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Renewed Hope For Defendants in False Claims Act Cases: Six Recent Cases That Appear to Limit the Scope of the FCA

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The False Claims Act (FCA) is widely considered the most powerful tool to prevent and redress fraud against the federal government. Through aggressive and creative application, both the federal government and *qui tam* relators have achieved unprecedented success in FCA actions. In fiscal year 2012, the U.S. Department of Justice (DOJ) recovered nearly $5 billion in settlements and judgments, the largest single year recovery on record.[1] Moreover, from January 2009 through fiscal year 2012, the DOJ recovered $13.3 billion under the FCA, the largest four-year total in the DOJ's history and more than a third of total recoveries since the act was amended in 1986.[2] As FCA victories quickly amass and recoveries continue to sky-rocket, several recent holdings may prove helpful to defendants and serve to curtail this trend by placing some important limitations on FCA liability and damages.

Takeda Pharmaceuticals. On January 11, 2013, the Fourth Circuit reaffirmed the strict pleading standard for FCA complaints in *United States ex rel. Nathan v. Takeda Pharmaceuticals N.A. Inc.*[3] In *Nathan*, the relator, a pharmaceutical company employee, brought a *qui tam* action against his employer, Takeda Pharmaceuticals, alleging that Takeda's targeted marketing of the gastric drug Kapidex for off-label use violated the FCA by causing false claims to be presented to the federal government for payment under Medicare. Specifically, the relator alleged that Takeda promoted the gastric drug Kapidex to rheumatologists, who did not typically treat patients with the conditions for which the drug was approved, and that Takeda marketed higher than approved doses of Kapidex for the treatment of certain conditions. The district court dismissed the relator's claim on the grounds that the relator did not plausibly allege that false claims had been presented to the government for payment and had failed to allege that Takeda caused doctors to write off-label prescriptions for reimbursement.

On appeal, the Fourth Circuit deemed the allegations set forth in the complaint to be ''inherently speculative in nature.''[4] Notably, the relator failed to allege that the targeted rheumatologists wrote off-label Kapidex prescriptions that were actually submitted for reimbursement. Further, while the relator claimed that a group of primary care physicians wrote prescriptions for Kapidex that were presented to the government for payment, he failed to plausibly allege that the prescriptions were written for off-label use. The relator also alleged that 9,000 Kapidex prescriptions were submitted to the government for reimbursement in two sales districts, but neglected to state the dosages of these prescriptions or even whether the doctors were subjected to Takeda's sample distribution practices. Given the nature of the vague assertions made in the complaint, the Fourth Circuit noted that Federal Rule of Civil Procedure 9(b) ''does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege

[1] Department of Justice Press Release, *Justice Department Recovers Nearly $5 Billion in False Claims Act Cases in Fiscal Year 2012* (December 4, 2012), http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html.

[2] *Id.*

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[3] 707 F.3d 451 (4th Cir. 2013), *petition for cert. filed,* (May 10, 2103) (No. 12-1349, 12A938).

[4] 707 F.3d at 461.

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simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.''[5] Rather, the relator must allege some facts with ''some indicia of reliability . . . to support the allegation that an actual false claim was presented to the government.''[6] Since the relator's allegations fell short of the Rule 9(b) pleading standards, the Fourth Circuit reaffirmed the district court's dismissal of the case.

Abbott Laboratories. In a February 25, 2013 opinion, a federal district court in Massachusetts dismissed a complaint against twenty-four drug manufacturers, distributors, and labelers, holding that the court lacked subject matter jurisdiction because the allegations were based on publicly disclosed facts. In *United States ex rel. Conrad v. Abbott Laboratories, Inc.*,[7] the relator filed a *qui tam* suit, alleging that defendants made fraudulent misrepresentations to the Centers for Medicare and Medicaid Services (CMS) by wrongfully listing their products as ''covered outpatient drugs'' eligible for Medicaid reimbursement. Accordingly, there were two classes of relevant drugs that were eligible for reimbursement: (1) drugs introduced after 1962 that were approved by the Food and Drug Administration (FDA) as safe and effective, and (2) drugs introduced prior to 1962 that received a specific numerical code based on a separate FDA review process.[8] The relator alleged that defendants listed unapproved drugs as FDA-approved covered drugs, listed drugs with false codes that indicated they were covered, and listed non-drug products as covered outpatient drugs.

