2020 Year-End Review of Top Health Care False Claims Act Enforcement Cases and Trends

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With 2020 receding like a departed shoreline on the horizon, it is time to take stock (and notice) of several interesting developments during the year under the federal False Claims Act (FCA) related to healthcare litigation. What follows is a review of some of the most significant cases and emerging trends in FCA enforcement affecting the healthcare industry over the past year.

Supreme Court Activity

While the Supreme Court did not decide any landmark FCA cases in 2020, it did make a notable decision in declining to take up a case using statistical sampling as a basis for FCA liability in *United States ex rel. Integra Med Analytics LLC v. Baylor Scott & White Health*.[1] On December 7, 2020, the Supreme Court rejected a petition for a writ of certiorari, seeking review of a decision by the U.S. Court of Appeals for the Fifth Circuit, which affirmed the dismissal of a $61.8 million FCA suit. The petitioner, relator Integra Med Analytics LLC, claimed that Baylor Scott & White Health increased the use of a specific Medicare diagnosis code to inflate its revenue improperly. Integra discovered the alleged fraud by using statistical analysis of Centers for Medicare & Medicaid Services data. In 2017, a Texas district court dismissed Integra's claims. In May 2020, the Fifth Circuit affirmed, holding that the appellant "does not present sufficient particular details of this alleged fraud claim," since the statistical analysis did not substantiate overbilling and might have been explained by new billing practices in the industry generally. The case is noteworthy because, while statistical sampling has been used to calculate damages,[2] it has not (yet) been used to establish liability in FCA cases and this case continues to foreclose that theory of relators.

A Trio of Circuit Courts Split on Objective Falsity

In 2020, the Courts of Appeals for the Third and Ninth Circuits decided cases that split from a 2019 Eleventh Circuit decision regarding "objective falsity." First, in *United States v. AseraCare, Inc.*, the Eleventh Circuit held that a reasonable disagreement between medical experts on a medical diagnosis could not, by itself, prove that the medical assessment was "objectively false."[3] Although the court remanded the case to provide the Department of Justice (DOJ) an opportunity to link evidence of "objective falsity" to the allegedly false certifications identified in the complaint, the district court refused to re-open discovery to allow an expert to testify as to whether "no reasonable physician" could have made the clinical judgments at issue. In February 2020, AseraCare settled the suit with DOJ for $1 million following a December 4, 2019 court order refusing DOJ's request to re-open discovery. The settlement fell far short of the $200 million that AseraCare allegedly overcharged the government for hospice services.

Second, in *United States ex rel. Druding v. Care Alternatives*, the Third Circuit held that a "difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity."[4] As in *Aseracare*, the case turned upon certification of Medicare patients for hospice care. A New Jersey district court disregarded expert testimony pertaining to 47 patient diagnoses, holding that falsity under the FCA required proof of "objective falsehood," so that a physician's subjective judgment could not be objectively false unless "there is evidence of factual inaccuracy." The Third Circuit reversed, distinguishing between legal and factual falsity.[5] The panel also faulted the trial court for conflating the elements of falsity and scienter in its formulation of "objective falsity." The trial court had followed the Eleventh Circuit's approach in *Aseracare*, but the Third Circuit explained that falsity and scienter must be analyzed separately as "objectivity speaks to the element of scienter, not falsity."[6]

Third, in *Winter ex rel. United States* v. *Garden Regional Hospital*, the Ninth Circuit addressed Medicare payments for hospital admissions.[7] The relator alleged that the hospital admitted patients for medically unnecessary conditions. Similar to the Third Circuit in *Druding*, the Ninth Circuit reversed a lower court decision that sought to "carve out an exception for clinical judgments and opinions" when considering falsity. The court held that an FCA claim based on an alleged lack of medical necessity may be sufficient to survive a motion to dismiss. And, like the *Druding* court, the Ninth Circuit faulted the district court for conflating scienter and falsity.

Given the circuit split regarding objective falsity in the medical/hospice context, the defendants in both cases filed petitions for a writ of certiorari with the Supreme Court in September 2020. Currently, both petitions remain pending.[8]

The First and Sixth Circuit Addressed the Public Disclosure Bar

In *United States ex rel. Holloway v. Heartland Hospice, Inc.*, the Sixth Circuit held that *qui tam* relators are agents of the federal government for the public disclosure bar so that a disclosure to a relator in a federal civil case may trigger the bar.[9] Specifically, the court concluded that three *qui tam* complaints filed against the defendant's parent company and related entities in South Carolina —which were unsealed in 2007 and stipulated to dismissal in 2008—triggered the public disclosure bar, as the relator in *Holloway* filed her complaint in Ohio in 2010. The court rejected the relator's argument that the cases were not "public" because the government declined to intervene. The court reasoned that a *qui tam* relator becomes a government agent subject to the public disclosure bar because the government is the real party in interest and exerts control over *qui tam* litigation. Additionally, the three South Carolina complaints disclosed for public-bar purposes the *Holloway* relator's allegations of fraud because they "depict[ed] essentially the same scheme." While *Holloway* is not a case of first impression regarding the public disclosure bar in the Sixth Circuit, the case is important regarding the status of relators.

