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FCA Watch

FCA Watch – August 2014

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General Developments

Cellco: First-to-File Bar

In *United States ex rel. Shea v. Cellco Partnership*, No. 12-7133, 2014 WL 1394687 (D.C. Cir. Apr. 11, 2014), the D.C. Circuit Court of Appeals dismissed a *qui tam* action under the first-to-file bar of the federal False Claims Act (FCA) and held that a relator in a previously dismissed *qui tam* suit cannot bring a new complaint. The first-to-file bar prohibits any person other than the federal government from bringing suit if a related action is "pending." In contrast, the Fourth, Seventh, and Tenth Circuits have held that the rule bars new suits only if the related action is ongoing. On July 1, 2014, the Supreme Court granted certiorari in a Fourth Circuit case to resolve the split on the first-to-file rule and provide clarity regarding the application of the Wartime Suspension of Limitations Act (WSLA), which is discussed further below. *See United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171 (4th Cir. 2013), *cert. granted*, 2014 WL 2931840 (U.S. July 1, 2014) (No. 12-1497).

Halliburton: Attorney-Client Privilege in FCA Investigations

A decision that made waves in the government contractor community was recently overturned by the D.C. Circuit Court of Appeals in *In re Kellogg Brown & Root, Inc.*, No. 14-5055, 2014 WL 2895939 (D.C. Cir. June 27, 2014). The trial court held that documents related to an internal investigation at Kellogg Brown & Root (KBR) are not protected from discovery by the attorney-client privilege and the work-product doctrine because KBR conducted the investigation for the purpose of complying with corporate policy and the Federal Acquisition Regulation's mandatory disclosure rule, not for the purpose of seeking legal advice or in anticipation of litigation. *United States ex rel. Barko v. Halliburton Co.*, No. 1:05-CV-1276, 2014 WL 1016784 (D.D.C. Mar. 6, 2014). The D.C. Circuit Court of Appeals vacated the production order, holding that the privilege applies if "obtaining or providing legal advice was one of the significant purposes of the internal investigation."

Kmart: Waiver of Work-Product Protection in OIG Investigations

In *United States ex rel. Garbe v. Kmart Corp.*, No. 3:12-cv-00881, 2014 U.S. Dist. LEXIS 73261 (S.D. Ill. May 29, 2014), the court held that Kmart's disclosure of documents to the Department of Health and Human Services' Office of Inspector General (HHS OIG) in response to a subpoena resulted in a waiver of attorney work-product protection. The information at issue was a subset of Medicare transactional data that was put into an "easier-to-understand format" by counsel. Although Kmart argued that the court should apply the selective waiver doctrine, the court held that Kmart could not "cherry-pick" the parties to which it chose to disclose information and that waiver as to one party constituted waiver as to all.

Gosselin: Actual Harm Requirement

In *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390 (4th Cir. 2013), *petition for cert. filed*, 82 U.S.L.W. 3700 (U.S. May 15, 2014) (No. 13-1399), Belgian shipping company Gosselin Group NV has asked the U.S. Supreme Court to decide whether the FCA requires the "mechanical imposition of a separate civil penalty" for every single invoice submitted under a fraudulent contract, absent evidence of actual economic harm to the government. At stake are more than 9,000 invoices that Gosselin presented to the Department of Defense for payment under a Direct Procurement Method contract, which the relator alleges Gosselin obtained through a false certification. The district court held that the relator presented insufficient evidence of monetary harm and the imposition of more than $24 million in fines would violate the Eighth Amendment's prohibition of excessive fines. The Fourth Circuit Court of Appeals reversed, explaining that the FCA protects the government against both economic and noneconomic harm in order to deter fraudulent conduct.

Wartime Suspension of Limitations Act

On July 1, 2014, the Supreme Court granted certiorari in the aforementioned *Carter* case, a *qui tam* action alleging fraudulent billing. The district court dismissed the action under the first-to-file bar and further held that the six-year statute of limitations under the FCA prevented the suit from going forward. As the alleged violations occurred before May 2005, plaintiffs had until May 2011 to file a timely suit. The Fourth Circuit Court of Appeals reversed, holding that the WSLA tolled the six-year statute of limitations for FCA suits, given that the United States was "at war" since 2002, the date that Congress authorized the use of military force in Iraq.

By contrast, the District Court for the District of Columbia held in the FCA case against Lance Armstrong, *United States ex rel. Landis v. Tailwind Sports Corp.*, No. 10-cv-00976, 2014 WL 2772907, at *20 (D.D.C. June 19, 2014), that the WSLA tolls statutes of limitations only for claims where fraud is an "essential ingredient." As FCA claims do not require specific intent to defraud the government, the court held that the WSLA could not suspend the FCA's statute of limitations in all cases.

Department of Justice's Push for More Compliance Remedies During Settlement

At the American Bar Association's Tenth National Institute on the Civil False Claims Act and *Qui Tam* Enforcement, Assistant Attorney General Stuart Delery emphasized the importance of using nonmonetary remediation efforts – *i.e.*, corporate integrity agreements – to resolve FCA suits. Delery noted that, by requiring companies to adopt effective compliance programs and promote ethical behavior, the Department of Justice (DOJ) hoped to deter repeat offenders.

