No. 08-15810-A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

JAMES HOPPER and COLIN HUTTO,

Plaintiffs-Appellants,

v.

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

Defendants-Appellees.

On Appeal from the U.S. District Court for
the Middle District of Florida, Tampa Division
Case No. 8:04-CV-02356-SDM-TGW

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES

Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
(202) 588-0302

March 24, 2009

Hopper v. Solvay Pharmaceuticals, Inc.
Eleventh Circuit Docket No. 08-15810-A

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Counsel for *amicus curiae* Washington Legal Foundation certifies that, in addition to parties and entities identified in the Certificate of Interested Persons filed by Appellants and Appellees, which parties and entities are hereby incorporated by reference into this Certificate, the following listed persons and entities may have an interest in the outcome of this case:

- Daniel J. Popeo (counsel for *amicus curiae*)
- Richard A. Samp (counsel for *amicus curiae*)
- Washington Legal Foundation (WLF), a public-interest law and policy center located in Washington, DC. WLF is a nonstock corporation; it has no parent corporation, and no publicly held company owns any of its stock.

/s/ Richard A. Samp
Richard A. Samp
Washington Legal Foundation

Counsel for *Amicus Curiae*

TABLE OF CONTENTS

Page

TABLE OF CITATIONS

Page(s)

Cases:

Page(s)

Statutes and Rules:

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States. It seeks to defend the rights of individuals and businesses against interference from excessive government regulation. WLF's members include physicians who seek to receive truthful information about potential "off-label" uses of FDA-approved products, and medical patients who want their doctors to have such information.

For more than 30 years, WLF has worked actively to ensure that patients have access to the latest medical advances, particularly where the patients are critically ill and have limited treatment options. *See, e.g., Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008). WLF supports granting patients and their doctors the option of employing FDA-approved medical products for any use for which at least some scientific evidence suggests they are safe and effective, without regard to whether those uses are specified on the FDA-approved labeling. To ensure that patients and their doctors have access to such scientific evidence, WLF believes that the federal government should encourage the dissemination of truthful information about off-label uses of FDA-approved

medical products. WLF successfully challenged the constitutionality of certain FDA restrictions on speech about off-label uses and has in place a permanent injunction against enforcement of those restrictions. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

WLF also has regularly participated in litigation regarding the scope of the civil False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* *See, e.g.*, *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008); *Rockwell Int'l Corp. v. United States ex rel. Stone*, 127 S. Ct. 1397 (2007); *Riley v. St. Luke's Episcopal Hosp.*, 196 F.3d 514 (5th Cir. 1999). WLF is concerned that, over the last two decades, excessive FCA activity has spawned abusive punitive litigation against businesses, both large and small, to the detriment of those businesses, their employees, their shareholders, and the public at large.

WLF is filing its brief because of its concern that Appellants' action, if allowed to proceed past the pleadings stage, could harm public health by reducing public knowledge regarding beneficial off-label uses of FDA-approved products. Appellants' brief focuses on their allegations that Appellees Solvay Pharmaceuticals, Inc., *et al.* (Solvay), engaged in improper promotional activities. But the issue in this case is whether Solvay violated the FCA, not

whether it improperly promoted Marinol.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing its brief due solely to its interest in ensuring improvements in public health care. WLF is filing with the consent of all parties.

STATEMENT OF ISSUES

Appellants raise two issues on appeal, relating to two separate provisions of the FCA.[1] The first issue focuses on 31 U.S.C. § 3729(a)(1) and whether factual allegations contained in the Second Amended Complaint (SAC) satisfy the particularity requirement of Fed.R.Civ.P. 9(b) despite the SAC's failure to identify who made the alleged false claims, when they occurred, and the substance of the claims.

The second issue concerns whether Appellants have adequately pleaded a violation of 31 U.S.C. § 3729(a)(2) by alleging that Solvay made false

---

[1] Those provisions are 31 U.S.C. § 3729(a)(1) & (2). Pursuant to those provisions, civil liability arises when a person:

> (1) 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; [or]
>
> (2) 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.

statements for the purpose of inducing the federal government pay a false or fraudulent claim, or whether Appellants must also allege facts indicating that the government did, in fact, pay a false or fraudulent claim in reliance on Solvay's alleged false statements. Solvay's brief focuses primarily on the first issue and cogently explains why allegations contained in the SAC are inadequate to allege a violation of § 3729(a)(1). Rather than repeating those arguments, WLF focuses much of this brief on demonstrating that Appellants have failed to meet the Rule 9(b) pleading standards with respect to § 3729(a)(2) and that Appellants arguments to the contrary are based on a misunderstanding of the Supreme Court's recent *Allison Engine* decision. WLF does not address Solvay's argument that Appellants waived their § 3729(a)(2) argument by failing to raise it in the district court.

