Case No. 08-15810-A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JAMES HOPPER,
COLIN HUTTO

Plaintiffs-Appellants,

v.

SOLVAY PHARMACEUTICALS, INC.,
UNIMED PHARMACEUTICALS, INC. n/k/a UNIMED PHARMACEUTICALS LLC

Defendants-Appellees.

BRIEF OF APPELLEES

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA, TAMPA DIVISION
CASE NO. 8:04-CV-02356-SDM-TGW

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1, Federal Rules of Appellate Procedure, and Eleventh Circuit Rule 26.1-1, Appellees Solvay Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc. n/k/a Unimed Pharmaceuticals LLC hereby certify the following listed persons and entities having an interest in the outcome of this case. No other entity or entities owns ten percent or more of the stock of Solvay Pharmaceuticals or Unimed:

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Solvay S.A. (publicly traded on Euronext Brussels Exchange Ticker Symbol: SOLB.BE)

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STATEMENT REGARDING ORAL ARGUMENT

Oral argument is not necessary for three reasons. First, the dispositive issue in this appeal has been authoritatively decided by clear and unambiguous Eleventh Circuit precedent. Second, the briefs adequately present the legal arguments such that the decisional process will not be significantly aided by oral argument. Third, Appellants have not set forth any reason why oral argument should be heard, as required by 11th Cir. R. 28-1(c). Accordingly, Appellees respectfully submit oral argument should not be heard.

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I. STATEMENT OF JURISDICTION

Appellants' statement of jurisdiction is accurate and correct.

II. STATEMENT OF ISSUES

A. Whether the district court correctly granted Solvay's Motion to Dismiss Relators' Second Amended False Claims Act Complaint on grounds that it did not satisfy Fed. R. Civ. P. 9(b) for its failure to allege an actual false claim or false record.

B. Whether Relators should be permitted to raise, for the first time in this appeal, a new argument based on *Allison Engine Co. v. United States ex rel. Sanders*, – U.S. –, 128 S. Ct. 2123 (2008), and, if so, whether *Allison Engine* alters the district court's Fed. R. Civ. P. 9(b) ruling.

III. STATEMENT OF THE CASE

A. Introduction

The Second Amended Complaint ("SAC") alleged a marketing campaign by Solvay Pharmaceuticals, Inc., and Unimed Pharmaceuticals, Inc., n/k/a Unimed Pharmaceuticals LLC (collectively "Solvay") to promote the drug Marinol for uses not approved by the United States Food and Drug Administration ("FDA"). The SAC claimed this "off-label" marketing campaign (so called because the drug is promoted for uses not listed on the FDA-approved label) resulted in unidentified false claims being submitted for reimbursement to Medicaid, Medicare, and other

government payors, in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729.

Despite having alleged the details of the purported off-label marketing campaign, the SAC does not contain particularized allegations about any actual false claim (31 U.S.C. § 3729(a)(1)),[1] or any actual false record made to get a claim paid (31 U.S.C. § 3729(a)(2)).[2] Based on these omissions, and as required by well-settled, unequivocal, and binding Eleventh Circuit precedent, the district court dismissed the SAC with prejudice for failure to satisfy Rule 9(b).[3] In reaching its decision, the district court relied on *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002), *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005) (*per curiam*), and *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006), which are cases in which this Court

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[1] 31 U.S.C. § 3729(a)(1) provides that "[a]ny 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 Forced of the United States a false or fraudulent claim for payment or approval . . . is liable to the United States Government. . . ."

[2] 31 U.S.C. § 3729(a)(2) provides that "[a]ny 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 . . . is liable to the United States Government. . . ." This brief refers to 31 U.S.C. § 3729(a)(1) claims based on the presentment of an actual false claim as "(a)(1) presentment claims," and refers to 31 U.S.C. § 3729(a)(2) claims based on false records made to get claims paid as "(a)(2) false records claims."

[3] *Hopper et al. v. Solvay Pharms., Inc. et al.*, 590 F. Supp. 2d 1352 (M.D. Fla. 2008).

mandated that FCA complaints provide particularized allegations of actual false claims (or false records) to satisfy Rule 9(b), or else suffer dismissal.

B. Course of Proceedings and Disposition in the District Court

Plaintiffs-Appellants James Hopper and Colin Hutto ("Relators") are former Solvay sales representatives who worked in Birmingham, Alabama. (Doc 84 - ¶¶ 14-15) Relator Hutto left Solvay in 2003, and Relator Hopper left Solvay in 2005. (*Id.*) Relators filed their first complaint against Solvay under seal on November 22, 2004, (Doc 3), following which the United States notified the district court of its investigation of Relators' allegations. (Doc 5) The Government interviewed Relators, obtained claims data and other relevant information from several State Medicaid Agencies (including Florida, New York, and California), sought documents and electronic data from Solvay pursuant to a subpoena, reviewed the documents produced by Solvay, and participated in discussions with Solvay's counsel to obtain electronic sales and marketing data and e-mails from the company. (Doc 13 – Pg 3)

About seven months into the Government's investigation, on July 7, 2005, Relators filed a First Amended Complaint. (Doc 11) Solvay had produced hundreds of thousands of pages, both in hard copy form and in electronic form, to the Government. (Doc 13 - Pg 3; Doc 17 - Pgs 2-13) The Government shared

these documents with Relators who, in turn, "databased and reviewed [them]. . . . " (Doc 92 - Pg 3, 15)

In July 2006, the Government requested a fourth six-month extension of time within which to decide whether to intervene. (Doc 22) The district court, however, ordered the Government to decide by October 27, 2006. (Doc 24) On the court-ordered date, the Government notified the district court that the United States "was not able to decide by the Court's deadline whether to proceed with the action" and thus advised the district court that it was "not intervening at this time." (Doc 25) On November 17, 2006, the district court ordered the action unsealed. (Doc 28)

Solvay moved to dismiss the First Amended Complaint. (Doc 56) While that motion was pending, Relators asked for, and were permitted, leave to file the SAC (Doc 84), which Solvay later moved to dismiss for its failure to plead a false claim with Rule 9(b)'s required specificity. (Doc 88) Relators opposed Solvay's motion to dismiss the SAC on grounds that a false claim had adequately been pled. (Doc 92) Issue was thus joined on whether the SAC had adequately alleged a violation of 31 U.S.C. § 3729(a)(1) (presentment of a false claim). Whether the SAC had adequately alleged a violation of 31 U.S.C. § 3729(a)(2) (false record to get a claim paid) was neither briefed nor argued by Relators in the district court.[4]

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[4] Relators raised the issue for the first time in this appeal.

