

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 08-15810

FILED U.S. COURT OF APPEALS ELEVENTH CIRCUIT DECEMBER 4, 2009 THOMAS K. KAHN CLERK

D.C. Docket No. 04-02356-CV-T-23-TGW

JAMES HOPPER,
COLIN HUTTO,

Plaintiffs-Appellants,

versus

SOLVAY PHARMACEUTICALS, INC.,
UNIMED PHARMACEUTICALS, INC.
UNITED STATES OF AMERICA,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(December 4, 2009)

Before BLACK, WILSON and COX, Circuit Judges.

COX, Circuit Judge:

Solvay Pharmaceuticals, Inc. and its wholly owned subsidiary, Unimed
Pharmaceuticals, Inc., manufacture and market Marinol, a synthetic form of THC, a

hallucinogenic compound found naturally in marijuana. Qui tam relators James Hopper and Colin Hutto allege that Solvay engaged in an off-label marketing campaign to increase sales of Marinol for purposes not approved by the United States Food and Drug Administration. The relators sought recovery on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, for claims paid by government health programs as a result of the marketing campaign. The district court dismissed their action because the relators' Second Amended Complaint failed to plead the submission of specific false claims with particularity as required by Federal Rule of Civil Procedure 9(b). The relators appeal. We affirm.

I. BACKGROUND & PROCEDURAL HISTORY

Relevant sections of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, prohibit the presentment of false claims to the government and the use of false records or statements to get a false claim paid or approved. The Act may be enforced through civil actions initiated by the government or suits by private individuals on behalf of the United States, called qui tam actions. The private plaintiffs in qui tam actions are known as "relators," and the Act entitles them to a percentage of any recovery made on behalf of the government from a False Claims Act defendant.

We summarize the allegations of the relators in this case, Hopper and Hutto, from their Second Amended Complaint. Solvay employed the relators as sales

representatives in its Mental Health Division. One of their duties was to implement what they allege to be an illegal marketing scheme for Marinol, a prescription drug manufactured and sold by Solvay.

In 1999, Solvay acquired Unimed, which owned the rights to manufacture and distribute Marinol, a synthetic form of THC, the active compound in marijuana.¹ Marinol is approved by the FDA for use as an appetite stimulant for AIDS patients and for the treatment of nausea and vomiting associated with cancer chemotherapy. According to the relators, Marinol is not particularly effective for these on-label uses, so sales of the drug did not generate substantial profits for Solvay. To increase Marinol sales, the relators allege, Solvay implemented an off-label marketing campaign for the drug beginning in 2001. The relators assert that Solvay instructed its sales representatives to encourage physicians to prescribe Marinol for appetite loss in cancer patients and for treatment of nausea in HIV patients, purposes for which Marinol was not approved. Because the FDA prohibits the marketing of drugs for off-label uses, the relators allege that Solvay's marketing scheme was illegal.

The relators assert that sales generated from the marketing scheme caused the government to pay false claims through Medicaid and other programs that provide

¹Unimed, a wholly owned subsidiary of Solvay, is a named defendant in this case, but most of the allegations in the Second Amended Complaint refer to Solvay. It is unclear which of these allegations are alleged to be attributable to Unimed. References to Solvay hereafter include Unimed.

prescription drug benefits. The government does not knowingly pay for drugs through these programs if they are prescribed for off-label uses. The relators allege that the marketing campaign convinced doctors to prescribe Marinol for off-label uses, and claims were ultimately submitted by state health programs and other third parties to the federal government to pay for some of those prescriptions. The relators do not allege that Solvay itself submitted any false claims. Rather, they allege that every time federal funds were used to pay for an off-label prescription, the third party who requested payment from the government made a false claim. (R.2-84 at 52-53.) Those false claims were attributable to Solvay, according to the relators, because the off-label marketing campaign caused the claims to be submitted against federal funds and because Solvay intended that its campaign cause the filing of false claims. (*Id.* at 60.) To support their allegations that the government paid false claims, the relators point to a marked increase in prescriptions for Marinol and an increase in Medicaid payments for Marinol between 2001 and 2005, years in which Solvay is alleged to have engaged in the marketing campaign.

