Mintz Levin Health Care *Qui Tam* Update

Recently Unsealed Whistleblower Cases

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Overview of *Qui Tam* Activity

- We identified 56 health care related *qui tam* cases that were unsealed in October and November 2017.
- The intervention rate for those unsealed cases was 20%, which is consistent with longer-term trends seen over the trailing twelve months. Of the 40 cases where the docket reports that the government declined to intervene, only 16 were dismissed immediately after declination, with the remaining 24 cases at least initially being litigated by relators.
- The 56 unsealed cases were filed in 34 different courts. Jurisdictions with the most unsealed cases were the Western District of Pennsylvania (which includes Pittsburgh) with five, the Central District of California (which includes Los Angeles) with four, and three cases unsealed in each of the District of Arizona, the Eastern District of Texas (Beaumont, Marshall, and Texarkana), and the Eastern District of New York (Brooklyn, Queens, and Long Island).
- Hospitals and healthcare systems were most frequently targeted, accounting for 10 of the 56 unsealed cases. Eight cases were brought against pharmaceutical companies and six targeted pharmacies.
- As is typical, former employees were the most frequent relator type, accounting for 23 of the 56 unsealed cases. Current employees only brought four of the cases. Experts and consultants accounted for eight cases.
- None of the cases were unsealed within the 60-day period specified by statute. The shortest time under seal was 71 days; the longest was over seven years. Twenty of the 56 unsealed cases were unsealed in less than a year, but the average time under seal was about two-and-a-half years.

Featured Cases

United States ex rel. Health Choice Group, LLC v. Bayer Corp., No. 17-cv-00126-RWS-CMC (E.D. Tex.)

Complaint Filed: June 19, 2017

Complaint Unsealed: October 31, 2017

Intervention Status: The government declined to intervene.

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Claims: False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.* and various state health care fraud and false claims act statutes

Defendants' Businesses: Defendants Bayer Corporation ("Bayer"), Amgen Inc. ("Amgen"), and Onyx Pharmaceuticals, Inc. are pharmaceutical companies. (Amgen and its subsidiary, Onyx, are collectively referred to as "Amgen"). Defendant AmerisourceBergen Corporation ("Amerisource") is a leading pharmaceutical wholesaler. Lash Group ("Lash"), a subsidiary of Amerisource, is a healthcare consulting firm that offers both clinical nurse educator services as well as reimbursement support services.

Relator: Health Choice Group, LLC ("Health Choice")

Relator's Relationship to Defendant: Health Choice is an affiliate of the National Healthcare Analysis Group, a research organization based in New Jersey founded by a former relator-side attorney, John Minnino, for the purpose of identifying, developing, and bringing FCA lawsuits against health care related entities.

Relator's Counsel: Samuel F. Baxter of McKool Smith P.C. and Mark Lanier of The Lanier Firm

Summary of Case: This lawsuit involves the marketing of Betaseron, a Bayer product approved for the treatment of multiple sclerosis, and Nexavar, a product co-marketed by Bayer, Amgen, and Onyx approved for the treatment of cancer. The relator alleges that defendants Bayer and Amgen, with assistance from Amerisource and Lash, unlawfully marketed Betaseron and Nexavar by (a) providing in-kind remuneration in the form of free nursing education and patient management services, which can reduce the time a physician spends providing oversight and follow-up care to patients; (b) providing nurse educators to recommend Betaseron and Nexavar to prescribers and patients, who were allegedly acting as undercover sales reps for Bayer and Amgen, a practice known as "White Coat Marketing"; and (c) providing in-kind remuneration in the form of reimbursement support services, allegedly saving prescribers thousands of dollars in administrative expenses. The defendants purportedly utilized these practices to induce the providers to prescribe Betaseron and Nexavar in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. (the "AKS"), the FCA and various state laws. The relator asserts that, as a result of the defendants' practices, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were "tainted by kickbacks," causing these programs to pay billions of dollars in improper reimbursements.

Current Status: This case is still in the early stages. On October 30, 2017, the United States declined to intervene in this case, which led to the unsealing of the complaint one day later on October 31, 2017. The relator filed an amended complaint on January 12, 2018. None of the defendants have formally responded to the amended complaint.

