Mintz Levin Health Care *Qui Tam* Update

Recently Unsealed Whistleblower Cases

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BY HOPE FOSTER, KEVIN MCGINTY, KERIME S. AKOGLU, LAVINIA WEIZEL AND DOMINIQUE WINDBERG

Trends & Analysis

- We have identified 24 health care–related *qui tam* cases that have been unsealed since our last *Qui Tam Update*. Of the 24 cases, five were filed within the past year, seven were filed in 2014, three were filed in 2013, five were filed in 2012 and three were filed in 2011. In the remaining case, in which multiple complaints were consolidated, two were filed in 2011 and one was filed in 2013. On average, cases were pending for 26 months before being unsealed.
- The 24 cases were filed in federal district courts in 11 states. Nine cases were filed in the District of Massachusetts, and four cases were filed in New York (three in the Southern District and one in the Western District). Two cases were filed in the Western District of Missouri. One case was filed in the Middle District of Tennessee and one case was filed in the Western District of Tennessee and later transferred to the District of Massachusetts. Of the remaining cases, one each was filed in the Northern District of California, the Middle District of Florida, the Eastern District of Louisiana, the District of New Jersey, the Western District of Oklahoma, the Eastern District of Pennsylvania and the District of Vermont.
- Unsealed filings show that the government affirmatively declined intervention in seven of the 24 recently unsealed cases. The government intervened — sometimes in part — in 12 of the cases. In one case, the government filed an application for a stay and administrative termination of the civil case, which was granted. Another was voluntarily dismissed by the plaintiff before any action was taken by the government. In the remaining cases, the docket was silent or the government's intervention status was otherwise unclear from the unsealed filings.
- Nature of the Claims
    - In three cases, the nature of the claims could not be determined from the unsealed materials. Of the remainder, 15 of the 24 recently unsealed cases involved both state and federal claims.
    - Approximately 25% of the cases involved claims for relief under federal and/or state anti-whistleblower retaliation provisions.
    - Four of the cases involved claims under the federal Anti-Kickback Statute, and one of those also involved claims under the Stark Law.
- In 16 of the unsealed cases, the relator was a former employee of the defendant. In four others, the relator was a health care provider, lawyer or administrator in the same industry as the defendant. In one case the relator was a patient. In the three remaining cases, the relator's relationship to the defendant could not be determined from the unsealed filings.

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Featured Cases

United States ex rel. Mark McGuire v. Millennium Laboratories, Inc., No. 12-cv-10132 (D. Mass.); *United States ex rel. Ryan Uehling v. Millennium Laboratories, Inc. et al.*, No. 12-cv-10631 (D. Mass); *United States, et al., ex rel. Wendy Johnson v. Millennium Laboratories, Inc.*, No. 12-cv-12387 (D. Mass.); *United States ex rel. Omni Healthcare Inc. and John Doe v. Millennium Laboratories, Inc.*, No. 14-cv-13052 (D. Mass.); *United States ex rel. Amadeo Pesce, Ph.D. v. Millennium Health*, No. 15-cv-10821 (D. Mass.); *United States ex rel. Omni Healthcare Inc. v. Millennium Laboratories, Inc.*, No. 13-cv-10825 (D. Mass)*; *United States, et al., ex rel. Estate of Robert Cunningham v. Millennium Laboratories of California, Inc.*, No. 09-cv-12209 (D. Mass.)*; *United States ex rel. Allstate Insurance Co. and Lawrence K. Spitz, M.D. v. Millennium Laboratories, Inc.*, No. 14-cv-14276 (D. Mass.)*

Note: For cases denoted with an asterisk, documents filed with the court (other than the unsealing orders) continue to be impounded by order of the Court despite the dismissal of those cases as a result of the settlement agreement discussed below.

Complaints Filed: *McGuire* (January 26, 2012); *Uehling* (April 9, 2012); *Johnson* (December 21, 2012); *Omni Healthcare Inc. and John Doe* (July 18, 2014); *Pesce* (March 12, 2015)

Complaints Unsealed: *McGuire* (November 24, 2015); *Uehling* (November 24, 2015); *Johnson* (November 24, 2015); *Omni Healthcare Inc. and John Doe* (October 16, 2015); *Pesce* (October 19, 2015).

Intervention Status: Intervened

Claims: Among other things, the U.S. government alleged that Millennium Laboratories, Inc. violated 31 U.S.C. §§ 3729-3733 — including, specifically, 31 U.S.C. § 3729(a)(1)-(2) (false claims, false statements), 31 U.S.C. § 3729(a)(7) ("reverse" false claims through failure to return an overpayment), and 31 U.S.C. § 3729(h) (retaliation). Relators and the government also alleged violations of the false claims statutes of 29 states and the District of Columbia, as well as violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7(b)(1)-(3).

Names of Relators: Mark McGuire; Ryan Uehling; Wendy Johnson; John Doe; Amadeo Pesce

Defendants' Business: Millennium Health, formerly Millennium Laboratories, Inc., is a clinical laboratory that provides urine drug testing and genetic testing services to physicians, clinics and hospitals.

Relators' Relationship to Defendant: McGuire is the director of laboratory services at a hospital whom defendant contacted with the goal of obtaining the hospital's urine drug testing business; Uehling is a former sales manager for Millennium; Johnson is a former internal auditor for Millennium; John Doe is a physician and a principal of Omni Healthcare Inc. who ordered genetic testing from Millennium; Pesce is a former employee who served as a Clinical Director and was later fired by Millennium.

Relators' Counsel: Counsel for McGuire — Greene LLP; Counsel for Uehling — Berg & Androphy; Counsel for Johnson — Durrell Law Office; Counsel for Omni Healthcare Inc. and John Doe — Vezina Law PLC and Todd & Weld LLP; Counsel for Pesce — Law Offices of Mark Allen Kleiman and Neylon & O'Brian, P.A.

Summary of Case: Relators, the U.S. government, and state governments alleged that, between 2008 and 2015, Millennium Laboratories, Inc. systematically billed federal health care programs for excessive and unnecessary testing, specifically urine drug testing and genetic testing. The government alleged that Millennium utilized a nationwide sales force to coerce its customers (physicians, clinics and hospitals) to increase the number of requested tests to be performed on each

submitted specimen. Millennium's drug testing structure, the government alleged, caused physicians to order a large number of tests without individual assessment of patients' needs. In addition, the relators and the government alleged that Millennium utilized a variety of kickback schemes to accomplish its goal of increased testing.

Current Status: Millennium Health, formerly Millennium Laboratories, Inc., agreed to pay a total of $256 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid and other federal health care programs for medically unnecessary urine drug and genetic testing and for providing free items to physicians who agreed to refer expensive laboratory testing business to Millennium. Within the recovery, Millennium will pay $227 million to resolve False Claims Act allegations that it systematically billed federal health care programs for excessive and unnecessary urine drug testing from 2008 through 2015. In addition, Millennium agreed to pay $10 million to resolve False Claims Act allegations that it submitted false claims to federal health care programs for genetic testing between 2012 and 2015. The resolution included a corporate integrity agreement ("CIA") with the Department of Health and Human Services — Office of Inspector General (HHS-OIG). In addition, Millennium will pay $19.2 million to the Centers for Medicare and Medicaid Services ("CMS") to resolve certain administrative actions related to Millennium's urine drug test billing practices. Because the False Claims Act allegations were originally brought in lawsuits filed by whistleblowers, the relators will receive $30.5 million from the False Claims Act recovery for the urine drug testing claims and $1.48 million from the False Claims Act recovery for the genetic testing claims.

Reasons to Watch: Millennium is one of the largest urine drug testing laboratories in the United States and conducts business nationwide. The allegations against Millennium were brought by several relators, former employees and customers, state governments, and the federal government. The investigation was also led by several teams, including the U.S. Attorney's Office of the District of Massachusetts, HHS-OIG and HHS Office of the General Counsel, CMS, the Office of Personnel and Management Office of Inspector General, the U.S. Postal Service Office of Inspector General, the Department of Veteran Affairs, and the FBI. This kind of cooperation between different government agencies is further proof of the government's commitment to enforcing its health care fraud laws. In addition, as with many cases of this magnitude, Millennium also committed to a Corporate Integrity Agreement ("CIA"), showing that the government still requires that settling companies agree to make certain changes to the way in which they conduct their operations and that they implement and maintain robust compliance programs. The government settled the claims brought against Millennium without a determination of liability. As part of the settlements, the cases will be dismissed.

United States of America and The Commonwealth of Massachusetts ex rel. Brian D. Sachs v. Martin E. Cutler, et al, No. 1:14-cv-11879-IT (D. Mass.)

Complaint Filed: 4/17/2014

Complaint Unsealed: 10/20/2015

Intervention Status: The United States declined to intervene on October 20, 2015.

Claims: False claims to Medicare in violation of the Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, ("FCA") premised on fraudulent billing and claim submission practices. The relator also brought claims under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq*. The relator further sought relief for retaliation claims under the FCA and the Massachusetts False Claims Act.

Name of Relator: Brian D. Sachs

Defendant's Business: Defendant Martin E. Cutler, M.D., an ophthalmologist, runs Cutler Eye & Skin Center, a medical practice with multiple offices in Massachusetts. Through the Cutler Eye & Skin Center, Dr. Cutler provided eye examinations and ran a "medispa" to provide cosmetic treatments such as Botox.

Relator's Relationship to Defendant: Relator Sachs is a former independent contractor and Director of Operations whom Dr. Cutler hired to serve as a medical practice consultant to the Cutler Eye & Skin Center. Mr. Sachs was brought on to address various general billing, morale, and

management issues and was hired due to his decades-long prior experience as a president and CEO of a medical billing company. Relator Sachs has alleged that he was wrongfully terminated for auditing and attempting to correct Defendants' billing practices to comply with federal and state laws.

Relator's Counsel: Durrell Law Office and Thomas & Associates

Summary of Case: Relator Sachs, a former consultant and Director of Operations of Cutler Eye & Skin Center, alleges that Cutler, in violation of state and federal law, engaged in a number of schemes which amounted to billing for medically unnecessary treatments and obtaining excessive reimbursement by exploiting at-risk populations while failing to provide basic testing to these patients.

Sachs charges that Dr. Cutler forced other providers, including an optometrist who worked at the Cutler Eye & Skin Center, to submit claims for reimbursement under Dr. Cutler's unique provider identification number because Dr. Cutler was a licensed ophthalmologist and would thus receive higher reimbursement rates. Dr. Cutler, however, did not furnish these services or personally supervise the services rendered.

The relator also alleges that Dr. Cutler made false statements to Medicare by including improper modifying codes in his diagnoses, and submitted false claims for reimbursement by inappropriately using the CPT code for Comprehensive Eye Exams without performing procedures required for use of the code, such as ophthalmoscopies.

The relator further claims that Dr. Cutler included diagnostic codes for conditions such as eye pain and diabetes in order to make it appear that the eye examinations conducted at Cutler Eye & Skin Center were performed to treat or diagnose a specific illness, symptom, complaint, or injury and hence were covered so that Dr. Cutler would receive reimbursement for what were in actuality uncovered routine eye examinations. The relator also contends that the examinations that were provided there were performed solely for the benefit of the provider and did not address the needs of those patients who actually had diabetes and other serious conditions and who required comprehensive eye examinations, such as ophthalmoscopies, which Dr. Cutler often did not provide.

In addition, the relator alleges that staff members routinely forged physician signatures on patient and billing documents in violation of Medicare requirements.

Finally, Sachs charges that Dr. Cutler knew that Medicaid and Medicare had overpaid him for years based on his false statements and he failed to take the required and appropriate steps to satisfy the obligation owed to the United States and the Commonwealth of Massachusetts to refund or return these overpayments.

Current Status: The United States declined to intervene on October 20, 2015. The case is currently ongoing.

Reasons to Watch: Although the United States declined to intervene in this case, it provides numerous examples of alleged non-compliant conduct that can occur at an ophthalmology office, such as fraudulent CPT coding and failure to provide all components necessary to bill for a Comprehensive Eye Examination under Medicare and Medicaid. The contentions in relator's complaint paint a troubling picture of Dr. Cutler and his staff, who allegedly eschewed responsibility and who also allegedly and repeatedly failed to comply with Medicare and Medicaid requirements despite receiving numerous admonitions from the relator, who was eventually terminated despite the fact that he was hired specifically to address these issues. This case is also a reminder of the care that medical offices should take in each step of the billing process, such as ensuring that the physicians who provide the services sign the forms.

United States of America ex rel. Hayward, et. al. v. SavaSeniorCare, LLC, et. al., No. 3:11-cv-0821 (M.D. Tenn.)

Complaints Filed: October 26, 2015 (United States' Complaint in Intervention); November 20, 2013 (Scott); December 6, 2011 (Kukoyi); August 26, 2011 (Hayward)

Complaints Unsealed: October 28, 2015

Intervention Status: On July 21, 2015, the United States gave notice of its intent to intervene in part,

and, on October 26, 2015, it filed a consolidated complaint in intervention. On October 29, 2015, the State of Tennessee gave notice of its election to decline to intervene. No further action on intervention has occurred.

Claims: The United States alleges that the defendant SavaSeniorCare, LLC and its subsidiaries (collectively "Sava") caused Medicare to pay for rehabilitative therapy services that were not medically reasonable or necessary, were not skilled in nature, or otherwise were not covered by Medicare's skilled nursing facility benefit. The United States claims that this resulted in multiple violations of the False Claims Act, 31 U.S.C. § 3729. Based on the same allegations, the United States further asserts common law claims of unjust enrichment and payment by mistake.

Names of Relators: Rita Hayward, Trammel Kukoyi, Terrence Scott

Defendant's Business: SavaSeniorCare, LLC, through its subsidiaries, owns and manages approximately 200 skilled nursing facilities in 23 states. Skilled nursing facilities provide complex, in-patient nursing and rehabilitative therapy services administered by, or under the supervision of, trained personnel, such as physical or occupational therapists and speech and language pathologists.

Relators' Relationships to Defendant: Former employees at three different facilities operated by Sava (one in Tennessee and two in Texas)

Relators' Counsel: Barrett Law Office, PLLC of Nashville, TN (Hayward); Berg Androphy of Houston, TX (Kukoyi); Waters & Kraus, LLP of Dallas, TX (Scott)

Summary of Case: According to the government's complaint in intervention, Sava engaged in a concerted, top-down effort to drive providers in all of its facilities to classify patients at the highest level of therapy needed and to extend the length of each patient's stay, solely to maximize Medicare reimbursements and regardless of each patient's medical needs. The United States alleges that this resulted in patients being "forced" to participate in more physical therapy than was warranted for their conditions and/or caused patients to exhaust their 100-day skilled nursing facility benefit without a medical justification.

Specifically, the United States contends that Sava set corporate goals for the number of days patient services were billed at the "ultra high" or "rehabilitative ultra" level without regard for the patient population or needs at particular facilities and aggressively enforced these targets through continuous monitoring of facilities by non-clinical staff, micromanagement of patient care and penalties, up to and including termination of employment. Purportedly, corporate monitoring focused almost exclusively on requiring justifications for why every patient was not classified at (and subjected to) the maximum amount of rehabilitative therapy reimbursable by Medicare per day. Additionally, Sava allegedly encouraged the use of group therapy and treatment modalities (such as heat or whirlpool therapy) to boost Medicare reimbursements without regard to the medical needs of patients, by, for example, setting goals of two modality treatments per therapist/per day regardless of patient population. Further, Sava allegedly employed specific strategies to increase the length of patients' stays regardless of medical need, including prohibiting clinical staff from writing discharge papers until approved by upper-level management.

In support of its allegations, the United States points to specific internal communications articulating these policies as well as dramatic increases across Sava facilities from 2006 to 2011 in the number of treatment days classified at the "ultra high" therapy level (from 21% in 2006 to 63% is 2011).

Sava also purportedly ignored the complaints of individual therapist employees who threatened to or did resign because they felt pressured to subject patients to excessive or wholly unnecessary rehabilitative therapy. Allegedly, therapists expressed concerns that they feared their licensure was in jeopardy because they were not permitted to exercise independent clinical judgment or because patients had complained to them of being "forced out of bed" to participate in daily therapy sessions.

Current Status: The case is currently pending.

Reasons to Watch: As the DOJ noted in a press release announcing its intervention in this case, Sava is one of the largest health care providers in the United States. In the time period covered by the complaint, Medicare paid over $1.4 billion to Sava. Additionally, the practice of allegedly over-prescribing intensive therapy has been the subject of increased scrutiny by the press and has drawn

the attention of the Department of Health and Human Services Office of the Inspector General ("OIG") and other watchdog groups. In a report issued in September of 2015, the OIG called for increased oversight and changes to the manner in which Medicare reimburses for physical therapy in skilled nursing facilities. Increasing press and regulatory focus in this area could draw additional *qui tam* activity.

This case also provides a reminder that relators are often current or former employees and complaints from such employees should be given careful attention as corporations create and implement goal-setting policies in the health care delivery context. This case is of additional interest because the United States has asserted common law claims of unjust enrichment and payment by mistake, as well as statutory claims under the federal False Claims Act, because the government is including these common law causes of action in many of its complaints in intervention.

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

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