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Health Care Enforcement Quarterly Roundup | Q1 2019

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INTRODUCTION

In this first installment of the *Health Care Enforcement Quarterly Roundup* for 2019, we continue to monitor trends we identified in 2018 and introduce new enforcement efforts that are expected to persist in the coming year. In this *Roundup*, we focus on increased enforcement activity against electronic health record (EHR) companies, enforcement against individuals (with an acute focus on the telemedicine industry), lower court interpretations of the landmark *Escobar*ruling, developments related to the Granston Memo and dismissal of False Claims Act (FCA) cases, potential changes to the FCA statute of limitations, and the current state of affairs in opioid litigations around the country.

Potential Changes To The FCA Statute Of Limitations

On March 19, 2019, the Supreme Court of the United States heard argument in C*ochise Consultancy Inc., et al v. United States ex rel. Hunt*[1], a case that may have significant ramifications for FCA litigants across the United States. *Cochise* addresses two issues: (1) whether relators may take advantage of the equitable tolling provision when facts are discovered after the FCA's standard six-year statute of limitations has expired; and (2) if so, whether the timing of the relator's discovery of the facts or the government's discovery controls.

The FCA provides that "[a] civil action under section 3730 may not be brought—

1. more than 6 years after the date on which the violation of section 3729 is committed, or
2. more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on

which the violation is committed, whichever occurs last."[2]

31 USC § 3731(b). The word "relator" is not included in either subsection. The Supreme Court will soon decide whether relators can avail themselves of subsection 2 to allow the filing of a complaint beyond the six-year period found in subsection 1.

The facts in the *Cochise* case are unique. In 2006, the US Department of Defense awarded the Parsons Corporation a $60 million contract to perform munitions cleanup in Iraq, with a caveat that Parsons must provide adequate security for its employees performing the cleanup. After soliciting bids for a security services subcontract, Parsons eventually awarded the subcontract to Cochise. The relator in the action alleged that an Army Corp of Engineers contracting officer accepted bribes from Cochise in exchange for the award of the subcontract. For several months in 2006, Cochise provided the security services required under the subcontract, resulting in the government allegedly paying Cochise at least $1 million more per month than it would have had the subcontract gone to another bidder. The alleged fraud came to the Federal Bureau of Investigation's (FBI) attention in 2010 when it interviewed the relator about his role in an unrelated kickback scheme for which the relator ultimately served 10 months in prison. Once he was released in 2013, the relator filed a qui tam action under seal alleging that Parsons and Cochise had violated the FCA. Of course, the relator filed suit beyond the six-year statute of limitations provided in Section 3731(b)(1), but within the window provided by the equitable tolling clause in Section 3731(b)(2), should it apply.

The government declined to intervene in the relator's action. The complaint was unsealed, and the contractors moved to dismiss, arguing that the claim was time-barred. According to the contactor, the relator could not avail himself of equitable tolling because the government had declined to intervene and the relator had known of the alleged fraud since 2006. The district court granted the motion to dismiss, but the US Court of Appeals for the Eleventh Circuit reversed, holding that when the relator learns of the fraud is immaterial as long as the relator sues within three years *after* the Government learns of the alleged fraud, even if relator knew about it years beforehand.

Previously, the Fourth and Tenth Circuits had held that a relator cannot benefit from the equitable tolling under Section 3731(b)(2) when the government declines to intervene. Although the Ninth Circuit has held that a relator may trigger the subsection, the time for equitable tolling begins when material facts are known (or should have been known) by either the relator *or* the government.

If the Supreme Court were to accept the relator's argument here, the result would be an increased discovery burden on both plaintiffs and defendants, alike. As Cochise pointed out at argument: "[t]en years . . . is a lifetime when we're talking about litigation," and memories fade and evidence is lost as time goes on. The expanded timeframe may not lead to more recoveries (the success rate for non-intervened cases is around 10 percent), but health care providers should nonetheless evaluate their data retention policies in light of an expected increase in discovery burden.

Practice Note: As we look towards the Supreme Court's decision in *Cochise*, another potential consequence for companies to consider is increased leverage in the hands of relators. Although though the success rate for non-intervened cases is low, a relator's ability to allege damages dating back 10 years, then treble them, will put significant financial pressure on *qui tam* defendants when these cases are filed.

Developments Related To The Granston Memo

Previous issues have covered the Granston Memo, which reiterates DOJ's long-standing authority

under 31 USC § 3730(c)(2)(A) to dismiss *qui tam* FCA lawsuits. The authority had been rarely used, and the Granston Memo was a significant development because it provided detailed guidance on when DOJ might seek to dismiss non-intervened cases and suggested that DOJ might exercise that authority with greater frequency. The Granston Memo highlights the "gatekeeper role" that DOJ must play with respect to FCA litigation and outlines seven considerations in evaluating whether to seek dismissal of a non-intervened case:

- Curbing meritless *qui tams*;
- Preventing parasitic or opportunistic *qui tam* actions;
- Preventing interference with agency policies and procedures;
- Controlling litigation brought on behalf of the United States;
- Safeguarding classified information and national security interests;
- Preserving government resources; and
- Addressing egregious procedural errors.

