complaint, the plaintiff may present a summons to the clerk for signature and seal. If the summons is properly completed, the clerk must sign, seal, and issue it to the plaintiff for service on the defendant." Fed. R. Civ. P. 4(b). The plaintiff is responsible for serving a summons with a copy of the complaint on the defendant within the time allowed by Rule 4(m). Fed. R. Civ. P. 4(c)(1). The time limit for service is 120 days after the complaint is filed and dismissal is required if the plaintiff fails to make a showing of good cause on or before the tenth day following the expiration of this 120-day period. Fed. R. Civ. P. 4(m); D. Mass. L. R. 4.1(b). See also Figueroa v. Rivera, 147 F.3d 77, 83 (1st Cir. 1998).

According to the Defendants, Kelly failed to serve them with a summons and a copy of her complaint until on or about January 9, 2014, Kelly Docket, Summons, ECF Nos. 10-14, more than 240 days after the service deadline had passed. Defs.' Mem. Dismiss 11 n.11. As the Relators correctly point out, however, the summonses for the Kelly Complaint were not issued until September 20, 2013. Kelly

Docket, Summons, ECF No. 8. The Defendants were served between January 9, 2014 and January 16, 2014, which is before the 120-day deadline had expired. See Relators Opp'n Defs.' Mot. Dismiss 35 n.4. The Court therefore rejects this grounds for dismissal.

C. Subject Matter Jurisdictional Bars

1. The First-to-File Rule in Relation to the Second Action

The Defendants argue that the Court lacks jurisdiction over the Second Action since this later action filed by Kelly is based on the same facts underlying the First Action. Defs.' Mem. Dismiss 11.

The first-to-file rule under 31 U.S.C. § 3730(b)(5) creates a jurisdictional bar in qui tam actions. This rule provides that "[w]hen a person brings an [FCA qui tam action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The first-to-file rule "serves the dual purpose of preventing parasitic claims based on allegations already available to the government and of avoiding duplicative suits." Nowak, 806 F. Supp. 2d at 334 (citing Duxbury I, 579 F.3d at 32). This rule is jurisdictional and "exception-free." Duxbury I, 579 F.3d at 33. It is intended to "provide incentives

to relators to 'promptly alert[] the government to the essential facts of a fraudulent scheme.'" United States ex rel. Heineman-Guta v. Guidant Corp., 718 F.3d 28, 34 (1st Cir. 2013) (quoting Duxbury I, 579 F.3d at 32) (alteration in original).

The First Circuit has held that 31 U.S.C. § 3730(b)(5) "bar[s] a later allegation if it states all the essential facts of a previously-filed claim or the same elements of a fraud described in an earlier suit." United States ex rel. Wilson v. Bristol Meyers Squibb, Inc., 750 F.3d 111, 117 (1st Cir. 2014) (quoting Duxbury I, 579 F.3d at 32) (internal quotation marks omitted). Under the "essential facts" test, the "first-to-file rule bars a later complaint even if that complaint 'incorporates somewhat different details.'" Heineman-Guta, 718 F.3d at 34 (quoting Duxbury I, 579 F.3d at 32).

At first blush, the essential facts test seems to bar this action. Indeed, the Relators explained in Garcia's October 2012 motion to amend that "[t]here is no question that the [First Action and the Second Action] share common issues of law and fact. In fact, the lawsuits involve the same basic facts and issues . . . [i]ndeed, the two suits would be virtually identical to each other." Relators' Mot. Am. 5. In addition, the Defendants give evidence of

numerous similarities between the two actions in their motion to dismiss. See Defs.' Mem. Dismiss 13-15. The Defendants argue that despite the additional information incorporated in the Kelly Complaint, the government had sufficient notice from the Garcia Complaint about the potential fraud. Simply put, according to the Defendants, the Garcia Complaint satisfied the purpose of the qui tam action. Heineman-Guta, 718 F.3d at 35-36 (holding that "if the first-filed complaint contains enough material information (the essential facts) about the potential fraud, the government has sufficient notice to launch its investigation" and "the purpose of the qui tam action . . . is satisfied").

The "essential facts" rule however, ought not bar the exercise of jurisdiction over the Second Action in this particular case. Kelly and Garcia co-filed the Garcia Complaint in 2006 and together promptly informed the government about the existence of a potential fraud. For Kelly then, the Second Action is not that of an opportunistic or parasitic plaintiff taking advantage of the facts and allegations advanced in an earlier action filed by another. Kelly subsequently moved voluntarily to dismiss herself from the First Action five years after initiating the litigation "based in substantial part on her

interest in minimizing the risk of adverse career impacts from proceeding in an unsealed case." Kelly Mot. Keep Name Sealed 3. Judge Gertner ordered Kelly's dismissal from the First Action without prejudice, August 2011 Order, meaning that she was not barred "from returning later, to the same court, with the same underlying claim." Semtek Int 'l, Inc. v. Lockheed Martin Corp., 531 U.S. 497, 505 (2001). After Kelly's dismissal, Judge Tauro held a status conference on April 24, 2012 that concerned the First Action. The Relators' attorney requested permission to file a new complaint in Kelly's name. Garcia Docket, Mot. Hr'g Tr., April 24, 2012, ECF No. 142, 8:1-2. Judge Tauro allowed the request and that same day ordered that the "Relators have until 5/31/2012 to file a complaint in a new case." April 2012 Order. An extension of time to file this complaint was ordered on May 31, 2012. May 2012 Order.

The first-to-file rule under 31 U.S.C. § 3730(b)(5) is "part of the larger balancing act of the FCA's qui tam provision, which 'attempts to reconcile two conflicting goals, specifically, preventing opportunistic suits, on the one hand, while encouraging citizens to act as whistleblowers, on the other.'" Wilson, 750 F.3d at 117 (quoting United States ex rel. LaCorte v. SmithKline

Beechem Clinical Labs., Inc., 149 F.3d 227, 233 (3d Cir. 1998)). Here, as Congress encouraged by enacting 31 U.S.C. § 3730 (b)(5), there is no doubt that Kelly blew her whistle in 2006 to highlight potential fraud by the Defendants.