Defendants challenged the district court's subject matter jurisdiction under the FCA's public disclosure bar, arguing that both the alleged misrepresented facts and true facts were available in a combination of five publicly disclosed sources. Specifically, defendants argued there were two CMS data publications – the drug product data files and the state utilization data files – that both set forth the alleged misrepresented facts. The drug product data files listed the drugs defendants allegedly misrepresented as covered outpatient drugs and the drugs defendants falsely coded; the state utilization files, on the other hand, showed how state Medicaid programs were reimbursed based on defendants' misrepresentations. Next, defendants pointed to three FDA publications that revealed that defendants' drugs were not actually approved and/or were inappropriately coded. First, the FDA *Orange Book* listed all the FDA-approved drugs (making defendants' unapproved drugs obvious by their absence); second, the Federal Register notices listed the proper coding for all of defendants' drugs, and the third publication also contained other relevant drug coding information.

Notwithstanding the ''substantial expertise'' required to uncover the alleged discrepancy using the five sources, the district court held that the suit was based clearly on information in the public domain.[9] After considering the Supreme Court's reasoning in *Schindler Elevator Corp. v. United Statesex rel. Kirk*,[10] the district court also concluded that the CMS data files at issue, which contained ''thousands of lines of unadorned data, organized into columns and sorted,'' qualified as an administrative report that was publicly disclosed under the FCA because each data file was ''obviously 'something that gives information,' a 'notification,' and an 'official or formal statement of facts' '' about the drugs at issue.[11] Likewise, the district court rejected the relators ''clever, but not persuasive'' argument that an omission was not a disclosure, and that the public disclosure bar would only apply if the FDA publication listing approved drugs also included a list of defendants unapproved drugs.[12] Applying the ''most natural meaning of the term 'disclosure,' '' the court found that it included ''disclosures by omission.''[13] Finally, while reflecting on the legislative intent behind the FCA, the court explained, ''Here, as in *Schindler Elevator*, anyone with time and the relevant expertise could have combed through the public sources identified above, discovered drug manufacturers who were out of compliance, and then filed the same suit. If *Schindler Elevator* was 'the opportunistic litigation that the public disclosure bar is designed to discourage,' then so, too, is this suit.''[14]

Anchor Mortgage. On March 21, 2013, the Seventh Circuit firmly rejected the government's ''gross trebling'' approach to FCA damages and instead adopted a ''net trebling'' method, which dramatically reduced the damages awarded in a FCA mortgage fraud case. In *United States v. Anchor Mortgage Corp.*,[15] the district court found that defendants had fraudulently applied for federal guarantees of 11 defaulted home mortgage loans and awarded nearly $2.7 million in treble damages stemming from the government's payments to lenders under the guarantees. When calculating damages pursuant to the FCA, the district court utilized the ''gross trebling'' approach, adding the amount the government had paid to lenders, trebling this total, then subtracting any amounts the government had earned from selling the properties that secured the loans. Thus, if the government paid $131,643.05 to guarantee a loan, this amount was trebled to $394,929.15 and the $68,200 sale price of the property was then subtracted, for a total for $326,729.15. This calculation was then repeated for the other parcels of land.

On appeal, Chief Judge Frank Easterbrook considered which theory of damages was appropriate, querying, ''but treble what?''[16] Ultimately, the Seventh Circuit held that the district court erred in its use of ''gross trebling,'' finding that ''net trebling'' was the ''preferred approach'' to calculating damages.[17] Thus, if the loan guarantee was $131,643.05, then the $68,200 sale price was immediately subtracted, for a total net loss of $63,443.05. After trebling the net loss, the new damage award totaled $190,329.15, approximately 40% less

[5] 707 F.3d at 456-457.
[6] 707 F.3d at 457.
[7] No. 1:02-cv-11738-RWZ, 2013 BL 50879 (D. Mass. Feb. 25, 2013).
[8] 2013 BL 50879 at *1-2.
[9] 2013 BL 50879 at *4.
[10] 131 S. Ct. 1885 (2011).
[11] 2013 BL 50879 at *5 (quoting *Schindler*, 131 S. Ct. at 1891).
[12] 2013 BL 50879 at *5-6.
[13] 2013 BL 50879 at *6.
[14] 2013 BL 50879 at *7 (quoting *Schindler*, 131 S. Ct. at 1894) (internal quotations omitted).
[15] 711 F.3d 745 (7th Cir. 2013).
[16] 711 F.3d at 748.
[17] 711 F.3d at 749.