STATEMENT OF THE CASE

Solvay is a pharmaceutical manufacturer authorized by the Food and Drug Administration (FDA) to market and distribute the drug Marinol. FDA has authorized the labeling of Marinol for two indications for which it has been determined (through exhaustive clinical trials) to be safe and effective: treatment of nausea and vomiting associated with cancer chemotherapy for certain oncology patients; and treatment of anorexia associated with weight loss

in AIDS patients.

Appellants are two former Solvay employees who have filed suit against Solvay under the *qui tam* provision of the FCA, alleging that Solvay defrauded the federal government. They allege that "[i]n order to increase Marinol® sales, Solvay crafted an off-label marketing campaign for the express purpose of selling the drug for unapproved purposes." Appellants Br. 5 (citing SAC ¶ 62). They allege that the campaign succeeded: between 1999 and 2005, annual sales of Marinol increased several-fold. They allege that almost one-quarter of all Marinol sales were reimbursed through the federal government's Medicaid program. They allege that some unspecified portion of the Medicaid funds paid for off-label Marinol prescriptions that were not properly reimbursable under Medicaid. They allege that the federal government provided reimbursement only because Solvay: (1) caused others to present false or fraudulent reimbursement claims to the federal government; and/or (2) made or caused to be made false records or statements to get false or fraudulent claims paid by the federal government – all in violation of 31 U.S.C. § 3729(a)(1) & (2).

Although they allege a grand conspiracy to promote Marinol for off-label uses, the SAC is surprisingly silent regarding how violations of the FCA were carried out. With regard to § (a)(1) allegations, the SAC says nothing about who

made the false claims, when they were made, or the substance of the claims. With regard to § (a)(2) allegations, the SAC says nothing about who made the false records or statements, when they were made, the substance of the records/statements, or how the records/statements caused the federal government to pay/approve false or fraudulent claims.

In August 2008, a Magistrate Judge issued a report recommending that the complaint be dismissed under Fed.R.Civ.P. 12(b)(6) for failure to state a cause of action upon which relief could be granted. Doc. 101. The district court adopted that report in its entirety in September 2008 and dismissed the case. Doc. 102. In this appeal, Appellants raise an argument they failed to raise in the district court: even if their § (a)(1) claims are foreclosed, the Supreme Court's recent *Allison Engine* decision indicates that Appellants have adequately stated a cause of action under § (a)(2).

SUMMARY OF ARGUMENT

Appellants devote much of their brief to arguing that they have established a cause of action under § 3729(a)(2), a provision (they assert) that requires nothing more than that a defendant makes (or causes others to make) a "false record or statement" in hopes of persuading the federal government to pay a claim. Appellants' argument is based on a misreading of both § 3729(a)(2) and

Allison Engine. That statute quite clearly requires a plaintiff to establish both that the federal government paid a false claim *and* that it was induced to do so by the false record/statement made (or caused to be made) by the defendant.

Appellants' claims under § 3729(a)(1) are doomed by the trilogy of Eleventh Circuit cases relied on by Solvay. Appellants allege that Solvay engaged in a widespread, illegal scheme to promote Marinol for off-label uses. But the issue here is whether Solvay is liable the FCA, not whether it has violated federal food and drug laws. It the absence of evidence of even a single instance in which a false claim was submitted to the federal government for payment – or even of evidence from someone who could testify regarding billing practices – Appellants' FCA claims cannot survive Rule 9(b) scrutiny.

ARGUMENT

I. APPELLANTS HAVE MISSTATED THE STANDARD OF REVIEW

Appellants set forth their views regarding the "standard of review" at Page 15 of their brief. Much of what Appellants write in that section is inaccurate.