Some district courts have disallowed successive actions filed by the same relator. In United States ex rel. Smith v. Yale New Haven Hosp. Inc., the court held that the difference alleged by the relator to support the filing of two successive qui tam actions was not material. 411 F. Supp. 2d 64, 74-75 (D. Conn. 2005). In United States ex rel. Bane v. Life Care Diags., the court sanctioned the relator for bringing a second qui tam action to target another defendant. No. 8:06-cv-467-T-33MAP, 2008 WL 4853599, at *7 (M.D. Fla. Nov. 10, 2008) (dismissing second qui tam suit filed by same relator on first-to-file grounds because the only difference was that the first qui tam action "identifie[d] the Breathe Easy Defendants as a party and [the second qui tam action] identifie[d] Life Care instead" and noting that "[p]iecemeal litigation by a relator is not allowed under the FCA").

The logic of these decisions, however, does not apply to this case. These courts penalized the relators who filed a second qui tam action because they did so with the

intention to modify or add elements or allegations that were not claimed in the first qui tam action. Here, because Kelly does not seek to modify or add allegations in the Second Action that were missing in the Garcia Complaint, the grounds for the above-cited holdings do not apply.

Rather, Kelly's situation reflects a combination of circumstances that, concurring together, lead to the conclusion that she ought not be barred by the first-to-file rule. Though Kelly voluntarily dismissed herself from the First Action after the United States and the individual states declined to intervene, she did so five years after having alerted the government in the Garcia Complaint to the existence of a potential fraud. She decided to bring the Second Action less than one year thereafter, relying on Judge Tauro's April 2012 Order which expressly permitted her to do so.[9]

[9] The Court's conclusion that the Second Action here is not barred by the first-to-file rule will not be undermined by the ruling of the United States Supreme Court in Kellogg Brown & Root Servs., Inc., et al. v. United States, ex rel. Carter, No. 12-1497 (Sup. Ct. cert. granted July 1, 2014); see United States ex rel. Carter v. Halliburton Co., 710 F.3d 171 (4th Cir. 2013). This Supreme Court case will resolve a different question: whether the first-to-file bar under 31 U.S.C. § 3730(b)(5) functions as a "one-case-at-a-time" rule such that when there is no prior claim pending, a relator may file a duplicative claim. This question is

2. Public Disclosure

Section 3730(e)(4)(A)(2005) of Chapter 31 lays out a public disclosure bar for qui tam actions, according to which "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a . . . civil . . . hearing, . . . unless . . . the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A)(2005).[10]

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not relevant to Kelly's case because the First Action was still pending when Kelly filed the Second Action.

[10] The public disclosure bar was amended as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901, effective March 23, 2010. It is the "timeless and universal" principle of non-retroactivity "that the legal effect of conduct should ordinarily be assessed under the law that existed when the conduct took place," see United States ex rel. May v. Purdue Pharma L.P., 737 F.3d 908, 915 (4th Cir. 2013) (citing Landgraf v. USI Film Prods, 511 U.S. 244, 265 (1994)), and not when the complaint was filed. Landgraf, 511 U.S. at 265; see Defs.' Mot. Dismiss 17 n.14. The Supreme Court has ruled that "[t]he presumption against retroactivity, however, is limited to statutes 'that would have genuinely 'retroactive' effect.'" May, 737 F.3d at 915 (citing Landgraf, 511 U.S. at 277). "Applying these principles, the Supreme Court has twice held that the 2010 FCA amendments may not be applied to cases arising before the effective date of the amendments." Id. (citing Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson, 559 U.S. 280, 283 n.1 (2010)). The amendment thus does not apply to the First Action, which addresses conduct that occurred before 2006, well before the amendment took effect. Nor does it apply to the Second Action filed in 2012 because it does not apply to pre-2010

The Defendants argue that the Relators' allegations were disclosed publicly by two earlier employment lawsuits made by former employees of Genentech, Inc., including Fauci, and are therefore barred under the public disclosure rule. Defs.' Mem. Dismiss 18-21. The issue before the Court, then, is whether these prior employment actions trigger the public disclosure bar.

In 2004, James Rediehs ("Rediehs"), a former Xolair sales representative, filed a complaint against Genentech, Inc., for wrongful termination. Defs.' Mem. Dismiss, Ex. A, Complaint (the "Rediehs Employment Compl."), ECF No. 125-4. Referring to this complaint (the "Rediehs Employment Complaint"), the Defendants argue that "Rediehs alleged that Genentech had retaliated against him for raising concerns about 'off-label marketing practices and other illegal marketing strategies' regarding Xolair." Defs.' Mem. Dismiss 3. The Defendants add that the "[Rediehs Employment Complaint] accused Genentech of (1) illegally promoting Xolair for off-label uses, . . . (2) encouraging doctors to use improper billing codes for Xolair to obtain higher reimbursement — a practice known as 'upcoding,' . . . (3) encouraging [DSHs] . . . to bill

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conduct, even where the complaint was filed after the effective date of the amendment. See id.

Medicare at inflated rates for Xolair, . . . and (4) paying honoraria and other alleged 'kickbacks' to induce doctors to prescribe Xolair." Id. The Defendants also suggest that "Rediehs claimed that Genentech had violated the FCA by terminating him after he confronted management about these practices." Id. Rediehs' action against Genentech, Inc. settled in 2005. Id.

In January 2006, Fauci filed a complaint against Genentech, Inc., for wrongful termination (the "Fauci Employment Complaint"). Defs.' Mem. Dismiss, Ex. B, Complaint and Jury Demand ("Fauci Employment Compl."), ECF No. 125-5. According to the Defendants, Fauci "repeated many of the allegations" that Rediehs had previously made. Defs.' Mem. Dismiss 4. The Defendants assert that Fauci accused Genentech, Inc., of "'encourag[ing] its sales representatives to engage in unlawful sales practices to improve Xolair sales, including paying kickbacks to doctors and illegally completing SMN forms" and also "of illegally marketing Xolair for 'off-label' uses, encouraging doctors to use improper medical codes for the administration of Xolair, or "upcoding," and engaging in a sales practice known as 'marketing the spread.'" Id.; Garcia Compl. ¶¶ 33-35. Fauci's employment action was dismissed in 2008. Defs.' Mem. Dismiss 4.

