IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES ex rel. Daron Street, M.D. and R. Steven Paulson, M.D.,	)	
Plaintiffs,	)	
	)	Case No. 17-CV-00293-GKF-JFJ
v.	)	
GENENTECH, INC.,	)	
Defendant.	)	

OPINION AND ORDER

This matter comes before the court on the Motion to Dismiss Plaintiff-Relators' Complaint [Doc. 48] of defendant Genentech, Inc. For the reasons set forth below, the motion is granted in part and denied in part.

Background/Procedural History

In order to understand the procedural history of this matter, it is first necessary to briefly consider a related case, MDL No. 2700 *In re: Genentech Herceptin (Trastuzumab) Marketing and Sales Practice Litigation*.

A. MDL No. 2700

In 2016, the United States Judicial Panel on Multidistrict Litigation created MDL No. 2700, *In re: Genentech, Inc. Herceptin (Trastuzumab) Marketing and Sales Practices Litigation*.[1] The Panel selected the Northern District of Oklahoma as the appropriate transferee district and assigned the matter to the Honorable Terence C. Kern. The MDL and cases therein are brought against defendant Genentech, Inc. and relate to the marketing and sales of Herceptin (Trastuzumab), a prescription medication for the treatment of certain types of breast cancer.

[1] For ease of reference, the court refers to MDL No. 2700 as "the MDL."

On March 20, 2019, Judge Kern granted Genentech's motion for summary judgment based on federal preemption and entered judgment in Genentech's favor. Plaintiffs appealed to the United States Court of Appeals for the Tenth Circuit.

On May 29, 2020, the Tenth Circuit reversed the grant of summary judgment in favor of Genentech and remanded the matter to this district for further proceedings. The mandate issued on August 7, 2020.[2]

B. This Case

On May 24, 2017, plaintiff-relators Daron Street, M.D. and R. Steven Paulson, M.D., initiated this action on behalf of the United States to recover damages sustained by, and penalties owed to, the government for Genentech's allegedly false claims regarding federal purchases of Herceptin. [Doc. 2]. The case was initially assigned to U.S. District Judge Claire V. Eagan, but was reassigned to Judge Kern, as the case relates to the MDL. [Doc. 11].

On August 30, 2019, pursuant to 31 U.S.C. § 3730(b)(4)(B), the United States notified the court of its decision not to intervene in this action[3] [Doc. 34], and, on October 7, 2019, the case was unsealed. [Doc. 35]. Relators served Genentech with Summons in this case on October 21, 2019. [Doc. 37].

On November 4, 2019, prior to Genentech filing a responsive pleading, Dr. Street and Dr. Paulson filed an unopposed motion to stay pending resolution of the appeal of Judge Kern's grant of summary judgment on federal preemption grounds in the MDL. [Doc. 38]. That same day, Judge Kern granted the stay. [Doc. 39].

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[2] On June 29, 2023, the MDL was reassigned to the undersigned.

[3] On the United States's motion, Judge Kern granted the government six separate extensions of time to notify the court of its decision regarding intervention. [Doc. 13; Doc. 16; Doc. 19; Doc. 24; Doc. 29; Doc. 33].

This matter remained stayed until August 24, 2020, when Judge Kern lifted the stay following issuance of the Tenth Circuit's mandate in the MDL. [Doc. 44]. Judge Kern directed that Genentech file a response to the Complaint on or before September 4, 2020. [Doc. 43].

On September 4, 2020, Genentech filed the motion to dismiss. [Doc. 48]. Realtors responded in opposition on October 16, 2020, [Doc. 60], and Genentech filed a reply on November 6, 2020 [Doc. 62].

On January 29, 2024, this matter was reassigned to the undersigned upon Judge Kern's retirement. [Doc. 76]. The motion to dismiss is ripe for the court's determination.

Allegations of the Complaint

The Complaint includes the following allegations:

Herceptin is a patent-protected medication used to treat patients with early stage, advanced, and metastatic breast cancer and tumors that overexpress the HER2 neu receptor. [Doc. 2, p. 5, ¶ 20]. Genentech develops, manufactures, and markets Herceptin. [*Id.* ¶ 22].

Genentech has sold Herceptin to the United States and maintains a list of authorized distributors for federal purchasers. [*Id.* at pp. 3-4, 6, ¶¶ 14, 25]. Authorized distributors include AmerisourceBergen Drug Corporation, Cardinal Health Specialty Distribution, Dakota Drug, DMS Pharmaceutical, and McKesson Plasma and Biologics. [*Id*. at p. 6, ¶ 25].

In the third quarter of 2004, 1% of Herceptin sales were to federal facilities. [*Id.* at p. 6, ¶ 26]. Since July 1, 2008, the United States has entered into over 50 contracts and grants to purchase Herceptin. For example, on April 11, 2012, the Department of Defense entered into a $40,686.47 contract with Cardinal Health to purchase Herceptin 440 mg MDV. On June 23, 2014, the DoD entered into a $30,216.41 contract with Cardinal Health to purchase Herceptin 440 mg MDV 1S. On August 4, 2014, the DoD entered into a $66,570.05 contract with Cardinal Health to purchase

Herceptin 440 mg MDV 1S. [*Id.* ¶ 27]. Additionally, on September 30, 2016, the U.S. Department of Veterans' Affairs awarded Genentech a five-year contract worth $3,850,225, 230.00 for the purchase of Herceptin. [*Id.* at pp. 6-7, ¶ 28].

Herceptin is manufactured as lyophilized (dehydrated and "freeze-dried" powder) medicine which is delivered in vials, labeled by Genentech as containing 440 milligrams of Trastuzumab (the active ingredient in Herceptin). The Herceptin product is mixed with a liquid (diluent), also provided by Genentech, which reconstitutes each vial of Herceptin into a multi-dose liquid solution. [*Id*. at p. 7, ¶¶ 31-32].

In 1998, as part of its Biologics Licensee Application (BLA) for Herceptin, Genentech submitted to the Food and Drug Administration a proposed label and Prescribing Information for Herceptin. [*Id*. ¶ 33]. The BLA was approved. [*Id.*]. The 1998 label claimed that the Herceptin vial contained 440 mg of Trastuzumab and provided a Preparation for Administration section that instructed: "Each vial of HERCEPTIN should be reconstituted with 20mL of [Bacteriostatic Water for Injection] as supplied, to yield a multi-dose solution containing 21 mg/mL Trastuzumab." [*Id*. at pp. 7-8, ¶ 34].