In 2004, the relators filed a complaint based on these allegations, under seal, pursuant to the qui tam provisions of the False Claims Act. *See* 31 U.S.C. § 3730(b)(2) (requiring complaints be filed under seal and submitted to the government so it can conduct an investigation). They filed a First Amended Complaint in 2005.

The Government was served with these complaints, investigated the allegations, and in 2006 ultimately chose not to intervene in the case. Shortly thereafter, the court ordered the lawsuit unsealed, and the relators sought leave to file a Second Amended Complaint (“Complaint”) , which the court granted.

The Complaint alleges that Solvay violated two subsections of the False Claims Act, 31 U.S.C. § 3729(a)(1) and (a)(2)², and parallel Illinois, California, and Massachusetts statutes. In a nutshell, it alleges that Solvay executed a sophisticated marketing plan for the purpose of inducing physicians to prescribe Marinol for uses not approved by the FDA, and this conduct “caused submission for reimbursement by Government Healthcare Programs of millions of dollars worth of prescriptions which were ineligible for such reimbursement.” (R.2-84 at 2.) It also alleges that Solvay gave kickbacks to physicians and other healthcare providers to induce them to prescribe Marinol for off-label purposes. (*Id.* at 3.) The complaint does not identify any specific false claims presented to a government healthcare program or any person or entity who submitted a claim. Nor does it allege that Solvay intended that the government rely on the alleged false statements or records in deciding whether to pay

²The Fraud Enforcement and Recovery Act of 2009 amended and renumbered sections of the False Claims Act relevant to this appeal. Pub. L. No. 111-21, 123 Stat. 1617. These amendments, however, do not apply retroactively to this case. *See infra* note 3. Citations to the U.S. Code herein refer to the pre-amendment sections of the False Claims Act that apply to this case and do not reflect the 2009 amendments.

claims. Instead, it alleges that Solvay's marketing campaign caused healthcare providers to submit claims to state healthcare programs, and the state programs submitted false claims to the federal government. (*Id.* at 62.)

Solvay filed a motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1), and 12(b)(6). The Rule 12(b)(6) motion was grounded in an assertion that the relators failed to plead their allegations of fraud with particularity as required by Rule 9(b). Solvay also asserted that the court lacked subject matter jurisdiction over the case because some of the allegations were based on publicly disclosed information, and the relators were not the original source. *See* 31 U.S.C. § 3730(e)(4)(A) (creating jurisdictional bar to claims where plaintiffs are not the original source for information in the complaint). The district court referred the matter to a magistrate judge who recommended that the motion to dismiss be denied as to subject matter jurisdiction. He recommended, however, that the federal claims be dismissed for failing to satisfy Rule 9(b) because the relators failed to plead with particularity their allegations that Solvay's marketing scheme caused the submission of actual false or fraudulent claims to the government. (R.2-101 at 26-27.) The magistrate judge also recommended that the court decline to retain supplemental jurisdiction over the state law claims. The relators filed objections to the magistrate judge's report, but the district court adopted

it in full, dismissed the relators' federal claims with prejudice, and declined to exercise supplemental jurisdiction over the state law claims. The relators appeal.

II. ISSUE ON APPEAL & CONTENTIONS OF THE PARTIES

The sole issue on appeal is whether the Complaint, which does not include allegations of specific false claims or allege that Solvay intended for its statements to influence the government's decisions to pay any claims, satisfies the particularity requirements of Rule 9(b). The relators brought claims under 31 U.S.C. § 3729(a)(1) and (a)(2). Subsection (a)(1) makes liable any person who *presents, or causes to be presented*, a false or fraudulent claim. Subsection (a)(2) makes liable any person who knowingly makes, uses, or causes to be made or used, a false record or statement *to get a false claim paid or approved*. Solvay contends that to satisfy the particularity requirements under either 31 U.S.C. § 3729(a)(1) or (a)(2), a complaint must identify actual false claims. The relators counter that the requirements of Rule 9(b) may be satisfied as to subsection (a)(1) without identifying specific false claims as long as the complaint contains factual allegations which reliably indicate that false claims were submitted to the government. As to subsection (a)(2), the relators argue that the presentment of a false claim to the government is not an element of the cause of action. So, they claim the particularity requirements of Rule 9(b) are satisfied by alleging that the defendants made false statements for the purpose of causing the

payment of false claims. For claims under subsection (a)(2), the relators argue they need not allege that false or fraudulent claims were actually submitted to or paid by the government.