Following the issuance of the Granston Memo, DOJ sought to dismiss more than a dozen *qui tam* FCA lawsuits.

Over the past several months, we have been closely following how the longstanding circuit split on how motions under 31 USC § 3730(c)(2)(A) should be handled is playing out in the current round of DOJ dismissal motions. The US Court of Appeals for the DC Circuit has held that the government has "an unfettered right to dismiss an action," and that the government's judgment to dismiss an action is "unreviewable."[3] The US Court of Appeals for the Ninth Circuit, however, has adopted a "two-step analysis . . . to test the [government's] justification for dismissal: (1) identification of a valid government purpose; and (2) a rational relation between dismissal and accomplishment of the purpose. If the United States satisfies the two-step test, the burden switches to the relator to demonstrate that the dismissal is fraudulent, arbitrary and capricious, or illegal."[4]

Since the issuance of the Granston Memo and DOJ's motions to dismiss of non-intervened FCA litigation, courts have been wrestling with the proper standard in reviewing the government's motion to dismiss. Many courts have reviewed the motion under both the *Swift*/DC Circuit approach and the *Sequoia Orange*/Ninth Circuit ("valid purpose" or "rational relationship") approach before concluding that the action should be dismissed under either approach.[5] Yet others have simply followed the law of their circuit and furthered the *Sequoia Orange* and *Swift* tests.[6]

The US District Court for the Eastern District of Pennsylvania recently decided a motion under 31 USC § 3730(c)(2)(A) in *EMD Serono*, one of the cases brought by National Health Care Analytics involving alleged "white coat marketing" in the pharmaceutical industry.[7] Acknowledging that the US Court of Appeals for the Third Circuit had not addressed the proper standard under this statute for dismissal, the court determined that the Ninth Circuit's reasoning in the *Sequoia Orange* rational relationship test was more persuasive. The court reasoned that because Section 3730(c)(2)(A) mandates a hearing before a court may dismiss a *qui tam* action over a relator's objection, the hearing would be superfluous if the government's right to dismiss was "unfettered." The district court

determined that requiring the executive branch to "provide some justification, no matter how insubstantial, for a decision not to pursue a false claim, acts as a check against the Executive from absolving a fraudster on a whim or for some illegitimate reason. It prevents the Executive from abusing power." In *EMD Serono*, the district court determined that the government's legitimate interest in avoiding litigation costs in a case that lacks sufficient factual and legal support satisfied the rational relationship test. Thus, the burden shifted to demonstrate that the dismissal was fraudulent, arbitrary and capricious, or illegal.[8] Relator claimed that the government did not do its due diligence in investigating the case to understand the merits and that the government's real reason for moving to dismiss was its dislike of the corporate relator. The court concluded that the relator failed to show that the government's decision was arbitrary and capricious citing the many investigative steps taken by DOJ and other federal agencies.[9]

The US District Court for the Southern District of Illinois followed the *Sequoia Orange* rational relationship test in *United States ex rel. CIMZNHCA v. UCB, Inc*.[10] In this case, however, the Court denied the government's motion to dismiss. The court noted that Section 3730(c)(2)(A) does not create "a particular standard for dismissal" and that courts are split regarding the appropriate standard to apply.[11] The court rejected the government's argument that dismissal was rationally related to a legitimate interest in avoiding the expense of substantial resources to litigate a case it believes to be without merit and contrary to the "policy prerogatives of the federal government's healthcare programs."[12] The court explained that for the government to have a valid purpose and a rational relationship between it and the dismissal, the government's decision to dismiss must be based on a "minimally adequate investigation, including a meaningful cost-benefit analysis." The court agreed that the government had failed to conduct an adequate investigation because it (1) failed to fully investigate the allegations against the specific defendants, and (2) did not conduct a meaningful cost-benefit analysis to support its concerns, including an assessment of the potential proceeds from the lawsuit. Finally, the court rejected the government's argument that there was a rational relationship between the government's expressed policy interest in healthcare fraud enforcement and the dismissal of the case, calling its arguments "curious at best," given that the allegations centered on in-kind remuneration, which the court described as a "classic violation of the [Anti-Kickback Statute]."

Enforcement Activity Against Individuals

Nearly every edition of the *Quarterly Roundup* has discussed some aspect of the Yates Memo and the changing landscape surrounding DOJ's policy on individual accountability. Most recently, we discussed Deputy Attorney General Rod Rosenstein's November 29, 2018, announcement of policy changes that significantly reduce companies' disclosure requirements and provide some level of credit for "meaningful assistance." This policy announcement may have raised more questions than it answered, however.