Relators allege that Genentech has modified the Herceptin label several times since 1998, but that each Herceptin label has claimed that the vial contained 440 mg of Herceptin and that reconstitution with 20 mL of Bacteriostatic Water for Injection would yield a multi-dose solution containing 21 mg /mL of Herceptin. [*Id.* at p. 8, ¶¶ 35-36]. Thus, with the sale of each vial of Hereptin to the United States, Genentech claims that (1) the vial contains 440 mg of Herceptin, and (2) if a healthcare provider follows the instructions for reconstitution on the Herceptin Label, the resulting multi-dose liquid solution is concentrated at a density of 21 mg of Herceptin per milliliter of solution, which would result in 20.952 mL of liquid solution. [*Id.* ¶¶ 37-38].

However, Relators allege that they have discovered that Genentech "regularly fills vials sold in the United States with less than 440 mg of Herceptin." [*Id.* ¶ 39]. In fact, Relators assert that approximately 90% of the lots of Herceptin released in the United States contained less than 440 mg of Herceptin. [*Id.* ¶ 40]. Thus, when healthcare providers follow the Preparation of Administration instructions provided by Genentech, a vial of Herceptin does not yield 20.952 mL of liquid solution. [*Id*. ¶ 46]. Rather, when they follow Genentech's instructions, providers cannot obtain more than 20.2 mL of liquid solution from a Herceptin vial, and Relators and the United States have received less drug product than the claim on Genentech's label promises they should receive. [*Id.* ¶¶ 47-48]. Specific to the United States, Relators allege that, "[g]iven the systematic under-filling of vials, many Herceptin vials purchased by the United States contained less Herceptin than the amount claimed by Genentech and for which the United States paid." [*Id.* ¶ 41].[4]

Additionally, Relators assert they discovered that, in 2002, Genentech's Herceptin Production Engineer stated in an internal Genentech email that the actual concentration of reconstituted Herceptin was 21.8 mg/mL, not the 21 mg/mL stated on the label. [*Id.* at pp. 8-9, ¶ 42; *see also id.* at p. 97]. Relators allege that, by misstating the concentration, Genentech caused purchasers—including the United States—to administer more Herceptin than necessary to patients and to purchase more Herceptin than they would otherwise purchase. [*Id.* at p. 9, ¶ 44]. That is, if the label included an accurate concentration of the reconstituted Herceptin solution, Relators and the United States would purchase fewer Herceptin vials.[5] [*Id.* ¶ 45].

[4] For ease of reference, the court refers to the allegations in the foregoing paragraph as the "Underfill Scheme."

[5] For ease of reference, the court refers to the allegations in the foregoing paragraph as the "Overconcentration Scheme."

The Relators allege that Genentech knew that most Herceptin vials sold in the United States did not contain 440 mg of Herceptin. [*Id.* at p. 10, ¶ 49]. Specifically, during a hearing in the MDL, Genentech's lead counsel stated that Genentech had produced certificates of analysis showing that "in every lot [of Herceptin] released in the United States, we were below 440. Almost every. Ninety percent, I think they said. So we knew," and that Genentech's "own manufacturing documents . . . show we're below 440, in [plaintiffs'] words, 90 percent of the time." [*Id.* ¶¶ 50-51]. Additionally, in 2002, Genenetch's Herceptin Production Engineer stated the actual concentration of reconstituted Herceptin was 21.8 mg/mL, not the labeled 21 mg/mL. [*Id.* ¶ 52]. Thus, Relators allege that because Genentech knew that the vast majority of Herceptin vials sold in the United States do not contain 440 mg of Herceptin, it also knew that the vials would not yield 20.952 mL of liquid Herceptin solution and, further, because Genentech also knew that its label did not accurately state the concentration of reconstituted Herceptin, it knew the vials would not yield 20.952 mL of liquid Herceptin medicine. [*Id.* ¶ 53].

In addition to the foregoing factual allegations, the Relators attached to the Complaint the following documents: (1) a printout from Genentech's website setting forth authorized Herceptin distributors [Doc. 2, pp. 17-20]; (2) MARIAN V. WROBEL ET AL., SALES OF DRUGS AND BIOLOGICALS TO LARGE VOLUME PURCHASERS (2005) [Doc. 2, pp. 22-68]; (3) Results of an Advanced Data Search for Herceptin, USA SPENDING, http://tinyurl.com/USASpendingGovHerceptin (last visited May 16, 2017) [Doc. 2, p. 70]; (4) Award Summary of Award No. SPM2DX10D0028 awarded by the DoD to Cardinal Health on April 11, 2012 [Doc. 2, p. 72]; (5) Award Summary of Award No. SPM2DX10D0028 awarded by the DoD to Cardinal Health on June 23, 2014 [Doc. 2, p. 74]; (6) Award Summary of Award No. SPM2DX10D0028 awarded by the DoD to Cardinal Health on August 4, 2014 [Doc. 2, p. 76]; (7)

Item Detail No. 50242-0134-68 from the National Acquisition Center [Doc. 2, p 78]; (8) Award Notice, U.S. General Services Administration, https://www.fob.gov/index?s=opportunity&mode=form&tab=core&id=a7acd54cd420422dc4372a529fl369c (last visited May 16, 2017) [Doc. 2, pp. 80-81]; (9) Trastuzumab (Herceptin®) National Drug Monograph, Veterans Affairs Pharmacy Benefits Management Services, HERCEPTIN_monograph.pdf (last visited May 23, 2017) [Doc. 2, pp. 83-95]; (10) Email from Tom White to Olivia Ware (Sept. 15, 2002, 11:52:19) [Doc. 2, p. 97]; and (11) Transcript of Recorded Proceedings at 43, *In re: Genentech Herceptin (Trastuzumab) Marketing and Sales Practice Litigation*, No. 16-MD-2700 (Nov. 17, 2016) [Doc. 2, pp. 99-100].

Based on the foregoing allegations and exhibits, the Relators assert two claims: (1) Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1), by Submission of False Claims, and (2) Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B), by Making or Using False Records or Statements Material to a False or Fraudulent Claim.