District Court Judge Steven Merryday referred the motion to Magistrate Judge Thomas Wilson, who heard oral argument on April 24, 2008. (Doc 98; Doc 100)

On August 1, 2008, the Magistrate Judge issued a report and recommended dismissal of the SAC for its failure to allege a false claim with the specificity this Circuit's Rule 9(b) jurisprudence requires. (Doc 101) Specifically, the Report and Recommendation ("R&R") recommended dismissal because the SAC's allegations that the purported off-label marketing campaign had resulted in the submission of millions of dollars worth of false claims "[we]re not supported by any facts concerning false claims actually submitted to the government for reimbursement." (Doc 101 - Pg 20) The R&R noted that the Relators themselves had "concede[d] that they cannot identify a specific false claim. . . , [any] information about the contents, or processing, of a false claim, such as who created a false claim or when false claims were created, the substance of the false representations, or alleged improper billing practices. . . [or any] knowledge of any false claim that was submitted to the government." (*Id.*)

The R&R relied on "three binding decisions" – *Clausen*, *Corsello*, and *Atkins*[5] – and observed that the Relators made no "meaningful attempt to

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[5] Because these decisions are binding precedent, they bind other panels unless and until the first panel's holding is overruled by the Court sitting *en banc*, or by the Supreme Court. *See, e.g., Smith v. GTE Corp.*, 236 F.3d 1292, 1301 n.8, 1303 (11th Cir. 2001); *United States v. Valladares*, 544 F.3d 1257, 1264 (11th Cir. 2008).

distinguish these three decisions."[6] (Doc 101 – Pgs 16, 22) In analyzing this Circuit's Rule 9(b) jurisprudence, the R&R also discussed and distinguished this Circuit's cases in which FCA complaints survived Rule 9(b) scrutiny notwithstanding the absence of particularized allegations of an actual and specific false claim. *See* Doc 101 - Pgs 23-25 (analyzing *United States ex rel. Walker v. R&F Props. of Lake County,* 433 F.3d 1349 (11th Cir. 2005) and *Hill v. Morehouse Med. Assocs., Inc.,* No. 02-14429, 2003 WL 22019936 (11th Cir. Aug. 15, 2003) (unpublished)). The R&R observed that, in those cases, the relators had alleged personal and direct knowledge about the billing process whereby actual false claims had actually been submitted. Absent some similar allegation in the SAC, the R&R concluded, this category of cases did not save the SAC:

> *Hill* is clearly distinguishable from *Clausen*, *Corsello*, and *Atkins*, since *Hill's* allegations of false billing were based upon personal knowledge and did not require any inference regarding the submission of false claims. There are no comparable allegations in this case and, thus, *Hill* provides the relators no support.

(Doc 101 - Pg 24). Likewise, the R&R noted that "*Walker* does not support the relators' position in this case. There are no allegations in this case that are similar

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[6] The R&R also relied on *Mitchell v. Beverly Enters., Inc.*, 248 Fed. Appx. 73 (11th Cir. 2007), noting with regard to Rule 9(b) that the "short shrift given to the issue in *Mitchell's* unpublished decision demonstrates that the Eleventh Circuit views the law as well-settled." (Doc 101 – Pgs 19-20)

to the allegations in *Walker* based upon personal knowledge regarding the submission of false claims." (*Id* - Pg 25)

Relators filed their Objections to the R&R (Doc 104), and urged the district court to overrule the R&R and deny Solvay's motion to dismiss. On September 8, 2008, the district court adopted the R&R in its entirety (Doc 106), following which Relators timely filed their notice of appeal. (Doc 107)

C. The Allegations in the SAC and Arguments Raised Before the District Court

1. Marinol – A Synthetic Form of Marijuana

Marinol (dronabinol) is a synthetic form of delta-9-tetrahydrocannbinol ("THC"), which is the major active component of marijuana. (Doc 84 - ¶ 36) The Drug Enforcement Administration ("DEA") originally scheduled Marinol, which Relators characterize as an "abusable hallucinogenic drug," as a Schedule II controlled substance. (Relators' Br. - Pg 4) In 1999, Marinol was re-classified as a Schedule III controlled substance, thereby making it easier to prescribe. (Doc 84 - ¶ 59)

The FDA first approved Marinol in 1985 for the treatment of "nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic[7] treatments." (*Id.* - ¶ 38) In 1991, six years after its initial FDA approval as an antiemetic treatment for cancer

[7] An "antiemetic" is an agent that prevents vomiting.

patients, the FDA approved Marinol "for anorexia associated with weight loss in patients with a confirmed diagnosis of AIDS." (*Id.* - ¶ 39) The next year, in 1992, the FDA approved a supplemental new drug application for Marinol for treatment of "anorexia associated with weight loss in patients with AIDS." (*Id.*) This condition is called "AIDS wasting syndrome." (*Id.*)

2. The FDA's Regulation of the Marketing of Prescription Drugs

The SAC acknowledged that "after [a] drug is approved for a particular use," the FDA "does not regulate how the drug is prescribed," (Doc 84 - ¶ 21), which means that, although the FDA might only approve a drug for one purpose, a physician may nonetheless prescribe the drug for any purpose, and not just the one for which the FDA approved it. This is known as an "off-label" prescription, or use, of that drug.[8] (*Id.*) Acknowledging that physicians may prescribe drugs off-label, the SAC alleged that the FDA nonetheless prohibits a drug manufacturer from marketing or promoting a drug for off-label uses. (*Id.* - ¶¶ 21, 23) Put

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[8] The United States Supreme Court has expressly recognized that, as part of the practice of medicine, physicians may prescribe FDA-approved medications for non-FDA approved off-label uses. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S. Ct. 1012, 1018 (2001) ("'[O]ff-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.").

differently, although a physician may prescribe a drug off-label, according to the SAC, the manufacturer may not promote a drug's off-label uses.

The SAC alleged that various federal healthcare programs, including Medicaid, Medicare, and CHAMPUS/Tricare, do not "knowingly pay for medications that are not prescribed for a medically accepted indication, or that are prescribed as a result of false or misleading information disseminated by [a] pharmaceutical manufacturer." (Doc 84 - ¶ 35) Relators acknowledged, however, that a state Medicaid program may elect to provide reimbursement for medication, even if it is prescribed for off-label use. (*Id.* - ¶ 232)

3. The Alleged Off-Label Marketing Campaign to Promote Sales of Marinol

The SAC alleged Solvay developed and executed a marketing plan for the purpose of "inducing physicians to prescribe the prescription drug Marinol . . . for uses which are neither FDA approved nor demonstrated to be safe and effective." (*Id.* - ¶ 3) At its core, the SAC alleged Solvay improperly conflated Marinol's on-label use as an appetite stimulant for AIDS patients with its other on-label use as an antiemetic for cancer patients, and then marketed Marinol off-label as an appetite stimulant for cancer (and other) patients.

Relators alleged that through 1999 Marinol sales languished, but that sometime in 2001, after Solvay implemented its alleged off-label Marinol marketing campaign, sales increased dramatically. (Doc 84 - ¶¶ 57-58, 62, 65, 70,

78, 115-116, 124, 138) The SAC then alleged particulars of a supposed off-label marketing campaign, including the following: marketing to specifically-targeted physicians, referred to as "Kahunas" because of their Marinol prescription patterns (Doc 84 - ¶¶ 105-109); marketing to long-term care providers (*Id.* - ¶¶ 169-192); and, alleged kickbacks to physicians for the purpose of having those physicians prescribe Marinol. (*Id.* - ¶¶ 193-221) None of these allegations was tethered to any (1) off-label (2) prescription (3) for Marinol (4) induced by a Solvay representative (5) for which a claim for reimbursement was made (6) to any state or federal healthcare agency. Indeed, despite having "databased and reviewed" the documents produced by Solvay to the Government, the SAC failed to identify one single allegedly false claim, false prescription, or false record used to get a claim related to Marinol paid by the Government.