Appellants implicitly concede, as they must, that a district court properly judges the adequacy of FCA fraud allegations under the heightened pleadings standards of Fed.R.Civ.P. 9(b). *See, e.g., United States ex rel. Clausen v. Laboratory Corp. of America*, 290 F.3d 1301, 1308 (11th Cir. 2002). Rule 9(b)

provides, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."[2]

Nonetheless, in the "Standard of Review" section of their brief, Appellants attempt to obscure the demanding nature of their pleading burden. They state, "A dismissal based on Rule 9(b) reduces to a finding of failure to state a claim upon which relief can be granted under Rule 12(b)(6)." Appellees Br. 15. Appellants' suggestion that their Rule 9(b) burden is somehow "reduce[d]" on appeal is incorrect. Rule 12(b)(6) states that a complaint may be dismissed for "failure to state a claim upon which relief can be granted," but it says nothing regarding the standards to be used in judging the adequacy of the claim set forth in a complaint. Rather, those standards are set forth in Rule 8(a) (applicable in most cases) and Rule 9(b) (applicable to cases, as here, alleging fraud). The demanding Rule 9(b) pleading standards are just as applicable on appellate review as they are in the district court. *Clausen*, 290 F.3d at 1308.

Appellants compound their error by concluding their "Standard of

---

[2] The second sentence of Rule 9(b) is not at issue in this appeal. The district court did not find any deficiencies in Appellants' allegations regarding Solvay's state of mind. Rather, the district court focused solely on deficiencies in the SAC's allegations regarding the "circumstances constituting fraud."

Review" section with the following sentence: "The Supreme Court recently framed the Rule 12(b)(6) inquiry as being whether the complaint sets out 'plausible entitlement to relief.'" Appellants Br. 15 (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558-63 (2007)). That assertion is incorrect. *Twombly* did not purport to "frame" a Rule 12(b)(6) inquiry; rather, its "plausible entitlement to relief" language was an effort to establish the standard for reviewing the adequacy of complaints to which Rule 8(a) is applicable. *Id.* Nowhere does *Twombly* suggest that a complaint alleging fraud can survive a Rule 12(b)(6) motion to dismiss if its allegations are merely "plausible." Rather, such complaints are properly dismissed unless they meet the far more demanding Rule 9(b) pleading standards.

II. APPELLANTS' § 3729(a)(2) ARGUMENT IS BASED ON A MISINTERPRETATION OF *ALLISON ENGINE*

Perhaps sensing that *Clausen* imposes an insurmountable hurdle to their claims under § 3729(a)(1), Appellants devote much of their brief to arguing that the SAC adequately states a claim for relief under § 3729(a)(2). Citing *Allison Engine* for the proposition that a "false record or statement" need not actually be presented to the federal government in order to establish a claim under § 3729(a)(2), Appellants argue that they need only allege that Solvay made, or

caused to be made, the requisite false statement for the purpose of inducing payment of a claim:

> Under *Allison*, a relator bringing a case under § 3729(a)(2) must allege that the defendant made "false statements *for the purpose* of causing false or fraudulent claims to be paid by the Government." Relators in this case have done so in spades. Proving a violation of the Act does not require a showing that false or fraudulent claims were actually paid. While the allegations of the Second Amended Complaint leave no doubt whatever that they were, the defendants' violations of subsection (a)(2) were complete when the false statements were made with the requisite state of mind.

Appellants Br. 28 (quoting *Allison Engine*, 128 S. Ct. at 2130) (emphasis added by Appellants).

Appellants' argument is based on a misreading of both § 3729(a)(2) and *Allison Engine*. That statute quite clearly requires a plaintiff to establish both that the federal government paid a false claim *and* that it was induced to do so by the false record/statement made (or caused to be made) by the defendant.

A full understanding of *Allison Engine*'s holding requires a discussion of the facts of that case. The Navy had contracted with two shipyards to build destroyers. The shipyards subcontracted with Allison Engine Co. to supply generator sets for those destroyers. The two False Claims Act relators were former employees of a subcontractor of one of Allison Engine Co.'s subcontractors. The relators alleged that Allison Engine Co. and its

subcontractors received payment for their work from the shipbuilders only by submitting false Certificates of Compliance stating that their work was completed in compliance with Navy specifications – when in fact (the relators alleged) the work was noncompliant. Addressing a variety of issues regarding the meaning of the FCA, the Supreme Court ultimately reversed a Sixth Circuit judgment that had been favorable to the relators. *Id.* at 2131.

