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The False Claims Act & Health Care: 2018 Recoveries and 2019 Outlook

By Mark A. Rush, Mary Beth Johnston, John H. Lawrence, Samuel P. Reger, Jared A. Kephart

In 2018, the False Claims Act¹ (“FCA”) continued to be one of the federal government’s (“Government”) preferred civil fraud enforcement tools across a variety of industries. The healthcare industry, however, remained the epicenter of FCA enforcement. Whistleblowers (“relators”), too, remained active in 2018, bringing an increased number of *qui tam* lawsuits against health care providers when compared with the previous year. Despite areas of uncertainty surrounding FCA actions in health care—from potentially shifting Department of Justice priorities and their impacts to the continued split amongst federal courts in their interpretation of *Universal Health Servs., Inc. v. U.S. ex rel. Escobar* and materiality—recent trends strongly suggest that health care-related FCA investigations, actions, and recoveries will remain robust in 2019.

This article analyzes FCA activity in 2018 by the numbers and considers how those numbers might shift in 2019.

Fiscal Year 2018 Civil Fraud Recoveries

In Fiscal Year (“FY”) 2018, the Government obtained close to \$2.9 billion² in total civil fraud recoveries, largely due to the operation of FCA.³ However, for the second straight year, civil fraud recoveries declined, down from \$4.9 billion in FY 2016 and \$3.5 billion in FY 2017.⁴ In fact, the Government’s recoveries since FY 2014 have yet to match that year’s record high recoveries of \$6.1 billion.⁵ The \$2.9 billion in civil fraud recoveries in FY 2018 marks the lowest total recoveries since FY 2009 (\$2.5 billion) and the first time since FY 2009 that total annual recoveries fell below \$3.0 billion.⁶

¹ 31 U.S.C. § 3729 *et seq.*

² U.S. Dep’t. of Justice, Fraud Statistics Overview (December 21, 2018), https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.

³ U.S. Dep’t. of Justice, Press Release, Justice Department Recovers Over \$2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018>.

⁴ U.S. Dep’t. of Justice, Fraud Statistics Overview (December 21, 2018), https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.

⁵ *Id.*

⁶ *Id.*

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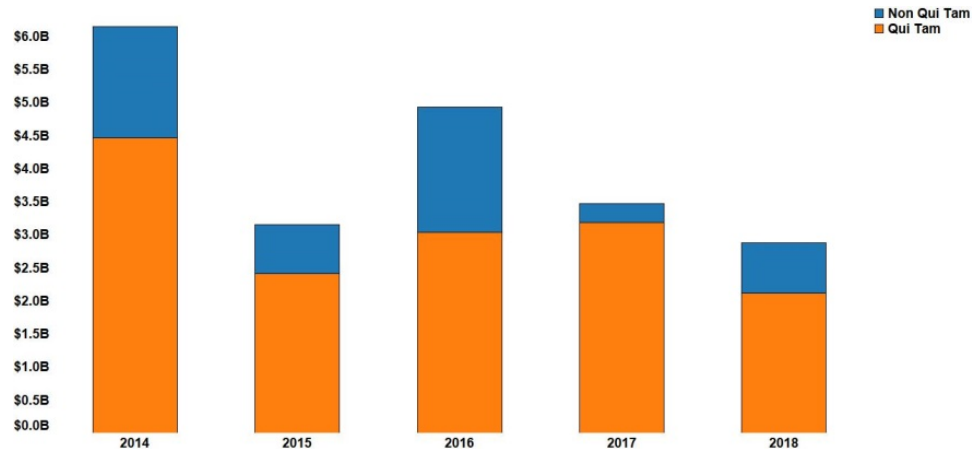


Figure 1: Total Civil Fraud Recoveries⁷

Recoveries in the health care industry, however, increased.⁸ In FY 2018, the Government recovered \$2.5 billion in civil fraud-related actions involving the health care industry, compared to \$2.2 billion recovered in FY 2017.⁹ In FY 2017, 63% of total civil fraud recoveries were in the health care industry. In FY 2018, that figure soared to 87% of all recoveries.¹⁰ In fact, FY 2018 was the ninth consecutive year that health care fraud recoveries surpassed \$2 billion.¹¹

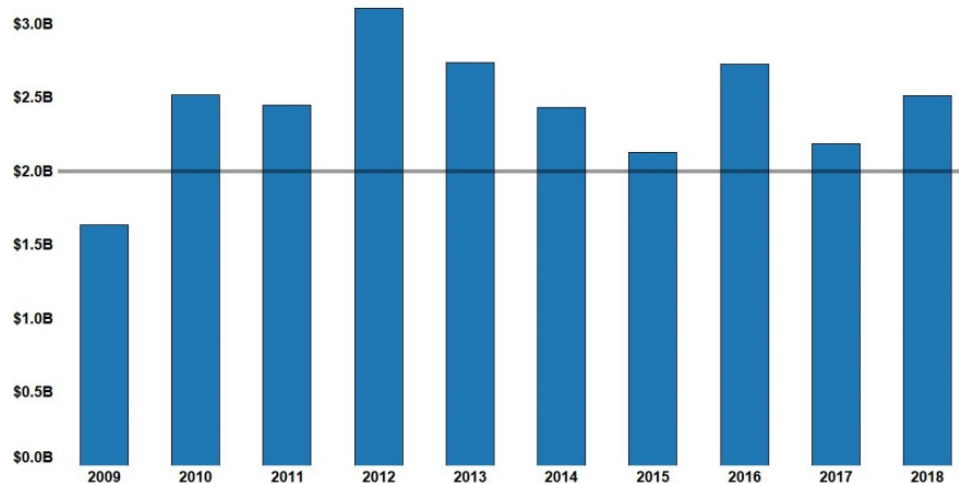


Figure 2: Civil Fraud Recoveries Related to the Health Care Industry¹²

The FY 2018 recovery figures would have been even higher were it not for substantial verdicts that were overturned as federal courts grappled with the materiality standard set

