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# The top healthcare FCA developments of 2020

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Just as with all other aspects of life, the COVID-19 global pandemic had a dramatic effect on False Claims Act (FCA) enforcement in 2020. Whether it was the driving factor behind the formation of COVID-19 fraud task forces in US attorneys' offices across the country or the reason that the Department of Justice (DOJ) investigations stalled for months, the heavy foot of COVID-19 left a sizable imprint on the FCA landscape. Nevertheless, the FCA and its warriors soldiered on with key developments, including several large-dollar settlements and significant rulings from courts across the country. This article highlights these and other top FCA developments in the healthcare space and looks ahead to what is in store for providers and payers in 2021.

## Recovery statistics

On January 14, 2021, DOJ announced that the government had recovered more than $2.2 billion in settlements and judgments in fiscal year (FY) 2020.[1] This amount marked a significant drop from the prior FY, in which more than $3 billion was recovered.[2] More than $1.6 billion of the recovered money in FY 2020 came from qui tam cases, with relators receiving $309 million for their efforts.[3] Although the government's total haul was significantly lower than in previous years, the number of new qui tams filed remained stable, with a small increase from 633 qui tams in FY 2019[4] to 672 new qui tams in FY 2020.[5] Consistent with prior years, healthcare-related settlements and judgments made up the majority of the recoveries—$1.8 billion out of the total $2.2 billion.

Two culprits in particular are to blame for the bulk of the 27% drop in DOJ's recoveries from 2019 through 2020. The elephant in the room was the COVID-19 pandemic. In short, like many Americans, DOJ's civil and criminal fraud sections were forced into a three-month hiatus wherein investigations were halted by the inability to conduct interviews or document collections, and litigations were stopped in their tracks by court closures. The hippopotamus in the room (of similar size, but slightly quieter) is DOJ's pending settlement with Purdue Pharma, a resolution that was reached in October that provides the United States with a delayed $2.8 billion claim in bankruptcy.[6] A payment of some or all of that money would more than eclipse the $800 million drop in recoveries for 2020.

## Notable healthcare settlements

Rigorous enforcement of the Anti-Kickback Statute (AKS) culminated in some of DOJ's largest healthcare settlements for 2020. First and foremost was the $591 million that Novartis paid to resolve claims that its sales department paid sham speaker fees to high-volume prescribers in order to induce them to write Novartis prescriptions.[7] DOJ was not done with Novartis, as the pharmaceutical company also agreed to pay an additional $51 million to resolve allegations that it used a charitable foundation to funnel kickback payments to

cover Medicare copays for Novartis drugs. Likewise, Gilead Sciences cut a $97 million check to resolve claims that it used a charitable foundation as a conduit to pay patient copays for its drug Letairis.[8]

Other significant settlements related to alleged kickback schemes included: (1) a $145 million settlement with Practice Fusion, a health information technology developer that received kickbacks in exchange for designing its software to increase OxyContin prescriptions;[9] and (2) the Oklahoma Center for Orthopaedic and Multi-Specialty Surgery paying a $72 million settlement to resolve allegations that it paid for patient referrals.[10] All told, according to our calculations, targets of AKS investigations paid more than $1.2 billion in settlements in 2020, a total that represents more than 54% of all the money DOJ recovered.

Another significant source of recovery revenue for DOJ came from medical providers that billed for allegedly medically unnecessary services. For instance, Universal Health Services entered into a $117 million settlement with DOJ to resolve claims that its inpatient and residential behavioral treatment facilities provided medically unnecessary services and/or failed to provide adequate services at all.[11] Similarly, Logan Laboratories Inc. and its former executives paid $41 million to resolve claims that they presumptively ordered extensive panels of drug tests for all of their patients at every visit without regard for the medical utility of those tests.[12]

As in years past, DOJ cast a wide net with its theories of liability in 2020. For instance, DOJ went back to an old favorite, the off-label marketing of drugs, in its pursuit of DUSA Pharmaceuticals, which resulted in a $20.75 million settlement.[13] DOJ played another blast from the recent past when it recovered more than a combined $50 million from Longwood Management Corporation,[14] Diversicare Health Services,[15] Guardian Elder Care Holdings,[16] and Saber Healthcare Group LLC[17] related to allegations that the four companies' skilled nursing facilities boosted revenues by upcoding therapy patients into the "Ultra High" category.

## Statute of limitations decisions

Much of the FCA action in 2020 occurred not in boardrooms but in courthouses. For instance, district courts in 2020 were eager to address the application of the FCA's statute of limitations provisions following the Supreme Court's ruling in *Cochise Consultancy, Inc. v. United States ex rel. Hunt*.[18]

In one such example, the U.S. District Court for the Eastern District of Texas denied a motion to dismiss a qui tam complaint under a straightforward application of the *Cochise* decision.[19] In that case, defendants argued that even if the three-year period in section (b)(2) of *Cochise* applied to nonintervened cases, relators were required to raise concerns with the government prior to filing the initial complaint in order to take advantage of the expanded statute of limitations provided by subsection (b)(2). The court rejected this argument under *Cochise*, which made clear that subsection 3731(b)(2) "applies in non-intervened actions."