Allison Engine includes a lengthy discussion of the requirements to state a claim under § 3729(a)(2). The Sixth Circuit had held that § (a)(2)'s requirement that a false claim be "paid or approved by the Government" could be met by demonstrating that the defendants were paid by a government contractor (in this case, the shipbuilders) using government funds. *Id.* at 2128. The Court rejected that interpretation, holding that the phrase should be "read literally" and requires that "the Government must literally pay the bill." *Id.* at 2129.[3] That holding definitively refutes Appellants' assertion that a § (a)(2) violation is complete upon a showing that a "false record or statement" was made with the requisite intent, without any need to demonstrate that the government paid a false claim.

Appellants apparently were led astray by the Court's separate discussion

[3] The Court also held that a § (a)(2) plaintiff must demonstrate that the defendant *intended* the federal government to pay the false claim at issue. *Id.*

of "presentment." *Allison Engine* held that § (a)(2) does not require a relator to demonstrate that the "false record or statement" was actually presented to the federal government. *Id*. at 2129-30. Rather, it is sufficient for the relator to demonstrate that the "false record or statement" was made to someone and that the government would not have paid the claim if the false record or statement had not been made. *Id.*[4]

Appellants misinterpret the Court's language at Page 2130 as suggesting that a § (a)(2) violation is complete once a defendant makes a false statement in hopes of facilitating the payment of a false or fraudulent claim. The language upon which Appellants rely sets up a contrast between what a § (a)(2) claimant is and is not required to demonstrate. The Court explained that the claimant need not demonstrate that the false statement that the defendant made (or caused to be made) was actually presented to the government; rather, in lieu of such a demonstration, the claimant need only show that the false statement was made

[4] Thus, the Court explained that the relators would need to demonstrate on remand that the false statement (the Certificate of Compliance) was made by the defendants to the shipbuilders because they intended "the statement to be used by the prime contractor to get the Government to pay its claim." *Id.* at 2130. If the shipbuilders would have been entitled to payment regardless whether they had been supplied Certificates of Compliance by Allison Engine Co. and the other subcontractors, then the defendants' allegedly false statements would not have been actionable because they could not be said to have been a cause of the payments from the federal government to the shipbuilders.

"for the purpose of getting a false or fraudulent claim paid by the government." *Id.* at 2130. But nothing in that language suggests, as Appellants would have it, that such a showing is the *only* element of a § (a)(2) claim. Any such interpretation would be inconsistent with the Court's holding, discussed above, that a § (a)(2) claim requires a showing that the government has actually paid a false claim and that payment was caused by the false statement. *Id.* at 2128-29. Rather, the quoted language simply suggests a means by which a claimant can make the requisite § (a)(2) showings without evidence that the false statement was ever presented to the federal government.

Indeed, in the absence of evidence that the government actually paid a claim, the concept of an FCA lawsuit makes no sense. In the absence of such payment, the government would have suffered no loss, and thus there would be no funds that relators could hope to recoup. Appellants may take issue with Solvay's promotional practices; but in the absence of evidence that the federal government has been defrauded of funds, that is an FDA enforcement issue, not an FCA matter. As this Court has made clear, "Underlying improper practices alone are insufficient to state a claim under the False Claims Act absent allegations that a specific fraudulent claim was in fact submitted to the government." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005).

Federal appeals courts that have considered § 3729(a)(2) claims in the months since *Allison Engine* was decided have uniformly understood the Supreme Court to have required claimants to show that the "false record or statement" caused the government to pay a false claim. For example, the Fifth Circuit recently explained:

> 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, where, and how of the alleged fraud" under Rule 9(b). [The claimant] 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. Rafizadeh v. Continental Common, Inc., 553 F.3d 869, 874 (5th Cir. 2008) (emphasis added).

Appellants allegations are similarly deficient under Rule 9(b). In asserting a § 3729(a)(2) claim, Appellants have failed to explain who made the "false records or statements," when they were made, the substance of the records/ statements, or how the records/statements caused the federal government to pay/approve false or fraudulent claims.

Appellants assert 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." Appellants Br. 26 (quoting SAC ¶ 272). Such a

generalized allegation comes nowhere near meeting the exacting requirements of Rule 9(b). Even accepting the allegations that Solvay engaged in illegal marketing practices, the blanket condemnation of all prescriptions written as a result of those practices does nothing to alert Solvay to which prescriptions are deemed fraudulent by Appellants and which are not.