4. The SAC's Generalized Allegations that Solvay Caused the Submission of False Claims to Medicaid

According to the SAC, after an unidentified Medicaid patient received an unidentified Marinol prescription for an unidentified malady, an unidentified third party (but not Solvay) sought reimbursement. Medicaid then allegedly reimbursed the unidentified third party, which could be a hospital, pharmacy, or other health care provider. Medicaid, in turn, allegedly sought federal reimbursement for the prescription by submission of quarterly Medicaid Statements of Expenditures ("QMSE"). (Doc 84 - ¶¶ 230—239)

The SAC included no allegation of any particular actually-falsified QMSE and, indeed, did not even attach a blank copy of one demonstrating where it might have been falsified in a manner that would get an off-label Marinol prescription reimbursed. The SAC nowhere described how Relators knew of any actually-falsified QMSEs and, indeed, acknowledged that a state Medicaid program may appropriately elect to provide reimbursement for medication, even if it is prescribed for an off-label use. (Doc 84 - ¶ 232)

Moreover, the SAC did not allege the particulars of any claim for reimbursement, any Marinol prescription, or any record made to get that claim paid. Instead, the SAC simply asserted that "[w]hen pharmacies, physicians and other healthcare providers submitted claims based upon a physician's prescription for Marinol [for an off-label indication] . . . the claims they submitted were false . . . ." (*Id.* - ¶ 239)

The closest the SAC came to alleging anything related to an actual false claim under the FCA's (a)(1) presentment prong, or an actual false record made to get that claim paid under the FCA's (a)(2) false record prong, did not occur until Paragraph 245 of the SAC. There, Relator Hopper was alleged to have illegally marketed Marinol's off-label indication to cancer physicians who wrote Marinol prescriptions over a certain period. However, the SAC nowhere described these prescriptions with any particularity (other than to generally allege they were for

Marinol); it did not allege any particular patients to whom the prescriptions were prescribed, the malady from which they suffered, whether the prescriptions were for an off-label indication, whether any government entity reimbursed it, or whether Medicaid had approved the reimbursement. The SAC conceded "it is impossible to determine at this juncture which of the 408 patients for whom physicians prescribed Marinol were eligible for Medicaid reimbursement." (Doc 84 - ¶ 248) The most the SAC said about these prescriptions was to surmise that "all or most of [these prescriptions] were for off-label uses." (*Id.* - ¶ 250) However, no specific false claim or record was identified.

5. The SAC's Generalized Allegations that Solvay Caused the Submission of False Claims to Other Government Healthcare Programs

Paragraphs 251 through 269 of the SAC discussed other Government healthcare programs, such as Medicare, Champus/Tricare, Champva, and the Federal Employees Health Benefit Program (collectively "non-Medicaid Government payors"), that allegedly reimbursed for off-label Marinol prescriptions. The SAC nowhere alleged that these payors were presented claims for payment, let alone any false ones. Nor did it discuss the mechanics, even hypothetically, of how such claims against non-Medicaid Government payors might be falsified. Likewise, the SAC did not allege any increase in Marinol

reimbursement, and did not allege any actual prescribing physicians, patients, or prescriptions.

D. Standard of Review

I. This Court reviews, *de novo*, a district court's order granting a motion to dismiss. *See, e.g., Corsello*, 428 F.3d at 1012.

II. As a matter of practice, this Court typically does not consider an issue raised for the first time on appeal unless it concerns a pure question of law where refusal to consider it would result in a miscarriage of justice. *Access Now, Inc. v. Southwest Airlines Co.*, 385 F.3d 1324, 1332 (11th Cir. 2004).

IV. SUMMARY OF ARGUMENT

A. The SAC alleged an FDA regulatory violation consisting of a purported off-label marketing campaign designed to increase Marinol sales. It further alleged an increase in Medicaid (but no other governmental payor) reimbursement contemporaneously with the marketing campaign. From these two allegations, the SAC asked the district court to infer that Solvay caused the submission of some impermissible claims, which the SAC asserted were false claims, for unauthorized (but completely unspecified) off-label Marinol prescriptions. The district court correctly determined that Fed. R. Civ. P. 9(b) did not permit the SAC to survive because it failed to allege actual false claims. The

district court's ruling was dictated by *Clausen*, *Corsello*, and *Atkins*, in which this Court mandated that a FCA complaint must identify specific allegedly false claims.

B. Acknowledging their failure to raise the argument in the district court, Relators argue for the first time on appeal that the SAC satisfied 31 U.S.C. § 3729(a)(2), which permits recovery for false records or statements made to get a false claim paid. They assert that the FCA, as recently construed in *Allison Engine Co. v. United States ex rel. Sanders*, - U.S. -, 128 S. Ct. 2123 (2008), does not require an FCA complaint to allege the presentment of an actual false claim in (a)(2) false record cases. Each Marinol prescription written as the result of defendants' alleged marketing practices, Relators now argue, was a false record or statement made to get an otherwise non-reimbursable Medicaid claim paid. The argument should be rejected on two grounds.

First, Relators' failure to allow the district court to consider this issue bars this Court from considering it for the first time here. Second, as Relators themselves acknowledge, even (a)(2) false record cases must satisfy Rule 9(b) pleading strictures. Significantly, *Allison Engine*, which had nothing to do with Rule 9(b) pleading strictures, does not alter the need to allege with specificity the false statement or record in an (a)(2) false record case. Applied here, the SAC failed altogether to allege any actual false record or statement with any particularity whatsoever, instead broadly alleging that "[e]ach prescription that was

written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false or fraudulent record or statement" used to get a claim paid. (Doc. 84 - ¶ 272)

V. ARGUMENT

A. The SAC Failed to Satisfy Rule 9(b)

1. This Circuit's Precedent Concerning 31 U.S.C. § 3729(a)(1) Mandated the SAC's Dismissal for Failure to Sufficiently Allege an Actual False Claim

The FCA subjects to civil liability "[a]ny person who knowingly presents, or caused to be presented, to . . . the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). "The submission of a false claim is . . . the *sine qua non* of a False Claims Act violation." *Atkins,* 470 F.3d at 1357. "Without the *presentment* of . . . a claim, . . . there is simply not actionable damage . . . ." *Id.* (citations omitted). "The [FCA] does not create liability merely for [the] . . . disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." *Id.* (citations omitted).

FCA complaints must satisfy Rule 9(b)'s requirement that fraud be pled with particularity. *Id.* "Particularity means that 'a plaintiff must plead "facts as to time,

place, and substance . . ." of the defendant['s] allegedly fraudulent acts, when they occurred, and who engaged in them.'" *Id.* (citing *Clausen*, 290 F.3d at 1311).

A relator does not satisfy Rule 9(b)'s directive by only "describ[ing] in detail what he believes is an elaborate scheme for defrauding the government by submitting false claims." *Atkins*, 470 F.3d at 1359. In addition, a relator must also "show[ ] that the defendants *actually submitted* reimbursement claims. . . ." *Id.* (emphasis in original) In words directly applicable to this case, this Court has ruled that it is insufficient to "portray[ ] the scheme and then summarily conclude[] that the defendants submitted [or caused to be submitted] false claims to the government for reimbursement." *Id.* This Circuit "decline[s] to make inferences about the submission of fraudulent claims because such an assumption would 'strip [ ] all meaning from Rule 9(b)'s requirements of specificity.'" *Corsello*, 428 F.3d at 1013 (quoting *Clausen*, 290 F.3d at 1312 n.21).