"For the purpose of the FCA, public disclosure occurs when the essential elements exposing the particular transaction as fraudulent find their way into the public domain." United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 54 (1st Cir. 2009). A fraud is publicly disclosed if "'the information is sufficient to put the government on notice of the likelihood of related fraudulent activity.'" United States ex rel. Poteet v. Lenke, 604 F. Supp. 2d 313, 319 (D. Mass. 2009) (Stearns, J.) (quoting United States ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 512 (6th Cir. 2009)). Consequently, "'once the government knows the essential facts of the fraudulent scheme, it has enough information to discover related fraud.'" United States ex rel. Bartz v. Ortho-McNeil Pharm., Inc., 856 F. Supp. 2d 253, 265 (D. Mass. 2012) (Stearns, J.) (quoting United States ex rel. Branch Consultants v. Allstate Ins. Co., 560 F.3d 371, 380 (5th Cir. 2009)).

Courts follow a sequential three-step analysis to determine whether a lawsuit is precluded by the public disclosure bar. Courts evaluate: "(1) whether there has been a prior, public disclosure of fraud; (2) whether that prior disclosure of fraud emanated from a source specified in the statute's public disclosure provision; and (3)

whether the relator's qui tam action is 'based upon' that prior disclosure of fraud. . . . If all three questions are answered in the affirmative, the public disclosure bar applies unless the relator qualifies under the 'original source' exception." Poteet I, 619 F.3d at 109. See also Bartz, 856 F. Supp. 2d at 260.

a. The Three-Step Analysis

Concerning the three-step analysis, there is little question but that the first two steps are met. The employment complaints by Rediehs and Fauci were filed in the context of a civil hearing within the meaning of step one. "Allegations contained in a civil . . . complaint that are on file in a court clerk's office . . . are 'publicly disclosed' for purposes of § 3730(e)(4)(A)." Id. at 261 (citing Poteet I, 619 F.3d at 111). The filing of these employment actions in federal court in 2004 and in January 2006 also means that they are public and pre-date the Garcia and Kelly Complaints within the meaning of step two.

The question to answer, then, is whether the First and Second Actions are "based upon" Rediehs' and Fauci's Employment Complaints within the meaning of step three. To determine if the public disclosure bar applies, the Court must compare the complaints at issue and extract any

"substantial similarit[ies]" in their factual assertions. Id. (alteration in original) (quoting Poteet I, 619 F.3d at 114). "[A]s long as the relator's allegations are substantially similar to information disclosed publicly, the relator's claim is 'based upon' the public disclosure even if he actually obtained his information from a different source." Id. (alteration in original) (quoting Ondis, 587 F.3d at 57). See also Nowak, 806 F. Supp. 2d at 331. Although additional details may "add some color to the allegation, [if] the allegation ultimately targets the same fraudulent scheme, [it] is enough to trigger the public disclosure bar. Poteet I, 619 F.3d at 115. "[T]he allegations disclosed publicly need not be identical to or as detailed as the allegations contained in the complaint." Nowak, 806 F. Supp. 2d at 330. The identity of the defendant is a "material element of a fraud claim." United States ex rel. Lisitza v. Johnson & Johnson, 765 F. Supp. 2d 112, 122 (D. Mass. 2011) (Stearns, J.) (quoting In re Natural Gas Royalties Qui Tam Litig., 566 F.3d 956, 962 (10th Cir. 2009)). "Only when an earlier filed suit has named a member of the same corporate family are courts inclined to find generic allegations sufficient to put the government on notice of a fraudulent scheme involving a specific defendant." Id.

The Court agrees with the Defendants that the complaints filed previously by Rediehs and Fauci described to a certain extent unlawful practices that the Relators later alleged in their complaints. Defs.' Mem. Dismiss 19, 21; Rediehs Employment Compl.; Fauci Employment Compl. These described practices include 1) inducing HCPs to prescribe Xolair for unapproved uses, including, for example, by illegally completing and influencing SMN forms, Rediehs Employment Compl. ¶¶ 15, 17-18; Fauci Employment Compl. ¶¶ 19, 38; Garcia Compl. ¶¶ 30-35; Kelly Compl. ¶¶ 230-31, 273-76; 2) providing improper payments, or "kickbacks" to physicians, Rediehs Employment Compl. ¶¶ 24-26; Fauci Employment Compl. ¶ 47; Garcia Compl. ¶¶ 25, 38; Kelly Compl. ¶¶ 18, 255-57; 3) manipulating coding and billing to obtain higher reimbursement rates, Rediehs Employment Compl. ¶¶ 14, 16, 19-22; Fauci Employment Compl. ¶ 21; Garcia Compl. ¶¶ 33, 36, 40; Kelly Compl. ¶¶ 276, 281-90; and 4) "marketing the spread," which refers to the difference between acquisition price of Xolair and the reimbursement rates provided by Medicare, Medicaid and other government heath programs, Fauci Employment Compl. ¶¶ 18-22. Also, despite what the Relators argue, see Relators Opp'n Defs.' Mot. Dismiss 12, Medicare is also named in the

Fauci Employment Complaint. Fauci Employment Compl. ¶¶ 18, 21; Kelly Compl. ¶ 297.

In addition, the Court observes that both employment actions were against Genentech, Inc., and not against Novartis. Genentech, Inc., and Novartis are not members of the same corporate family, but the District of Massachusetts has held that "for purposes of prior disclosure, specifying a formulaic drug as part of a kickback scheme is synonymous with naming the company that produces it." Lisitza, 765 F. Supp. 2d at 122 n.15. Also, a marketing partner of Novartis, Robert Rindini, who participated in meetings and discussions about these practices, is mentioned in the Fauci Employment Complaint. Fauci Employment Compl. ¶ 26.