Moreover, it is absolutely implausible to label a prescription "fraudulent." A prescription is simply an authorization by a doctor to dispense a prescription drug to a patient. There can be nothing "false" about such an authorization, given that a doctor is entitled by law to use his professional judgment to authorize use of *any* FDA-approved drug to treat his patients as he deems appropriate – even if the use is off-label. Of course, such off-label uses may or may not be reimbursable by Medicaid; but there is no fraud in writing a prescription for such non-reimbursable uses. No fraud could occur unless and until someone (whether a hospital, a doctor, or a pharmacy) submits a claim for Medicaid reimbursement despite knowing that the claim is not reimbursable. Accordingly, if all Appellants can point to as examples of "false record[s] or statement[s]" are unspecified prescriptions, then they have not even begun to make out a claim under § (a)(2).

In sum, Appellants have failed to state a claim under § 3729(a)(2). Their

arguments to the contrary are based on a fundamental misunderstanding of the Supreme Court's *Allison Engine* decision.

III. APPELLANTS HAVE FAILED TO SATISFY RULE 9(b)'S REQUIREMENT THAT THE ELEMENTS OF THEIR § 3729(a)(1) CLAIM BE PLEADED WITH PARTICULARITY

Solvay's brief ably demonstrates why Appellants' § 3729(a)(1) claim fails to meet the "particularity" requirements of Rule 9(b) and thus why the district court acted properly in dismissing that claim under Rule 12(b)(6). Solvay quite properly relies on a trilogy of 11th Circuit decisions – *Clausen, Corsello*, and *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (5th Cir. 2006) – for the proposition that it is insufficient for an FCA plaintiff to allege an elaborate scheme to defraud but to fail to provide even a single concrete example of a false claim submitted (or caused to be submitted) by the defendant. WLF will not repeat all of Solvay's arguments here but rather will highlight a few points it deems important.

In particular, WLF wishes to highlight the importance of off-label uses in our health care system. From a policy perspective, there are major drawbacks to any interpretation of the FCA that would encourage fraud lawsuits against manufacturers whose drugs are determined by doctors to have valuable off-label uses.

The medical community's knowledge regarding the safety and efficacy of FDA-approved drugs and devices inevitably outpaces FDA-approved labeling. Physicians who regularly work with such drugs and devices learn of safe and efficacious uses for the drugs/devices that are not included within the labeling (generally referred to as "off-label" uses). In some fields such as oncology, a significant portion of all medically-accepted treatments involves off-label uses of FDA-approved drugs and medical devices. Accordingly, were doctors limited to using therapeutic products only as labeled, doctors would be providing sub-optimal care to their patients. In many cases, doctors simply could not treat their patients properly without resort to off-label uses. Indeed, the U.S. Supreme Court has officially recognized off-label treatments as an important part of medical care in this country. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350, 351 n.5 (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. . . . Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize."). FDA and Congress similarly recognize the importance

of off-label uses; for example, in 1997, Congress explicitly prohibited efforts to limit the authority of physicians to put FDA-approved products to off-label uses. *See* 21 U.S.C. § 396 (providing that nothing in the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, "shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). To ensure that doctors learn about safe and effective off-label uses, the courts, Congress, and FDA have all recognized that there are circumstances under which it is entirely appropriate for manufacturers to disseminate information about off-label uses of their medical products.

In light of that history, it is inconceivable that Congress simultaneously intended that the FCA should be interpreted in a manner that would greatly discourage off-label uses. Yet that would be the effect of Appellants' proposed interpretation. When a manufacturer discusses potential off-label uses of its product, it is always foreseeable that someone *might* be induced thereby to put the product to that use and to seek Medicaid reimbursement for the use, even when the use is not properly reimbursable. If the manufacturer could under those circumstances be held liable for "causing" a false claim to be asserted even

in the absence of evidence that it did anything to encourage the filing of nonreimbursable claims, then manufacturers would be more reluctant to say anything at all about those off-label uses. The result would be that fewer patients would have access to the latest medical advances.[5] Appellants allege that Solvay's marketing scheme encouraged doctors to prescribe Marinol for off-label uses, but they have provided absolutely no evidence that Solvay did anything to encourage others to seek Medicaid reimbursement for those off-label uses when they are not properly reimbursable by Medicaid.[6]