In *United States ex rel. Wood v. Allergan, Inc.*,[20] the U.S. District Court for the Southern District of New York granted defendant's motion to dismiss finding that the relator's FCA claims were time barred. The relator had alleged that defendant had violated the FCA through a kickback scheme from 2003 through 2011. Relator originally filed a qui tam complaint in 2010, which was ultimately dismissed under the first-to-file bar. Relator filed another complaint against defendant in 2019, which defendant moved to dismiss as untimely. Relator argued that although on its face 31 U.S.C. § 3731(b) barred his FCA claims, those same claims should be subject to "equitable tolling." The district court found that even if the limitations periods in 31 U.S.C. § 3731(b) were subject to equitable tolling, relator could not establish that he had been pursuing his rights diligently and that the first-to-file rule was not an "extraordinary circumstance."

In *United States ex rel. Goodman v. Arriva Med., LLC,*[21] the district court declined to dismiss an FCA complaint on a motion to dismiss holding that the timeliness issue was a plausibly contestable issue of fact. The court acknowledged defendants' "legitimate concerns about…how long it took the Government to uncover [defendants'] involvement"; however, the court could not "jump to the conclusion that the amount of time it took to become aware of [defendants] was unreasonable."

## False claims civil actions dismissal decisions

In 2018, then-director of DOJ's Commercial Litigation Branch's Fraud Section Michael Granston authored a memo outlining the seven factors the government would assess before exercising its authority to dismiss cases under 31 U.S.C. § 3730(c)(2)(A) .[22] Although it may have taken a little longer than two years, the government began to flex its dismissal muscles in 2020, resulting in a widening circuit split over just how broad that authority is.

In *United States v. Academy Mortgage Corporation,*[23] a relator brought a qui tam action alleging that a mortgage lender certified loans for Federal Housing Administration insurance even though the loans failed to meet certain federal requirements. The government declined to intervene in the suit and then filed a motion seeking dismissal of the action under 31 U.S.C. § 3730(c)(2)(A).

The district court denied the government's motion to dismiss after applying the burden-shifting test of *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, which requires the government first to identify a "valid government purpose" and then show "a rational relation between dismissal and accomplishment of the purpose."[24] On appeal, the Ninth Circuit determined that it did not have jurisdiction to review the denial of dismissal where there had been no final ruling and where the collateral order doctrine did not apply.

Just two weeks later, this same issue came to a head in the Seventh Circuit. In *United States v. UCB, Inc.,*[25] the relator alleged that a pharmaceutical company illegally provided kickbacks to physicians for prescribing certain prescription drugs. The government intervened and moved to dismiss under 31 U.S.C. § 3730(c)(2)(A) . The government urged the court to apply the dismissal standard announced in *Swift v. United States,*[26] which gives the government "unfettered" discretion to dismiss, while the relator argued for the more demanding burden-shifting test of *Sequoia Orange*. The district court applied the *Sequoia Orange* test and determined that dismissal was arbitrary and capricious, rejecting the motion. The Seventh Circuit reversed the district court's denial. However, instead of picking between the *Swift* or *Sequoia Orange* standards, the Seventh Circuit determined that the government had supported its motion to dismiss the complaint in light of Fed. R. Civ. P. 41(a)(1)(B).

Similarly, in *United States ex rel. Brutus Trading, LLC v. Standard Chartered Bank,*[27] a district court determined that it need not opine on which test should apply, because on the current motion, the government had met the burden of the more demanding *Sequoia Orange* test.

## Materiality decisions

For the past four years, following the Supreme Court's decision in *Universal Health Services., Inc. v. United States ex rel. Escobar,*[28] the FCA's materiality requirement has been the primary battlefront of FCA litigation. Although the fighting at the front was somewhat subdued in 2020, two circuit courts entered the fray.

In *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center, Inc.,*[29] the Ninth Circuit reversed a lower court's dismissal of an FCA case alleging that defendant had exerted pressure on its physicians to disregard its own admission criteria and thereby admit patients based on false certifications of medical necessity. The

district court reasoned that it was immaterial whether defendant followed its admission criteria because "[t]here is no mention of the InterQual criteria in any of the relevant statutes or regulations." However, the Ninth Circuit found that a false certification of medical necessity is not an "insignificant regulatory or contractual violation" and concluded that a false certification of medical necessity can be material because medical necessity is a statutory prerequisite to Medicare reimbursement.