Rule 9(b) promotes several important objectives. First, the rule safeguards a defendant's reputation. *See Durham v. Business Mgmt. Assoc.*, 847 F.2d 1505, 1511 (11th Cir. 1988). Second, the rule notifies defendants of the exact claims against them so that they may prepare an adequate defense. *Id.* at 1511. Third, the rule "eliminate[s] fraud actions in which all the facts are learned through discovery *after* the complaint is filed." *Friedlander v. Nims*, 755 F.2d 810, 813 (11th Cir. 1985) (emphasis added); *Atkins*, 470 F.3d at 1360 n.17 ("[U]nlike *qui tam* relators,

when the government brings an FCA action . . . , we may assume that it does not do so solely to use the discovery process as a fishing expedition for false claims, for it already possesses that which the *qui tam* relator may need discovery to find."); *Clausen,* 290 F.3d at 1313 n.24 ("When a plaintiff does not specifically plead the minimum elements of their allegation, it enables them to learn the complaint's bare essentials through discovery and may needlessly harm a defendants' [*sic*] goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are baseless allegations used to extract settlements.").[9]

Here, as to Relators' § 3729(a)(1) claim, Rule 9(b) particularity means Relators had to identify not only details of alleged improper practices, but also details about specific claims third-parties allegedly submitted to the Government. Nor did the SAC, even lacking an allegation of an actual false claim, allege facts such as the actual claim amounts, actual dates on which claims were filed, why the claims were false, who presented the false claims, and the like, as mandated by *Clausen*, *Corsello*, and *Atkins*.[10]

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[9] Here, of course, Relators were given access to, and "databased and reviewed," the hundreds of thousands of documents produced by Solvay to the United States, but *still* did not identify one single allegedly false claim.

[10] Leaving aside the SAC's lack of any particularized allegation of an actual false claim or first-hand knowledge of a billing practice that led to one, the SAC never explained why the district court could infer that physicians (1) failed to notify the Government that prescriptions were for an off-label use; (2) concealed

In *Clausen*, the relator alleged six different schemes by which LabCorp had allegedly submitted false claims. 290 F.3d at 1303. The complaint alleged conversations between the relator and LabCorp employees regarding the company's policies and procedures, specific descriptions and (in some cases) technical codes for unnecessary medical tests that gave rise to alleged false claims, and the testing histories of three patients, identified by their initials, for whom allegedly unnecessary testing had been performed. *Id.* at 1304-05. The relator asserted that these allegations sufficiently alleged "the submission of false claims to the United States." *Id.* at 1305. Because the complaint had not included any information regarding the "specific dates or amounts of any claims submitted to the Government, or copies or detailed sources of information about the claims themselves," however, the district court dismissed it. *Id.*

After dismissal, the *Clausen* relator filed an amended complaint to which he attached a blank "Health Insurance Claim Form" (submitted by healthcare providers to Government healthcare programs to obtain reimbursement), and described, including reference to specific medical test codes, how improper testing would have shown up on that form. 290 F.3d at 1306. This, however, was insufficient because "still no copies of a single actual bill or claim or payment were provided. No amounts of any charges by LabCorp were identified. No actual

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from Medicaid that a prescription was for an off-label use; (3) or otherwise failed to obtain necessary Medicaid approval for reimbursement.

dates of claims were alleged. Not a single completed Form 1500 was provided." *Id.* In short, the relator "did not add any billing information to support his allegation that actual false claims were submitted for payment, such as the amount of any charges." *Id.* As before, the district court dismissed the amended complaint because "'[t]he particularity requirement of Rule 9 is a nullity if [relator] gets a ticket to the discovery process without identifying a single false claim by amount.'" *Id.* at 1307.

On appeal, this Court affirmed the dismissal. The relator's "failure to allege with any specificity if – or when – any actual improper claims were submitted to the Government is indeed fatal to his complaints. . . ." 290 F.3d at 1312. Acknowledging that the complaint "raise[d] questions about LabCorp's internal testing policies," this Court found dispositive that "nowhere in the blur of facts and documents . . . regarding six alleged testing schemes can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government." *Id.* Nor had relator "provide[d] any additional information linking the . . . schemes to the submission of any actual claims or any actual charges." *Id.* at 1313. This Court rejected the sort of inferential leap urged here to the effect that false claims inexorably flowed from the scheme. Instead, this Court held that unarticulated false claims are not actionable:

> We cannot make assumptions about a False Claims Act defendant's submission of actual claims to the

> Government without stripping all meaning from Rule 9(b)'s requirement of specificity or ignoring that the 'true essence of the fraud' of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme.

Id. at 1312 n.21.

Likewise, *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005) (*per curiam)* affirmed the dismissal of a *qui tam* action filed by a sales representative, who alleged various schemes involving referral-inducing kickbacks to physicians and false billing to Medicare for unnecessary treatments. This Court determined dismissal was appropriate due to the relator's failure to allege an actual false claim with specificity:

> Corsello argues that a pattern of improper practices of the defendants leads to the inference that fraudulent claims were submitted to the government, but we disagree. Because it is the submission of a fraudulent claim that gives rise to liability under the False Claims Act, that submission must be pleaded with particularity and not inferred from the circumstances. Although we construe all facts in favor of the plaintiff when reviewing a motion to dismiss, we decline to make inferences about the submission of fraudulent claims because such an assumption would "strip [ ] all meaning from Rule 9(b)'s requirements of specificity."
>
> . . . .
>
> . . . In short, Corsello provided the "who," "what," "where," "when," and "how," of improper practices, but he failed to allege the "who," "what," "where," "when," and "how" of fraudulent submissions to the government.

Corsello, 428 F.3d at 1013-14 (citation omitted) (quoting *Clausen*, 290 F.3d at 1312 n.21).

Then, in *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006), this Court affirmed dismissal of an FCA complaint alleging a scheme to defraud the Government based on the complaint's failure to tether the purported scheme to the particulars of any actual false claims:

> As the plaintiff did in *Clausen,* [the relator] has described in detail what he believes is an elaborate scheme for defrauding the government by submitting false claims. He cites particular patients, dates and corresponding medical records for services that he contends were not eligible for government reimbursement. Just like the *Clausen* plaintiff, though, [the relator] fails to provide the next link in the FCA liability chain: showing that the defendants *actually submitted* reimbursement claims for the services he describes. Instead, he portrays the scheme and then summarily concludes that the defendants submitted false claims to the government for reimbursement.

Id. at 1359 (emphasis in original).