Yates Memorandum and Cooperation Credit

Deputy Associate Attorney General Stephen Cox addressed several of these questions in January 2019 while providing keynote remarks at the Advanced Forum on False Claims and *Qui Tam* Enforcement.[13] Cox acknowledged that "[m]uch ink has been spilled about the [2018] changes" but that interested parties should "stay tuned on this front." Cox primarily focused on the award of cooperation credit in civil cases, stating that DOJ no longer takes an "all or nothing" approach. Although companies must still identify all responsible individuals if they want to receive maximum credit, DOJ now has "significant discretion" to offer credit when companies honestly and "meaningfully assist the government's investigation." Cox emphasized this new discretion several

times and provided a range of tactics companies can use to obtain a more favorable resolution, including voluntary disclosure, sharing information from internal investigations, and making witnesses available.

Cox also focused on the establishment of compliance programs, stating on several occasions that DOJ "will reward companies that invest in strong compliance measures." The speech emphasized that the existence of an "effective and robust" compliance program could mean the difference between a "mistake" and a "knowing violation." Cox even went so far as to say that compliance programs could mean the difference between an FCA action and alternative remedies. Although these statements do not completely explain DOJ's current stance on cooperation credit and individual accountability, they do provide some much-needed clarity. It appears that moving forward DOJ will take a more relaxed approach to cooperation credit and will reward companies that have protections in place. Unfortunately, it appears that healthcare entities must continue to wait for real answers to many of the other questions raised by DOJ's November 2018 announcement.

Continued Individual Prosecution

Despite this more relaxed approach to cooperation credit, individual accountability remains a top priority in 2019, in accordance with prior DOJ statements. In April 2019, a South Florida health care facility owner was found guilty for his involvement with the "largest health care fraud scheme ever charged by the DOJ."[14] The facility owner perpetrated the almost 20-year-long fraud scheme by bribing doctors to admit patients to nursing and assisted living facilities, where the patients then received inadequate or unnecessary treatments. The facility owner additionally bribed state regulators and even college officials in exchange for admission. Though the defendant-facility owner has yet to be sentenced, the co-conspirators were given significant jail time and monetary punishments. Although this is just one case, it represents the DOJ's continued focus on individual accountability in 2019.

Acute Focus on Telemedicine

DOJ's on individual accountability is particularly important with respect to telemedicine. Telemedicine is a burgeoning field, with a projected market increase of 18 percent annually over the next six years, reaching $103 billion in 2024.[15] In light of this recent surge in profitability, DOJ has begun paying extra attention to telemedicine, with at least one recent HHS-OIG report asserting that more than one-third of all telemedicine claims are improper.

The report's claim is further supported by a recent increase in telemedicine prosecutions. In April 2019, DOJ announced charges against 24 defendants, including owners of various telemedicine companies, for their alleged involvement in a health care fraud scheme resulting in $1.2 billion in loss.[16] This scheme involved the payment of kickbacks and bribes by durable medical equipment (DME) companies to medical professionals working with telemedicine companies, in exchange for the referral of Medicare beneficiaries. DOJ alleges that the defendants paid doctors to prescribe medically unnecessary DME without ever seeing patients or after only a brief telephone conversation. The prosecution involves charges in at least seven districts across the United States, including New Jersey, Florida, Texas, Pennsylvania, and California. Additionally, DOJ prosecuted several other individuals in connection with unrelated telemedicine schemes in late 2018.[17] In light of this recent trend, companies should exercise extreme caution and consult with regulatory experts prior to opening telemedicine practices. Companies can expect to see increased scrutiny and further prosecution of telemedicine companies moving forward.

Practice Note: DOJ has recently re-emphasized its willingness to exercise significant discretion and reward companies that invest in strong compliance programs. Looking forward, health care companies should maintain detailed and up-to-date documentation of all compliance programs, in case such an FCA case should arise. A lawyer should be consulted if an updated compliance program is needed.

Increased FCA Enforcement Against EHR Companies

The federal government has offered substantial incentives to providers to adopt and use certified electronic health record (EHR) technology. As of October 2018, the federal government had paid over $38 billion in EHR incentive payments through the Promoting Interoperability Program (formerly, the Meaningful Use Program).[18] Other federal health care program policies also encourage use of certified EHR technology through enhanced payments or avoidance of decreased reimbursement. These EHR-related payment policies, however, have triggered increased oversight and enforcement attention on EHR vendors who have allegedly misrepresented the capabilities of their EHR software and allegedly paid kickbacks to customers.