While the Court recognizes some overlap between the facts underlying the Rediehs and Fauci Employment Complaints and the Garcia and Kelly Complaints, the earlier employment actions cannot be said to have sufficiently exposed the essential elements of the alleged fraud so as to have put the government on notice and "enable [it] to adequately investigate the case," Nowak, 806 F. Supp. 2d at 330 (citing United States ex rel. Findley v. FPC-Boron Emps.' Club, 105 F.3d 675, 688 (D.C. Cir. 1997)), especially as far as Novartis is concerned. Moreover, for

the following reasons, the allegations contained in the Garcia and Kelly Complaints cannot be considered "substantially similar" to those earlier publicly disclosed.

The Court concurs with the Relators that their complaints contain allegations that go far beyond what is alleged in the Rediehs and Fauci Employment Complaints. Relators Opp'n Defs.' Mot. 13. The Garcia Complaint provides critical details about unlawful practices, such as targeting physicians of specific clinics and hospitals. Garcia Compl. ¶¶ 40-42. Garcia's and Kelly's complaints also offer significant details about the off-label marketing practices. Id. ¶¶ 13, 25, 30-31; Kelly Compl. ¶¶ 191-255. Rediehs' claims regarding off-label marketing, on the other hand, consist of two paragraphs. Rediehs Employment Compl. ¶¶ 1, 20. There is no express mention of off-label promotion in the Fauci Employment Complaint. Also, the kickback activity is detailed in the Garcia Complaint, which lists numerous types of advantages offered to HCPs. Garcia Compl. ¶¶ 38-39. This is even more true for the Kelly Complaint, which details the type of benefits, gives detailed examples, and also alleges an entirely new target market - the patients themselves. See Kelly Compl. ¶¶ 18, 256-69. Ultimately, the Garcia and

Kelly Complaints allege a wider scheme in terms of geographic location, time period, and types of fraud. Relators Opp'n Defs.' Mot. Dismiss 14. Both Relators advance a nationwide scheme, "around the United States," by Novartis and Genentech, Inc. Garcia Compl. 2; Kelly Compl. ¶ 1. On the contrary, Fauci and Rediehs limited their employment claims to Massachusetts, New York, New Jersey, and Illinois. Fauci Employment Compl. ¶¶ 11, 38; Rediehs Employment Compl. ¶ 2.

The analysis of the three-step test leads this Court to conclude that the public disclosure bar does not apply. In the interest of completeness, the Court also analyzes whether the Relators can qualify as "original sources" of their allegations.

b. Original Sources

The Defendants argue that the Relators cannot qualify as "original sources" because they have not demonstrated direct and independent knowledge of the information on which their fraud allegations are based, Defs.' Mem. Dismiss 21-26, and that they failed to provide information about alleged fraud to the government before filing the First and the Second Actions. Id. 24 n.17, 26 n.18.

As a preliminary matter, the Defendants argue that because of the six-year statute of limitations period

applicable to FCA cases, 31 U.S.C. § 3731(b)(1), the original source exception to the public disclosure bar as it applies to Kelly limits the time period during which Kelly could be an original source to the seven-month period between June 8, 2006, six years before the filing of the Second Action, and "late 2006," when Kelly left Novartis. Defs.' Mem. Dismiss 26 n.19. The Relators answer that Kelly filed her original complaint on March 14, 2006, so the allegations going back to 2003 fall within the six-year statute of limitations. Relators Opp'n Defs.' Mot. Dismiss 34. The Relators posit that the Kelly Complaint amounts to an amended complaint so that the allegations in it "are timely pursuant to Federal Rule of Civil Procedure 15(c)." Relators Opp'n Defs.' Mot. Dismiss 34-35.

Under 31 U.S.C. § 3731(b)(1), "[a] civil action under [§] 3730 may not be brought more than 6 years after the date on which the violation of [§] 3729 is committed." 31 U.S.C. § 3731(b)(1). Rule 15(c) permits an amended pleading to relate back to the date of an original pleading "when the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." Fed. R. Civ. P. 15(c). Kelly dismissed herself from the First Action on August 2011 and filed on June 8,

2012 a new and independent complaint for the Second Action. The new complaint does not constitute an "amended complaint" of the Garcia Complaint and is limited by the six-year statute of limitations period. The Court therefore rules that the six-year statute of limitations applies in this case. This means that for the Second Action, the claims alleged by Kelly are limited, in accordance with 31 U.S.C. § 3731(b)(1), to the period starting from June 8, 2006, six years before the filing of the Second Action.

Turning back to the matter of original sources, even if information is publicly disclosed, a relator may still bring a qui tam action if he or she is the original source of the information. 31 U.S.C. § 3730(e)(4)(B); see Ondis, 587 F.3d at 58. The statute defines an "original source" as "an individual . . . who has knowledge . . . and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B); see Ondis, 587 F.3d at 58; see also United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 719 F.3d 31, 34 (1st Cir. 2013). "'Direct' is defined as 'marked by absence of an intervening agency, instrumentality, or influence: immediate.'" Ondis, 587 F.3d at 59. "Knowledge that is based on research into

public records, review of publicly disclosed materials, or some combination of these techniques is not direct." Id. Information learned secondhand cannot constitute direct and independent knowledge. United States ex rel. Estate of Cunningham v. Millennium Labs. of Cal., Inc., 713 F.3d 662, 674 (1st Cir. 2013); see also Bartz, 856 F. Supp. 2d at 267. In addition, direct and independent knowledge can be shown by reference to, for example, "specific emails, conversations, meetings, promotional materials, and sales reports," so long as these were collected directly and not from public disclosures or another source. Nowak, 806 F. Supp. 2d at 333.

