Mintz Levin Health Care *Qui Tam* Update

Recently Unsealed Whistleblower Cases

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Overview of *Qui Tam* Activity

- We identified 47 health care-related *qui tam* cases that were unsealed in August and September 2017.
- Over those two months, the rate of intervention was relatively high — at least 34%. For the twelve months that ended November 30, 2017, the intervention rate was 20%, and in September and August the government intervened, in whole or in part, in 14 cases and declined to intervene in 27. Intervention status could not be determined for six cases.
- The 47 unsealed cases were filed in 30 different courts. Four cases were filed in the Central District of California (which includes Los Angeles) and the Southern District of Texas (which includes Houston), while three each were filed in the Northern District of Texas (Dallas-Fort Worth), the Eastern District of New York (Brooklyn, Queens and Long Island), and the District of Massachusetts.

- The unsealed cases include eight cases against hospitals, six cases against outpatient clinics, six cases against physicians or physician practice groups, and four against pharmaceutical companies. In a continuing trend of cases targeting elder care services, three of the unsealed cases were brought against operators of skilled nursing facilities.
- Twenty-one cases were brought by current or former employees. Two cases were brought by consultants to defendants, and three were brought by relators representing themselves to be "experts" in the relevant field. One case was brought by an entity that had done business with the defendant. The latter three categories of relators illustrate that the types of "insiders" who can act as *qui tam* whistleblowers are not limited to current and former employees.
- There is some evidence that the Department of Justice ("DOJ") is beginning to act more quickly on its investigations of sealed cases. Four cases were unsealed in 93 days or less, and six more were unsealed less than one year after filing. However, at least one case remained under seal for six and a half years, and the average time under seal for this group of cases was just over two years.

Featured — The Novo Nordisk Cases

A set of seven related *qui tam* actions against pharmaceutical manufacturer Novo Nordisk Inc. (and other affiliated entities, collectively referred to as "Novo Nordisk") were unsealed and settled in September 2017. Novo Nordisk, which is headquartered in Princeton, New Jersey, is a subsidiary of the Danish firm Novo Nordisk A/S, and sells three drugs targeted at diabetes populations: Novolog, Levemir, and Victoza. The *qui tam* cases summarized below all concerned alleged false claims primarily arising from sales of Victoza (liraglutide), a non-insulin, once-daily injectable prescription medication used in the treatment of adults with type 2 diabetes.

***United States ex rel. Dastous v. Novo Nordisk, Inc.*, No. 1:11-cv-1662 (D.D.C.)**

Complaint Filed: December 28, 2010 (transferred to the District of Columbia from the District of Massachusetts on September 15, 2011)

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: False statements, records, and claims in violation of the FCA, 31 U.S.C. §§ 3729-33 ("FCA"), as well as counterpart claims for violations of state false claims acts. Additionally, claims were brought under the California Insurance Frauds Prevention Act (Cal. Ins. Code § 1871) and the Illinois Insurance Claims Fraud Prevention Act (740 Ill. Comp. Stat. § 92), analogues to the FCA that are applicable to private parties rather than the government.

Relator: Peter Dastous

Relator's Relationship to Defendant: Dastous was a sales representative ("Diabetes Care Specialist") for Novo Nordisk who was responsible for selling the company's diabetes products to endocrinologists throughout an assigned region.

Relator's Counsel: Phillips & Cohen LLP

United States ex rel. Doe v. Novo Nordisk, Inc., No. 1:17-cv-791 (D.D.C.)

Complaint Filed: February 22, 2016 (transferred to the District of Columbia from the Northern District of Texas on April 28, 2017)

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: False statements and fraudulent billing in violation of the FCA as well as counterpart claims for violations of state false claims acts, and also allegations of violations of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(2)(A)-(B)) ("AKS").

Relator: John Doe

Relator's Relationship to Defendant: Doe 1 was employed by co-defendant Practice Therapeutics as a Registered Nurse and served as a certified diabetes educator for Novo Nordisk's "Changing Life with Diabetes" program. Doe 2 was employed by Novo Nordisk as a certified diabetes educator.

Relator's Counsel: Kendall Law Group LLC

United States ex rel. Ferrara v. Novo Nordisk, Inc., No. 1:11-cv-74 (D.D.C.)