III. STANDARD OF REVIEW

We review de novo the grant of a motion to dismiss pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted. *Leib v. Hillsborough County Pub. Transp. Comm'n*, 558 F.3d 1301, 1305 (11th Cir. 2009).

IV. DISCUSSION

A complaint under the False Claims Act must meet the heightened pleading standard of Rule 9(b), which states “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” *See United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1309-10 (11th Cir. 2002) (noting “it was ‘well settled’ and ‘self-evident’ that the False Claims Act is ‘a fraud statute’ for the purposes of Rule 9(b)” (citation omitted)). A False Claims Act complaint satisfies Rule 9(b) if it sets forth “‘facts as to time, place, and substance of the defendant’s alleged fraud,’ specifically ‘the details of the defendants’ allegedly fraudulent acts, when they occurred, and who engaged in them.’” *Id.* at 1310 (*quoting United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.*, 19 F.3d 562, 567-68 (11th Cir. 1994)).

The district court held that the relators' Complaint did not satisfy the particularity requirements of Rule 9(b) because it failed to include specific allegations of "the actual presentment of false claims." (R.2-101 at 25.) The court did not distinguish between the relators' allegations under 31 U.S.C. § 3729(a)(1) and their allegations under § 3729(a)(2). It reasoned that our precedents require all False Claims Act complaints to identify specific false claims, and the court appears to have concluded that these precedents apply equally to subsections (a)(1) and (a)(2) of the Act. Because the Complaint did not identify a specific false claim, the court found it did not satisfy Rule 9(b) and was subject to dismissal, pursuant to Rule 12(b)(6), for failing to state a claim upon which relief can be granted. (R.2-101 at 20.)

Indeed, in cases on which the district court relied, *Clausen; United States ex rel. Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005), *cert. denied*, 549 U.S. 810, 127 S. Ct. 42 (2006); and *United States ex. rel Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006), we did not differentiate between claims raised under subsection (a)(1) and subsection (a)(2) of the False Claims Act. The relators acknowledge that under subsection (a)(1), a plaintiff must prove that the defendant submitted or caused to be submitted a false claim to the government. But, they contend that submission of an actual false claim is not an element of a subsection (a)(2) claim. So, we will consider the claims separately.

A. 31 U.S.C. § 3729(a)(1)

31 U.S.C. § 3729(a)(1) contains a “presentment clause.” It imposes liability on a person who “knowingly *presents, or causes to be presented,* to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval.” *Id.* (emphasis added). In *Clausen*, we explained that “[w]ithout the *presentment* of such a claim, while the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required under the False Claims Act.” 290 F.3d at 1311 (emphasis in original). We reasoned, “if Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of *an actual false claim* for payment being made to the Government.” *Id.* (emphasis in original).

In *Clausen*, the relator alleged that a medical testing corporation billed the government for unnecessary laboratory tests. *Id.* at 1303. The complaint included detailed allegations of a scheme to overcharge; it identified the patients who received tests, specified which tests were improper, and set forth the dates on which the procedures were performed. *Id.* at 1304-05. We upheld the dismissal of the complaint pursuant to Rule 9(b), however, because it failed to provide any information linking the testing schemes to the submission of actual false claims. *Id.* at 1313. The

complaint included “the conclusory allegation that [the defendant] submitted bills to the Government ‘on the date of service or within a few days thereafter.’” *Id.* We explained that if “Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion.” *Id.*

We considered similar circumstances in *Corsello*, in which a relator alleged that medical equipment companies engaged in kickback and referral schemes to falsify certificates of medical necessity to submit false claims for Medicare payments. 428 F.3d at 1011. Here, too, the relator failed to allege specific fraudulent submissions to the government. *Id.* at 1014. The relator argued “that a pattern of improper practices of the defendants leads to the inference that fraudulent claims were submitted to the government” *Id.* at 1013. Nevertheless, we upheld the dismissal of the complaint because it did not allege that “a specific fraudulent claim was in fact submitted to the government.” *Id.* at 1014 (citing *Clausen*, 290 F.3d at 1311).