In 2017, DOJ announced a settlement with eClinicalWorks (eCW), an EHR vendor, to resolve an FCA lawsuit originally brought as a *qui tam* action by a whistleblower.[19] DOJ's complaint-in-intervention alleged that eCW made material false statements and concealed material facts about the capabilities of its software in connection with the government's EHR certification process.[20] It also alleged that eCW paid purported kickbacks in connection with certain marketing arrangements (*i.e.*, a referral program, site visit program, and a reference program) with influential customers to induce them to recommend eCW's EHR software, in violation of the federal Anti-Kickback Statute (AKS).[21]

As part of the settlement, eCW agreed to pay $155 million and to enter into a novel, five-year Corporate Integrity Agreement (CIA) with the HHS OIG.[22] Among other things, the CIA required eCW to engage an independent Software Quality Oversight Organization to assess eCW's software quality control systems and to regularly report to OIG and eCW on its reviews and recommendations.[23] Further, the CIA required eCW to offer free upgrades and data transfers to its current customers.[24] This was a ground-breaking settlement that raised the question of whether this was the beginning of government and whistleblower attention on (and FCA actions against) EHR vendors. This question was seemingly answered in the affirmative when DOJ announced a second settlement with an EHR vendor in early 2019.

On February 6, 2019, EHR vendor Greenway Health LLC (Greenway) entered into a similar settlement to resolve an FCA case filed by the US Attorney's Office in Vermont. Interestingly, a whistleblower did not initiate the Greenway case. Rather, DOJ pursued it directly.[25] Like eCW, Greenway faced allegations that its EHR system did not function in the way it represented it during the certification process.[26] One specific allegation was that Greenway provided some customers whose EHR software was improperly calculating certain meaningful use measures (which providers are required to achieve to be eligible for incentive payments) with incorrect calculations in order to enable them to receive incentive payments.[27] According to DOJ, this allegedly caused some Greenway customers to submit false claims to HHS for payment under the Promoting Interoperability Program.

Like in the eCW case, the government complaint against Greenway also alleged that certain payments from Greenway to its customers pursuant to certain reference, referral, and site visit programs violated the AKS.[28] Additionally, the government accused Greenway of giving its favored

customers extravagant gifts, including “iPads, meals, travel, tickets to sporting events and entertainment, all for the purpose of inducing these users to either continue using Greenway’s products or recommend Greenway to other health care providers . . . .”[29] To resolve these allegations, Greenway agreed to pay $57.25 million, and to enter into an eCW-like CIA.[30]

Practice Note: While many questions remain, including whether a court would agree with DOJ that the AKS applies to these situations, we expect to see continued government and relator scrutiny of EHR vendors. In light of this continued focus, EHR vendors should ensure that they: (1) take care to accurately and transparently demonstrate their software during HIT certification program testing; (2) review, and consider improvements to, their systems and other procedures for identifying, responding to and correcting software design and quality issues that call into question EHR software’s conformity to applicable EHR certification criteria or present patient safety or clinician usability risks; and (3) review existing customer reference, referral and marketing arrangements for compliance with the Anti-Kickback Statute.

State Of Affairs In Opioid Litigation

The federal government continues to seek out novel legal strategies in tackling the opioid epidemic, including continued expansion of its coordinated effort by the Prescription Interdiction & Litigation (PIL) Task Force to deploy criminal, civil, and regulatory tools to combat the opioid epidemic. In February 2019, DOJ unsealed its FCA and Controlled Substances Act complaint in *United States c. Oakley Pharmacy, et al*[31] and obtained a temporary restraining order (TRO) against two pharmacies, their owner, and three pharmacists. The government’s complaint alleges that the pharmacies and pharmacists filled prescriptions for controlled substances outside of the normal course of professional practice and in violation of the pharmacists’ corresponding obligation to ensure that prescriptions are issued to patients for a legitimate medical purpose. The complaint further alleges that the defendants dispensed controlled substances despite various “red flags” of diversion and abuse (*e.g.*, unusually high dosages of oxycodone and other opioids, dangerous combinations of opioid prescriptions with other controlled substances, and patients travelling long distances to get and fill prescriptions). The complaint also includes allegations that the pharmacies falsely billed Medicare for illegally dispensed prescriptions. The TRO—which prevented the parties from dispensing controlled substances, including opioids—was converted to a preliminary injunction (PI) on March 8, 2019, extending the terms indefinitely.[32] Several defendants have agreed to accept the terms of the PI, but others have not, leading the Court to schedule a hearing on the PI for June 12, 2019.[33] While DOJ has previously obtained TROs and a PIs against physicians for prescribing opioids upon filing a complaint, this is the first case in which the agency has taken this combination complaint and TRO action against a pharmacy and pharmacists. An example of the PIL Task Force in action, the additional conversion of the TRO to a PI adds to the unique nature of this enforcement action.