Rule 12(b)(6) Legal Standard

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss a claim that "fail[s] to state a claim upon which relief can be granted." "To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead sufficient factual allegations 'to state a claim to relief that is plausible on its face.'" *Brokers' Choice of Am., Inc. v. NBC Universal, Inc.,* 861 F.3d 1081, 1104 (10th Cir. 2017) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim is facially plausible 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* (quoting *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009)). "Mere 'labels and conclusions' and 'a formulaic recitation of the elements of a cause of action' are insufficient." *Estate of Lockett ex rel. Lockett v. Fallin*, 841

F.3d 1098, 1107 (10th Cir. 2016) (quoting *Twombly,* 550 U.S. at 555). The court accepts as true all factual allegations, but the tenet is inapplicable to legal conclusions. *Iqbal*, 556 U.S. at 678. "Accordingly, in examining a complaint under Rule 12(b)(6), [the court] will disregard conclusory statements and look only to whether the remaining, factual allegations plausibly suggest the defendant is liable." *Waller v. City & Cnty. of Denver*, 932 F.3d 1277, 1282 (10th Cir. 2019) (quoting *Khalik v. United Air Lines*, 671 F.3d 1188, 1191 (10th Cir. 2012)). The court "must determine whether the complaint sufficiently alleges facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed." *Lane v. Simon*, 495 F.3d 1182, 1186 (10th Cir. 2007) (quoting *Forest Guardians v. Forsgren*, 478 F.3d 1149, 1160 (10th Cir. 2007)).

"Generally, the sufficiency of a complaint must rest on its contents alone." *Gee v. Pacheco*, 627 F.3d 1178, 1186 (10th Cir. 2010). The U.S. Court of Appeals for the Tenth Circuit has recognized that "[t]here are exceptions to this restriction on what the court can consider, but they are quite limited: (1) documents that the complaint incorporates by reference; (2) documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity; and (3) matters of which a court may take judicial notice." *Id.* (internal citations and quotations omitted).[6]

Analysis

Genentech contends that the Complaint should be dismissed based on three primary arguments: (1) the public disclosure bar precludes Relators' claims; (2) Relators' allegations fail to state a claim upon which relief can be granted pursuant to Rule 12(b)(6); and (3) Relators fail

[6] Genentech also seeks dismissal pursuant to Federal Rule of Civil Procedure 9(b). That standard is set forth in the section of this Order directed to Rule 9. *See infra* pp. 22-23.

to plead fraud with particularity as required by Federal Rule of Civil Procedure 9(b). Additionally, specific to the Overconcentration Scheme, Genentech argues that the claim is time-barred. The court separately considers each argument.

A. Public Disclosure Bar

"The False Claims Act 'covers all fraudulent attempts to cause the government to pay out sums of money.'" *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 736 (10th Cir. 2019) (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). Pursuant to the FCA, "'a private person (the relator) may bring a *qui tam*' suit on behalf of the government and also for [him]self alleging that a third party made fraudulent claims for payment to the government." *Reed*, 923 F.3d at 736 (quoting *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000)). "But there are limits to a relator's right to bring a *qui tam* suit," one of which "is 'known as the public disclosure bar,'" found in section 3730(e)(4)(A) of Title 31. *Reed*, 923 F.3d at 736-38.

Prior to 2010, § 3730(e)(4)(A) provided:

> [n]o court *shall have jurisdiction* over an action under [the False Claims Act] based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

False Claims Amendments Act, Pub. L. No. 99-562, §§ 3, 4, 100 Stat. 3154 (amended effective March 23, 2010) (emphasis added). Under the earlier version, courts apply a "two-step inquiry when a relator files a qui tam action." *United States ex rel. Boothe v. Sun Healthcare Grp., Inc.*, 496 F.3d 1169, 1173 (10th Cir. 2007). First, the court considers "whether the relator's action is 'based upon' a preexisting public disclosure of the defendant's wrongdoing." *Id*. If so, the court determines "whether the relator was the 'original source of the information,'" and, if not, the court

is required to "dismiss the action for lack of subject matter jurisdiction." *Id*. Thus, public disclosure is a jurisdictional bar.

Effective March 23, 2010, Congress amended the public disclosure bar to provide as follows:

> The court shall dismiss an action or claim under [the False Claims Act], unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). Although the Tenth Circuit has not resolved the issue, "[t]he federal courts of appeals that have confronted the issue have unanimously held that the 2010 'amendments transformed the public disclosure bar from a jurisdictional bar to an affirmative defense.'" *Reed*, 923 F.3d at 737 n.1 (quoting *United States ex rel. Prather v. AT&T, Inc*., 847 F.3d 1097, 1102 (9th Cir. 2017), *cert denied*, 582 U.S. 950 (2017)).

The Complaint in this matter includes factual allegations both pre-dating and post-dating the 2010 amendments to § 3730. Relators urge the court to apply the current version of the statute to all of the claims. [Doc. 60, p. 25 n.6]. Genentech contends that the court must apply the version of the statute in effect at the time of the relevant conduct. [Doc. 48, p. 10]. That is, Genentech argues "[t]he pre-2010 version applies to conduct that occurred before the amendment, and the post-2010 version applies to conduct that occurred after the amendment." [*Id.*].

The court need not resolve the issue because, pursuant to either version and under the

circumstances of this case, determination of the applicability of the public disclosure bar at the motion to dismiss stage is inappropriate.

Looking first to the pre-2010 statute, as recognized by the U.S. Court of Appeals for the Tenth Circuit, "the jurisdictional question of whether a 'public disclosure' has occurred arises out of the same statute that creates the cause of action" and therefore "the jurisdictional inquiry is necessarily intertwined with the merits." *United States ex rel. Holmes v. Consumer Ins. Grp.*, 318 F.3d 1199, 1203 (10th Cir. 2003). Such "'intertwined' jurisdictional inquiries should be resolved under Federal Rule of Civil Procedure 12(b)(6) or, after proper conversion into a motion for summary judgment, under Rule 56." *Id.* Where a defendant raises a factual challenge to jurisdiction such that the court must rely on affidavits and other evidentiary material submitted by the parties, the challenge is properly resolved on a motion for summary judgment. *Id.*; *United States ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1518 (10th Cir. 1996).

Genentech brings a factual challenge to jurisdiction and asks the court to consider evidentiary material outside of the pleadings—specifically, certain news media reports regarding lawsuits filed related to Herceptin. *See* [Doc. 48-1 to 48-3]. Thus, insofar as the pre-2010 version of the statute applies, resolution of the public disclosure bar is inappropriate on Genentech's Rule 12(b)(6) motion to dismiss.