Garcia expressly alleges that he brought the First Action "based upon direct and unique information obtained during the period of [his] employment." Relators Opp'n Defs.' Mot. Dismiss 21; Garcia Compl. ¶ 4. As a sales representative at Genentech, Inc., Garcia: 1) attended staff meetings, debriefings, and participated in discussions or received instructions concerning Xolair marketing for unapproved uses and how to increase Xolair sales, Garcia Compl. ¶¶ 24-25, 40-41; 2) received promotional literature about Xolair's unapproved uses and was encouraged to pass the information to physicians, id. ¶¶ 31, 42; and 3) acquired "first-hand knowledge that many

Novartis and Genentech representatives throughout the country fill[ed] out [SMN forms] themselves . . . in order to facilitate the transaction for the physicians and increase sales." Id. ¶ 33.

The conclusion is similar as to Kelly. She expressly alleges that "[t]hrough her position . . ., [she] attained and possesses extensive, intricate personal and inside knowledge of the unlawful acts." Kelly Compl. ¶ 158. Kelly describes emails in which Xolair sales managers of Novartis distributed off-label studies to sales representatives and discussed the "Competitive Acquisition Program" ("CAP"), the purpose of which was to push doctors to increase prescriptions of Xolair. Id. ¶¶ 237, 259-66. Kelly also describes in the complaint kickbacks in favor of physicians. Id. ¶¶ 257, 261-63. The Court accepts that Garcia and Kelly received first-hand information and instructions, directly and independently, while they worked as sales representatives at Genentech, Inc. and at Novartis.

Concerning the requirement of providing information to the government before filing suit, the Relators have met this standard through the declarations attached as exhibits B and C to their opposition to the Defendants' motion to

dismiss.[11] In these exhibits, the Relators testify that they met on February 14, 2006 with several representatives and government agents to whom they disclosed all of the allegations stated in the Garcia Complaint. Relators Opp'n Defs.' Mot. Dismiss, Ex. B, Decl. Frank Garcia, ECF No. 141-2; id., Ex. C, Decl. Allison Kelly, ECF No. 141-3. Consequently, the Relators can qualify as "original sources" of their allegations in accordance with 31 U.S.C. § 3730(e)(4)(B).

D. Pleading Fraud with Particularity Under Rule 9(b)

The Relators filed this claim under 31 U.S.C. § 3729(a)(1) and (2), which sets forth liability for any person who (1) "knowingly" presents a false or fraudulent claim for payment or approval to the government, or (2) "knowingly" makes a false record or statement to get a

[11] In their opposition to the Defendants' motion to dismiss, the Relators attached four exhibits. Exhibits B and C are declarations of Garcia and Kelly, dated August 5 and August 4, 2014, respectively. Exhibit D is the "Disclosure Statement" that the Relators provided to the government on March 16, 2006. Relators Opp'n Defs.' Mot. Dismiss, Ex. D, Relators' Mandatory Disclosures ("Disclosure Statement"), ECF No. 141-4. In their reply memorandum, the Defendants argue that these exhibits are attempts to supplement the pleadings and the Court should therefore not consider them for purposes of Rule 9(b). Reply 11 (citing Trans-Spec Truck Serv., Inc. v. Caterpillar Inc., 524 F.3d 315, 321 (1st Cir. 2008). The public disclosure bar, however, is not brought under Rule 12(b)(6). The Court may therefore consider the exhibits to the Relators' opposition.

false or fraudulent claim paid by the government. 31 U.S.C. § 3729(a)(1) & (2). The Relators also sued the Defendants in the name of individual states under these states' cognate qui tam provisions. See Garcia Compl. ¶¶ 20, 58-268; Kelly Compl. ¶¶ 50-51, 337-819.

The Defendants argue that the Garcia and Kelly Complaints do not meet the pleading requirements of Rule 9(b). According to them, Garcia's and Kelly's complaints are "replete with sweeping and conclusory allegations regarding off-label, kickback, and other purported 'schemes,'" Defs.' Mem. Dismiss 28, meaning that the Relators did not plead fraud with particularity either as to the scheme, id. at 27-28, or as to the existence of actual false claims, id. at 30-32. According to the Relators, they amply pled specific facts alleging especially that the Defendants provided to physicians studies that purported to support off-label use of Xolair and false statements that Medicaid and Medicare would pay for the prescriptions. See Relators Opp'n Defs.' Mot. Dismiss 28-30. The Relators also state that their Complaint meets the particularity requirement of Rule 9(b) by relying on the Disclosure Statement. Id. at 24-26.

Rule 9(b) requires, "at a minimum," that the complaints set forth "the who, what, where, when, and how

of the alleged fraud." United States ex rel. Worsfold v. Pfizer Inc., No. 09-11522, 2013 WL 6195790, at *5 (D. Mass. Nov. 22, 2013) (Gorton, J.). "Conclusory accusations related to 'plans and schemes' are insufficient." Id. Rule 9(b) may be satisfied where "some questions remain unanswered" as long as "the complaint as a whole is sufficiently particular to pass muster under the FCA." Id. (quoting United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009)).

When claiming a § 3729(a)(1) violation, the burden a relator carries under Rule 9(b) depends in large part on whether the relator has alleged that the defendant submitted false claims directly (for example, by submitting false claims itself) or indirectly (for example, by inducing a third party to submit false claims by offering payments or kickbacks). Id. (citing Duxbury I, 579 F.3d at 29). When alleging an indirect claim, a relator must "provid[e] factual or statistical evidence to strengthen the inference of fraud beyond possibility, without necessarily providing details as to each false claim." Id. at *5 (quoting Duxbury I, 579 F.3d at 29). "Put differently, absent evidence of each of the particular false claims for reimbursement that were submitted, a relator may satisfy Rule 9(b) by alleging particular

details of a scheme to submit false claims paired with 'reliable indicia' that lead to a strong inference that false claims were actually submitted." Id.

When bringing a claim under § 3729(a)(2), "it is not enough to allege that records or statements at issue were made in violation of federal law; a relator must allege that the statements were actually false." Id. (citing Rost, 507 F.3d at 733). In a factually analogous case, Judge Gorton noted that "mere allegations that a company intended to promote off-label uses and profit from such sales fails to demonstrate that [the Defendants] intended to do so at the government's expense." Id. at *8.