Complaint Filed: November 4, 2015

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: False or fraudulent claims for reimbursement in violation of the FCA as well as counterpart claims for violations of state false claims acts, and also allegations of violations of the AKS. Additionally, claims were brought under Chicago and New York City's false claims acts and Ohio's whistleblower statute, as were various claims for discrimination (sex, age, and religion) and retaliation in violation of federal law.

Relator: Lesley Ferrara & Shelly Kelling

Relator's Relationship to Defendant: Ferrara and Kelling were both sales representatives for Novo Nordisk.

Relator's Counsel: Murphy Anderson PLLC

United States ex rel. Kennedy v. Novo Nordisk, Inc., No. 1:13-cv-1529 (D.D.C.)

Complaint Filed: October 15, 2010 (transferred to the District of Columbia from the Southern District of Texas on October 3, 2013)

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: False or fraudulent claims for reimbursement in violation of the FCA as well as counterpart claims for violations of state false claims acts, and also allegations of violations of the AKS. Additionally, a retaliation claim was brought under the FCA.

Relator: Elizabeth Kennedy

Relator's Relationship to Defendant: Kennedy was a sales representative for Novo Nordisk.

Relator's Counsel: Berg & Androphy

United States, et al., ex rel. Myers v. Novo Nordisk, Inc., No. 1:11-cv-1596 (D.D.C.)

Complaint Filed: September 25, 2012

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: False or fraudulent claims for reimbursement in violation of the FCA, as well as counterpart claims for violations of state false claims acts, and also retaliation in violation of the FCA.

Relator: David Myers

Relator's Relationship to Defendant: Myers was a "Direct Business Manager" for Novo Nordisk.He supervised local sales representatives.

Relator's Counsel: Bailey & Glasser, LLP and Bailess Law, PLLC

United States ex rel. Smith v. Novo Nordisk, Inc., No. 1:16-cv-1605 (D.D.C.)

Complaint Filed: August 8, 2016

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: N/A

Relator: Greg Smith, Clint Houck, and Brent Shirkey

Relator's Relationship to Defendant: N/A

Relator's Counsel: Lee R. Glass & Neal A. Roberts

United States ex rel. Stepe v. Novo Nordisk, Inc., No. 1:13-cv-221 (D.D.C.)

Complaint Filed: May 24, 2012 (transferred to the District of Columbia from the District of New Jersey on February 21, 2013)

Complaint Unsealed: September 1, 2017 (in part)

Intervention Status: On July 27, 2017, the United States intervened in part.

Claims: False or fraudulent claims for reimbursement in violation of the FCA as well as counterpart claims for violations of state false claims acts, violations of the AKS, and also retaliation in violation of the FCA.

Relator: Mckenzie Stepe

Relator's Relationship to Defendant: Stepe was a sales representative for Novo Nordisk.

Relator's Counsel: N/A

Summary of Cases

These cases all involved claims against Novo Nordisk and certain of its business affiliates in connection with alleged "off-label" marketing of Victoza, which had been approved for use in adults with type 2 diabetes but was not approved for pediatric use. In fact, Victoza's label expressly warned that the drug was not recommended for use in children. Also, the drug was not approved for weight loss purposes.

Although varying as to the specific conduct at issue, relators in each of these cases generally alleged that Novo Nordisk began to market the drug for off-label indications shortly after it was

approved in 2010. They claimed that Novo Nordisk deliberately courted, as potential customers, pediatric diabetes care providers. The relators also alleged that Novo Nordisk marketed Victoza for weight loss through a strategic publication strategy meant to work around legal restrictions on Novo Nordisk's ability to market Victoza for off-label, unapproved uses. Novo Nordisk allegedly accomplished this by funding research about the potential weight loss applications of the drug, which was later published and then disseminated to treating physicians.

Current Status

The government intervened in part in July 2017 and then promptly settled the Victoza cases against Novo Nordisk in September 2017. The DOJ issued a press release on September 5, 2017 announcing the $58 million global settlement. In its announcement, the DOJ did not address relators' allegations about purported off-label marketing practices of Novo Nordisk. Instead, the DOJ emphasized that Novo Nordisk had failed to comply with the Risk Evaluation and Mitigation Strategy ("REMS") required by the Food and Drug Administration ("FDA") in connection with its approval of Victoza. Specifically, the REMS required that Novo Nordisk put prescribing physicians on notice of the potential risk that Victoza presented for a rare form of thyroid cancer. Allegedly, Novo Nordisk "instructed its sales force to provide statements to doctors that obscured the risk information and failed to comply with the REMS" requirements. The settlement resolved both the federal and state false claims act allegations relating to Novo Nordisk's alleged promotion of Victoza for unapproved pediatric and weight-loss uses.