Permitting insubstantial FCA claims to proceed past the pleadings stage can be devastating for a pharmaceutical company, both in terms of potential

---

[5] Appellants assert, of course, that information allegedly distributed by Solvay about off-label uses of Marinol was inaccurate and that there were no medically appropriate off-label uses of the drug. But determinations of that sort are more appropriately made by FDA during the course of enforcement proceedings (or perhaps in FCA proceedings filed by the federal government) rather than by private plaintiffs during the course of FCA litigation.

[6] Appellants assert that Solvay's alleged efforts to promote off-label uses of Marinol could not possibly have succeeded unless Medicaid reimbursement were sought wherever possible for all off-label prescriptions. But that assertion is belied by the evidence submitted by Appellants: Medicaid did *not* provide reimbursement for the great majority of Marinol prescriptions, so the sales increase would have occurred even in the absence of Medicaid. Moreover, among the minority of Marinol prescriptions that were reimbursed by Medicaid, Appellants provide no information regarding how many were written for on-label uses.

reputational injury and in terms of the disruptive effect of such suits. As this Court has explained:

> "The particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim." *United States v. Lab. Corp. of Am.*, 2001 WL 1867721, at *1 (N.D Ga. May 16, 2001), *quoted in Clausen*, 290 F.3d at 1307. If given such a ticket, the next stage of [the] litigation is clear. The plaintiff will request production of every ... claim submitted by the Defendant [during the time period corresponding to Plaintiff's claim's]. At that point, the Defendant can decide to settle the case to avoid the enormous cost of such discovery and the possible disruption of its ongoing business.

Atkins, 470 F.3d at 1359.

Finally, defendants simply are in no position to respond intelligibly to sweeping and ill-defined fraud charges of the type at issue here. In the absence of more specificity, Solvay will be in no position to examine the alleged false claims and determine, for example, that: (1) it never communicated with the doctor who submitted the reimbursement claim; (2) the prescription at issue was for an on-label use, or for an off-label use deemed reimbursable under Medicaid in one or more States; (3) the pharmacist/doctor/hospital in question believed in good faith that the prescription was reimbursable by Medicaid; or (4) no claim was ever submitted to Medicaid. Providing defendants with the means to respond adequately to fraud charges is one of the reasons why Rule 9(b) imposes a heightened pleading standard in fraud cases. Particularly when, as here, the

FCA relator is alleging that the defendant engaged in widespread fraud, it should be incumbent on the relator to provide at least *some* details regarding how, when, and by whom the alleged fraud took place. As the Sixth Circuit has held, "Where a complaint alleges a complex and far-reaching fraudulent scheme, then that scheme must be pleaded with particularity and the complaint must also provide examples of specific fraudulent conduct that are representative samples of the scheme." *United States ex el. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 444-45 (6th Cir. 2008) (internal quotations omitted). Given the SAC's failure to include even "representative samples" of specific false claims, the district court properly dismissed the complaint.

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court affirm the judgment of the district court.

Respectfully submitted,

/s/ Richard A. Samp
Daniel J. Popeo
Richard A. Samp
(Counsel of Record)
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

Counsel for *amicus curiae*

March 24, 2009

Counsel wish to thank Michael Rybak, a student at American University's Washington College of Law, for his assistance in preparing this brief.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point proportionately spaced CG Times type. According to the word processing system used to prepare this brief (WordPerfect 12.0), the word count of the brief is 4,872, not including the corporate disclosure statement, table of contents, table of authorities, certificate of service, and this certificate of compliance.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 24th day of March, 2009, I deposited copies of the *amicus curiae* brief of the Washington Legal Foundation in the U.S. Mail, First-Class postage prepaid, addressed to the following:

Frederick M. Morgan, Jr.
Jennifer M. Verkamp
Morgan Verkamp LLC
700 Walnut Street
Suite 400
Cincinnati, OH 45202

Jack E. Fernandez
Zuckerman Spaeder LLP
101 East Kennedy Blvd.
Suite 1200
Tampa, FL 33602

John R. Fleder
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Washington, DC 20005

/s/ Richard A. Samp
Richard A. Samp