In this case, the Relators allege that the Defendants have induced HCPs to submit false claims - that is to say, the Defendants have violated the FCA by making "indirect claims" rather than "direct claims."[12] Garcia Compl. 2; Kelly Compl. ¶ 1.

1. Garcia Complaint

Referring to the specific literature about unapproved uses, Garcia alleges that his manager stressed the

[12] Even when the Relators allege that sales representatives of the Defendants filled out SMN forms themselves, it appears that these representatives did so on behalf of physicians. These representatives did not submit anything directly to the government themselves. See Garcia Compl. ¶ 33; Kelly Compl. ¶¶ 215, 273-76.

importance of "noting to allergists the 'rush immunotherapy' educational literature." Garcia Compl. ¶ 31. Garcia also asserts that he was instructed to promote Xolair for unapproved uses to doctors and to inform them that the usages would be covered by Medicaid and Medicare. Id. ¶¶ 25, 40-41. In addition, he states that Xolair's sales increased in the 2000s. Id. ¶ 26. Garcia also alludes to unlawful practices related to SMN forms, such as filing them out with "inaccurate and misleading information," id. ¶ 33, as well as to illegal kickback activity in violation with the AKA, id. ¶¶ 38-39.

Apart from these allegations, Garcia advances no evidence of any SMN forms that were submitted because of the Defendants. Garcia can identify no claims for reimbursement to Medicare, Medicaid, or any other federal health care program. Also, the Exhibits attached to the Garcia Complaint are the official description, indications, usage, and contradictions of Xolair, blank SMN forms, and health insurance claim forms that do not evidence the actual making of false claims. Id., Ex. 1, Xolair Official Description, ECF No. 1-4; id., Ex. 2, Xolair Statement Medical Necessity, ECF No. 1-4; id., Ex. 3, Health Insurance Claim Form, ECF No. 1-5.

Garcia is not required to provide details as to each false claim under § 3729(a)(1), but he fails to provide even a single example of fraudulent conduct resulting in reimbursement of Xolair by a federal health care program and does not advance information regarding the alleged nationwide fraud and the importance of the false claims. Garcia does not adduce any specific evidence of a fraudulent scheme nor any reliable indicia that the alleged fraudulent schemes resulted in the submission of false claims to the government. While Garcia names his manager, Jerry Kelly, in his complaint, Garcia. Compl. ¶ 23, he does not identify any physicians with whom either Garcia or his supervisor discussed unapproved uses or the submission of SMN forms. The information contained in the Garcia Complaint barely suggests that fraud took place, and it provides no factual or statistical evidence to strengthen the inference of fraud beyond possibility. Accordingly, the Garcia Complaint falls short of the pleading standard of Rule 9(b).

2. Kelly Complaint

The Kelly Complaint contains more detailed allegations and provides more information about the Defendants' practices than does the Garcia Complaint. As determined above, see supra p. 40-41 n.11, the six-year statute of

limitations applies to the Kelly Complaint and the Court will thus examine the allegations claimed under the Second Action that concern the period starting from June 8, 2006.

With regard to the allegations and evidence that concern the period after June 2006, Kelly provides the following: 1) examples of kickback activity such as Novartis inviting HCPs to upscale meals and drinks to promote sales of Xolair on October 24 and November 14, 2006, Kelly Compl. ¶¶ 262-63; 2) references to emails that illustrate how the Defendants pushed for Xolair sales, id. ¶ 257; 3) references to a slide presentation reflecting the objectives of the CAP, showing that seven doctors were targeted in 2006 and 2007, id. ¶ 266, and reflecting the Defendants' "efforts to maximize billing of Medicaid patients," id. ¶ 267; 4) descriptions of unlawful practices in general such as instructing HCPs to use improper medical codes for the administration of Xolair, id. ¶¶ 280-92; 5) affirmations that Xolair sales increased from 2003 through 2008, id. ¶¶ 20-21; 6) references to an FDA report concerning Xolair, dated July 9, 2009 ("FDA Report") that demonstrates widespread off-label use of Xolair, id. ¶ 13; 7) a roster of Novartis sales representatives in 2006, id., Ex. A, Email dated August 25, 2006, ECF No. 1-3, and a "Xolair Rapid Action Report" of 2006, id., Ex. C, Xolair

Rapid Action Report, ECF No. 1-5 (Part 1), ECF No. 1-6 (Part 2), ECF No. 1-7 (Part 3).

In sum, Kelly describes numerous sales practices of the Defendants in relation to Xolair that she learned about from her own experience at Novartis. From this perspective, she provides sufficiently detailed information about Novartis' sales and marketing practices seeking to incentivize HCPs to prescribe Xolair and increase its sales.

Yet the detailed information she provides regarding the instructions she and her colleagues received from their manager to promote Xolair to HCPs, even for unapproved uses, are nothing more than improper marketing practices and illegal kickback activities used by Novartis to increase sales. Such allegations are not sufficient by themselves to make out a violation under the FCA.[13] As with

[13] The AKA provides no private right of action. United States ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 37 (D.D.C. 2003). "Rather, it is a statute providing for criminal penalties for its violation." Id. It has been ruled that "Courts, without exception, agree that compliance with the [AKA] is a precondition of Medicare payment, such that liability under the [FCA] can be predicated on a violation of the [AKA]", but that "[t]he FCA ... attaches liability not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment," and that "a claim under [31 U.S.C. § 3729 (a)(1)] requires proof that a false or fraudulent claim was 'presented' to the government." U.S. v. Infomedics, Inc., 847 F.Supp.2d 256,

Garcia, there is no evidence of any false statement, SMN form, or claim that effectively was submitted. Kelly identifies no claims for reimbursement to Medicare, Medicaid, or any other federal health care program. Kelly fails to provide even a single example of fraudulent conduct resulting in reimbursement of Xolair by a federal health care program and does not give sufficient information regarding the nationwide fraud and the importance of false claims she alleged. On the contrary, Kelly devotes almost 100 pages of her complaint to a recitation of the 123 counts, Kelly Compl. ¶¶ 325-819, 11 pages to allegedly off-label studies that the Defendants purportedly encouraged their sales forces to share with physicians, id. ¶ 2240, and 60 paragraphs to a summary of the law and the regulatory history of Xolair. Id. ¶¶ 102-40, 165-90. The allegation that Novartis closely guarded information in order to conceal fraudulent practices, id. ¶ 163, does not exempt Kelly from the requirement to make specific allegations in support of her claims.