Relatedly, in *United States ex rel. Banigan v. PharMerica Inc.*, a panel of the First Circuit agreed with the district court that an earlier FCA action involving the same scheme triggered the public disclosure bar, but concluded that the relator was an "original source of the information," and that dismissal was therefore inappropriate.[10] The court explained that, under the version of the public disclosure bar in effect prior to the 2010 amendments to the FCA, an "original source" must have both direct and independent knowledge of the information on which the allegations are based.[11] The defendant argued that the relator's knowledge was indirect because the relator had learned about the scheme from others and had not participated in or observed the scheme directly, but the court rejected this argument. The court stated that the FCA requires direct and independent knowledge only of the information on which allegations are based, not direct and independent knowledge of the fraud. Relators also are not required to have contemporaneous knowledge of the alleged fraudulent scheme, but can uncover it after the fact as long as they have knowledge of the predicate factual basis on which the fraud allegations are based. Therefore, the court remanded the case for further proceedings.

Significant Settlements

There were a handful of notable FCA settlements involving the healthcare industry in 2020. In July 2020, DOJ announced that Novartis agreed to pay $642 million in two separate settlements

resolving claims that it violated the FCA.[12] In the first settlement, Novartis agreed to pay $51 million to resolve allegations that it illegally paid the copayment obligations through charitable foundations for patients taking its drugs Gilenya and Afinitor. In the second settlement, Novartis agreed to pay $591 million to resolve FCA claims that it paid kickbacks to doctors to induce them to prescribe the Novartis drugs Lotrel, Valturna, Starlix, Tekturna, Tekturna HCT, Tekamlo, Diovan, Diovan HCT, Exforge, and Exforge HCT. DOJ alleged that Novartis hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when the events were really just a means to provide bribes to doctors.[13] Novartis paid physicians honoraria, purportedly as compensation for delivering a lecture regarding a Novartis medication, but, as Novartis knew, many of these programs were really just social events held at expensive restaurants, with little or no discussion about the Novartis drugs. Indeed, some of the so-called speaker events never even took place; the speaker was simply paid a fee in order to induce the speaker to prescribe Novartis drugs.

In September 2020, DOJ announced that Gilead Sciences, Inc. (Gilead) agreed to pay $97 million to resolve claims that it violated the FCA by illegally using a foundation with 501(c)(3) status for tax purposes as a conduit to pay the copayments of thousands of Medicare patients taking Gilead's pulmonary arterial hypertension drug, Letairis, and to induce those patients to purchase Letairis. Letairis is approved for the treatment of pulmonary arterial hypertension. DOJ alleged that Gilead used the foundation because it knew that the prices Gilead set for Letairis could otherwise pose a barrier to those purchases. From 2007 through 2010, Gilead made payments to the foundation, which, in turn, used those funds to pay copayments of patients prescribed Letairis. DOJ alleged that Gilead routinely obtained data from the foundation detailing how much the foundation had spent for patients on Letairis; it then used this information to decide how much to pay to the foundation and to confirm that its payments were sufficient to cover the copayments of only patients taking Letairis. DOJ also alleged that, to generate revenue from Medicare and induce purchases of Letairis, Gilead referred Medicare patients to the foundation, which resulted in claims to Medicare to cover the cost of Letairis.

In October 2020, DOJ announced a global settlement of criminal and civil liability with Purdue Pharma (Purdue) and members of the Sackler family related to enabling the distribution of prescription opioids without a legitimate medical purpose.[14] Regarding the civil settlement, Purdue agreed to pay $2.8 billion and the Sackler family agreed to pay $225 million to resolve FCA liability. These resolutions do not include the criminal release of any individuals, including members of the Sackler family, nor are any of the company's executives or employees receiving civil releases. Purdue's settlement resolves allegations that from 2010 to 2018, Purdue caused false

claims to be submitted to federal healthcare programs, specifically Medicare, Medicaid, TRICARE, the Federal Employees Health Benefits Program, and the Indian Health Service. DOJ alleged that Purdue promoted its opioid drugs to healthcare providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion. For the Sacklers, their settlement resolves allegations that, in 2012, particular family members knew that the legitimate market for Purdue's opioids had contracted. Nevertheless, they requested that Purdue executives recapture lost sales and increase Purdue's share of the opioid market. These Sacklers approved a new marketing program beginning in 2013 called "Evolve to Excellence," through which Purdue sales representatives intensified their marketing of OxyContin to extreme, high-volume prescribers who were already writing "25 times as many OxyContin scripts" as their peers, causing healthcare providers to prescribe opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion.[15]