Similar issues were again presented in *Atkins*, where a relator alleged that psychiatrists improperly sought payments from Medicare and Medicaid for psychiatric services that were not actually rendered, were provided with substandard levels of care, and were medically unnecessary. 470 F.3d at 1354. The complaint in *Atkins* described “an elaborate scheme for defrauding the government by submitting false

claims.” *Id.* at 1359. It cited “particular patients, dates and corresponding medical records for services” that were not eligible for reimbursement. *Id.* We upheld the dismissal of the complaint, however, because the relator failed “to provide the next link in the [False Claims Act] liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes.” *Id.* (emphasis in original).

Like in *Clausen*, *Corsello*, and *Atkins*, the Complaint in this case offers detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe. The Complaint also includes what the relators describe as “a highly-compelling statistical analysis [that] renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of Marinol resulted from [Solvay’s illegal marketing] campaign.” (Appellants’ Br. at 19.) But, the Complaint does not allege the existence of a single actual false claim. In fact, we are unable to discern from the complaint a specific person or entity that is alleged to have presented a claim of any kind, let alone a false or fraudulent claim.

The relators contend that the illegal marketing campaign first induced physicians to write off-label prescriptions for Marinol. Then, pharmacies and other healthcare providers submitted claims to various state healthcare programs for reimbursement. Finally, these state agencies submitted claims to the federal

government for payment. (R.2-84 at 52-53.) The Complaint does not identify specific persons or entities that participated in any step of this process. Nor does it allege dates, times, or amounts of individual false claims.

We will assume *arguendo* that when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription will be borne by the federal government, and when a claim is ultimately submitted to the federal government to pay for that prescription, 31 U.S.C. § 3729(a)(1) may have been violated. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732-33 (1st Cir. 2007) (suggesting that submitting off-label prescriptions for federal reimbursement could lead to the filing of false claims). Nonetheless, the relators' Complaint does not identify a single physician who wrote a prescription with such knowledge, does not identify a single pharmacist who filled such a prescription, and does not identify a single state healthcare program that submitted a claim for reimbursement to the federal government. The relators contend that their Complaint "contains factual allegations which reliably indicate that false claims were submitted to the Government." (Appellants' Br. at 16.) We disagree. The Complaint piles inference upon inference to suggest that Solvay's marketing campaign influenced some unknown third parties to file false claims. We cannot conclude that the Complaint satisfies the particularity requirements of Rule 9(b) by offering "some indicia of reliability . . . of *an actual false*

claim for payment being made to the Government.” *Clausen*, 290 F.3d at 1311 (emphasis in original).

This is not a case like *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, in which a relator alleged personal knowledge of the defendants’ billing practices that gave rise to a well-founded belief that the defendant submitted actual false or fraudulent claims. 433 F.3d 1349, 1360 (11th Cir. 2005). The relator in *Walker* pled a claim with particularity because the complaint included allegations grounded in first-hand knowledge that explained why she believed a specific defendant submitted false or fraudulent claims to the government. *Id.* Here, unlike in *Walker*, the relators do not allege personal knowledge of the billing practices of any person or entity. The complaint does little more than hazard a guess that unknown third parties submitted false claims for Medicaid reimbursement.

The relators’ allegations pursuant to 31 U.S.C. § 3729(a)(1) are deficient under Rule 9(b). The “central question” in such a claim “is whether the defendant ever presented [or caused to be presented] a ‘false or fraudulent claim’ to the government.” *Clausen*, 290 F.3d at 1311 (quotation and citation omitted). Therefore, Rule 9(b) requires that actual presentment of a claim be pled with particularity. Because the relators’ complaint fails to assert the “‘who,’ ‘what,’ ‘where,’ ‘when,’ and ‘how’ of fraudulent submissions to the government,” *Corsello*, 428 F.3d at 1014, the district

court did not err by concluding the complaint failed to plead allegations of fraud with particularity.