On April 10, 2019, the Court in the I*n re National Prescription Opiate* multi-district litigation (MDL) in the Northern District of Ohio—involving more than 1,600 opioid-related cases—indicated that it will not permit any further delays in a bellwether trial involving two plaintiff Ohio counties, Cuyahoga and Summit, set to begin on October 21, 2019.[34] The defendant drug manufacturers, distributors, and pharmacies had argued in an emergency motion that the court’s case management order did not allow sufficient time to complete expert depositions. In its order, the court noted that plaintiffs had identified 24 experts and defendants had identified 98 experts. The order went on to note that if plaintiffs were to present testimony from 24 experts, “no jury will be able to follow the evidence, let alone find in their favor.” With regard to defendants’ 90-plus experts, the court noted its belief that “any jury will reject their arguments,” and further noted that neither plaintiffs nor defendants would be

able to call even a fraction of the witnesses in the time allotted for the trial. Accordingly, the court ordered the parties to identify 10 experts each to be made available for two days of deposition testimony; additional experts were ordered to be made available for a single day of testimony. The court's rejection of the defendants' emergency motion makes clear that Judge Dan Polster will not easily be swayed from seeing the bellwether cases go to trial this year.

Judge Polster has consistently encouraged the parties to seek a global settlement that would not only address the monetary issues in the case, but also address the underlying opioid crisis by reducing the quantity of pills in circulation and helping to ensure that the pills that are manufactured are used for legitimate purposes.[35] He has previously noted that "everyone shares some of the responsibility, and no one has done enough to abate it . . . include[ing] the manufacturers, the distributors, the pharmacies, the doctors, the federal government and state government, local governments, hospitals, third-party payers and individuals." By pushing the parties towards commencement of the first bellwether trial on October 21, 2019, the pressure to reach such a global settlement may be increased.

The criminal prosecutions of individuals from companies involved in the production, distribution, and sale of opioids also continues. The closely watched racketeering prosecution against Insys Therapeutics' former CEO and other executives is currently being deliberated by the jury in District of Massachusetts.[36]

Just last week, on April 17, 2019, DOJ announced charges against 60 individuals, including dozens of medical professionals, in a massive case involving more than 350 thousand prescriptions for controlled substances and more than 32 million pills.[37] The Appalachian Regional Prescription Opioid (ARPO) Strike Force enforcement action spans 11 federal districts in seven states and, notably, includes 31 physicians, seven pharmacists, eight nurse practitioners, and seven other licensed medical professionals. The alleged conduct includes illegal prescription and distribution of opioids and other dangerous narcotics and other health care fraud schemes.

Concurrent with DOJ's announcement of this prosecution, HHS announced that, since June 2018, it has excluded more than 2,000 individuals from participation in Federal health care programs, including more than 650 providers excluded for conduct related to opioid diversion and abuse. The US Drug Enforcement Agency (DEA) also announced that, since July 2017, it has issued 31 immediate suspension orders and 129 orders to show cause, and has received 1,386 surrenders for cause for violations of the Controlled Substances Act.

Both Attorney General William Barr and HHS Secretary Alex Azar reinforced the Trump Administration's prerogative to combat the opioid crisis head-on. Attorney General Barr noted that "[t]he opioid epidemic is the deadliest drug crisis in American history, and Appalachia has suffered the consequences more than perhaps any other region." Secretary Azar stated that "[r]educing the illicit supply of opioids is a crucial element of President Trump's plan to end this public health crisis . . . It is also vital that Americans struggling with addiction have access to treatment and that patients who need pain treatment do not see their care disrupted, which is why federal and local public health authorities have coordinated to ensure these needs are met in the wake of this enforcement operation." The ARPO Strike Force operates in Alabama, Kentucky, Ohio, Pennsylvania, Tennessee, West Virginia, and, as recently announced, in Virginia.

Practice Note: The first months of 2019 have seen several significant developments in opioid-related lawsuits and enforcement around the United States. From the closely watched Ohio MDL to cases in several other states against companies and individuals—including the continued enforcement activity

of the PIL Task Force and ARPO Strike Force—the pressure on manufacturers, suppliers, dispensers, and prescribers will remain a top enforcement priority for federal and state law enforcement agencies.

Continued Interpretations Of The Escobar Ruling

The Supreme Court's important ruling in *United Health Services, Inc. v. United States ex rel. Escobar*,[38] has resulted in various interpretations as the courts wrestle with the application of the Supreme Court's two-part test for implied certification and its "demanding" and "rigorous" standard for establishing materiality.[39] The Court held that implied certification may be a basis for liability in FCA cases "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual provisions makes those representations misleading half-truths."[40]

In the years since this ruling, the Supreme Court has declined petitions seeking clarity around these issues, and it has continued to do so in 2019 to date. As detailed below, in the first quarter of this year, the Supreme Court denied five petitions for writ of certiorari presenting questions concerning materiality and implied certification in the light of government knowledge of the alleged falsity.