Reasons to Watch: This case is one of three filed by the relator and its counsel in the Eastern District of Texas in 2017 containing similar allegations. *See also Health Choice Advocates, LLC v. Gilead Sciences, Inc.*, 5:17-cv-00121-RWS-CMC and *Health Choice Advocates, LLC v. Eli Lilly and Company, Inc.*, 5:17-cv-001234-RWS-CMC. While the government declined to intervene, this case and its counterparts are worth watching as examples of FCA and AKS cases that focus on conduct by pharmaceutical companies that allegedly blurs the line between healthcare providers, such as physicians and nurses to whom patients traditionally look for unbiased medical advice, and sales representatives who are tasked with increasing the use of certain pharmaceuticals as part of patients' treatment regimens. It remains to be seen whether the free services provided by the defendants will be found to be unlawful kickbacks to prescribers in violation of the FCA. This case also warrants attention because it raises the question of whether Bayer's and Amgen's alleged payments to Amerisource and Lash in exchange for the deployment of nurse educators to recommend their products to patients and prescribers legally circumvents the anti-kickback laws that have been viewed in certain circumstances to prohibit companies like Bayer and Amgen from *directly* employing and utilizing these nurse educators.

United States ex rel. Schaller v. Prime Diagnostics Imaging Corporation, Inc., No. 2:12-cv-05579-JFB-AYS (E.D.N.Y.)

Complaint Filed: November 13, 2012

Complaint Unsealed: November 15, 2017

Intervention Status: Partial intervention by the United States on November 15, 2017, as against Drs. Anna Lerner Angeles, Marc Allen, and Anthony Rizzo.

Claims: FCA, 31 U.S.C. § 3729 *et seq.*

Defendants' Businesses: Prime Diagnostics Imaging Corporation, et al., ("Prime Diagnostics") provides noninvasive diagnostic imaging services, including ultrasound services. The complaint also names several individual physicians who offered services from Prime Diagnostics in their offices.

Relators: Victor Schaller, Jr. ("Schaller") and Joseph Faiella-Tommasino, PA, Ph.D. ("Tommasino")

Relator's Relationship to Defendant: Schaller was originally hired as an outside accountant for Prime Diagnostics and then served as its Chief Financial Officer. Tommasino was a consultant who introduced Prime Diagnostics to medical practices interested in offering its services.

Relator's Counsel: Obermayer Rebmann Maxwell & Hippel LLP

Summary of Case: The relators allege that Prime Diagnostics paid illegal kickbacks to physicians to induce them to order its diagnostic imaging services. The defendants purportedly disguised these kickbacks as payments for renting office space in the physicians' offices. The defendants used this office space for administering Prime Diagnostics' diagnostic imaging services to the physicians' patients. The complaint asserts that the defendants based the rental payments on the volume and value of referred services from the physicians to Prime Diagnostics and exceeded fair market value. The amounts of rental payments allegedly ranged from $12,000 to $48,000 per year.

Current Status: On December 27, 2017, the United States and the relators entered into settlement agreements with defendants Angeles, Allen, and Rizzo, against whom the United States had intervened. The relators continue to pursue their claims against the remaining defendants, and litigation is still pending.

Reasons to Watch: This an example of what has recently become a common government enforcement scenario. A supplier of items or services sets up an arrangement that is structured to satisfy the AKS safe harbors and the Stark Law's exceptions, but the amounts paid under the arrangement do not comply. When trying to comply with the safe harbors, providers must remember that all of the elements must be satisfied and that payments should not be based on the volume or value of referrals.

United States ex rel. Martino-Fleming v. South Bay Mental Health Centers, No. 1:15-cv-13065-PBS (D. Mass.)

Complaint Filed: August 11, 2015

Complaint Unsealed: October 30, 2017

Intervention Status: The Commonwealth of Massachusetts elected to intervene on October 30, 2017; the United States declined to intervene on November 1, 2017.

Claims: FCA, 31 U.S.C. § 3729 *et seq.;* Massachusetts False Claims Act, Mass. Gen. Laws c. 12, §§ 5A *et seq.*; Massachusetts Medicaid False Claims Act, Mass. Gen. Laws c. 118E, §§ 40 and 44; 130 C.M.R. §§ 450.237, 450.260(A), and 450.260(I)

Defendants' Business: South Bay Mental Health Center ("South Bay") provides mental health services through 17 mental health clinics in Massachusetts. South Bay employs over 500 clinicians and provides services to over 30,000 patients per year.

Relator: Christine Martino-Fleming

Relator's Relationship to Defendant: The relator is a licensed mental health counselor who worked for South Bay as its Coordinator of Staff Development and Training. She was responsible for training South Bay's clinicians in documentation and billing and for examining qualifications of clinicians and their supervisors.