Healthcare

New Secretary of Health and Human Services

Sylvia Burwell has been confirmed and will succeed Kathleen Sebelius as Secretary of Health and Human Services. Previously, Burwell was the Director of the Office of Management and Budget. During her confirmation hearing before the Senate Committee, she promised to use "the full extent of the law" to recoup any federal funds that have been misspent on the state health insurance exchanges mandated by the Affordable Care Act.

Health and Human Services' Proposed Rules

In May, the HHS OIG issued two proposed anti-fraud rules. The first proposed rule would expand the HHS OIG's authority to exclude persons from federal funded healthcare programs based on: (1) convictions of an offense in connection with obstruction of an audit; (2) failure to supply payment information by any individual that "orders, refers for furnishing, or certifies the need for" items or services provided through Medicare or state health programs; and (3) making (or causing to be made) a false statement, omission, or misrepresentation of a material fact in applications to participate as a service provider or supplier under a federal health care program. The second proposed rule would empower HHS OIG to impose civil monetary penalties for: (1) failure to grant HHS OIG timely access to records; (2) ordering or prescribing while excluded; (3) making false statements, omissions, or misrepresentations in an enrollment application; (4) failure to report and return an overpayment; and (5) making or using a false record or statement that is material to a false or fraudulent claim.

Release of Medicare Billing Records

On April 9, 2014, Medicare released detailed data of payments to participating doctors across the country. The data specify physicians' names, specialties, locations, and procedure-related information, such as the number of patients treated, frequency, average amount billed, and average reimbursement. The unprecedented release may cause an increase in FCA litigation. The American Medical Association has expressed concerns that the data could be misinterpreted and expose ethical doctors to unwarranted attacks.

On a related note, in *Assocs. Against Outlier Fraud v. Huron Consulting Grp., Inc.*, No. 13-1237 (L), 2014 WL 2118992, at *1 (2d Cir. May 22, 2014), the Second Circuit Court of Appeals recently affirmed the dismissal of a *qui tam* action against the Huron Consulting Group Inc. alleging fraudulent billing practices. The relator contended that Huron had submitted Medicare claims for "outlier patients" – patients whose level of care is very expensive compared to the average – although it was not entitled to reimbursement, but the court noted that the relator failed to identify any statute or regulation that prohibited the submission of the claims.

Health and Human Services Report on Questionable Medicare Lab Billing

On July 9, HHS OIG released a report on questionable Medicare billing by clinical laboratories. Using about a dozen indicators (such as average number of claims per ordering physician and percentage of duplicate lab tests) and associated thresholds, the government identified over a thousand labs that showed patterns of high and potentially fraudulent billing. The study found that in 2010 Medicare allowed $1.7 billion in claims linked to such practices. The HHS OIG recommended stronger oversight and review of laboratories involved, as well as steps to improve the detection of questionable billing patterns. As with the release of Medicare billing records, the HHS report may potentially spur relators to bring FCA actions.

Off-Label Promotion of Prescription Drugs

Given the uncertainty surrounding off-label promotion of prescription drugs, the Food and Drug Administration (FDA) announced on June 6, 2014 that it would undertake a comprehensive review and issue guidance concerning (1) manufacturer responses to unsolicited requests; (2) scientific exchange; (3) interactions with formulary committees, payors, and similar entities; and (4) dissemination of third-party clinical practice guidelines.

New cases concerning off-label use include *United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2014 WL 2112357, at *2-3 (D.N.J. May 20, 2014), in which the District Court for the District of New Jersey dismissed in part an FCA *qui tam* complaint alleging that Bayer promoted off-label uses of Trasylol, a drug approved to prevent excess bleeding during heart surgery. The court held that compliance with FDA regulations was not a "condition of payment" under the federal health care statutes and, rather, the drugs were covered by federal health care programs for uses that were reasonable and necessary. Since the relator had failed to plausibly allege that the drug's

off-label uses were unreasonable or unnecessary, the court dismissed the allegations concerning off-label use. Allegations concerning alleged kickbacks survived the motion to dismiss.

Cases Involving Alleged Kickbacks

The government continues to actively pursue FCA cases alleging violations of the Anti-Kickback Statute – as evidenced by recent cases against medical device and diagnostic companies, and healthcare providers. In *United States ex rel. Judd v. Quest Diagnostics Inc.*, No. 2:10-cv-04914 (D.N.J. May 30, 2014), the court declined to dismiss a *qui tam* action brought by a physician against Quest Diagnostics. Kickback allegations included the provision of free medical supplies, discounted testing fees, and free access to Quest's patient database. The court held that the relator was the "original source" of the information and the complaint satisfied Federal Rule of Civil Procedure 9(b).

In addition, the government has recently settled FCA kickback allegations against several companies, including Medtronic for $9.9 million and King's Daughters Medical Center for $40.9 million and an agreement to enter a corporate integrity agreement.