More recently, in *Barys v. Vitas Healthcare Corp.*, 298 Fed. Appx. 893 (11th Cir. 2008), this Court followed its earlier holdings in *Clausen*, *Corsello*, and *Atkins*, and affirmed the Rule 9(b) dismissal of an FCA action for failure to plead fraud with sufficient specificity. Even though the relator attached allegedly fraudulent claims to her complaint, this Court ruled she had not alleged any facts (as distinguished from conclusory statements) to support an inference that the

claims were fraudulent. This Court also rejected the Relator's suggestion that the Court should "relax" the Rule 9(b) pleading requirements because the defendants held the documents necessary to prove the alleged fraud. Citing *Clausen*, this Court ruled that "a more lenient pleading standard cannot be used to base claims of fraud on conclusory allegations." 298 Fed. Appx. at 897.[11]

Two other Eleventh Circuit cases do not support Relators' position. Relators cite *Hill v. Morehouse Med. Assocs., Inc.*, No. 02-14429, 2003 WL 22019936 (11th Cir. Aug. 15, 2003) (unpublished) and *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349 (11th Cir. 2005) for the proposition that an FCA complaint may proceed if the allegations of the alleged scheme are strong enough to permit a court to infer that a false claim must have emanated from it. (Relators' Br. – Pgs 31-33) Neither *Hill* nor *Walker*, however, stand for that proposition. Rather, *Hill* and *Walker* stand for the proposition that this Court has permitted certain FCA actions to proceed where a relator has alleged first-hand and direct knowledge about the billing processes by which actual false claims have, in fact, been presented.

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[11] *Clausen* rejected the argument that a more lenient pleading standard (not needing to allege actual false claims) should apply in instances where the defendant uniquely holds the evidence of the fraud or where the alleged fraud is complex. 290 F.3d at 1314 n.25. Thus, *Barys* and *Clausen* mandate rejection of Relators' argument that, because their job descriptions did not provide them access to the alleged false claims, they should somehow be excused from identifying those alleged false claims. (Relators' Br. - Pg 19)

Here, the district court determined correctly that those cases had no application to the SAC because Relators failed to assert allegations of first-hand knowledge of billing. (Doc 101 - Pgs 23-25) Moreover, as this Court noted in *Atkins*, *Hill* is a non-binding, unpublished decision superseded by *Clausen* to the extent *Hill* is inconsistent with it. *See Atkins*, 470 F.3d at 1358 n.15.

In sum, as had the complaints in *Clausen*, *Corsello*, and *Atkins*, the SAC here alleged various purported regulatory violations, but failed to identify the particulars of any actual false claim emanating from those alleged violations. And, unlike *Hill* and *Walker*, the SAC alleged no first-hand or direct knowledge about how actual false claims made their way through the system for ultimate reimbursement. Thus, although Relators may have alleged the "'who,' 'what,' 'where,' 'when,' and 'how' of improper practices," they did not provide the "'who,' what,' 'where,' 'when,' and 'how,' of fraudulent submissions to the government." *Corsello*, 428 F.3d at 1014.

2. The "Strong Inference of Fraud" Standard Advocated by Relators Conflicts with this Court's Precedent

Relators posit the SAC should not have been dismissed because Relators provided a "strong inference" that a false claim, somewhere, was submitted. (Relators' Br. - Pg 25) Quite simply, this runs directly contrary to the law of this Circuit, which prohibits "inferring" or "assuming" the existence of a false claim or a false record in support of a claim. *See, e.g., Clausen*, 290 F.3d at 1312 n.21

("We cannot make assumptions about a False Claims Act defendant's submission of actual claims to the Government. . . ."); *Corsello*, 428 F.3d at 1013 ("[W]e decline to make inferences about the submission of fraudulent claims. . . .").

Relators' reliance on *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S. Ct. 2499 (2007) to support their "strong inference" argument is misplaced, and the district court correctly rejected it.[12] (Doc 101 – Pg 22) As the district court correctly noted, *Tellabs* involved the Private Securities Litigation Reform Act ("PSLRA"), not the FCA. The PSLRA requires, as a statutory element, allegations that "state with particularity facts giving rise to a *strong inference that the defendant acted with the requisite state of mind.*" 15 U.S.C. § 78u-4(b)(2) (emphasis added). Because Congress left the key term "strong inference" undefined, *Tellabs* focused on what sorts of allegations constituted a "strong inference" regarding a defendant's state of mind.

By contrast, the FCA requires, as a statutory element, that the allegations sufficiently identify a "false claim." And unlike "scienter" in the PLSRA context,

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[12] Relators assert that Solvay "recognizes" that *Tellabs* was "highly instructive" to the Rule 9(b) analysis. (Relators' Br. - Pgs 21-22) Solvay recognized no such thing. To the contrary, Solvay cited *Tellabs* in its Response in Opposition to Motion to Amend Complaint for the proposition that the district court should consider alternative reasons, other than false claims or illegal marketing, that might account for the increase in Marinol sales. (Doc 74 – Pgs 12-13) Solvay raised the argument merely to object to a proposed SAC on the ground of futility. In any event, as Solvay argued when briefing the 9(b) issue in connection with the motion to dismiss, *Tellabs* does not supplant the requirements of Rule 9(b) particularity. (Doc 97 - Pgs 4-5)

which involves assessing a defendant's subjective state of mind through inferences from circumstantial facts, a "claim" is a palpable and concrete document capable of ready and precise identification. As made clear in *Clausen*, *Corsello*, and *Atkins*, in the FCA context a relator must allege such a claim or record with sufficient particularity, and without resort to "inferences" or "assumptions."

Simply put, *Tellabs* had nothing to do with Rule 9(b), and it certainly did not announce a new standard for Rule 9(b) in FCA cases. Rule 9(b) still requires a relator to identify the claim or claims alleged to be false with particularity, and the district court correctly noted that *Tellabs* "provides no basis for this court to disregard the Eleventh Circuit's binding precedent in *Clausen*, *Corsello*, and *Atkins*." (Doc 101 - Pg 22). Indeed, no federal circuit court has adopted Relators' analysis of the applicability of *Tellabs* to an FCA action.

Relators cite an unpublished district court case, *United States ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., Inc.*, 2008 WL 395012 (S.D. Ga. Feb. 8, 2008), for the proposition that an FCA complaint can survive Rule 9(b) dismissal if it alleges a sufficiently strong "inference" that a false claim was submitted. Relators misconstrue *Digiovanni*, which does not mention *Tellabs*, and which certainly does not justify changing Eleventh Circuit pleading strictures.

On pages 23 through 24, and page 33 of their Brief, Relators quote from *Digiovanni*: "Even though the Complaint does not specifically identify 'claims'

submitted to the Government, the allegations of improper billing – together with supporting documentation – strongly imply an allegation that [the defendant] was submitted [*sic*] claims to Medicare. . . ." 2008 WL 395012 at *4. This passage, however, ignores the *very next three sentences*, which make clear the level of specificity that the *Digiovanni* relator had actually provided about the alleged false claim itself:

> For example, with respect to patient number V010945265, the Complaint alleges that [the hospital] included charges for reusable equipment on the patient's bill and that Medicare reimbursed [the hospital] $5,681.62 for this patient. These allegations . . . arguably meet the particularity requirement for pleading that [the defendant-hospital] was inflating patient bills submitted to Medicare Part A. However, the Court specifically holds that this is the only scheme that is even arguably pled with particularity.

