

DOJ Targets Individuals for Violations of False Claims Act and Anti-Kickback Statute

Bostwick and Warner Chilcott Cases Demonstrate Impact of Yates Memo on Health Care Industry



Kiran Patel is a litigation associate in Dentons' New York office. His practice includes a focus on white collar and government investigation matters, often involving the False Claims Act and Anti-Kickback Statute.

Less than one year after Deputy Attorney General Sally Yates' memorandum on "Individual Accountability for Corporate Wrongdoing" ("Yates Memo"), the impact of the U.S. Department of Justice's (DOJ's) heightened focus on individuals is already being felt in the health care industry. This article explores that issue through two examples: (1) the October 2015 indictment of Carl Reichel, former President of Warner Chilcott; and (2) the January 2016 settlement between DOJ and David Bostwick. As law enforcement continues to target health care providers and suppliers, attorneys representing organizations and individuals in the health care industry are advised to take note of this development.



Jeremy D. Sherer is a health care associate in Dentons' Washington, D.C. office. His practice focuses on regulatory matters involving Medicare reimbursement, health care fraud and abuse, and related compliance issues.

YATES MEMO

The Yates Memo was issued September 9, 2015, and calls for a renewed government focus on combating corporate misconduct by "seeking accountability from the individuals who perpetrated the wrongdoing."¹ The Yates Memo signals that in addition to prosecuting **companies** believed to be responsible for fraud or other misconduct, DOJ will now more vigorously pursue the officers, employees, and other **individuals** whose leadership and decisions resulted in such wrongdoing.

The Yates Memo sets forth a number of tactics for achieving this goal, including:

1. a focus on individual targets from the inception of an investigation;
2. regular communication between civil and criminal DOJ attorneys examining the same facts; and
3. a requirement that in order to qualify for cooperation credit, corporations must provide DOJ all relevant facts relating to the individuals responsible for misconduct.

FEDERAL CIVIL FALSE CLAIMS ACT AND ANTI-KICKBACK STATUTE

The federal civil False Claims Act (FCA), a relic of the Civil War, has become an increasingly effective tool to fight various types of fraud, including health care fraud.² FCA liability attaches when a person, for example: (1) “[k]nowingly presents, or causes to be presented, to an officer or employee of the United States Government...a false or fraudulent claim for payment or approval,” (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,” or (3) “conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.”³

A key component of the FCA is its so-called *qui tam* provision, a mechanism that allows private citizens to file a complaint on behalf of the government alleging a violation of the FCA.⁴ These individuals, often referred to as “whistleblowers,” are compensated handsomely if their case settles or judgment is awarded in their favor. In such cases, the whistleblower is entitled to up to 30 percent of the recovery.⁵ Because of this “bounty,” many FCA enforcement actions in the health care sector begin with a *qui tam* lawsuit.

The federal health care program anti-kickback statute, 42 U.S.C. § 1320a-7b (AKS), is a criminal law that generally prohibits paying for, or accepting payment for, the referral of patients covered by Medicare, Medicaid, or other federal health care programs. It was enacted in 1972 to protect federal health care programs from fraud, waste and abuse.⁶

INDICTMENT OF WARNER CHILCOTT’S FORMER PRESIDENT

On October 29, 2015, DOJ announced that Warner Chilcott U.S. Sales, LLC, a subsidiary of pharmaceutical manufacturer Warner Chilcott PLC, had agreed to pay \$125 million and plead guilty to a felony charge of health care fraud. On the same day, federal agents in Boston arrested Carl Reichel, the former president of

the company’s pharmaceutical division. Reichel was charged with one count of conspiracy to violate the AKS.

The indictment alleges that between 2009 and 2011 Reichel “established a sales strategy of providing remuneration to [health care professionals (HCPs)], in the form of free dinners, ‘speaker’ payments, and food and drink for HCPs and their staff to induce HCPs to prescribe Warner Chilcott drugs.”⁷ According to the allegations, “Reichel instructed the sales force to sign up high prescribing physicians as paid ‘speakers’ for Warner Chilcott.”⁸ The speakers were allegedly paid \$600-\$1,200 for attending dinners, but “unlike speaker events at other pharmaceutical companies, Reichel communicated that the...events should be roundtables: informal dinners without a clinical lecture.”⁹

The indictment further alleges that “Reichel instructed the sales representatives that if an HCP did not prescribe Warner Chilcott drugs at a sufficient level after attending free dinners, the sales representative should communicate to the HCP, explicitly or implicitly, that the free dinners would cease if the physician did not increase his or her prescribing habits.”¹⁰ One alleged tactic for delivering this message was to tell current or potential speakers who were not prescribing at a sufficient level that they could not be used until they gained more “clinical experience” with Warner Chilcott drugs.¹¹ Reichel also allegedly implemented hiring practices that sought to identify inexperienced but aggressive sales representatives who were not cautious about rules, whom Reichel “approvingly referred to...as ‘Type A crazy.’”¹²

The indictment of a senior executive such as Reichel makes good on the promise in the Yates Memo that DOJ “will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation.”¹³ As further evidence of this mandate at work, DOJ also previously charged three lower-level employees,

as well as one of the physicians alleged to have received meals and speaker fees in exchange for prescribing Warner Chilcott's osteoporosis drugs.¹⁴ Ultimately, however, the government's charging decisions do not necessarily mean that its case will lead to a conviction. The Reichel case proceeded to trial, and the jury disagreed with the government's assessment—Reichel was acquitted on June 17, 2016.

BOSTWICK SETTLEMENT

On January 8, 2016, Dr. David Bostwick agreed to pay the United States between \$2.6 and \$3.75 million over the next five years to settle alleged violations of the FCA, the AKS, and the federal physician self-referral law. Bostwick was the founder, owner, and chief executive officer of Bostwick Laboratories (Bostwick Lab), a pathology laboratory headquartered in Virginia.

The *qui tam* lawsuit against Bostwick Lab and Dr. Bostwick was filed by Michael Daugherty, the president of LabMD, one of Bostwick Lab's competitors.¹⁵ Daugherty alleged that Bostwick Lab, under the direction of Dr. Bostwick, was submitting false claims to Medicare for reimbursement. The allegations include that Bostwick Lab submitted claims for payment for services that were not ordered by a physician and that Bostwick Lab improperly incentivized physicians to provide it with business. If proven, such allegations could support liability under the FCA and AKS, respectively.

The specific service at issue is called the Fluorescence In Situ Hybridization test (the "FISH test"), a test for bladder cancer that the American Urological Association does not include as part of its "Best Practices Policy Recommendations" for the diagnosis of bladder cancer, on the ground that "insufficient data are available to recommend use in the evaluation of patients with microscopic [blood in the urine]."¹⁶ Daugherty alleged that Bostwick Lab, under Dr. Bostwick's direction, "reflexively"

conducted the FISH test, often without the ordering physician's consent, and then submitted the resulting claims to federally funded programs for reimbursement.¹⁷

Although the investigation in *Bostwick* began before the Yates Memo was published, the dual focus on Bostwick Lab as an entity and Dr. David Bostwick as an individual is a good example of the second step that the Yates Memo prescribes: "Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation."¹⁸

CONCLUSION

While the Yates Memo indicates a heightened focus on individual prosecutions, its goals are not entirely new. To be sure, DOJ did pursue individuals for violations of the FCA and AKS prior to the Yates Memo. Nonetheless, the issuance of such a clear directive on the topic from a senior DOJ official will surely influence prosecutors' approach to cases involving alleged corporate wrongdoing. As DOJ attorneys consider their strategy and priorities in investigations and prosecutions, we can expect them to give renewed attention to the issue of holding individuals accountable.

The impact of this development will be felt in the health care industry, as the cases involving Carl Reichel and Dr. David Bostwick demonstrate. Going forward, those in the health care industry should be alert to the increased focus on individuals and should consider related issues such as whether separate counsel should be retained for an individual employee when a company is defending a legal action or undertaking an internal investigation.

Endnotes:

1. Memorandum from Deputy Attorney General Sally Quillian Yates to Department of Justice Staff Regarding Individual Accountability for Corporate Wrongdoing, September 9, 2015. Available at www.justice.gov/dag/file/769036/download.

2. See *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 782 (2000).
3. 31 U.S.C. § 3729(a).
4. 31 U.S.C. § 3730(b).
5. Tax Relief and Health Care Act of 2006, P.L. 109-432 (120 Stat. 2922) (Dec. 20, 2006).
6. Office of Public Affairs, Office of Inspector General of the Department of Health & Human Services, Fact Sheet November 1999, available at oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.
7. *United States of America v. W. Carl Reichel*, No. 15-cr-10324 (D. Mass.), D.E. 1, ¶ 11-a.
8. *Id.* at ¶ 11-i.
9. *Id.*
10. *Id.* at ¶ 11-h.
11. *Id.* at ¶ 11-m.
12. *Id.* at ¶ 11-q.
13. Yates Memo at 2.
14. DOJ Press Release, October 29, 2015, available at www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.
15. *U.S. ex rel. Daugherty v. Bostwick Laboratories*, 2012 WL 6593804 (Dec. 18, 2012).
16. *Id.*
17. *Id.*
18. See Yates Memo.

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