Omnicare: cGMP Violations Alone Are Not Sufficient to Allege a Violation of the FCA

Earlier this year, the Fourth Circuit Court of Appeals held in *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694 (4th Cir. 2014) that a defendant's failure to comply with a particular statute or regulation – in this case, Current Good Manufacturing Practice (cGMP) regulations – is actionable under the FCA only if compliance is a condition of payment by the government. In May, the relator petitioned for certiorari, urging the Court to resolve a circuit split on whether a lack of compliance with cGMPs alone is sufficient to allege an FCA violation.

Customs Duties

Cases Involving Alleged Unpaid Customs Duties

Customs duties have also been an area of focus for FCA relators. For example, OtterBox, a company that manufactures waterproof cases for electronic devices, has agreed to pay $4.3 million to settle an FCA action filed by a former employee alleging that the company knowingly underpaid customs duties to the government. In May, the federal government announced that it reached a $10 million settlement with Dana Kay Inc. and Siouni & Zar Corp., two New-York based importers of women's clothes, concerning the alleged underpayment of customs duties. In *United States ex rel. Valenti v. Wingfield*, No. 3:11-cv-368 (M.D. Fla. May 16, 2014), the court refused to dismiss FCA claims against C.R. Lawrence Co., Inc. and Southeastern Aluminum Products, Inc., two shower enclosure manufacturers, alleging that they understated the value of their imported products and made false statements to U.S. customs authorities in order to circumvent antidumping and countervailing duties on aluminum extrusion imports.

Banking/Financial Services

Cases Involving Noncompliant Mortgages

In June, SunTrust reached a $968 million settlement with the DOJ and state attorneys general, admitting to abuses in its mortgage origination, servicing, and foreclosure practices. Part of the settlement ($418 million) resolved potential liability under the FCA for the bank's false certification that the mortgages it originated and underwrote from January 2006 to March 2012 met Federal Housing Administration (FHA) requirements. The bank allegedly failed to implement a functioning quality control program to single out bad loans and failed to report compliance problems to the government. The remainder of the settlement has been allocated to provide relief to borrowers for SunTrust's allegedly deficient loan servicing practices.

In late June, U.S. Bank settled allegations by the DOJ that it falsely certified compliance with FHA requirements in violation of the FCA in the course of originating and underwriting mortgages from January 2006 to December 2011. As part of the $200 million settlement, the bank admitted that it failed to verify the mortgages' eligibility for FHA insurance, that its quality control program was defective, and that it failed to report bad loans to the government.

Insurance

Court Denies Motion to Reduce Treble Damages in FCA Suit

As part of a longstanding FCA suit brought against State Farm Fire & Casualty Co., a federal district court in Mississippi denied State Farm's request to reduce a treble damages award. The *qui tam* complaint was first brought in 2006 and alleged that the insurer knowingly submitted a false flood claim in the aftermath of Hurricane Katrina. According to the relators, State Farm knew that the damages were less than the claimed $250,000. After trial, a jury awarded treble damages of $750,000. The district rejected State Farm's argument that the amount should be offset by the relators' settlement with co-defendants, as State Farm failed to show that the "damages assessed against it have in fact and in actuality been previously covered by relators or the U.S."

Suit Dismissed Against AIG

Relators failed for the second time to survive dismissal in an FCA action brought against AIG and other financial institutions in federal district court in California. The suit alleged that the defendants defrauded taxpayers by obtaining more than $137 billion in government bailouts related to failed collateralized debt obligations. After the first dismissal, the court had given the relators an opportunity to amend their complaint to address relators' failure to allege that they were the original source of the information or that the defendants actually submitted false claims or made false statements. The court ultimately held that the amended complaint was similarly deficient, and dismissed the complaint for failure to satisfy Federal Rule of Civil Procedure 9(b) and the public disclosure bar.

For-Profit Education

Case Against Education Management Corporation Moves Forward

In mid-June, Education Management Corporation (EDMC) failed to remove relators as parties to an FCA suit alleging that it paid commissions to admissions representatives in violation of the Higher Education Act's Incentive Compensation Ban. According to EDMC, the relators' theory that the compensation plan "as implemented" violated the FCA was based on media articles about other for-profit corporations, such as the University of Phoenix, and was thus subject to the public disclosure bar. EDMC also contended that relators concocted the theory too late in the course of the litigation, about four years after the initial complaint. The court rejected these arguments, finding that the relators were the original source of the information concerning EMDC, and that the relators' theory comported with their original complaint.

Court Denies Motion for Summary Judgment in Florida College FCA Dispute

A federal court in Florida recently denied motions for summary judgment by both parties in an FCA suit against Keiser University. The complaint, brought by former admissions department employees, alleged that the school provided admissions officers with gifts and prizes worth more than $1 billion as incentives to enroll as many students as possible. The court found genuine issues of material fact about whether Keiser used state and federal funds to pay admissions officers based on their enrollment numbers and lied about doing so to the government.

FCA Watch is published by the Litigation Department of Weil, Gotshal, & Manges LLP, 767 Fifth Avenue, New York, NY 10153, +1 212 310 8000, www.weil.com.

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