In *United States ex rel. Janssen v. Lawrence Memorial Hospital*,[30] the Tenth Circuit affirmed summary judgment for defendant after relator failed to establish materiality. Relator had alleged that defendant: (1) falsified patients' arrival times to increase Medicare reimbursement and (2) falsely certified compliance with the Deficit Reduction Act's requirements to train its employees on the FCA. The Tenth Circuit first determined that the materiality analysis must consider the recipient of the misrepresentation just as the Supreme Court in *Escobar* focused on the likely reaction of the recipient, which included both subjective and objective analysis. Here, the government's inaction against the defendant despite awareness of the "detailed allegations from a former employee" demonstrated that the alleged misconduct was immaterial. The court next found that defendant's alleged misconduct was "minor or insubstantial" and did not go to the "essence of the bargain," especially in light of the "complex matrix of Medicare reporting and reimbursement."

## Falsity decisions

In 2020, two courts in the Ninth Circuit grappled with and then veered away from the Eleventh Circuit's decision in *United States v. AseraCare, Inc.*[31] First, the Ninth Circuit in *Winter* rejected the district court's requirement that relators must allege objective falsity and concluded that "[a] physician's certification that inpatient hospitalization was 'medically necessary' can be false or fraudulent for the same reasons any opinion can be false or fraudulent."[32] The Ninth Circuit specified that its decision did not conflict with *AseraCare* by reasoning that the Eleventh Circuit did not consider whether a medical opinion could ever be false or fraudulent, but whether a reasonable disagreement between physicians *without more* was sufficient to prove falsity at summary judgment.

Piggybacking off of the *Winter* decision, the U.S. District Court for the District of Arizona also weighed in on the falsity debate. In *United States ex rel. Scott v. Arizona Ctr. for Hematology & Oncology PLC*,[33] the district court denied the defendants' motion for summary judgment as to falsity. The district court distinguished this case from *AseraCare* by observing that relator did not rely solely on the difference of opinion of the medical experts, but also presented evidence that a 2013 audit of defendants' medical practice—by auditors selected by defendants themselves—found that certain billing practices were improper. This conflicting evidence, distinct from the parties' expert analyses, was sufficient to create a question of fact that had to be resolved by the jury.

## Knowledge/scienter decisions

Falsity's kissing cousin, scienter, was also a focus of several courts in 2020. More often than not, district courts incorrectly conflated falsity with scienter, leaving the circuit courts to clean up the mess.

For instance, in *United States ex rel. Druding v. Care Alternatives*,[34] relators brought a qui tam action alleging that defendant routinely admitted and recertified inappropriate patients for hospice care. The district court granted summary judgment to the defendants, reasoning that a mere disagreement among experts as to necessity of care could not establish that the admitting physicians' clinical judgments were objectively false. The Third Circuit reversed and explained that the district court's "objective" falsity standard improperly conflated the separate elements of scienter and falsity. The Third Circuit clarified that a claim based on a medical conclusion regarding a patient's care could be deemed "legally false" if the claim did not conform to certain regulatory requirements.

While this decision centered on the falsity element, the Third Circuit importantly recognized that the scienter element "helps to limit the possibility that…providers would be exposed to liability under the FCA any time the Government could find an expert who disagreed with [a] certifying physician's medical prognosis."

Revisiting the *Winter* decision once again,[35] after ruling that an FCA claim based on an alleged lack of medical necessity may be sufficient to survive a motion to dismiss, the Ninth Circuit noted that the district court had wrongly conflated the separate elements of scienter and falsity. Like the court in *Druding*, the Ninth Circuit emphasized that while an opinion may be "scientifically untrue" and therefore false, it is not actionable unless it was made with the requisite intent, and an opinion with no basis in fact can be fraudulent if expressed with scienter. The court also cautioned that, at least at the pleadings stage, scienter may be "alleged generally" under Fed. R. Civ. P. 9(b), that "specific intent to defraud" is not required under the FCA, and that a "complaint needs only to allege facts supporting a plausible inference of scienter."[36]

Not falling into the falsity/scienter conflation trap, the Fifth Circuit tackled the issue of scienter head-on in *United States ex rel. Drummond v. BestCare Laboratory Services, LLC*.[37] In this case, the government alleged that defendant submitted false claims for travel reimbursements when lab samples were actually shipped, and defendants failed to prorate mileage. On appeal, the defendants did not contest that they had engaged in the alleged conduct; rather, they argued that they did not act with the requisite scienter, because they had a "good faith" belief the practices were lawful based on their interpretation of subregulatory guidance. The Fifth Circuit rejected this argument and explained that the guidance at issue made it clear there was "no way to read the Manual to suggest" defendants' practices of billing for miles "not actually traveled by anyone" were lawful.