Turning to the current version of the statute, the court joins those courts that have concluded that "the 2010 'amendments transformed the public disclosure bar from a jurisdictional bar to an affirmative defense.'" *Reed*, 923 F.3d at 737 n.1 (collecting cases). It is proper to dismiss on the pleadings based on an affirmative defense "only when the complaint itself admits all the elements of the affirmative defense by alleging the factual basis for those elements." *Fernandez v. Clean House, LLC*, 883 F.3d 1296, 1299 (10th Cir. 2018). That is, "[o]nly when the plaintiff pleads itself

out of court—that is, admits all the ingredients of an impenetrable defense—may a complaint that otherwise states a claim be dismissed under Rule 12(b)(6)." *Id.* (quoting *Xechem, Inc. v. Bristol-Myers Squibb Co*., 372 F.3d 899, 901 (7th Cir. 2004)).

Relators do not "admit[] all the ingredients" of the public disclosure bar. Rather, they allege "Relators do not believe the facts and circumstances of Genentech's violation of the FCA have been publicly disclosed" and, further, even if public disclosure had occurred, "Relators qualify as original sources under 31 U.S.C. § 3730(e)(4)(B)." [Doc. 2, p. 3, ¶¶ 9-10]. Further, the Complaint includes no factual allegations regarding media coverage of Herceptin, nor is there any allegations from which the court may reasonably infer that Relators are not original sources. Thus, dismissal based on the public disclosure bar affirmative defense is improper.

Additionally, as previously stated, Genentech asks the court to consider material outside of the pleadings to determine the motion. "Ordinarily, consideration of material attached to a defendant's answer or motion to dismiss requires the court to convert the motion into one for summary judgment and afford the parties notice and an opportunity to present relevant evidence." *Tal v. Hogan*, 453 F.3d 1244, 1264-65 n.24 (10th Cir. 2006).[7] Genentech asserts that conversion is unnecessary because the court may take judicial notice of the news media reports. [Doc. 48, p. 12 n.1].[8]

[7] Pursuant to Federal Rule of Civil Procedure 12(d), "[i]f, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion."

[8] Although Genentech primarily relies on the news media reports, it also argues that information regarding government contracts to purchase 440 mg Herceptin vials drawn from certain public government websites and incorporated into Relators' Complaint also constitute public disclosures. *See* [Doc. 48, pp. 16-17]. But Genentech concedes that it is only when the facts found on the websites are combined with the information in the news media reports that an inference of fraud may be drawn. *See* [Doc. 62, p. 8 ("Anyone could have combined the information disclosed in the

Significantly, Genentech cites no Tenth Circuit authority regarding the propriety of judicial notice under the circumstances. Instead, Genentech relies on a single decision of the U.S. Court of Appeals for the Ninth Circuit, *Von Saher v. Norton Simon Museum of Art at Pasadena*, 592 F.3d 954 (9th Cir. 2010). In that case, the circuit stated that it took judicial notice of certain publications "solely as an indication of what information was in the public realm at the time." *Id.* at 960. However, *Von Saher* was not a *qui tam* action and did not consider application of the public disclosure bar. Further, and of more significance to this court, the Ninth Circuit ultimately denied the defendant's motion to dismiss based on the affirmative defense of the statute of limitations. *Id.* at 960, 969. In doing so, the court rejected the defendant's argument that "[plaintiff] is precluded as a matter of law from making the required showing of reasonable diligence, because the facts underlying her claim were publicly available," reasoning that "[a] claim may be dismissed under Rule 12(b)(6) on the ground that it is barred by the applicable statute of limitations only when 'the running of the statute is apparent on the face of the complaint,'" and "there [were] no facts on the face of [plaintiff's] complaint which foreclose a showing of lack of reasonable notice as a matter of law." *Id.* at 969. Thus, although the court ostensibly took judicial notice of various publications to indicate what was in the public realm, the court did not rely on the judicially noticed publications to establish reasonable notice and bar plaintiff's claims as a matter of law. *Id.* For these reasons, *Von Saher* is not persuasive and the court declines to take judicial notice of the news media reports provided by Genentech. Thus, the court may not consider the news media reports without converting the motion to a motion for summary judgment.

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media reports and on those websites to generate allegations substantially the same as those in the Complaint.")]. Having reviewed the websites incorporated by reference into the Complaint, the court concludes that, standing alone, the information disclosed does not "lead to a plausible inference of fraud" as there is no information related to the alleged underfilling/overconcentration. *See Reed,* 923 F.3d at 748.

Based on the foregoing, under either the pre- or post-2010 version of § 3730, proper resolution of the public disclosure bar at this stage requires the court to convert the motion to a motion for summary judgment. "[C]ourts have broad discretion in determining whether or not to accept materials beyond the pleadings" and convert the motion. *Lowe v. Town of Fairland*, 143 F.3d 1378, 1381 (10th Cir. 1998); *see also* 5C CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1366 (3d. ed. Feb. 2024 update) ("[F]ederal courts have complete discretion to determine whether or not to accept the submission of any material beyond the pleadings that is offered in conjunction with a Rule 12(b)(6) motion and rely on it, thereby converting the motion, or to reject it or simply not consider it."); *see also Prager v. LaFaver,* 180 F.3d 1185, 1189 (10th Cir. 1999) ("We agree with our sister circuits that if a defendant attaches to a 12(b)(6) motion materials referred to by the plaintiff and central to his claim, the court has discretion to consider such materials."); *Lowe*, 143 F.3d at 1381 ("[T]he district court did not abuse its discretion in failing to convert Defendants' Fed. R. Civ. P. 12(b)(6) motion into a motion for summary judgment."). Given the lengthy procedural delay in this matter, as well as the potential applicability of two versions of the statutory public disclosure bar, the court declines to exercise its discretion to convert the motion to dismiss to a motion for summary judgment.

Based on the foregoing, Genentech's motion to dismiss based upon the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A), is denied.

B. Rule 12(b)(6)

Genentech next contends that dismissal is warranted pursuant to Federal Rule of Civil Procedure 12(b)(6) because Relators fail to state a claim for relief upon which relief can be granted. Specifically, Genentech argues: (1) there were no "false" claims because Genentech's Biologics License Application (BLA) expressly permitted variability in the fill levels of Herceptin vials; (2)

the FDA's approval of the BLA precludes the requisite scienter; and (3) the FDA's approval of the BLA prevents Relators from alleging materiality. Because Genentech's arguments in this regard hinge on the court's consideration of the BLA, the court must first determine if it may consider the BLA to determine the motion to dismiss.