The Court began the year by denying petitions in *Gilead Scis., Inc. v. U.S. ex rel. Campie*[41] and *U.S. ex rel. Harman v. Trinity Industries, Inc.*[42]

In *United States ex rel. Campie v. Gilead Sciences, Inc.*,[43] the US Court of Appeals for the Ninth Circuit recognized the Supreme Court's holding in *Escobar* that a claim for FCA liability may be predicated on an implied certification theory, but that "two conditions must be satisfied."[44] The Ninth Circuit reversed the district court's dismissal, finding there was a genuine issue of material fact regarding whether alleged violations were material to the government's payment for certain FDA-approved drugs.[45] The court explained that given that the drugs were FDA-approved, and the government continued to pay for their use, it would be "an uphill battle" for relators in establishing sufficient materiality.[46] However, the parties' dispute regarding "what the government knew and when, call[e]d into question its 'actual knowledge'" and not simply "the mere possibility that the government would be entitled to refuse payment if it were aware of the violations."[47] As such, the court held that plaintiffs' had adequately pled the conditions necessary for an implied certification claim.[48]

In January, the Court also denied the petition for cert in *U.S. ex rel. Harman v. Trinity Industries, Inc.*.[49] As in *Gilead*, Trinity Industries' petition raised questions about the impact of continued payment on materiality under the FCA. In *Trinity Industries*, the lower court denied the defendant's motion for judgment as a matter of law. On appeal, however, the Fifth Circuit reversed.[50] The court held that, unlike *Gilead*, the government continued to pay for the guardrails at issue "with full knowledge of Harman's claims about the product's purported deficiencies."[51] In its petition to the Supreme Court, the relator asked whether continued payment by the government is enough, standing alone, to deem a violation not material under the FCA.

Following its denials in *Trinity Industries* and *Gilead*, the Court has denied three other FCA petitions in 2019. The first, *Brookdale Senior Living Communities, Inc. v. U.S. ex rel. Prather*,[52] asked (1) whether materiality determinations may be negatively impacted by a failure to plead facts regarding how the government treated other claims the government knew to be out of compliance with the relevant regulation; and (2) whether an FCA claim must contain allegations concerning the defendant's knowledge that the alleged violation was material to the government's

payment. In *Brookdale*, the Sixth Circuit held that because the plaintiff alleged the government had no knowledge of the falsity of the claims, any government past practices concerning similar claims violating the same regulation, "has no bearing on the materiality analysis."[53]

In April 2019, the Court denied two other petitions. In *United States Ex Rel. Rose v. Stephens Inst.*,[54] a Ninth Circuit panel suggested that it might determine that the Supreme Court in *Escobar* did not establish an exclusive method of determining liability in an implied false certification claim with its two condition test, were it not for previous three-judge panel decisions that constrained the *Rose* panel. Based on this binding precedent, the court held that *Escobar's* two conditions are necessary to establishing allegations based on an implied false certification theory.

In *Rose*, a defendant art school agreed to an incentive compensation ban, one of the requirements for schools seeking eligibility for Title VI grants from the Department of Education.[55] The ban prohibits schools from tying employee compensation to enrollment or the receipt of financial aid for students. The Ninth Circuit held that the relators' allegations that the defendant made specific representations to the government that students applying for federal financial aid were "eligible borrower[s]" and "accepted for enrollment in an eligible program," but failed to disclose that it was not in compliance with the incentive compliance ban, could be sufficient to find that these representations were "misleading half-truths."[56]

In their petition for cert, the defendant presented the questions of (1) whether general evidence that the Department of Education cared about compliance with the incentive compensation ban but never denied payment based on its violation could establish materiality; and (2) whether an enforcement policy for the incentive compensation ban developed by the Department of Education which stated that students attending noncompliant schools were nonetheless eligible for financial aid would preclude the relators from establishing an FCA claim regarding violations of the ban.

In a second cert denial issued in April 2019, the Supreme Court denied the petition of the relators in *U.S. ex rel. Berg v. Honeywell Int'l, Inc.* [57] The relators requested cert to consider whether (1) the existence of government knowledge of the alleged violation was "sufficient to 'negate' FCA falsity, materiality or scienter," or if such evidence should be understood to provide only a reasonable inference concerning materiality; and (2) the use of the "government knowledge" concept by the Ninth Circuit improperly "short-circuit[ed]" the three-prong scienter analysis it was required to perform under the FCA.