Kelly's allegations suggest that fraud was probable. But the factual and statistical evidence resulting from the information she gives in support of these allegations,

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262 (D. Mass. 2012) (Gorton, J.) (emphasis added) (internal citations and quotation marks omitted).

including the FDA Report, is not sufficient to strengthen the inference of fraud beyond possibility. Kelly does not provide reliable indicia that the alleged underlying schemes resulted in submission of false claims, nor does she bring forward evidence that the physicians who prescribed Xolair sought federal reimbursement. The First Circuit has noted that:

> It is a serious matter to accuse a person or company of committing fraud, . . . At most, [relator] raises facts that suggest fraud was possible . . . [i]t may well be that doctors who prescribed [the drug] for off-label uses as a result of [defendant]'s illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed [the drug] for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it.

Rost, 507 F.3d at 733. Consequently, absent proof of a false statement that resulted in the submission of a single claim, the Court concludes that Kelly has not met the requirements of Rule 9(b).

Even were the Court to consider allegations and evidence concerning the period prior to June 8, 2006, as well as the allegations stemming from the course of her employment at Novartis for which no date is given in her complaint, the result would be the same. In particular, for the same reasons just mentioned, the pleading standard

of fraud is not met when Kelly refers to: 1) Novartis managers that rejected sales representatives' objections about Xolair marketing practices, Kelly Compl. ¶ 196; 2) the promotional literature Kelly received about Xolair's unapproved uses, id. ¶¶ 231, 240; 3) the "target list" of hospitals and physicians she received, id. ¶ 235; 4) the information that patients themselves were targeted for kickbacks, that Kelly distributed around thirty gift baskets to Xolair prescribers, or that an HCP was awarded an all-expense paid trip to a Bahamas Resort, id. ¶¶ 18, 255-57; 5) the filing of SMN forms with misleading information, id. ¶¶ 270-79; and 6) a document called "Respiratory Field Sales 2003 Roster" for Novartis and Genentech, Inc., Kelly Compl., Ex. B, Respiratory Field Sales 2003 Roster, ECF No. 1-4. These allegations fail to meet the pleading standards articulated by Rule 9(b).

3. Disclosure Statement

The Relators attached a Disclosure Statement to their opposition to the Defendants' motion to dismiss. Disclosure Statement. The Disclosure Statement identifies Garcia's manager, who allegedly targeted doctors to induce them to prescribe Xolair and instructed Garcia to do the same. Disclosure Statement 5. Garcia also disclosed the names of five doctors who prescribed Xolair. Id. He

outlines briefly the existence of discussions with these physicians about the prescription of the drug for off-label uses and about submissions of SMN forms despite patients not meeting the approved indications. Id. at 5-6. A "Genentech/Novartis Xolair Field Sales 2006 Roster" with information about the Defendants' sales representatives is also attached to the Disclosure Statement, as is a list of "High-Prescribing Physicians," "Low-Prescribing Physicians" and "Non-Prescribing Physicians." Id. at 16, 37. The Disclosure Statement also contains information about kickback activities that occurred prior to 2006 that comes mainly from Kelly's calendars. This information expressly names physicians that benefited from these activities and describes the kickbacks briefly, such as lunches and dinners. Id. at 5-6.

In Duxbury I, the First Circuit concluded that the relator's complaint satisfied Rule 9(b) because he had identified by name and location "eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves." 579 F.3d at 30.

Here, Kelly's additional allegations directly suggest the existence of illegal kickback activities and that fraud was probable. But again they do not strengthen the

inference of fraud beyond possibility: they do not provide information about the filing of the false claims themselves - the effective submission of false claims seeking federal reimbursement to Medicare, Medicaid, or any other federal health care program.

For the aforementioned reasons, Garcia and Kelly did not plead fraud with particularity as required under Rule 9(b) for the claims alleging violations under 31 U.S.C. § 3729(a)(1) and (2).

E. Dismissal with Prejudice and Leave to Amend

According to the Defendants, the Relators should not be permitted further to amend the complaint and the Court should dismiss the case with prejudice. Defs.' Mem. Dismiss 35 (citing Gagne, 565 F.3d at 48 (affirming denial of leave to amend because of "relators' repeated failure to cure the deficiencies in their pleadings")); United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (Saris, J.) (dismissing complaint with prejudice for failing to comply with Rule 9(b) in light of the striking lack of detail the relator provided as to the defendant in his argument for a violation of the FCA)). The Defendants allege that the Relators have already filed, collectively, five complaints: the Garcia Complaint, the Garcia Amended Complaint, the Fauci Complaint, the

complaint filed jointly by Kelly and Garcia in 2006, and the Kelly Complaint. Defs.' Mem. Dismiss 35. The Defendants refer also to the Consolidated First Amended Complaint filed in 2014, which the Court struck from the docket. Id.

In their opposition to the Defendants' motion to dismiss, the Relators argue that they should be given leave to amend if (as turns out to be the case) the Court rules that they failed to plead fraud adequately. To support their request, the Relators argue that the complaints were not unsealed until January 23, 2014, that this is the first time they have faced a motion to dismiss, and that their complaints have not been previously amended. Relators Opp'n Defs.' Mot. Dismiss 37. In addition, the Relators explain that they can amend their complaints to provide far more precise details of the wrongdoing alleged regarding the voluminous disclosures provided to the Government and excerpted in exhibits here. Id.

Federal Rule of Civil Procedure 15(a)(2) states "[t]he court should freely give leave [to amend a pleading] when justice so requires." Fed. R. Civ. P. 15(a)(2). The First Circuit has held that a court should consider the "number and nature of prior amendments to a complaint" in deciding

a motion for leave to amend. ACA Fin. Guaranty Corp. v. Advest, Inc., 512 F.3d 46, 56 (1st Cir. 2008).