1. Consideration of the BLA

As previously stated, the Tenth Circuit has a recognized a "limited" exception to the general rule prohibiting consideration of matters outside the pleadings on a motion to dismiss. Pursuant to the exception, a court may consider "documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity." *Gee,* 627 F.3d at 1186. Relators refer to the BLA in the Complaint.[9] [Doc. 2, p. 7, ¶ 33]. However, Relators object to the court's consideration of the document, arguing that it is not central to their claims. [Doc. 60, p. 14 n.2].

Relators allege that the Herceptin **label** inaccurately stated that the vial contained 440 mg of Herceptin, when, in fact, the vials did not. [Doc. 2, ¶¶ 34-41]. Likewise, Relators assert that the Herceptin label and Preparation of Administration instructions provided by Genentech stated that proper reconstitution would yield 21 mg/mL of liquid solution; however, reconstitution

[9] In the motion, Genentech asserts that the Relators *quote* from the Herceptin BLA in paragraphs 33 through 36 of the Complaint. [Doc. 48, p. 21]. However, only paragraph 34 includes quoted material and it is not clear to the court that the quoted language originated in the BLA. *See* [Doc. 2, p. 7, ¶ 34 ("The 1998 Label claimed that the vial contained 440 mg of Trastuzumab and provided a Preparation for Administration section that instructed: 'Each vial of HERCEPTIN should be reconstituted with 20 mL of [Bacteriostatic Water for Injection] as supplied, to yield a multi-dose solution containing 21 mg/mL Trastuzumab.'")]. Rather, construing the Complaint's allegations in Relators' favor, it appears that the quoted language comes from the final label that was approved by the FDA, rather than the proposed label submitted as part of the BLA. *See* [Doc. 2, p. 7, ¶ 33 (noting that the FDA approved the BLA)]. Based on the allegations of the Complaint, it is not clear that the FDA approved the label as submitted. Further, the quoted statement does not appear in the portions of the BLA submitted by Genentech with its motion. Thus, although the Relators clearly *refer* to the BLA, the court is not satisfied that they *quote* from the BLA.

pursuant to Genentech's instructions did not, in fact, yield 20.952 (or 21) mg/mL of liquid solution. [Doc. 2, ¶¶ 34-38, 42-43, 46-47, 52-53, 56-57, 61-62]. As a result, the United States received less drug product than the Herceptin label promised or, alternatively, purchased more Herceptin than they would otherwise purchase. [Doc. 2, ¶¶ 44, 48]. Thus, Relators' claims relate to the Herceptin label affixed to 440 mg vials, the Preparation for Administration instructions provided by Genentech, and the public contracts for sale of same. Thus, the BLA is not central to Relators' claims. Although the BLA provides useful background information, Relators could have pled their claims without any mention of the document. *See Maher v. Oklahoma ex rel. Okla. Tourism & Recreation Dep't*, 165 F. Supp. 3d 1089, 1093 (W.D. Okla. 2016). Moreover, even if the proposed label and prescribing information included in the BLA were central to Relators' claims, Genentech did not include those sections of the BLA in the exhibits attached to its response.

Instead, it appears that the BLA is central to Genentech's defense that the BLA permitted variability in the Herceptin vials. But centrality to a defense—rather than a claim—does not permit the court to consider material outside of the pleadings. *See Scanlan v. Texas A&M Univ.,* 343 F.3d 533, 537 (5th Cir. 2003); *Burke v. Holdman,* 750 F. App'x 616, 622-23 (10th Cir. 2018) (unpublished)[10]; *Becher v. United Healthcare Servs., Inc*., 374 F. Supp. 3d 1102, 1106 (D. Kan. 2019) ("At the motion to dismiss stage, the court cannot properly consider extrinsic evidence that isn't central to a plaintiff's claim. This is the rule even if the extrinsic evidence is central to the defendant's 'theories of defense.'").

Finally, even if the court could properly consider the BLA, the court would decline to exercise its discretion to do so. *See Prager,* 180 F.3d at 1189. Genentech has not submitted a

[10] "Unpublished decisions are not precedential, but may be cited for their persuasive value." 10th Cir. R. 32.1(A).

complete copy of the BLA but, instead, may have "cherry-picked" those portions most advantageous to its defenses. And neither party has submitted the label affixed to the vial, the Preparation for Administration instructions provided by Genentech, or public contracts for the court's consideration—all of which are central to Relators' claims. "In reviewing a Rule 12(b)(6) motion, [the court's] role 'is not to weigh potential evidence that the parties might present at trial' but instead to assess whether the 'complaint alone is legally sufficient to state a claim for which relief may be granted.'" *Walker v. BOKF, Nat'l Ass'n*, 30 F.4th 994, 1002 (10th Cir. 2022) (quoting *Evans v. Diamond*, 957 F.3d 1098, 1100 (10th Cir. 2020)). To consider only the portions of the BLA selected by Genentech to determine the claims in this matter would lead the court far afield of its role. Thus, the court does not consider the BLA to determine Genentech's motion to dismiss.

2. Substantive Arguments

Title 31, section 3729 of the United States Code imposes liability on "any person who[:] (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" to the U.S. government. 31 U.S.C. §§ 3729(a)(1)(A), (B). To state a plausible claim, Relators must allege: "(1) a false statement or fraudulent course of conduct; (2) made with the requisite scienter; (3) that is material; and (4) that results in a claim to the Government or conceals, decreases, or avoids an obligation to pay the Government."[11] *United*

[11] "Under § 3729(a), liability can attach when a government payee submits either a legally or factually false request for payment." *United States ex rel. Lemmon v. Envirocare of Utah, Inc*., 614 F.3d 1163, 1168 (10th Cir. 2010). In their response, Relators suggest that factually false claims may not include a materiality requirement. [Doc. 60, p. 20]. The Tenth Circuit has recognized that "[w]ith respect to 31 U.S.C. § 3729(a)(1)(A), the Supreme Court has unequivocally stated a materiality requirement exists." *United States ex rel. Janssen v. Lawrence Mem'l Hosp.,* 949 F.3d 533, 539 n.8 (10th Cir. 2020), and made no distinction between factually false and legally

States ex rel. Janssen v. Lawrence Mem'l Hosp., 949 F.3d 533, 539 (10th Cir. 2020).

As previously stated, Genentech argues that Relators fail to plausibly allege a claim upon which relief can be granted pursuant to Rule 12(b)(6) on three separate grounds. The court separately considers each argument.

First, Genentech argues that Relators have not alleged a false statement or fraudulent course of conduct because the BLA expressly permitted variability in the fill levels of Herceptin vials. The court declines to consider the BLA and therefore does not decide this issue.