Reasons to Watch

The Novo Nordisk cases are consistent with the government's continuing focus on pharmaceutical marketing practices, yet also address substantive issues relating to delivery of patient care. While off-label marketing claims of the type brought by relators here are common, the government's intervention ultimately focused on the alleged failure of Novo Nordisk to comply with the REMS requirements imposed by the FDA. Perceived failures to respect marketing restrictions often draw government scrutiny. But here, as in recent FCA cases turning on questions of medical necessity, the government used the FCA to address matters involving clinical judgment. In such cases, the FCA is being employed as a tool to influence not only how claims are paid, but also how and on what basis physicians exercise their clinical judgment. Using the FCA to enforce the Victoza REMS may signal an increasing willingness by the government to use its enforcement powers to shape and guide the delivery of patient care.

Other Recently Unsealed Cases

United States ex rel. Fesenmaier v. Sightpath Medical, Inc., No. 13-SC-30003-RHK/FLN (D. Minn.)

Complaint Filed: April 1, 2015

Complaint Unsealed: August 18, 2017

Intervention Status: Partial intervention by the United States on August 14, 2017, as against Sightpath Medical, Inc. and TLC Vision Corporation for the purposes of settlement, and against Precision Lens, Paul Ehlen, and Jitendra Sawrup to file a complaint in intervention.

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

Defendants' Businesses: Defendant Sightpath Medical, Inc. ("Sightpath") provides both mobile cataract and glaucoma surgical services and equipment, and LASIK and other refractive surgical services and equipment. The Cameron-Ehlen Group, Inc. d/b/a Precision Lens ("Precision Lens") distributes intraocular lenses and other eye-related surgical products.

Relator: Kipp Fesenmaier

Relator's Relationship to Defendants: The relator worked in various capacities for Midwest Surgical Services, Inc., a company that merged with another entity in 2007 to form Sightpath. The relator left Midwest Surgical Services in 2007 and then worked for a competitor in the same industry.

Relator's Counsel: Susan M. Coler of Halunen Law, Jennifer M. Verkamp and Frederick M. Morgan of Morgan Verkamp, LLC

Summary of Case

The relator alleged that defendants Sightpath and Precision Lens paid unlawful kickbacks to physicians to incentivize them to use defendants' products and services. These incentives purportedly took such forms as sham consulting agreements, discounted equipment, travel, and entertainment.

The complaint asserted, for example, that defendants paid physicians above fair market value and commercially unreasonable monthly stipends ranging from $ 5,000 to $8,000 for consultancy services and questioned whether defendants provided any services at all. Defendants also allegedly provided free and discounted use of their mobile surgery equipment. Further, the complaint detailed numerous examples of defendants' provision to physicians of high-end dinners, free fishing and golfing, and trips to luxury resorts to hunt. The relator alleged that these extensive remunerations were intended to and did induce physicians to utilize the defendants' products and services.

Current Status

On Monday, August 21, 2017, the DOJ issued a press release stating that Sightpath Medical, TLC Vision Corporation, and their former CEO, James Tiffany, had agreed to pay more than $12 million to the United States to resolve this FCA case, predicated on alleged kickback violations. In the settlement agreement the United States contended that between January 1, 2006, and January 1, 2015, Sightpath provided physicians with items of value to induce the use of Sightpath's ophthalmologic products and services, thus submitting false claims to the United States for them. The relator will receive 19.5% of the amounts recovered in connection with the settlement agreement.

As stated in the press release, the United States intervened in the *qui tam* suit against Precision Lens and owners Paul Ehlen and Jitendra Sawrup, and the United States will continue to pursue its claims against those defendants. On November 15, 2017, the court granted the government's Request for an Extension of Time to Serve the United States' Complaint in Intervention on defendants Precision Lens, Paul Ehlen and Jitendra Sawrup until mid-January 2018. The United States declined to intervene in the case against other physician defendants named in the complaint. On November 16, 2017, pursuant to a Notice of Partial Voluntary Dismissal with the government's consent, the court dismissed the relator's claims in the action against the physician defendants as to whom the government had declined to intervene.