In *Berg*, the Ninth Circuit affirmed the district court's grant of summary judgment to defendant Honeywell.[58] *Berg*concerns certain energy-saving improvements provided by Honeywell to a US Army base. The relators alleged that Honeywell's project proposals fraudulently obtained orders and order modifications by making false savings promises premised on a faulty "Electrical Baseline Adjustment" that did not properly account for electricity costs and "low infiltration rates" that did not properly account for heat infiltration to the buildings on base. The Ninth Circuit held that because Honeywell had disclosed the assumptions and calculations used to create its proposals and qualified its statements based on those assumptions, those statements could not be false. The relators argued that Honeywell's statements were "objectively false" because the Electrical Baseline Adjustment was improper under statutory and regulatory requirements.[59] However, the court explained that because "the Army should have rejected Honeywell's proposals under the ESPC statutes and regulations does not mean that Honeywell's detailed calculations were false."[60] Further, the relators presented no evidence to rebut the inference, created by the evidence of knowledge on the part of the government of the calculations and assumptions, that Honeywell did not knowingly make a false claim, and that the alleged misrepresentations were not material to the government's decision

to pay the claims, given demonstrated government knowledge of the alleged misrepresentations for at least five or six years before ceasing payment.[61]

Case to Watch: Ruckh v. Salus Rehabilitation LLC

The Eleventh Circuit will soon hear arguments in *Ruckh v. Salus Rehabilitation, LLC, et al*,[62] another case involving the impact of continued government payments on the FCA's materiality standard.

In *Ruckh*, the Middle District of Florida overturned the jury's $350 million verdict, stating that the relator failed to prove that the government would have refused to pay defendants' claims if it had known of the alleged violations. Further, the court reasoned, the relator had not proven that the government refused, or even threatened to refuse, to pay claims despite knowledge of the lawsuit, evidence, and judgments for the relator. In a July 2018 amicus brief to the Eleventh Circuit, DOJ asserted that the district court placed too much emphasis on the government's inactions and misunderstood the *Escobar* decision.

If the *Ruckh* decision is upheld, it would further emphasize the importance of the government's payment decision vis-à-vis a determination of materiality. Oral arguments are currently tentatively scheduled for the week of July 22. We will be watching this case closely.

[1] Dkt. No. 18-315 (S. Ct.).

[2] 31 USC § 3731(b).

[3] *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003).

[4] *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998).

[5] See *United States ex rel. Stovall v. Webster Univ.*, No. 3:15-cv-3530, 2018 WL 3756888 (D.S.C. Aug. 8, 2018); *United States ex rel. Sibley v. Delta Regional Med. Ctr.*, No. 4:17-cv-53, 2019 WL 1305069 (N.D. Miss. Mar. 21, 2019); *United States ex rel. Davis v. Hennepin Cnty.*, No. 18-cv-1551, 2019 WL 608848 (D. Minn. Mar. 14, 2019).

[6] See *United States ex rel. Toomer v. TerraPower, LLC*, No. 4:16-cv-226, 2018 WL 4934070 (D. Idaho Oct. 10, 2018) (following 9th Circuit precedent

and applying *Sequoia Orange*). See *also United States ex rel. Kammarayii v. Sterling Ops., Inc*., No. 15-1699, 2019 WL 464820 (D.D.C. Feb. 6, 2019)

(following D.C. Circuit precedent and applying *Swift*); U*nited States ex rel. Schneider v. J.P. Morgan Chase Bank, N.A.*, No. 14-cv-1047, 2019 WL

1060876 (D.D.C. Mar. 6, 2019).

[8] *Id.* at *5.
[9] In *United States ex rel. Sibley v. Delta Regional Med. Ctr.*, the Northern District of Mississippi also recently granted dismissal under Section 3730(c)(2(A) on the ground that the government had “unfettered discretion” to do so and, similar to *EMD Serono*, found that the government had, in any event, met the *Sequoia Orange* standard. No. 4:17-cv-000053, 2019 WL 1305069, at *8-10 and 15 (N.D. Miss. Mar. 21, 2019).

[10] *United States ex rel. CIMZNHCA v. UCB, Inc.*, No. 3:17-cv-00765 (S.D. Ill.), ECF No. 83 (April 15, 2019).

[11] *Id.* at 3.

[12] *Id.* at 5.

13] *See* Press Release, US Dep't of Justice, *Deputy Associate Attorney General Stephen Cox Delivers Remarks at the 2019 Advanced Forum on False Claims and Qui Tam Enforcement* (Jan. 28, 2019).
[14] *See* Press Release,US Dep't of Justice, *South Florida Health Care Facility Owner Convicted for Role in Largest Health Care Fraud Scheme Ever Charged by The Department of Justice, Involving $1.3 Billion in Fraudulent Claims* (Apr. 5, 2019).
[15] A. Lee Bentley, III & Jason Mehta, *Telemedicine in the Justice Department's Cross-Hairs,* MEDICAL ECONOMICS (Apr. 8, 2019).