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than the district court's original calculation.[18] The Seventh Circuit also examined other appellate decisions, noting that ''the norm is net trebling'' in civil litigations and concluded that the government's ''loss is the amount paid on the guaranty less the value of the collateral, whether or not the agency has chosen to retain the collateral. The damages should not be manipulated through the agency's choice about when (or if) to sell the property it receives in exchange for its payments.''[19]

MedQuest Associates. In an April 1, 2013 decision, the Sixth Circuit limited the application of the ''false certification'' theory, which allows for FCA liability ''when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.''[20] In *United States ex rel. Hobbs v. MedQuest Associates, Inc.*, the government intervened after a relator brought a *qui tam* action against her employer, a diagnostic testing company, alleging that MedQuest and three of its subsidiaries failed to comply with certain Medicare regulations, resulting in MedQuest filing false claims for reimbursement. On summary judgment, the district court awarded the government over $11 million dollars and concluded that MedQuest violated the FCA by (1) certifying in its enrollment application that it would abide by Medicare rules and regulations, then allowing unapproved physicians to supervise certain diagnostic tests in violation of the rules, and (2) failing to reregister a newly acquired facility to reflect this change in ownership, instead submitting claims for payment using the former owner's Medicare billing code.

On appeal, MedQuest argued that the alleged violations breached the conditions of participation in the Medicare program, not the conditions of payment for tests and services. The Sixth Circuit concurred, finding that the false certification theory was applicable only where the underlying regulation was a condition of payment, ''meaning that the government would not have paid the claim had it known [MedQuest] was not in compliance.''[21] Since the government failed to show that MedQuest intended to violate Medicare regulations at the time of its enrollment application and the certification did not contain language conditioning payment on compliance with the supervising-physician requirement, the government's allegations failed on the express certification theory. The Sixth Circuit also rejected the government's argument that MedQuest implicitly certified the supervising-physician requirements as a condition of payment, finding this claim was ''only possible by weaving together isolated phrases from several sections in the complex scheme of Medicare regulations.. . . it is not reasonable to expect Medicare providers to attempt such an approach to statutory interpretation in their efforts to comply with the FCA.''[22] Further, in the absence of regulations conditioning payment on an accurate enrollment form reflecting current ownership, and without any legal support demonstrating that the new facility owners were not legally entitled to use the old billing code, the Sixth Circuit held that MedQuest was not liable under the FCA.

Finally, the Sixth Circuit expressed concern about the expansive application of the FCA, noting, ''Recently, this court reaffirmed its view that '[t]he False Claims Act is not a vehicle to police technical compliance with complex federal regulations'. . . . where, as in this case, the violations would not 'natural[ly] tend[ ] to influence' CMS's decision to pay on the claims,. . . . the 'blunt[ness]' of the FCA's hefty fines and penalties makes them an inappropriate tool for ensuring compliance with technical and local program requirements like the special supervision requirements at issue in this case.''[23]

Evonik Degussa. On April 4, 2013, a federal district court in the Eastern District of Louisiana struck down a ''rather novel legal theory'' brought under the FCA and cautioned against using the FCA as a general means to redress regulatory non-compliance.[24] In *Ricalde v. Evonik Degussa Corp.*, the relator, a former laboratory technician, brought a *qui tam* action against Evonik, a company that produced a super-absorbent material for its corporate customers who then incorporated this material into products such as diapers, tampons, adult incontinence products and food packages, which were then sold to the public. The relator alleged that he learned about various quality control, testing, recordkeeping, reporting, product storage, and labeling deficiencies during the course of his employment. Because the end-products were defective when sold, FCA liability was purportedly triggered when the government directly purchased those products or reimbursed Medicare and Medicaid recipients who purchased the products for personal use. Accordingly, the alleged ''false claims'' in this case were the misrepresentations that Evonik either explicitly or implicitly made to its customers when it sold them the allegedly defective material. In response, Evonik argued there were no allegations in the complaint to suggest that it ever presented a claim – let alone a false claim – to the government for payment, a key requirement of the FCA.

After noting that the Rule 9(b) heightened pleading standard applies to complaints brought under the FCA, the district court held that it was ''beyond dispute that the complaint does not allege any detail whatsoever as to any *specific* claim that was presented to the government for payment.''[25] While this lack of detail might not be fatal in cases where the court could inescapably conclude that the plaintiff has alleged a scheme showing false claims were presented to the government, the district court found the relator's complaint devoid of any such allegations. Notably, the court found no allegation that Evonik made misrepresentations to the government in order to get the government to purchase its products, or that Evonik ever made misrepresentations to its customers so they submitted false claims to the government. Further, there were no allegations that the government actually contracted with any of Evonik's customers specifically to manufacture products for government use. Even had Evonik's customers directly contracted with the government, the district court noted

[18] *Id.*

[19] 711 F.3d at 749-51.