Relator's Counsel: Waters & Kraus, LLP

Summary of Case: The relator alleges that South Bay knowingly submitted false claims to Massachusetts Medicaid, Massachusetts Behavioral Health Partnership, and several Managed Care Organizations for mental health services provided by unlicensed, unqualified, and unsupervised clinicians employed by South Bay. The complaint asserts that many of South Bay's clinicians are therapists who hold master's degrees but are not licensed as social workers in accordance with Massachusetts regulations. These clinicians thus need to be supervised by a qualified supervisor to meet the regulatory requirements. For example, some clinicians purportedly had degrees from unaccredited schools or were missing core clinical classes and were therefore ineligible for licensure. In addition, the complaint alleged that South Bay's supervisors were also not always appropriately qualified and that South Bay did not provide sufficient supervision to some of its unlicensed and least experienced clinicians. Claims submitted in connection with care provided by purportedly unlicensed clinicians were alleged to constitute false claims in violation of the FCA.

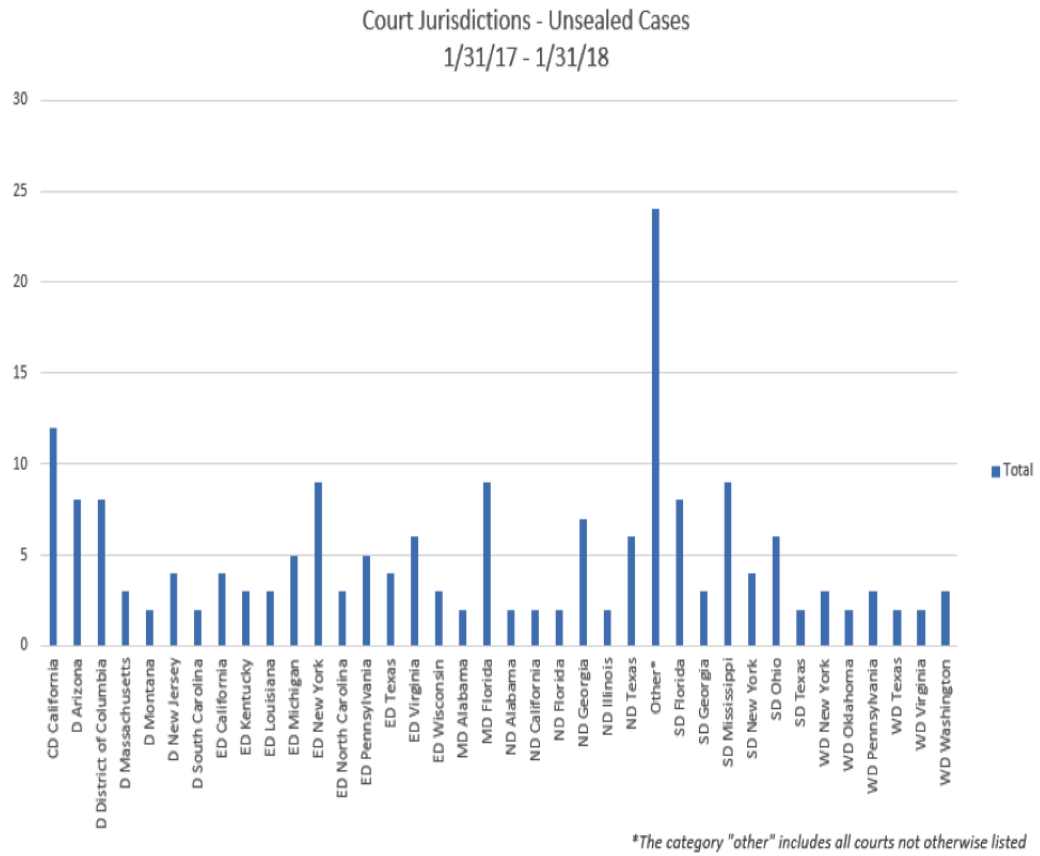
Current Status: The parties are still actively litigating the case. Most recently, on February 16, 2018, the defendants filed a motion to dismiss the complaint. The defendants argued that the complaint failed to identify when and whether any claims for payment arising out of the alleged regulatory violations were made or paid. Therefore, the defendants contended that the relator's complaint failed to provide representative claims and did not allege any false claims with particularity.

Reasons to Watch: Although the federal government declined to intervene in this case, the Commonwealth of Massachusetts chose to intervene in the alleged violations of Massachusetts state law. The Commonwealth's Attorney General will continue to pursue the case in federal court, without assistance from the federal government. The allegation of unlicensed care provided in violation of Massachusetts regulations parallels *Universal Health Services v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), which addressed the question of whether alleged failure to comply with those very regulations was sufficiently material to give rise to FCA liability. In addition to arguing that fraud is not pleaded with requisite particularity, the defendants in this case also seek dismissal for failure to satisfy the materiality standard set forth in *Escobar*. Thus, this case will continue the development of law concerning materiality in the wake of *Escobar*.