B. 31 U.S.C. § 3729(a)(2)

In *Clausen*, we relied on the “presentment clause” of 31 U.S.C. § 3729(a)(1) to require that a complaint allege with particularity that the defendant submitted or caused to be submitted an actual false claim to the government. See *Clausen*, 290 F.3d at 1307 (quoting § 3729(a)(1)). In cases following *Clausen*, we have never explicitly considered whether the pleading requirements of § 3729(a)(1) apply with equal force to claims under § 3729(a)(2). See, e.g., *Corsello*, 428 F.3d at 1012 (noting relator brought claims under both subsections (a)(1) and (a)(2), but not distinguishing between claims in analysis). Subsection (a)(2) does not contain a presentment clause. It imposes liability on any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.”³

³In May 2009, Congress enacted the Fraud Enforcement and Recovery Act, which amended 31 U.S.C. § 3729(a)(2) (2003), replacing the words “to get a false or fraudulent claim paid or approved by the government” with the words “material to a false or fraudulent claim.” Pub. L. No. 111-21, §4, 123 Stat. 1617, 1621. Section 4(f)(1) of the Act provides that this change “shall take effect as if enacted on June 7, 2008, and apply to all *claims* . . . that are pending on or after that date.” *Id.* §4(f)(1), 123 Stat. at 1625 (emphasis added). We interpret the word “claim” in section 4(f) to mean “any request or demand . . . for money or property,” as defined by 31 U.S.C. § 3729(b)(2)(A) (as amended May 2009). While this *case* was pending on and after June 7, 2008, the relators do not allege that any *claims*, as defined by § 3729(b)(2)(A), were pending on or after June 7, 2008. Therefore, we conclude the Fraud Enforcement and Recovery Act does not apply retroactively to this

The relators contend that because subsection (a)(2) does not contain a presentment clause, proof that a false claim was submitted to the government is not an element of the cause of action. Plaintiffs are not required to allege what they are not required to prove. Therefore, the relators argue, their Complaint need not allege that a false claim was submitted to the government. We agree that 31 U.S.C. § 3729(a)(2) does not demand proof that the defendant presented or caused to be presented a false claim to the government or that the defendant's false record or statement itself was ever submitted to the government. We conclude, however, that a plaintiff must show that (1) the defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government; and (2) the defendant's false record or statement caused the government to actually pay a false claim, either to the defendant itself, or to a third party. The Complaint fails to satisfy the first requirement; it does not allege that Solvay intended its false statements to influence the government's decision to pay a false claim. Therefore, even if we were to assume that it alleges with particularity that the government paid a false claim, the Complaint remains deficient.

In *Allison Engine Co. v. United States ex rel. Sanders*, ___ U.S. ___, 128 S. Ct.

case. See *United States v. Sci. Applications Int'l Corp.*, No. 04-1543, 2009 WL 2929250, at *13-14 (D.D.C. Sept. 14, 2009) (concluding Fraud Enforcement and Recovery Act not retroactive because no claims were pending on or after June 7, 2008).

2123 (2008), the Supreme Court discussed the presentment requirement of § 3729(a)(2):

[T]he concept of presentment is not mentioned in § 3729(a)(2). The inclusion of an express presentment requirement in subsection (a)(1), combined with the absence of anything similar in subsection (a)(2), suggests that Congress did not intend to include a presentment requirement in subsection (a)(2). . . . What § 3729(a)(2) demands is not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting “a false or fraudulent claim paid or approved by the Government.”

__ U.S. at __, 128 S. Ct. at 2129-30. The relators interpret this language to suggest that § 3729(a)(2) is violated as soon as a defendant makes a false or fraudulent statement for the purpose of causing the government to pay a false claim. In their view, § 3729(a)(2) may be violated even if a false claim is never submitted to or paid by the government. Essentially, the relators contend that *Allison Engine* teaches that subsection (a)(2) is an attempt provision, imposing liability for statements made with the intent to defraud the government, whether or not the government actually pays a false claim. We disagree; the language of § 3729(a)(2) suggests it demands proof that the government paid a false claim, and *Allison Engine* does not cast doubt on this conclusion.