Garcia's original complaint was filed on March 14, 2006, eight years ago. Garcia amended his complaint in 2007. Later, on August 8, 2011, when granting Kelly's motion to dismiss herself from the case, Judge Gertner also ordered Garcia to file a new complaint. August 2011 Order. Garcia did not comply with this order and did not take the opportunity to amend his complaint at that point. Instead, more than one year later, on October 10, 2012, Garcia got around to filing a motion to amend his complaint and consolidate it with the Kelly Complaint. Relators' Mot. Am. On April 18, 2014, this Court denied Garcia's motion and accordingly decided to strike from the docket the Consolidated First Amended Complaint. April 2014 Order. Also, because Kelly co-filed the Garcia Complaint in 2006, she had six years after this date to get new evidence and bring it to the Court when she filed her complaint in 2012. Despite alleging more information than Garcia, the Kelly Complaint does not give sufficient information under Rule 9(b). The "voluminous disclosures" referred to by the Relators seem to be a reference to the Disclosure Statement attached to the opposition to the Defendants' motion to dismiss. Disclosure Statement. Setting aside the fact

that the Disclosure Statement was given to the government long before the present motion before the Court (and could, therefore, have been alleged in one of these many complaints), the Disclosure Statement does not actually help the Relators. As discussed earlier, the information in the Disclosure Statement is not sufficient to meet the pleading standard set by Rule 9(b).

A court may deny leave to amend for the "repeated failure to cure deficiencies, and futility of amendment," United States ex rel. Carpenter v. Abbott Labs., Inc., 723 F. Supp. 2d 395, 410 (D. Mass. 2010) (Stearns, J.); precisely the failures present in this case. Accordingly, justice does not require the Court to give the Relators leave to amend yet again. Garcia's and Kelly's complaints are dismissed with prejudice.

F. The Relators' State Law Claims

The Defendants argue that the Court ought dismiss the individual states' qui tam claims on the same grounds as the dismissal of the FCA claims. Defs.' Mem. Dismiss 35-37. Garcia and Kelly admit that the states on whose behalf they seek to sue the Defendants have statutory provisions substantially similar to FCA § 3729(a)(1) and (2), 31 U.S.C. § 3729(a)(3), and 31 U.S.C. § 3729(a)(7). Garcia Compl. ¶ 20; Kelly Compl. ¶ 51.

When the states' qui tam provisions and the FCA's provisions are "substantially similar," "the state statutes may be construed consistently with the federal act." E.g., New York v. Amgen Inc., 652 F.3d 103, 109 (1st Cir. 2011). In any case, here the Court declines to exercise supplemental jurisdiction over the state law claims as all of the federal claims have been dismissed. 28 U.S.C. § 1367(c). See also Rossi v. Gemma, 489 F.3d 26, 39 (1st Cir. 2007) (quoting Rodriguez v. Doral Mortg. Corp., 57 F.3d 1168, 1177 (1st Cir. 1995)) ("As a general principle, the unfavorable disposition of a plaintiff's federal claims at the early stages of a suit . . . will trigger the dismissal without prejudice of any supplemental state-law claims.").

Here, the Relators' claims for relief under § 3729(a)(1) and (2) are dismissed for pleading deficiencies under Rule 9(b). The Relators' claims for relief under 31 U.S.C. § 3729(a)(3) and 31 U.S.C. § 3729(a)(7) were dismissed by the Court on September 19, 2014. Elec. Clerk's Notes, Sept. 19, 2014, ECF No. 148. The Court declines to exercise supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(c). Consequently, the Relators' claims for relief under the

individual states' qui tam statutes are dismissed, albeit without prejudice.

G. Fauci's Action

Pursuant to Federal Rule of Civil Procedure 41(a) and 31 U.S.C. § 3730(b)(1), Fauci has filed a notice of voluntary dismissal of his action with prejudice as to himself, but without prejudice as to the United States and the individual states named in the Fauci Complaint. Relator Fauci's Corrected Notice of Voluntary Dismissal. Garcia, Novartis, Genentech, Inc., and Roche Holdings, Inc. stipulated to Fauci's dismissal of his action. Id. The United States and the individual states have consented to this dismissal with prejudice as to Fauci but without prejudice as to them. United States' Notice of Consent to Relator Fauci Notice Voluntary Dismissal; Am. Notice of State Consent to Relator Notice Voluntary Dismissal & Request for Entry Final Order Closing Case.

It is hereby ordered that Fauci's Action is dismissed with prejudice as to Fauci, but without prejudice as to the United States and the individual states named in the Fauci Complaint. Accordingly, this opinion has not addressed any issues raised in the motions to dismiss as they relate to Fauci. Defs.' Mem. Dismiss; Novartis & Roche Mem. Dismiss.

III. CONCLUSION

All claims asserted in the name of the United States and the individual states named in Fauci's Action are dismissed with prejudice as to Fauci, but without prejudice as to the United States and to those individual states.

Although the Court has jurisdiction to hear Garcia's and Kelly's claims alleging the Defendants' fraudulent practices, the claims alleged in Garcia's and Kelly's complaints, pursuant to 31 U.S.C. § 3729(a)(1) and (2) and to the individual states' equivalent qui tam provisions, lack the particularity required under Rule 9(b) for pleading fraud. Accordingly, all claims asserted in the name of the United States and of the individual states named in the First Action filed in 2006 by Garcia are dismissed with prejudice as to Garcia, but without prejudice as to the United States and the individual states. All claims asserted in the name of the United States and of the individual states named in the Second Action filed in 2012 by Kelly are dismissed with prejudice as to Kelly, but without prejudice as to the United States and the individual states.

The motions of Garcia and Kelly further to amend their complaints are DENIED and the Defendants' motion to dismiss

the First Action filed in 2006 by Garcia and the Second Action filed in 2012 by Kelly is ALLOWED.

Judgment may be entered for the Defendants.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE