Qui Tam Defense

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Mintz Levin Health Care ***Qui Tam*** Update
Recent Developments and Unsealed Cases

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Trends and Analysis

- We have identified 24 health care-related *qui tam* cases unsealed since last month's *Qui Tam Update*. Of those, only 2 were filed in 2013. Nearly half were filed before 2011.
- Among the 24 recently unsealed cases, the government has declined to intervene in about 55% of the cases in which the unsealed filings included the government's decision on intervention.
- With the government's recently announced settlement with Wyeth for $490.9 million, 2013 appears to be on track to be a record year for False Claims Act recoveries.
- Subject matter of claims:
    - Nearly half of the 24 recently unsealed cases involved both state and federal claims.
    - Claims for relief under state or federal anti-whistleblower retaliation provisions appeared in one-fourth of the recently unsealed cases.
- Identity of Relators:
    - Almost all of the relators in the 24 cases were former employees of the defendants.
    - Relators in one case were not employed by or affiliated with the defendant company. Instead, the relators were medical researchers whose research "allowed them to closely observe Defendants' application for and performance of Government-funded contracts." *See United States ex rel. DeGregorio v. Accelerated Medical Diagnostics, LLC*, No. 2:12-cv-02931-KJM-KJN (E.D. Cal.).
    - One case involved Caryatid, LLC, a self-styled "professional relator" describing itself as "engaged in the business (among others) of acquiring information regarding, and investigating, alleged violations of the Federal (31 U.S.C. § 3729) and District of Columbia (D.C. Code §§ 2-308.14) False Claims Acts." Based on a search of PACER and LEXIS records, no other unsealed federal cases have been brought by this relator. *See United States ex rel. Caryatid, LLC v. Alcon, Inc.*, No. 1:10-cv-00045-RLW (D.D.C.).

Selected Recently Unsealed Cases

United States ex rel. Theis v. Northwestern Univ., No. 1:09-cv-01943 (N.D. Ill.)

Complaint filed: March 20, 2009

Complaint unsealed: July 30, 2013

Intervention status: Intervened

Claims: Defendants allegedly violated the False Claims Act by submitting claims for expenditures of federal grant money obtained from the National Institutes of Health (NIH) that did not meet NIH guidelines.

Name of Relators: Melissa Theis

Defendants' Businesses: Research university/school of medicine, an affiliated comprehensive cancer research center, and two researchers at the school of medicine.

Relator's Relationship to Defendants: Relator is a former employee.

Relator's counsel: Behn & Wyetzner, Chartered

Summary of case: Northwestern University allegedly applied for and received payment from the federal government for costs that were unallowable under NIH grant guidelines. One principal investigator (PI) was allegedly permitted to apply for and receive payment under federal grants both for unbudgeted and excessive vendor and consultant services and for frequent personal travel and living expenses incurred from January 1, 2003 to August 31, 2013. In addition, the PI allegedly used leftover grant money to pay his own salary at the end of grant periods, contrary to NIH guidelines. These amounts allegedly personally benefited the PI, his friends, and family.

Current Status: Northwestern University settled on July 30, 2013 for $2,930,000, with no admission of wrongdoing. The PI was not a party to the settlement agreement. Relator is to receive $498,100.

Reasons to Watch: This case focuses on a prominent research center's alleged noncompliance with the NIH Grants Policy Statement by seeking payment for, and failing to refund, unallowable costs. The case is notable for the extent of the multi-agency investigation, notwithstanding the relatively modest settlement: the allegations were investigated by HHS, the FBI, the NIH, and the U.S. Attorney's Office.

United States ex rel. Campbell v. Wyeth, Inc, No. 5:07-cv-00051-M (W.D. Okla.)

Complaint filed: April 20, 2009

Complaint unsealed: July 30, 2013

Intervention status: Initially declined; the government later intervened for settlement purposes.

Claims: Violation of the False Claims Act by submitting claims allegedly resulting from off-label marketing of a drug for uses not approved by the Food and Drug Administration (FDA), as well as claims under analogous false claims laws of 21 states and the District of Columbia.

Name of Relator: Mark Campbell

Defendant's Business: Pharmaceutical research and manufacturing.

Relator's Relationship to Defendant: Relator is a Wyeth sales account manager.

Relator's counsel: Vogel, Slade & Goldstein, LLP

Summary of case: Relator alleged that Wyeth illegally marketed Rapamune, its kidney transplant drug, for off-label uses not approved by the FDA. Specifically, Relator claimed that Rapamune was marketed to physicians for use in liver, heart, pancreas, and non-kidney transplant patients, and, in addition, for use in combination with immunosuppressive drugs other than those approved for use with Rapamune. The result of this allegedly unlawful marketing purportedly caused federal programs to improperly pay for large numbers of Rapamune prescriptions for unapproved uses. Relator alleged that, in 2007, Wyeth's Rapamune sales were $364.8 million, of which 90% were for off-label uses.

Current Status: On July 30, 2013, Wyeth agreed to settle this and a related False Claims Act case for $490.9 million. Wyeth will pay $257 million to resolve civil allegations and $234 million in criminal fines and penalties. Wyeth also pleaded guilty to a criminal information charging it with one count of misbranding a drug under the Food, Drug, and Cosmetic Act.

Reasons to Watch: This is the latest in a long line of cases charging a pharmaceutical company with off-label marketing practices. The case illustrates the government's continued interest in scrutinizing off-label drug marketing, as well as the substantial challenges that pharmaceutical companies may confront if their sales representatives are viewed as having engaged in unlawful marketing. The extensive investigation underscores the government's interest: the case was investigated by the FBI, FDA, HHS, the Defense Criminal Investigative Service, the Office of Personnel Management, the Department of Veterans' Affairs, and TRICARE Program Integrity. Given the billions of dollars the government has recovered in off-label False Claims Act settlements in the past decade, there is every reason to expect that off-label marketing will continue to attract attention from government agencies and would-be whistleblowers alike.

United States ex rel. Prieve v. Mallinckrodt, Inc., No. 3:08-cv-01863-TEH (N.D. Cal.)

Complaint filed: April 25, 2011

Complaint unsealed: July 15, 2013

Intervention status: Intervened

Claims: Causing the alleged submission of claims for payment for prescriptions induced by kickbacks and for prescriptions for off-label uses in violation of the False Claims Act, as well as analogous false claims laws of 16 states and the District of Columbia.

Name of Relator: John Prieve

Defendant's Business: Mallinckrodt is a pharmaceutical manufacturer.

Relator's Relationship to Defendant: Relator was formerly employed as a district manager in a division of Mallinckrodt selling Restoril, Tofranil PM, and Magnacet.

Relator's counsel: Nolan Auerbach & White, P.A.

Summary of case: Relator alleged that Mallinckrodt unlawfully induced the prescription of Tofranil-PM and Restoril through a variety of kickback programs purportedly designed to funnel payments to physician "consultants." These alleged schemes included the creation of clinical trials solely to generate sales and the selection of physicians to participate in speakership programs, preceptorships, advisory panels, and other programs intended to induce the prescription of Mallinckrodt's drugs. Relator also alleged that Mallinckrodt instructed its sales force to promote Tofranil-PM, a tricyclic antidepressant, for off-label uses in connection with fibromyalgia, migraines, and other indications.

Current Status: On July 18, 2013, Mallinckrodt agreed to pay $3.5 million to settle the case. Relator's share will be approximately $600,000.

Reasons to Watch: The combination of kickback and off-label allegations involved a multi-agency investigation, including HHS, FDA, the FBI, and the National Association of Medicaid Fraud Control Units.

United States ex rel. Marquis v. OmniGuide, Inc., No. 4:12-cv-00207-RC-ALM (E.D. Tex.)

Complaint filed: April 11, 2012

Complaint unsealed: August 1, 2013

Intervention status: Declined

Claims: Allegedly failing to disclose known safety and effectiveness risks associated with OmniGuide's medical device products, fraudulently marketing its medical device products, making false statements regarding reimbursement, causing the submission of claims for payment for medical devices induced by kickbacks in violation of the False Claims Act, as well as analogous false claims laws of 22 states and the District of Columbia.

Name of Relator: Charles Marquis

Defendant's Business: Medical device manufacturer.

Relator's Relationship to Defendant: Relator was formerly employed as a sales representative at OmniGuide.

Relator's counsel: Waters & Krauss LLP

Summary of case: Relator made several related allegations: (1) OmniGuide intentionally failed to disclose to the FDA known safety and effectiveness risks associated with its laser fiber technology by intentionally omitting a complete description, falsely certifying that its technology was as safe and effective as predicate devices, and failing to notify the FDA of known adverse events and failure rates; (2) OmniGuide fraudulently marketed its fibers as procedure-specific, safe, and effective, when, in fact, the fibers were identical and all experienced high failure rates; (3) OmniGuide instructed its sales staff to misrepresent its fibers' reimbursement status by claiming that the company had CPT codes for its devices when, in fact, it did not; (4) OmniGuide paid commissions to a third-party, designated by a particular doctor, to induce that doctor to use and promote the devices.

Current Status: The United States government declined to intervene and the lawsuit is proceeding. There is no settlement information to date.

Reasons to Watch: Similar to *Nelson v. Alcon Laboratories*, discussed in last month's *Qui Tam Update*, this case involves allegations of, among other things, false certification of compliance with FDA laws and regulations

regarding manufacturing and product safety. In addition, both cases were filed in Texas, and the government declined to intervene in each instance. Like *Nelson*, the government's decision not to intervene may indicate a reluctance to allocate governmental resources to cases with less egregious violations than other precedents such as *United States ex rel. Eckard v. GlaxoSmithKline and SB Pharmco Puerto Rico*, (D. Mass.). By comparison, the kickback allegations in *OmniGuide* involve, at most, one doctor, and the government could have decided that the decision to evaluate the materiality of adverse events and safety risks is one best left to the FDA.

For more information, including details relating to the above cases, please contact Hope S. Foster at 202.661.8758 or HSFoster@mintz.com.

About Our Health Care Enforcement Defense Practice

Mintz Levin's Health Care Enforcement Defense Practice is comprised of health law, employment, and white collar defense attorneys with experience in government investigations and health care regulatory compliance matters. We regularly help clients conduct internal investigations designed to detect and correct problems before the government becomes involved. We have represented clients in federal and state government investigations and litigation across the country in matters initiated by the Criminal and Civil Divisions at the Department of Justice, United States Attorneys, the Office of Inspector General for the Department of Health and Human Services, the Drug Enforcement Administration, State Attorneys General, Medicare and Medicaid contractors, and the 50 Medicaid Fraud Control Units. We have helped clients avoid potentially ruinous civil fines, incarceration, other criminal and administrative penalties, and exclusion by combining our regulatory knowledge with our investigative, employment-related, and litigation capabilities.

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