We have repeatedly held that the submission of a false claim is the “*sine qua non* of a False Claims Act violation.” *Clausen*, 290 F.3d at 1311. Improper practices

standing alone are insufficient to state a claim under either § 3729(a)(1) or (a)(2) absent allegations that a specific fraudulent claim was in fact submitted to the government. *Corsello*, 428 F.3d at 1014. Subsection (a)(2) relieves plaintiffs of the presentment requirement found in subsection (a)(1): the burden of proving that the defendant presented or caused to be presented a false claim to the government. But, the text of § 3729(a)(2)—proscribing false statements made “to get a false or fraudulent claim *paid or approved by the Government*”—suggests Congress intended this subsection to impose liability for false statements that actually cause the government to pay amounts it does not owe. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (citing 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.01[B], at 2-20 (2d ed. 2003) (“[A] plaintiff must also show that the defendant made or used . . . a false record in order to cause [a] false claim to be actually paid or approved.”)). A defendant’s false statements themselves need not be presented to the government, and the defendant need not personally submit a false claim. Nevertheless, because the Act protects the government from loss due to fraud, and it is not “an all-purpose antifraud statute,” *Allison Engine*, ___ U.S. at ___, 128 S. Ct. at 2130, the relators must show that the government paid a false claim to prove a violation of subsection § 3729(a)(2). Subsection (a)(2) is not, as the relators contend, a separate “attempt” provision of the False Claims Act. Nothing

in *Allison Engine* conflicts with our conclusion. If *Allison Engine* speaks to this issue at all, it implies that under 31 U.S.C. § 3729(a)(2), a relator must prove that the government paid a false claim. The opinion states, “[o]ur reading of § 3729(a)(2) . . . gives effect to Congress’ efforts to protect the Government from loss due to fraud but also ensures that ‘a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct.’” *Id.* (citation omitted). If the government has not paid funds it does not owe, it has suffered no loss. To impose liability in such a case would do nothing to protect the government from loss due to fraud, and it would extend liability beyond the “natural, ordinary and reasonable consequences” of a defendant’s conduct.

We hold that under § 3729(a)(2),⁴ a plaintiff must prove that the government in fact paid a false claim.⁵ Therefore, the relators’ Complaint must allege with

⁴Because the May 2009 amendments to 31 U.S.C. § 3729(a)(2) do not apply retroactively to this case, *see supra* note 3, we do not consider whether actual payment of a false claim is an element of this subsection as amended by the Fraud Enforcement Recovery Act of 2009.

⁵Our precedents interpreting 31 U.S.C. § 3729(a)(1) speak of the “submission” of false claims. *See, e.g., Clausen*, 290 F.3d at 1311 (discussing the submission and presentment of claims, not the payment of false claims). We have not explicitly considered whether a violation of § 3729(a)(1) occurs when a false claim is submitted, but the government does not pay the claim. The Third Circuit has held that payment of a false claim is not an element of a subsection (a)(1) claim, but actual payment is an element of a subsection (a)(2) claim. *Schmidt*, 386 F.3d at 242. Because the relators do not allege that Solvay submitted or caused to be submitted false claims that went unpaid, we do not address whether actual payment of a claim is an element of 31 U.S.C. § 3729(a)(1). We do consider whether actual payment of a claim is an element of 31 U.S.C. § 3729(a)(2), and we answer that it is an element.

particularity, pursuant to Rule 9(b), that Solvay's false statements ultimately led the government to pay amounts it did not owe. The relators contend that they have done so. Their Complaint alleges that state health programs presented false claims of uncertain amounts on uncertain dates to the government, and this resulted in a marked increase in Medicaid payments. As discussed above, these allegations would be insufficient to state a claim under subsection (a)(1) of the Act. Because liability under subsection (a)(1) is predicated upon the defendant itself submitting or directly causing the submission of a false claim, we require a plaintiff prove the "who," "what," "where," "when," and "how" of fraudulent submissions to the government." *Corsello*, 428 F.3d at 1014. But, under subsection (a)(2), a plaintiff must prove that the defendant made false statements to get a false claim paid or approved, not that the defendant caused the submission of the claim itself. So, our analyses in *Clausen*, *Corsello*, and *Atkins* do not necessarily foreclose the possibility that, for claims under subsection (a)(2), general allegations of improper government payments to third parties, supported by factual or statistical evidence to strengthen the inference of fraud, like those in the relators' Complaint, could satisfy the particularity requirements of Rule 9(b). The identity of the person or entity who submitted or caused to be submitted a claim for payment is not an element of a § 3729(a)(2) cause of action. So, in the appropriate case, we may consider whether the particularity requirements of