Finally, in December 2020, DOJ announced that TriWest agreed to pay $179 million to resolve claims that it received overpayments from the U.S. Department of Veterans Affairs (VA) in connection with the administration of certain VA healthcare programs.[16] TriWest is responsible for administering certain portions of the VA Patient-Centered Community Care Program (PC3) and the VA's former Veterans Choice Program (Choice). Both programs have enabled veterans to obtain medical care from providers in their communities. As an administrator of these programs, TriWest is paid by the VA to coordinate medical appointments and make payments to healthcare providers. The settlement resolved allegations that TriWest retained overpayments from the VA in connection with its administration of the PC3 and Choice Programs. The alleged overpayments included payments by the VA to TriWest twice for the same services as well as payments for services for which TriWest received full or partial reimbursement from certain healthcare providers.

Trends for 2021

While there were significant developments over 2020, when DOJ released its statistics for the year, they showed that the government recovered $2.2 billion in settlements and judgments, a sharp decline of $900 million from the previous year and a 10-year low.[17] It is difficult to attribute why, but the lower figure may reflect impacts from COVID-19, which closed courts and delayed investigations and cases. What is known, however, from the recently released statistics is that there was a record increase in new FCA cases and investigations initiated in 2020. In that year 922 new cases were opened by the government and qui tam relators combined, with DOJ initiating 250 new cases (a 70 percent jump from 2019 and the most since 1994) and 672 initiated by relators. With

most of these new cases currently in the pipeline, it portends a sharp increase in FCA enforcement/litigation activity this year, which will have significant impacts for those in the healthcare industry.

1 No. 20-581, 2020 WL 7132371 (Dec. 7, 2020).

2 *See, e.g.*, *United States v. Life Care Centers of America*, 114 F. Supp. 3d 549, 560 (E.D. Tenn. 2014).

3 938 F.3d 1278 (11th Cir. 2019). The *Aseracare* decision generated considerable commentary. For more information, *see AseraCare is here! And in our clinical judgment, the Eleventh Circuit is not objectively wrong* (Sept. 19, 2019), https://nicholsliu.com/aseracare-is-here-and-in-our-clinical-judgment-the-eleventh-circuit-is-not-objectively-wrong/.

4 952 F.3d 89 (3rd Cir. 2020).

5 *Id.* at 96 ("A claim can be proven 'false' in two ways: factually, when the facts contained within the claim are untrue, and legally, 'when the claimant falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.'") (ellipsis omitted).

6 *Id.* at 100.

7 953 F.3d 1108 (9th Cir. 2020).

8 *See RollinsNelson LTC Corp. v. United States*, No. 20-805; *Care Alternatives v. United States*, No. 20-371.

9 960 F.3d 836 (6th Cir. 2020). Simply stated, the "public disclosure bar" forbids lawsuits "that merely feed off prior public disclosures of fraud." *Id.* at 843. Therefore, once a fraudulent scheme is exposed, an opportunistic relator cannot use the public information to file a follow-on, parasitic action.

10 950 F.3d 134 (1st Cir. 2020).

11 *See id.* at 136. The court explained that the "public disclosure bar was jurisdictional in nature until the FCA was amended through the Patient Protection and Affordable Care Act of 2010 ("PPACA")." *Id.* The PPACA amendments revised "the prior language of the provision, which provided that 'no court shall have jurisdiction over an action' that is based on a prior public disclosure, 31 U.S.C. § 3730(e)(4)(A) (2006), with a mandate that courts 'shall dismiss' such an

action." *Id.* (citing Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, at 901 (2010)).

12 U.S. Dep't of Justice, Office of Public Affairs, *Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians* (July 1, 2020), https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.

13 *Id.* (stating "In a case pending in the Southern District of New York, the United States alleged that Novartis hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when in fact the events served as nothing more than a means to provide bribes to doctors."); *see* 7/1/20 Order, *United States ex. rel. Bilotta v. Novartis Pharm. Corp.*, No. 1:11-cv-00071 (S.D.N.Y.).

14 Because the settlement was not final by the time fiscal year 2020 (FY2020) ended, the settlement amounts are excluded from DOJ's statistics for FY2020. Members of the Sackler family own Purdue Pharma.

15 U.S. Dep't of Justice, Office of Public Affairs, *Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family* (Oct. 21, 2020), https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.

16 U.S. Dep't of Justice, Office of Public Affairs, *TriWest Healthcare Alliance Corp. Agrees to Pay $179.7 Million to Resolve Overpayments from the Department of Veterans Affairs* (Dec. 31, 2020), https://www.justice.gov/opa/pr/triwest-healthcare-alliance-corp-agrees-pay-1797-million-resolve-overpayments-department.

17 As noted above, this total can be seen as an undercount because it excludes the non-final Purdue/Sackler settlements.

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