Health Care *Qui Tam* Litigation Trends

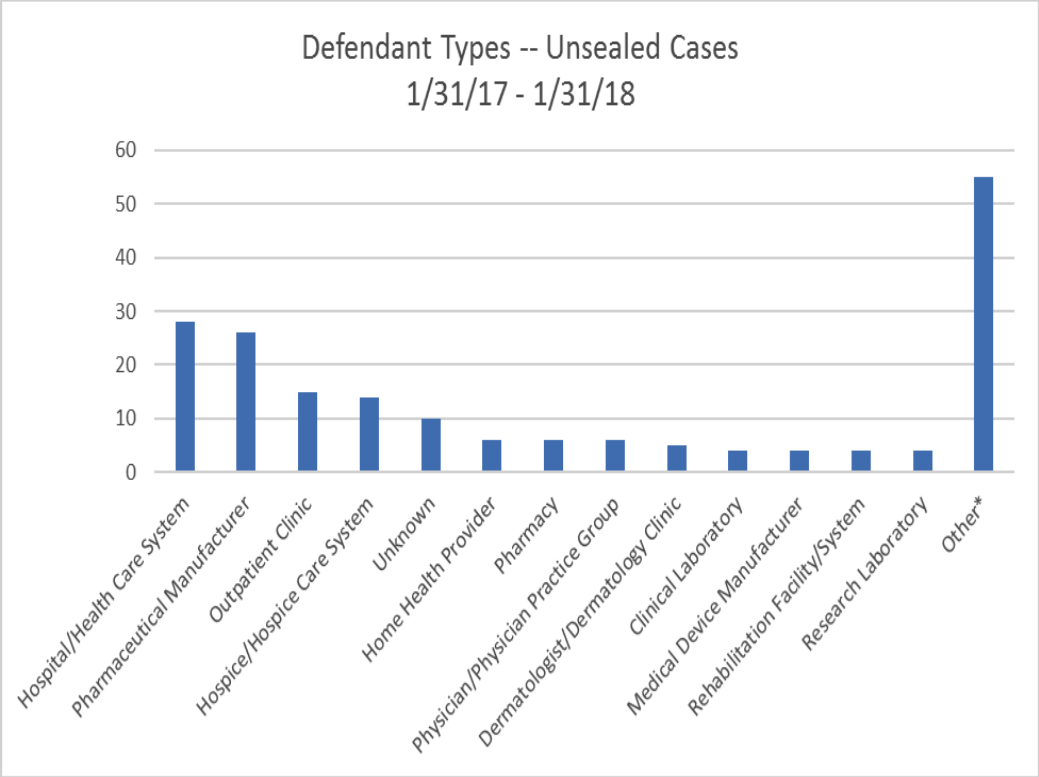
Mintz Levin maintains a database of unsealed health care *qui tam* actions. This enables us to follow and analyze trends in the cases that have been unsealed. The following are some trends in *qui tam* filings against health care-related entities in the twelve months ended January 31, 2018:

Where were cases filed? Although cases were unsealed in jurisdictions throughout the country, some interesting trends have emerged as to jurisdictions where the most cases have been unsealed:

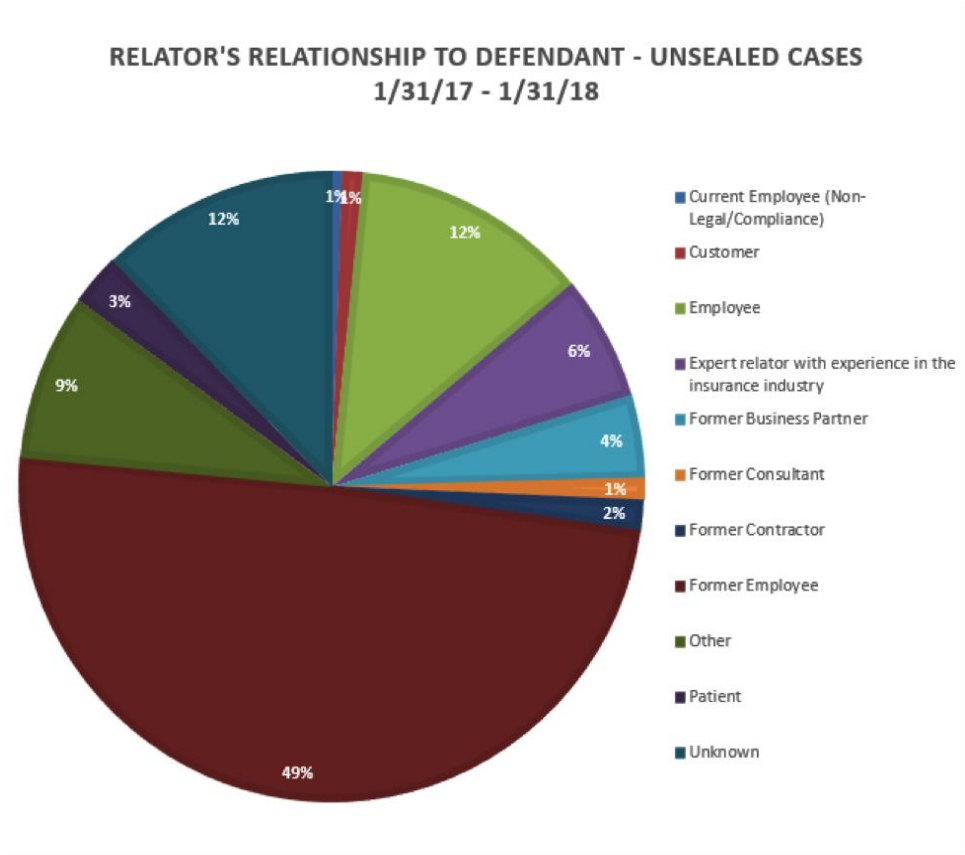


Over the twelve months ended on January 31, there was significant activity in California, with the Central District – which includes Los Angeles – being most active. Florida – including the Southern District (Miami) and the Middle District (Tampa, Orlando, and Jacksonville) continues to be active, as are courts in Ohio.

What kinds of businesses were targeted? Hospitals, pharmaceutical manufacturers, outpatient clinics, hospices and pharmacies were most frequently sued in cases unsealed over the 12-month period ended January 31, 2018.

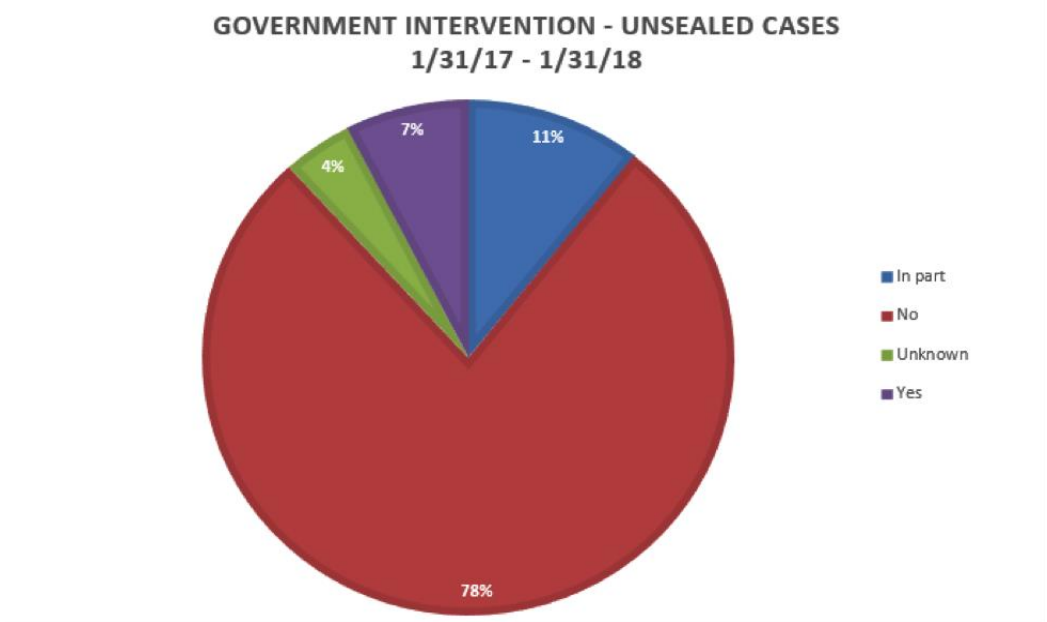


Who brought the cases? The various relator types can be seen in the following chart. The categories in the key are shown in the pie chart with “Current Employee (Non-Legal/Compliance)” at 12 o’clock and then continuing clockwise around the chart.



As is typical, the ranks of relators consist overwhelmingly of current and former employees. But the significant presence of contractors on the lists demonstrates that service providers can also be a source of whistleblower lawsuits. Expert relators also appear to be a growing segment.

How frequently did the government intervene?



Intervention rates continue to be extremely low, with the government declining to intervene in almost four out of every five cases unsealed over the twelve months ended January 31, 2018.

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 includes 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.