Id. at *4-5. Thus, the *Digiovanni* relator's allegation only passed Rule 9(b) muster because it provided detailed and specific documentation reflecting the impermissible charges on a particular patient's bill and Medicare's corresponding reimbursement to the defendant-hospital for that patient.[13]

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[13] The other cases cited by Relators (Relators' Br. – Pg 21) to support the "strong inference" standard have no bearing on the Rule 9(b) analysis in the *qui tam* context. Indeed, *Rotella v. Wood*, 528 U.S. 549, 560, 120 S. Ct. 1075, 1083-84 (2000) was a non-FCA case upholding dismissal of a Federal Racketeer Influenced and Corrupt Organizations ("RICO") lawsuit on grounds that the RICO statute of limitations began to run when the plaintiff learned of his RICO injury, not when he learned of the injury. Likewise, *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Blue Cross Blue Shield of Georgia,* 755 F. Supp. 1040, 1052 (S.D. Ga. 1990) pre-dates *Clausen, Corsello,* and *Atkins* by over a

3. Off-Label Cases from Other Courts have Rejected Arguments Like Those Presented Here by Relators

Although this Circuit has yet to consider an FCA case predicated on alleged off-label marketing, other federal courts that have considered the issue have typically rejected complaints for failure to articulate an actual false claim emanating from the alleged regulatory violations. *See, e.g., United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570MLM, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006); *United States ex rel. West v. Ortho-McNeil Pharm., Inc.*, No. 03 C 8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007); *United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6 (D. Mass 2006), *aff'd on this ground but remanded on other grounds*, 507 F.3d 720 (1st Cir. 2007); *United States ex rel. McDermott v. Genentech, Inc.*, No. 05-147-P-C, 2006 WL 3741920 (D. Me. Dec. 14, 2006) (Recommended Decision), *aff'd*, 2007 WL 2128410 (D. Me. July 24, 2007).

For example, *United States ex rel. McDermott v. Genentech, Inc.* involved marketing the drug Rituxan off-label to treat rheumatoid arthritis. 2006 WL 3741920 at *2. As here, the *McDermott* relator alleged illegal kickbacks to promote Rituxan's off-label use. Unlike here, the *McDermott* relator also alleged the company trained sales representatives on how to avoid detection of their off-

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decade, and did not address pleading specificity, as it relates to the need to plead an actual false claim.

label promotion activities. *Id.* Pointing to a more than four-fold increase in Rituxan sales between 2000 and 2005, from $424 million to $1.8 billion, the *McDermott* relator argued that this increase "c[ould] only occur if a governmental medical reimbursement system reimburses claims for widespread use of that drug." *Id.* at *4. In lieu of alleging an actual false claim, the *McDermott* relator alleged that because of the "secret and confidential nature of the reimbursement claims . . . it would be impossible for anyone to identify them without formal discovery and court assistance." *Id.* at *10. The district court, relying on *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004) (citing this Circuit's *Clausen* decision), dismissed the complaint pursuant to Rule 9(b) for its failure to identify any actual alleged false claim. *McDermott*, 2006 WL 3741920 at *11. *See also West*, 2007 WL 2091185 (dismissing an FCA complaint brought by relator-sales representative even though he interacted on a daily basis over several years with defendant's customer-hospital employees and physicians, and even though the defendants had allegedly instructed physicians to prescribe off-label and distributed articles promoting off-label use).

Likewise, the relator in *United States ex rel. Rost v. Pfizer, Inc.*, alleged that the defendants marketed the drug Genotropin off-label, and thereby knowingly caused the submission of false claims. 446 F. Supp. 2d at 9. As here, and as in *McDermott*, the *Rost* relator had alleged a post-marketing increase in drug sales,

with a significant percentage of these sales being for off-label use.[14] *Id.* at 10. This alleged marketing campaign, the *Rost* relator argued, "must have caused physicians to prescribe Genotropin" off-label, and that "some of these prescriptions were inevitably submitted" for government reimbursement. *Id.* at 27-28.

The court dismissed the *qui tam* complaint because notwithstanding detailed allegations of illegal marketing and promotion of Genotropin, and alleged bribes, kickbacks, and other purported financial incentives, the complaint failed to allege a false claim with particularity. *Rost* reasoned that:

> [l]iability under the FCA . . . does not rest on violations of federal law or regulations. Instead, FCA liability flows solely from the existence of a false claim for payment that has been submitted to the government. To satisfy the pleading requirements of Rule 9(b), therefore, Plaintiff must identify actual false claims submitted to the government.

Id. at 27.

Like the district court here, *Rost* rejected the relator's argument that a false claim inevitably followed as a consequence of the scheme. "No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants' activities." *Id.* at 28.

In affirming the district court's reasoning in *Rost*, the United States Court of Appeals for the First Circuit noted that the alleged practices, "while illegal, are not

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[14] The relator claimed that approximately 60% of all adult sales and 25% of all pediatric sales of Genotropin were for off-label uses. 446 F. Supp. 2d at 10.

a sufficient basis for an FCA action because they do not involve claims for government reimbursement. As presently pled, the complaint does not sufficiently establish that false claims were submitted for government payment in a way that satisfies the particularity requirement." *Rost*, 507 F.3d at 732-33 (citation omitted). The court rejected the relator's argument that the complaint had achieved the objective of giving notice to the defendants of the false claims. This was so, the First Circuit reasoned, because the complaint had *not* given the defendants notice of false claims third parties had submitted for federal reimbursement based on off-label uses. Rather, the complaint only alleged illegal drug promotion practices. The *Rost* court observed, moreover, that notice is not the only reason for Rule 9(b)'s pleading strictures because the mere accusation of fraud often causes harm, and a strict rule of pleading discourages plaintiffs from filing fraud allegations in the hope that embarrassing discovery will force settlement. *Id.* at 733. Acknowledging that defendants' illegal marketing may well have caused physicians to prescribe the drug off-label, the *Rost* court also noted that those same doctors and their patients may never have sought reimbursement.[15] *Id.* at 732. The same precise analysis governs here.

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[15] The First Circuit remanded the case because the district court never ruled on the *Rost* relator's request to file an amended complaint. 507 F.3d at 733. On remand, the district court permitted the *Rost* relator to file an amended complaint. *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11 (D. Mass. 2008). In that amended complaint, the *Rost* relator satisfied Rule 9(b) because he alleged actual

To date, only two courts have permitted an off-label marketing-based FCA complaint to survive Rule 9(b) without alleging the details of an actual false claim, and neither appears to remain good law. The first is *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001). That case flies in the face of controlling Eleventh Circuit precedent. Moreover, the court in *Rost* concluded that *Parke-Davis* conflicted with its own Circuit's Rule 9(b) standard, as articulated in *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004).[16] *Rost*, 446 F. Supp. 2d at 27. It is thus unlikely that *Franklin* remains good law even in the courtroom where it was decided.

The second case is *United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 512 F. Supp. 2d 1158 (N.D. Ill. 2007). Like the *Parke-Davis* case, however, *Kennedy* contradicts its own Circuit's precedent, which requires relators to plead the particulars of an alleged false claim at an individualized transaction level. *See United States ex rel. Fowler v. Caremark Rx, LLC*, 496 F.3d 730, 741-42 (7th Cir. 2007).

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false claims and provided the details thereof, including the codes which revealed the drug for which reimbursement was sought from Medicaid, the medical diagnosis accompanying the claims, the dispensation dates, and the prescription dosages. *Id.* at 15 (D. Mass. 2008). The Relators in this case made no such similar detailed allegations. Moreover, unlike *Rost*, the Relators in this case "made no request to file another amended complaint." (Doc 101 – Pg 26) (citing *Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) (en banc)).