Turning to the false statement requirement generally, as previously stated, "[u]nder § 3729(a), liability can attach when a government payee submits either a legally or factually false request for payment." *Lemmon*, 614 F.3d at 1168. Factually false claims generally require that "the payee has submitted 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'" *Lemmon,* 614 F.3d at 1168 (quoting *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc*., 543 F.3d 1211, 1217 (10th Cir. 2008)). The Complaint alleges that, through its labelling and Preparation for Administration instructions, Genentech represented the Herceptin vials purchased by the government contained 440 mg and that reconstitution would yield 21 mg/ML of liquid solution. [Doc. 2, pp. 8, ¶¶ 36-38]. However, Relators allege that the vials did not contain 440 mg of Herceptin and, further, reconstitution pursuant to the Preparation for Administration instructions does not yield 21 mg/mL of liquid solution. [Doc. 2, pp. 8, ¶¶ 39-40, 46-47]. Thus, Relators allege that Genentech provided an incorrect description of the goods—Herceptin—and therefore has adequately alleged a factually

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false claims. Thus, for purposes of this motion, the court concludes a materiality requirement exists. However, the court acknowledges that the issue was briefed several years ago and, then, not fully briefed. Accordingly, in applying a materiality requirement to a factually false claim at this stage of the litigation, the court does not foreclose subsequent argument directed to the issue.

false statement. Genentech's motion to dismiss in this regard is denied.

Second, Genentech contends that the FDA's approval of the BLA with variability in Herceptin fill levels precludes a finding of scienter. Again, the court declines to consider the BLA. Turning to the scienter requirement generally, both § 3729(a)(1)(A) and § 3729(a)(1)(B) require that the defendant act "knowingly." The FCA defines "knowingly" to "mean that a person, with respect to information[:] (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Thus, as explained by the U.S. Supreme Court, the definition "encompass[es] three mental states" and "either actual knowledge, deliberate ignorance, or recklessness will suffice." *United States ex rel. Schutte v. SuperValu Inc*., 143 S. Ct. 1391, 1400 (2023). Relators allege that Genentech had actual knowledge both that the Herceptin vials did not contain 440 mg of Herceptin and, further, that reconstitution of the vials would not yield 21 mg/ML of liquid solution. [Doc. 2, pp. 8-10, ¶¶ 49-51, 53]. Specifically, Relators include factual allegations as to counsel's statements in the MDL. Construing these allegations in the light most favorable to Relators, the Complaint sufficiently alleges that Genentech acted "knowingly." Thus, Relators have plausibly alleged the scienter requirement and Genentech's motion to dismiss in this regard is denied.

Third, Genentech contends that the FDA's express approval of the BLA with variability in Herceptin fill levels prevents Relators from alleging materiality. Specifically, Genentech argues that, because the Relators acknowledge that the government has possessed the BLA since 1998 but fail to allege that the government ever refused payment for non-conforming vials, Relators have "failed to show that the provision of allegedly under-filled or over-concentrated vials of Herceptin was material." [Doc. 48, p. 26]. However, as previously stated, the court declines to

consider the BLA. The Complaint does not otherwise include any allegations from which the court can reasonably infer the United States was aware of the alleged underfill/overconcentration but continued to pay for Herceptin. Thus, Genentech's argument is not persuasive.

As recognized by the U.S. Supreme Court, "[m]ateriality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2002 (2016) (quoting 26 R. Lord, WILLISTON ON CONTRACTS § 69:12, p. 549 (4th ed. 2003)). "[W]hether an alleged instance of noncompliance with statutory, regulatory, or contractual requirements 'goes to the very essence of the bargain or is only minor or insubstantial' is a relevant consideration in the 'holistic' inquiry into the FCA's materiality requirement." *United States ex rel. Sorenson v. Wadsworth Bros. Constr. Co., Inc.*, 48 F.4th 1146, 1157 (10th Cir. 2022) (quoting *Janssen*, 949 F.3d at 540). Here, Relators allege that the government contracted to purchase Herceptin 440 mg vials, but that, "[g]iven the systematic under-filling of vials, many Herceptin vials purchased by the United States contained less Herceptin than the amount claimed by Genentech and for which the United States paid." [Doc. 2, pp. 6, 8, ¶¶ 27, 41]. Taking the allegations of the Complaint as true and considering them in the light most favorable to Relators, the Relators have sufficiently alleged that the fill levels of the Herceptin vials goes "to the very essence of the bargain." *Sorenson*, 48 F.4th at 1157.[12] Thus, Relators have sufficiently pled materiality.

Based on the foregoing, Relators plausibly allege a violation of § 3729(a) claim. Thus,

[12] Further, as previously recognized by this court, although the Supreme Court has "noted the possibility that materiality could be decided on a motion to dismiss," the Court "did not suggest that the issue should be routinely decided at such a stage." *United States ex rel. Strauser v. Stephen L. LaFrance Holdings, Inc.*, No. 18-CV-673-GKF-FHM, 2019 WL 1086363, at *14 (N.D. Okla. Mar. 7, 2019) (quoting *United States ex rel. Brooks v. Stevens-Henager Coll.*, 305 F. Supp. 3d 1279, 1301 (D. Utah 2018)).

Genentech's motion to dismiss is denied insofar as it is premised on Federal Rule of Civil Procedure 12(b)(6).

C. Rule 9

Genentech next argues that Relators fail to plead fraud with particularity as required by Federal Rule of Civil Procedure 9.

1. Rule 9 Standard

The Tenth Circuit has recognized that "Rule 9(b) joins with 8(a) to form the general pleading requirements for claims under the FCA." *Lemmon*, 614 F.3d at 1171. Pursuant to Rule 9, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).[13] In the context of the FCA, the Tenth Circuit has described the standard as follows:

> The purpose of Rule 9(b) is to afford defendant[s] fair notice of plaintiff's claims and the factual ground upon which [they] are based. Thus, claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." Practically speaking, FCA claims comply with Rule 9(b) when they provid[e] factual allegations regarding the who, what, when, where and how of the alleged claims. But, in determining whether a plaintiff has satisfied Rule 9(b), courts may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control. This reflects the principle that Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim.

United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730, 745 (10th Cir. 2018) (internal

[13] Pursuant to Rule 8(a), "[a] pleading that states a claim for relief must contain: (1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support; (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and (3) a demand for the relief sought, which may include relief in the alternative or different types of relief." Fed. R. Civ. P. 8(a)(1)-(3).

citations and quotations omitted). In considering the motion, the court "must accept as true all well-pleaded facts, as distinguished from conclusory allegations, and view those facts in the light most favorable to the non-moving party." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726 (10th Cir. 2006).