Rule 9(b), as to the details of the alleged false claims at issue, are more relaxed for claims under 31 U.S.C. § 3729(a)(2) than for claims under § 3729(a)(1). *See United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 29 (1st Cir. 2009) (distinguishing between qui tam actions alleging that the defendant made a false claim and actions in which the defendant induced third parties to file false claims; reasoning, “[i]n the latter context . . . a relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim”) (quotation and citation omitted). Nevertheless, because we conclude the relators’ Complaint in this case is deficient whether or not it alleges with particularity that a false claim was paid by the government, we do not reach this issue.

Whether the relators’ Complaint alleges with particularity the payment of a false claim is a question we need not answer. Even if it did, the Complaint remains deficient because it fails to allege that the defendants intended for the government to rely on their false statements in deciding whether to pay a false claim.

To be liable under 31 U.S.C. § 3729(a)(2), a defendant must make a false record or statement “to get a false or fraudulent claim paid or approved by the Government.” It is insufficient for a plaintiff to show merely that “a false statement *resulted in* the use of Government funds to pay a false or fraudulent claim.” *Allison Engine*, ___ U.S.

at ___, 128 S. Ct. at 2128 (emphasis added). “Instead, a plaintiff asserting a § 3729(a)(2) claim must prove that the defendant intended that the false record or statement be material to the Government’s decision to pay or approve the false claim.” *Id.* at ___, 128 S. Ct. at 2126.

The relators in this case claim that their Complaint “allege[s] copiously that [the] defendants intended their off-label campaign to cause the submission of false claims.” (Appellants’ Br. at 26.) But, their complaint does not link the alleged false statements to the government’s decision to pay false claims. It fails to allege that the defendants intended for the government to rely on the substance of their off-label marketing campaign to decide to pay a claim. The Complaint alleges that Solvay intended for physicians to rely on their false statements to write off-label prescriptions. (R.2-84 at 2.) It does not allege that, aside from the unnamed physicians, any person or entity had knowledge of the off-label marketing campaign—not any pharmacists, state health programs, or significantly, the federal government. We cannot infer that because Solvay allegedly intended its marketing campaign to convince physicians to write off-label prescriptions, Solvay intended for that campaign to influence the government’s decision to pay for those prescriptions.

If a . . . defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment

of a false claim “by the Government.” In such a situation, the direct link between the false statement and the Government’s decision to pay or approve a false claim is too attenuated to establish liability.

Allison Engine, ___ U.S. at ___, 128 S. Ct. at 2130.

To illustrate why the relators’ Complaint is deficient, compare this case with *Duxbury*, a recent First Circuit case involving the off-label promotion of a prescription drug. In *Duxbury*, the relator “alleged facts . . . that support his claim that [the defendant] *intended* to cause the submission of false claims.” 579 F.3d at 30 (emphasis in original). For example, the complaint in *Duxbury* alleged, in part, that the defendant pharmaceutical marketer gave a healthcare provider “more than \$5,000 of [prescription drugs] *so that* [the provider] could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product and that [the provider] *was reimbursed* by Medicare for the free [prescription drugs].” *Id.* at 31 (quotations omitted) (emphasis in original). The First Circuit found these and similar allegations supported the claim that the defendant intended its false statements to be material to the government’s decision to pay a claim. *Id.* at 30 (citing *Allison Engine*, ___ U.S. at ___, 128 S. Ct. at 2126). In contrast, the relators’ Complaint in this case alleges that Solvay intended its statements to be material to physicians’ decisions to write off-label prescriptions. It does not allege that Solvay intended its false statements to play any role in the government’s decision to reimburse state health

programs for the cost of those prescriptions. Because the relators failed to allege any connection between Solvay's alleged false statements and the government's decision to pay amounts it does not owe, the Complaint does not meet the particularity requirements of Rule 9(b).

V. CONCLUSION

Therefore, we affirm the district court's dismissal of the relators' federal claims for failure to comply with Federal Rule of Civil Procedure 9(b). And, we find no error in the court's declining to retain supplemental jurisdiction over the state law claims.

AFFIRMED.