[16] *Karvelas* was decided after *Parke-Davis*.

B. The SAC Remains Deficient Under 31 U.S.C. § 3729(a)(2) Even After *Allison Engine*

Before this appeal, Relators did not argue that the SAC satisfied Rule 9(b) under section (a)(2) of the FCA, which creates liability for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2). Instead, Relators only argued that the SAC satisfied this Circuit's Rule 9(b) pleading strictures under section (a)(1) of the FCA, which creates liability for presenting or causing to be presented a false or fraudulent claim. On this argument the parties joined issue, and on this issue the district court, applying Eleventh Circuit precedent, granted Solvay's motion to dismiss.

Now, for the first time, Relators argue on appeal that, even if their pleading fails under (a)(1), their (a)(2) claim must be allowed to survive because (a)(2) only requires allegations of a false record or statement made to get a claim approved; it does not require any allegation that an actual false claim was presented to the Government for payment. (Relators' Br. – Pgs 25-28) Relators attempt to justify their failure to raise this argument in the district court by noting that *Allison Engine Co. v. United States ex rel. Sanders*, - U.S. -, 128 S. Ct. 2123 (2008) was not decided until after this case had been fully briefed and argued to the Magistrate Judge. This argument should be rejected.

1. This Court Should Not Consider the *Allison Engine* Argument Raised for the First Time on Appeal

"'[A]n issue not raised in the district court and raised for the first time in an appeal will not be considered by this court.'" *Access Now*, 385 F.3d at 1331 (quoting *Walker v. Jones*, 10 F.3d 1569, 1572 (11th Cir. 1994)). Relators seek to justify their failure to have raised their *Allison Engine* argument below because it was decided "[a]fter briefing and argument to the Magistrate Judge, but before his report and recommendation." (Relators' Br. - Pg 25) Relators urge this Court to consider this new argument because "Supreme Court decisions apply retroactively and prospectively to all cases on direct appeal whenever applied to the litigants before the Court . . . [such that] Appellate courts have the discretion to resolve a question for the first time on appeal, especially if the issue is legal in nature and failure to consider it would result in a miscarriage of justice." (*Id.* - Pg 25 n.8) This Court should not consider this new argument because Relators have waived any right to raise it on appeal.

Certainly, justice would not miscarry for this Court's refusal to consider this newly-raised argument here. Relators had ample opportunity to address *Allison Engine* in the district court. *Allison Engine* was decided on June 9, 2008, nearly two months before the Magistrate Judge issued his R&R (Doc 101), and three months before the district court adopted that R&R and granted Solvay's motion to dismiss. (Doc 106) Yet, Relators never once filed supplemental authority or

sought supplemental argument before the various rulings. Nor did they seek reconsideration after them.

Moreover, nearly seven months before the Magistrate Judge issued the R&R on August 1, 2008, counsel for Relators in this case filed an *amicus curiae* brief for Senator Charles Grassley on January 22, 2008 in the very *Allison Engine* case Relators seek to argue for the first time here. *See* Brief of Senator Charles Grassley as Amicus Curiae in Support of Respondents, No. 07-214, 2008 WL 205086 (U.S. Jan. 22, 2008). Indeed, Relators' counsel himself made this precise argument just six months before Solvay even filed its motion to dismiss the SAC in *United States ex rel. Howard v. Lockheed Martin*, 499 F. Supp. 2d 972 (S.D. Ohio 2007).[17] In *Howard*, Relators' counsel "argue[d] that they [were] not required under the FCA to plead the actual presentment of claims based on a recent Sixth Circuit precedent." *Id.* at 976. The "recent Sixth Circuit precedent" to which *Howard* cited was none other than *United States ex rel. Thacker v. Allison Engine Co., Inc.*, 471 F.3d 610 (6th Cir. 2006).

As this Court has noted, "'[t]oo often our colleagues on the district court complain that the appellate cases about which they read were not the cases argued before them.'" *Access Now*, 385 F.3d at 1331 (quoting *Irving v. Mazda Motor Corp.*, 136 F.3d 764, 769 (11th Cir. 1998)). Certainly, the district court here would

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[17] *Howard* was decided on June 28, 2007, and Solvay filed its Motion to Dismiss on December 28, 2007. (Doc 88)

share a similar sentiment if this Court considered this new argument now. The retroactivity of *Allison Engine* is irrelevant given the ample opportunity Relators had to raise it in the district court. *See, e.g., Deffenbaugh-Williams v. WalMart Stores,* 188 F.3d 278, 282 (5th Cir. 1999) (even when the law changes while a case is pending appeal, remand is not appropriate where the case law is "within the reach of an informed attorney.").

2. Even If This Court Proceeds to the Merits of *Allison Engine*, that Case Does Not Justify Reversal

Even if this Court proceeds to the merits of Relator's argument based on *Allison Engine*, and it should not for the reasons discussed above, that case does not alter the basic Rule 9(b) legal landscape applicable here. The *Allison Engine* case simply clarifies that in an (a)(2) false records case a relator need only prove that a defendant made a false record or statement intending to get a false claim paid, and need not prove the actual false claim for payment was presented to the Government itself.

Nowhere does *Allison Engine* address the specificity with which the actual false claim (§ 3729(a)(1)) or the actual false record to get a false or fraudulent claim paid or approved by the government (§ 3729(a)(2)) must be pled. Indeed, *Allison Engine* does not even remotely call into doubt prior cases where courts required the identification of a false record used to get a false claim paid to support an (a)(2) claim. *See, e.g., United States ex rel. Willard v. Humana Health Plan of*

Texas, Inc., 336 F.3d 375, 380 (5th Cir. 2003) (observing "the trial court correctly found: [Relator] has also failed to state a cause of action under 31 U.S.C. § 3729(a)(2). Under [(a)(2)], the plaintiff must identify both a false claim *and a false record or statement made or used to get that false claim paid.* . . . [Relator] has not identified any other document or statement used to get an allegedly false claim paid.") (emphasis added); *Unterschuetz v. In Home Personal Care, Inc.*, No. 06-CV-851, 2008 WL 4572512 at *4 (D. Minn. Oct. 14, 2008) (finding that (a)(2) claim failed to satisfy Rule 9(b) where relator did not "provide the dates on which [timecards were falsified], or any evidence showing the recreated timecards contained false or fraudulent information.").