2. Consideration of the Schemes

In this portion of the motion, Genentech makes arguments directed specifically to either the Underfill Scheme or the Overconcentration Scheme. In response, Relators state that the Underfill Scheme and Overconcentration Scheme "support the same two counts of the Complaint" and argue "[t]o the extent Genentech seeks dismissal of a subset of the allegations (*e.g.*, the 'over-concentration claim' . . .), this partial relief is not available." [Doc. 60, p. 14, n.1]. But the cases on which Relators rely interpret Federal Rule of Civil Procedure 12(b)(6), not Rule 9. Rule 12(b)(6) permits dismissal for "failure to state *a claim* upon which relief can be granted." Fed. R. Civ. P. 12(b)(6) (emphasis added). Rule 9, on the other hand, is not framed in terms of a "claim" but, instead, permits dismissal when "fraud" has not been pled with sufficient particularity. Fed. R. Civ. 9(b); *see also United States ex rel. Sikkenga*, 572 F.3d at 728 (affirming dismissal pursuant to Federal Rule of Civil Procedure 9(b)). Further, as previously stated, specific to the FCA, the Tenth Circuit has stated that "claims under the FCA need only show the specifics of a *fraudulent scheme* and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Polukoff,* 895 F.3d at 745 (emphasis added). Thus, courts in the Tenth Circuit have separately analyzed different theories or schemes pled to support FCA claims. *See Sikkenga,* 472 F.3d at 727-28; *United States ex rel. Ernst v. HCA Healthcare, Inc.,* No. 19-CV-02085-TC-JPO, 2021 WL 5415868, at *5 (D. Kan. Nov. 19, 2021); *United States ex rel. Schroeder v. Medtronic, Inc*., No. 17-2060-DDC-KGG, 2021 WL 4168140 (D. Kan. Sept. 14, 2021); *United*

States ex rel. Lovato v. Kindred Healthcare, Inc., No. 15-CV-02759-CMA-NYW, 2020 WL 9160872 (D. Colo. Dec. 14, 2020), *adopting report and recommendation,* 2021 WL 1085423 (D. Colo. Mar. 22, 2021). Thus, the court separately considers the Underfill Scheme and the Overconcentration Scheme.

3. Underfill Scheme

Genentech first faults Relators for failing to identify any of the individuals who supposedly participated in the alleged misconduct. However, the Complaint alleges that the government entered into contracts for the sale of Herceptin with authorized distributors of Genentech, including Cardinal Health Specialty Distribution, pursuant to which the government agreed to pay a specific sum of money. [Doc. 2, pp. 6-7, ¶¶ 25-28]. Thus, the Complaint includes allegations directed to the parties to relevant contracts. Insofar as Genentech argues that Relators fail to identify any of the individuals who participated in the alleged misconduct, the court is mindful that the alleged deficiencies may have "resulted from [Relators'] inability to obtain information in the defendant's exclusive control." *Polukoff*, 895 F.3d at 745. It is unlikely that Relators would have independent knowledge of, or the ability to obtain information, regarding persons involved in Genentech's internal decision-making processes.

Genentech also asserts that "the Complaint fails to explain what the alleged scheme entailed," again pointing to the FDA's alleged approval of fill variability through the BLA. [Doc. 48, p. 27]. Specifically, Genentech argues "there are no allegations showing how this alleged conduct, which was expressly approved by [the] FDA, supposedly constituted a scheme to defraud the government." [*Id*.]. However, the court does not consider the BLA and its alleged approval of fill variability. Rather, the court confines itself to the Complaint. *See Sikkenga*, 472 F.3d at 726.

Taking the Complaint's allegations as true, Relators allege that Genentech represented that each Herceptin vial contained 440 mg of Herceptin and, if the healthcare provider followed the reconstitution instructions provided by Genentech, the resulting multi-dose liquid solution would be concentrated at a density of 21 mg of Herceptin per milliliter (mL) of solution. [Doc. 2, pp. 7-8, ¶¶ 34-38]. However, Genentech knew the representations to be false and that reconstitution would not yield the desired amount. [Doc. 2, p. 10, ¶¶ 49-51, 53]. Nevertheless, Genentech "charge[d] purchasers for the labeled amount of Herceptin despite knowing it does not provide the labeled amount of Herceptin in the vast majority of the Herceptin packages." [Doc. 2, p. 2, ¶ 5; *see also* Doc. 2, p. 10, ¶ 48]. Thus, viewed in the light most favorable to Relators, the Complaint adequately describes the "what," "why," and "how" of the alleged fraudulent scheme.

Turning to "when," Genentech contends that "[t]he Complaint also fails to identify with particularity when the alleged scheme occurred." [Doc. 48, p. 28]. The court agrees that Relators could have been more precise in their pleading in this regard. However, given the totality of the Complaint's allegations, Relators' failure to explicitly articulate a timeframe is not fatal. *See Schroeder,* 2021 WL 4168140, at *12 n.12 ("Relator would strengthen the Complaint if he listed specific dates and times when Medtronic allegedly paid these remunerations. But our Circuit has said those details, at least in the context of this case, aren't essential."). Relators allege that the government purchased Herceptin beginning in 2004 through 2016. [Doc. 2, pp. 6-7, 13, ¶¶ 26-28, 64-65]. Further, Relators allege that "[a]pproximately 90% of the lots of Herceptin released in the United States contained less than 440 mg of Herceptin." [Doc. 2, p. 8, ¶ 40]. The specific dates alleged coupled with the high percentage of Herceptin vials that were inaccurately filled provide adequate notice of the relevant timeframe, at least at this stage of the proceeding.

Viewed in the light most favorable to Relators, the Complaint's allegations "show the specifics of a fraudulent scheme." *Polukoff*, 895 F.3d at 745.