[16] *See* Press Release, US Dep't of Justice, *Federal Indictments & Law Enforcement Actions in One of the Largest* Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over $1.2 Billion in Losses (Apr. 9, 2019).
[17] *See* Press Release, US Dep't of Justice, *Tennessee Nurse Practitioner Pleads Guilty for Role in $65 Million Tricare Fraud*(Nov. 28, 2018), Press

Release, *US Dep't of Justice, Burlington, New Jersey, Doctor Arrested for Role in $20 Million Telemedicine Compounded Medication Scheme* (Nov. 16,

2018), Press Release, US Dep't of Justice, *Four Men and Seven Companies Indicted for Billion-Dollar Telemedicine Fraud Conspiracy, Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes* (Oct. 15, 2018).

[18] here

[19] Press Release, US Dep't of Justice, *Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations*(May 31, 2017)

[20] *United States , ex rel. Brendan Delaney v. eClinicalWorks, LLC*, Complaint in Intervetion, 2:15-CV-00095, D. Vermont (May 12, 2017).

[21] *Id.* ¶¶79-85.

[22] Press Release, US Dep't of Justice, *Electronic Health Records Vendor to Pay $155 Million to Settle False Claims Act Allegations* (May 31, 2017), .

[23] *Id.*; Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and eClinicalWorks, LLC.
[24] Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and eClinicalWorks, LLC.

[25] Press Release, US Dep't of Justice, *Electronic Health Records Vendor to Pay $57.25 Million to Settle False Claims Act Allegations* (Feb. 6, 2019), .

[26] *Id.*

[27] *United States v. Greenway Health, LLC*, Complaint, 2:19-CV-00020 at ¶¶ 76-112, D. Vermont (February 6, 2019).

[28] *Id.* ¶¶113-125.
[29] *Id.* ¶¶ 126-27.

[30] Press Release, US Dep't of Justice, *Electronic Health Records Vendor to Pay $57.25 Million to Settle False Claims Act Allegations* (Feb. 6, 2019); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Greenway Health, LLC.

[31] Case No. 2:2019-cv-000009 (M.D. Tenn., Feb. 8, 2019), at Dkt. No. 10; *see also* Press Release, US Dep't of Justice, J*ustice Department Files First of its Kind Action to Stop Tennessee Pharmacies' Unlawful Dispensing of Opioids* (Feb. 8, 2019).
[32] *United States v. Oakley, et al.*, Case No. 2:2019-cv-000009 (M.D. Tenn., Mar. 8, 2019), at Dkt. No. 51.

[33] *Id.*, at Dkt. No. 55 (Mar. 25, 2019).

[34] *In re: National Prescription Opiate Litigation Case*, Case No. 1:17-md-02804-DAP (N.D. Ohio), at Dkt. No. 1537.

[35] *See id.*, at Dkt. No. 58 (Jan. 9, 2018).

[36] *United States v. Babich, et al.*, Case No. 16-cr-10343 (D. Mass.).

[37] S*ee* Press Release, US Dep't of Justice, *Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals: Charges Involve Over 350 Thousand Prescriptions for Controlled Substances and Over 32 Million Pills*; *ARPO Strike Force Grows to 10 Districts, Expanding to Include the Western District of Virginia* (Apr. 17, 2019).

[38] 579 U.S. ___, 136 S. Ct. 1989 (2016),

[39] *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489-90 (3d Cir. 2017) (affirming dismissal on different grounds citing

"'demanding' and 'rigorous'" standard for materiality required by the Supreme Court in *Escobar*).

[40] 579 U.S. ___, 136 S.Ct. 1989, 2001 (2016).
[41] 139 S. Ct. 783 (2019).
[42] 139 S. Ct. 784 (2019).
[43] 862 F.3d 890 (9th Cir. 2017).
[44] *Id.* at 901 (citing Escobar, 136 S.Ct. at 2000).
[45] *Id.* at 905-07.

[46] *Id.* at 905.

[47] *Id.* at 906-07.

[48] *Id.* at 907.

[49] 139 S. Ct. 784 (2019).

[50] *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 647 (5th Cir. 2017).

[52] No. 18-699, 2019 WL 1231774 (U.S. Mar. 18, 2019).
[53] *United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 834 (6th Cir. 2018).
[54] 909 F.3d 1012, 1018 (9th Cir. 2018).

[55] *Id.* at 1017.

[56] *Id.* at 1018.

[57] No. 18-1030, 2019 WL 485403 (U.S. Apr. 1, 2019).

[58] *United States ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535, 537 (9th Cir. 2018).

[59] *Id.* at 537-38.

[61] *Id.* at 538.
[62] 304 F. Supp. 3d 1258, 1260 (M.D. Fla. 2018).

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