[20] *United States ex rel. Hobbs v. MedQuest Associates, Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (citing United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 305 (3d Cir.2011)).

[21] 711 F.3d at 714.

[22] 711 F.3d at 715.

[23] 711 F.3d at 717 (citations omitted).

[24] *Ricalde v. Evonik Degussa Corp.*, CIV A. No. 11-1400, slip. op. at 20 (E.D. La. Mar. 26, 2013).

[25] CIV A. No. 11-1400, slip op. at 12.

the FCA would not be implicated under a false certification theory ''unless payment under the contracts was conditioned upon compliance with the standards that Evonik allegedly violated.''[26] The district court went on to say that the FCA was ''not a vehicle used by the government to redress breaches of contract or general allegations of fraud or to punish a manufacturer's decision to ignore governmental safety regulations.''[27] Instead, ''[t]he focus of the act is the presentation to the government of a false claim for payment'' and the allegations were simply ''far too attenuated to imply'' that a false claim was ever presented.''[28]

Johnson & Johnson. In a June 12, 2013 decision, the First Circuit declined to reinstate a relator's kickback claims against Ortho Biotech Products (OBP), a subsidiary of Johnson & Johnson. In *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*,[29] the relator, a former employee responsible for marketing the anemia drug Procrit in the western United States, alleged that OBP offered kickbacks to healthcare providers across the nation from approximately 1992 to 2003 in violation of the FCA. The alleged kickbacks, which included free Procrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria, caused providers and hospitals to submit false claims for payment to Medicare for Procrit. In 2007, the district court dismissed the relator's complaint with prejudice, but the First Circuit reversed in part, finding that the complaint was pled with sufficient particularity as to the alleged false claims submitted by eight healthcare providers from 1992 to 1998.

On remand, the district court significantly restrained the scope of discovery, limiting the claims temporally to an eight month period between November 1997 and July 1998, in part because the claims accruing prior to November 1997 were time-barred by the FCA's six-year statute of limitations. Further, the district court found that the relator was only the ''original source''[30] for claims arising during his employment at OBP and that the court lacked subject matter jurisdiction over any claims arising after his termination in July of 1998. Since the relator only possessed ''direct and independent knowledge'' of OBP's activities in the western United States, the district court also limited discovery to that region.[31] After discovery was completed pursuant to the ruling, the parties stipulated that there was no evidence to support the alleged kickback scheme, which ultimately resulted in the claims being dismissed on summary judgment.

On appeal, the relator argued that the district court misinterpreted the ''original source'' rule when concluding it lacked subject matter jurisdiction and claimed that the district court's discovery limitations directly contradicted the First Circuit's prior decision to remand the 1992 to 1998 kickback claims. The First Circuit declined to reach the merits of the original source claim, instead holding that the district court imposed ''reasonable limitations on the scope of discovery'' that were ''entirely consistent'' with its previous ruling.[32] Accordingly, the district court was ''not required to expand the scope of discovery'' based on the amended complaint's ''bald assertions'' that the kickback scheme was nationwide in scope.[33] As such, the district court acted within its discretion to prevent the relator from undertaking a ''fishing expedition,'' especially given that any inferential support for the amended complaint's nationwide allegations ''evaporated'' when the relator failed ''to uncover any admissible evidence to support even [the] more modest regional kickback claim.''[34]

As the six cases above demonstrate, some courts are clearly resisting more aggressive and attenuated applications of the FCA. From courts' mounting opposition to using the FCA as a general device to remedy regulatory non-compliance to requiring false claims to be pled with particularity to limiting the scope of discovery, these recent decisions provide a thoughtful framework and some valuable tools for defendants facing FCA lawsuits.

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[26] CIV A. No. 11-1400, slip op. at 14 n.5.

[27] CIV A. No. 11-1400, slip op. at 15.

[28] *Id*.

[29] No. 12-2141, 2013 BL 155930 (1st Cir. June 12, 2013).

[30] Pursuant to 31 U.S.C. § 3730(e)(4)(A), courts do not have jurisdiction over FCA suits that are based on certain types of publicly disclosed information unless the relator was the ''original source'' of the information. An ''original source'' must have ''direct and independent'' knowledge of the information supporting his claims, which was ''provided. . .to the Government before filing an action.'' 2013 BL 155930 at *2.

[31] 2013 BL 155930 at *4.

[32] 2013 BL 155930 at *7.

[33] *Id*.

[34] 2013 BL 155930 at *7-8 (internal quotation omitted).

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