Genentech also asserts that the claims do not satisfy the requirements of Rule 9 because Relators fail to allege that false claims were submitted as part of the scheme. *See id.* Specifically, Genentech cites *Sikkenga* for the proposition that a complaint must identify false claims that were actually submitted to the government. [Doc. 48, pp. 29-30]. However, district courts within the Circuit, including the undersigned, have recognized that the Tenth Circuit has retreated from *Sikkegna*'s bright-line rule. *United States ex rel. Allison v. Sw. Orthopaedic Specialists, PLLC*, No. CIV-16-0569-F, 2020 WL 5984814, at *6 n.4 (W.D. Okla. Oct. 8, 2020) ("Defendants rely on [*Sikkenga*], for their argument that the [Second Amended Complaint] should identify a specific false claim, which the SAC fails to do. However, the court of appeals has stepped back from such a requirement."); *see also United States v. Novo Nordisk*, No. CIV-15-000114-PRW, 2022 WL 16716299, at *6 (W.D. Okla. Nov. 4, 2022); *United States ex rel. Ernst v. HCA Healthcare, Inc*., No. 19-2085-JWL, 2020 WL 6868775, at *5 (D. Kan. Nov. 23, 2020); *Lovato*, 2020 WL 9160872, at *13; *United States ex rel. Wagner v. Care Plus Home Health Care*, *Inc.*, No. 15-CV-260-GKF-JFJ, 2017 WL 6329850, at *4 (N.D. Okla. Dec. 11, 2017). Further, as previously stated, Relators allege that "[a]pproximately 90% of the lots of Herceptin released in the United States contained less than 440 mg of Herceptin," and that the government entered into contracts to purchase Herceptin from 2004 to 2016, with over fifty contracts in one year. [Doc. 2, pp. 6, 8, ¶¶ 26-28, 40]. "Based on th[ese] alleged fact[s], a reasonable factfinder could infer that submitting a false claim to the government was an inevitable byproduct." *Schroeder*, 2021 WL 4168140, at *24. Thus, Relators have sufficiently alleged facts that "provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Polukoff*, 895 F.3d at 745.

Based on the foregoing, Relators have pled their claims with sufficient particularly pursuant to Rule insofar as they are premised on the Underfill Scheme 9(b). Genentech's motion to dismiss on this basis is denied as to the Underfill Scheme.

4. Overconcentration Scheme

In contrast, the Overconcentration Scheme is premised upon a single email, authored by Genentech's Herceptin Production Engineer Tom White and dated September 25, 2002, which Relators describe as stating that "the actual concentration of reconstituted Herceptin was 21.8 mg/mL, not the 21 mg/mL claimed by Genentech's Label." [Doc. 2, p. 97; Doc. 2, pp. 8, ¶ 42]. Unfortunately, Relators' theory is undercut by the email's substance. The email indicates that Genentech "target[s] 450 mg in a vial" which, when reconstituted with the diluent, results in a "theoretical concentration" of 21.8 mg/mL of the reconstituted product. [Doc. 2, p. 97]. Mr. White goes on to state that "we actually have between 440 and 450 mg in our vials." [*Id.*]. Thus, neither the Complaint nor the email identify any actual instances of overconcentration—only a "theoretical" overconcentration. Although Relators need not include allegations as to specific false claims that were submitted, they must allege sufficient facts to "provide an adequate basis for reasonable inference that false claims were submitted as a part of th[e] scheme." *Lemmon,* 614 F.3d at 1172. Reliance on a "theorical concentration" resulting from a range of "targeted" fills, absent any factual allegations that overconcentration actually occurred, does not "provide an adequate basis for reasonable inference that false claims were submitted as a part of th[e] scheme." *Id.*; *Cf id.* (noting that plaintiff had listed the contracts that were purportedly violated).

Nor have Relators otherwise explained the "what" and "how" of the alleged Overconcentration Scheme. The Underfill Scheme is straightforward—the United States received less Herceptin than Genentech represented it would receive and for which the United States paid.

In the Overconcentration Scheme, however, the theory appears to be that the government received the amount of Herceptin for which it paid and, in some instances, more. To cast the scheme as fraudulent, Relators' assert that "[b]y misstating the concentration, Genentech causes Relators and other purchasers—including the United States—to administer more Herceptin than necessary to patients and to purchase more Herceptin than they would otherwise purchase" and "[i]f Genentech stated the accurate concentration of the reconstituted Herceptin solution on the Herceptin Label, Relators and the United States would purchase fewer Herceptin vials." [Doc. 2, p. 9, ¶¶ 44-45]. But Relators' are conclusory and therefore not entitled to the presumption of truth. *Sikkenga*, 472 F.3d at 726.

Moreover, unlike the Underfill Scheme, the Complaint includes no allegations as to "when"—the timeframe in which the vials that resulted in an overconcentration were allegedly distributed. Finally, the court notes that Relators do not include the Overconcentration Scheme in the Complaint's description of the Nature of the Action or Potential Damages [Doc. 2, pp. 1-2, 13-14, ¶¶ 1-7, 64-68], and therefore Relators fail to allege the consequences of the alleged fraud. *See Koch v. Koch Indus., Inc.,* 203 F.3d 1202, 1236 (10th Cir. 2000).

As previously stated, "[t]he purpose of Rule 9(b) is to afford defendant[s] fair notice of plaintiff's claims and the factual ground upon which [they] are based." *Polukoff,* 895 F.3d at 745 (internal quotations omitted). Relators have provided Genentech a single email, written in very technical language, upon which Genentech is to glean all of the relevant details of the fraudulent scheme. Given the dearth of factual allegations directed to the Overconcentration Scheme, the court concludes that Relators have failed to sufficiently allege the specifics of the scheme and have not provided Genentech fair notice of the claims in this regard. Thus, Genentech's motion to dismiss pursuant to Federal Rule of Civil Procedure 9(b) is granted insofar as the FCA claims are

premised on the Overconcentration Scheme.[14]

Conclusion

WHEREFORE, the Motion to Dismiss Plaintiff-Relators' Complaint [Doc. 48] of defendant Genentech, Inc. is granted in part and denied in part. The motion is granted insofar as Relators' claims pursuant to 31 U.S.C. §§ 3729(a)(1) and 3729(a)(1)(B) are premised on the Overconcentration Scheme. The motion is otherwise denied.

IT IS FURTHER ORDERED this matter is set for Status/Scheduling Conference on April 10, 2024 at 2:30 p.m.

IT IS FURTHER ORDERED that defendant Genentech's deadline to file an Answer pursuant to Federal Rule of Civil Procedure 12(a)(4) is extended to April 26, 2024.

IT IS SO ORDERED this 14th day of March, 2024.

GREGORY K. FRIZZELL
UNITED STATES DISTRICT JUDGE

[14] Because the Overconcentration Scheme allegations are dismissed pursuant to Federal Rule of Civil Procedure 9(b), the court does not consider Genentech's argument that the Overconcentration Scheme is untimely. *See* [Doc. 48, p. 31].