The *Allison Engine* case involved a Navy contract with two shipyards to build guided missile destroyers. The prime contractor shipyards subcontracted with other businesses, among them Allison Engine, to build and assemble the electrical power generators for those destroyers. – U.S. –, 128 S. Ct at 2127. Although the prime contractor shipyards presented claims for payment to the Government, the subcontractors did not. Rather, these subcontractors submitted claims for payment to the prime contractor shipyards, which, in turn, submitted their own claims to the Government. *Id.* After the Government paid the prime contractor shipyards, they, in turn, paid the subcontractors using Governments funds. *Id.* At trial, the Relators introduced evidence that the defendant-

subcontractors had issued certificates of compliance to the shipyards "that falsely stated that their work was completed in compliance with the Navy's requirements," but did not introduce evidence of the actual false claim the shipyards ultimately submitted to the Government. *Id.*

At the close of the relators' case, the subcontractors moved for, and were granted, directed verdicts. The district court determined that, even in an (a)(2) false record case, the relators still had to prove the actual false claims the shipyards had presented to the government. *Id.*

The United States Court of Appeals for the Sixth Circuit reversed the district court. It reasoned that an (a)(2) false record claim did not require proof of the actual claim the shipyard ultimately submitted to the government. *Allison Engine Co.*, 471 F.3d at 622. Rather, instead of proving the ultimately-submitted false claims, a relator pursuing an (a)(2) claim need only prove that the false statements or records resulted in "obtaining or getting payment or approval of the claim." *Id.* at 621. Applied to the case at hand, the Sixth Circuit determined that proof of the subcontractors' false certification to the shipyard, plus proof that the subcontractors had been paid using government funds, should have been sufficient to result in denial of the subcontractors' motion for directed verdict.

Although the United States Supreme Court affirmed the Sixth Circuit, it did not adopt the Sixth Circuit's reasoning. The Supreme Court did agree that

§ 3729(a)(2) did not require proof that an actual false claim had been presented **to the Government.** 128 S. Ct. at 2129. However, the Supreme Court did not agree that § 3729(a)(2) was satisfied simply by evidence of a false record plus proof that government funds had been expended. *Id.* at 2128. Rather, the Court held, § 3729(a)(2) required proof:

> 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." Therefore, a subcontractor violates § 3729(a)(2) if the subcontractor submits a false statement to the prime contractor intending for the statement to be used by the prime contractor to get the Government to pay its claim.

Id. at 2130 (quoting § 3729(a)(2)).

Certainly, *Allison Engine* did not address the core issue now raised by Relators, which is whether, even assuming Relators had argued their (a)(2) theory in the district court, Relators had adequately pled a false record with Rule 9(b) specificity. The *Allison Engine* case provides no answer to that question. Nothing in *Allison Engine* relaxes the Rule 9(b) pleading standards in (a)(2) false records cases.[18] Pleading an (a)(2) false records case still requires identification of the allegedly false records, what about them is false, who falsified them, when they were falsified, and how they were used to get the Government to pay a false claim.

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[18] Indeed, the false records used by the subcontractors in *Allison Engine* were, in fact, introduced as evidence at trial. 471 F.3d at 613, 622-23.

Indeed, at least two Circuits have adopted this analysis. *See United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 874 (5th Cir. 2008) ("Despite the fact that § 3729(a)(2) does not require presentment, a relator alleging a § 3729(a)(2) violation must still show the 'who, what, when, when, and how of the alleged fraud' under Rule 9(b). Rafizadeh has failed to meet several of the Rule 9(b) requirements: 'what' statements were in the budget, 'who' prepared it, and 'how' it was used to get government funds."); *United States ex rel. Marlar v. BWXT Y-12, LLC*, 525 F.3d 439, 447 (6th Cir. 2008) (dismissing FCA complaint and refusing to await Supreme Court's decision in *Allison Engine*, observing that "[w]hile [relator] is correct that we have previously held that proof of 'presentment' is not required for actions under subsections [3729] (a)(2) and (a)(3), we have repeatedly held that proof of a false claim is required . . . .") (citations omitted).

Applied here, the SAC contained no allegations regarding any specific Marinol prescriptions constituting the false records allegedly made to get a claim paid. Thus, the SAC lacks a necessary predicate for an (a)(2) false record claim to proceed. *See Rost*, 507 F.3d at 733 ("[T]he plain language of § 3729(a)(2) requires proof of a 'false record or statement' for liability to attach. . . ."). Instead, the SAC simply and summarily asserted that "[e]ach prescription that was written as a result of defendants' illegal marketing practices and illegal kickbacks represents a false

or fraudulent record or statement" that was ultimately used to get a false claim paid by the Government. (Doc 84 - ¶ 272)

This type of conclusory allegation is insufficient. *Barys v. Vitas Healthcare Corp.*, 298 Fed. Appx. 893 (11th Cir. 2008). *See also United States ex rel. Joshi v. St. Lukes Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006). The *Joshi* relator, for example, had contended that his FCA complaint satisfied Rule 9(b)'s particularity requirement because it alleged that "every invoice for nurse anesthetist work was fraudulent because no nurse anesthetist was medically supervised or directed." *Id.* at 565. In rejecting the relator's contention, the Eighth Circuit observed that "assuming *arguendo* the complaint can be interpreted to have alleged 'every' claim was fraudulent, Rule 9(b) requires more than such conclusory and generalized allegations." *Id.* at 557. The same reasoning applies here.

VI. CONCLUSION

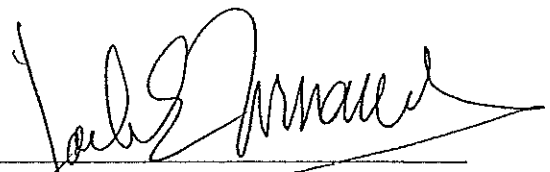
The Government investigated this case for years. Solvay produced hundreds of thousands of documents to the Government. The Government made these documents available to the Relators. The Relators filed three versions of their complaint. And yet, the SAC still failed to provide particularized allegations of any specific fraudulent claim. This failure was fatal to the SAC.

This Circuit has repeatedly rejected the argument Relators make here, that a false claim may be inferred from the existence of a purported regulatory violation.

The *Allison Engine* case, moreover, does not change, alter, or modify this precedent. "[N]owhere in the blur of facts and documents [alleged in the SAC regarding the off-label marketing] schemes can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government." *Clausen*, 290 F.3d at 1312. For this reason, the Court should affirm the district court's order dismissing the SAC with prejudice for failure to plead a false claim with the specificity this Court requires.

Dated: March 13, 2009

Respectfully submitted,



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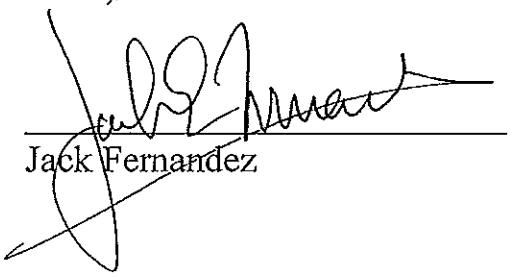
CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B). This brief contains 8,947 words.



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CERTIFICATE OF SERVICE

I certify that on this 13th day of March 2009, three true and correct copies of the foregoing Brief of Appellees were mailed by Federal Express to:

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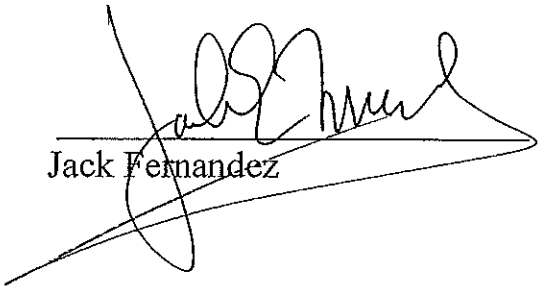
The Brief of Appellees was filed with the Clerk on March 13, 2009 pursuant to Fed. R. App. P. 25(a)(2)(B) by Federal Express, and was electronically filed on the same date.



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