Reasons to Watch

As this case shows, the government is continuing to focus enforcement activity on conduct that potentially raises questions about whether physicians have exercised independent clinical judgment in connection with ordering services for patients. Meals, travel, and entertainment benefits provided

to physicians by product suppliers or service providers can be considered remuneration in exchange for referrals. Particular care should be taken to ensure that marketing activities do not cross that line.

United States ex rel. Safren v. St. Agnes Healthcare, Inc., No. 1:16-cv-02537-ELH (D. Md.)

Complaint Filed: July 11, 2016

Complaint Unsealed: August 16, 2017 (unsealed with Court's Order of Dismissal)

Intervention Status: United States intervened on August 16, 2017.

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

Defendant's Business: The defendant St. Agnes Healthcare, Inc. ("St. Agnes") operates an acute care general hospital in Baltimore, Maryland and offers inpatient and outpatient services to patients.

Relator: Dr. Jonathan Safren

Relator's Relationship to Defendants: Dr. Safren was employed as a cardiologist by St. Agnes from June 3, 2011, to June 20, 2013.

Relator's Counsel: Jonathan Biran of Biran Kelly, LLC

Summary of Case

This matter involves evaluation and management ("E&M") services provided by physicians to new and returning patients. The Healthcare Common Procedure Coding System ("HCPCS") is a standardized coding system designed to ensure that federal health care programs pay for services rendered to patients in accordance with the level of resources necessary to provide such care. Physicians use Current Procedural Terminology Codes ("CPT Codes") to bill their services provided to patients under the HCPCS system. HCPCS has two different series of CPT Codes for (1) E&M services performed on a new patient and (2) E&M services provided to an established patient. The CPT Codes for new patients carry higher reimbursements rates to compensate physicians for the anticipated additional time it will take to provide a detailed and comprehensive examination of a new patient. The CPT Manual defines a new patient as a patient who has not received professional services from the physician or physician group within the previous three years.

The relator's complaint contended that newly hired cardiologists at St. Agnes Healthcare, Inc., improperly submitted claims to Medicare using new patient CPT Codes where the physician should have submitted the CPT Codes for existing patients. In June 2011, St. Agnes acquired the practice group of twelve mid-Atlantic cardiovascular associates, and the cardiologists became employees of St. Agnes. During the time of their transition to St. Agnes, St. Agnes' Director of Compliance allegedly directed the cardiologists to bill office visits using the new patient CPT Codes regardless of whether a physician in the group had seen the patient within the last three years. The relator asserted that even after he raised a concern about this billing practice, St. Agnes reached a consensus that physicians would follow the billing directive and bill the initial patient visit as a new patient visit, even if the physician had provided services to that patient within the prior three years.

Current Status

On Wednesday, August 23, 2017, the DOJ issued a press release stating that St. Agnes Healthcare agreed to pay the United States $122,928 to resolve claims that St. Agnes submitted false claims to Medicare by billing for E&M services at a higher reimbursement rate than federal health care

programs allowed. The United States contended, in the settlement agreement, that between June 3, 2011, and June 3, 2014, St. Agnes improperly received more reimbursement than it was entitled to under Medicare due to these improper billing practices. The relator will receive $20,000.

Reasons to Watch

Although this was a small dollar value case, this settlement is an example of enforcement activity directed toward miscoding or "upcoding" of claims. Proper coding of claims is often difficult and judgmental. This complexity offers opportunities to try to bill for more intensive or acute services than might ordinarily be warranted. However, such billing practices invite close enforcement scrutiny, which creates a risk that good faith judgments about coding in complex cases may be subject to regulatory challenge. Providers, therefore, should be careful in coding procedures and services, so as to avoid such scrutiny. And, as this action indicates, in doubtful cases the government is likely to treat claims with greater skepticism where a provider elects to code services as a more intensive – and more highly compensated – level.

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. We recently provided an analysis of the trends during 2017 as part of our Health Care Enforcement Year in Review and 2018 Outlook. See here for that discussion.

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.