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

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forth in *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*.¹³ Furthermore, the \$2.9 billion recovered in FY 2018 does not include the millions of dollars various state Medicaid programs recouped as a result of the Government's health care-related enforcement actions, or any recoveries under the various state false claim acts.¹⁴

Even considering only *qui tam* actions in which the Government intervened, FY 2018 recoveries from interventions totaled \$1.99 billion.¹⁵ Of this amount, \$1.86 billion—or 93%—involved the health care industry.¹⁶ Similarly, as illustrated in the graph at Figure 3, from FY 2014 to FY 2018, total recoveries from actions in which the Government intervened have generally declined.¹⁷ However, the same is not true for the health care industry.¹⁸ Recoveries in health care-related actions where the Government intervened actually rose in FY 2018 to \$1.9 billion from \$1.7 billion in FY 2017.¹⁹ As such, despite the decline in total civil fraud recoveries, efforts to combat fraud in health care remain robust and are currently the primary focus of FCA actions.

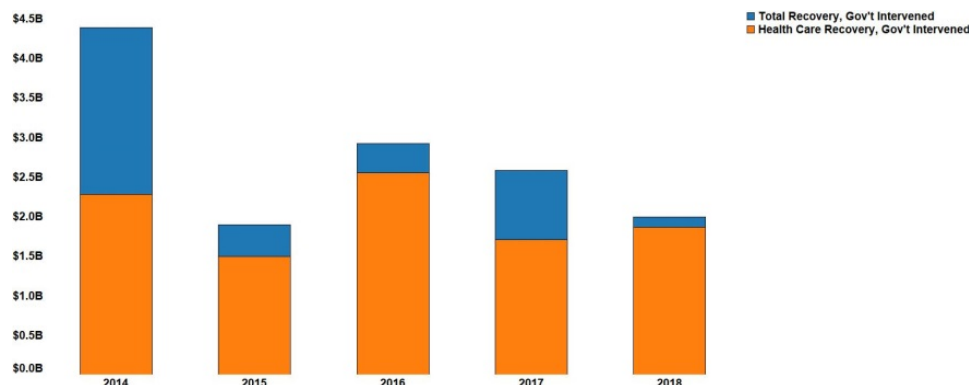


Figure 3: Civil Fraud Recoveries in Government Intervened Matters²⁰

This “lopsided” enforcement environment is also evident in the number of FCA actions filed last year.²¹ In FY 2018, 767 new FCA actions were filed, 645 of which were *qui tam* or whistleblower actions (which amounts to an average of 12 new *qui tam* cases per week).²² Of the 767 new FCA actions, more than 66% (506) were related to the health care industry.²³

¹³ *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). See, e.g., *United States ex rel. Ruckh v. Salus Rehabilitation, LLC*, 2018 WL 375720 (M.D. Fla. Jan. 11, 2018) (vacating a \$348 million jury verdict upon considering *Escobar's* materiality requirements).

¹⁴ U.S. Dep't. of Justice, Press Release, Justice Department Recovers Over \$2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018>.

¹⁵ U.S. Dep't. of Justice, Fraud Statistics Overview (December 21, 2018), https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

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Figure 4: FCA Actions Filed in FY 2018²⁴ **Figure 5: Health Care-Related FCA Actions Filed in FY 2018²⁵**

The highlighted numbers from the past year are consistent with historic percentages and underscore some notable trends.

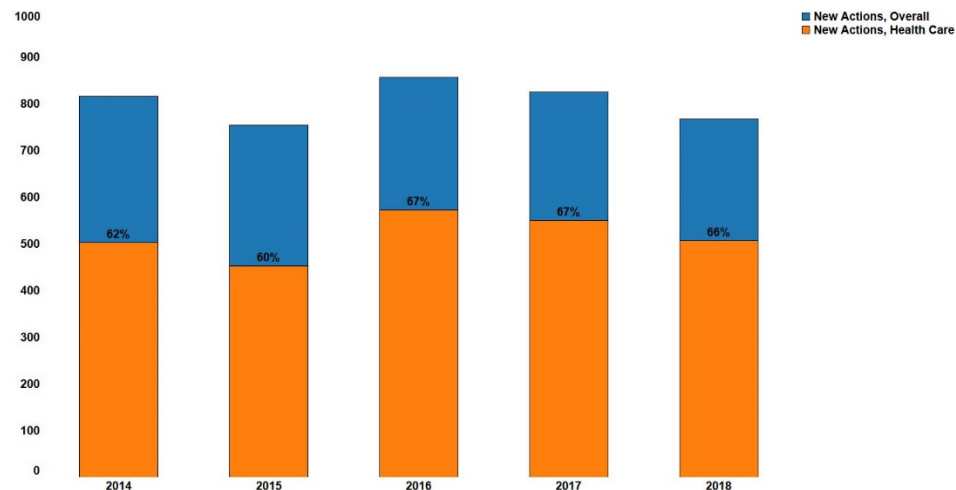


Figure 6: Percentage of New Health Care-Related FCA Actions²⁶

Neither the number of new FCA actions nor the number of new FCA health care-related actions have changed significantly since 2014.²⁷ The consistency in the number of actions filed is remarkable in light of the significant decrease in civil fraud recoveries overall. These numbers may suggest that the average settlement amounts or assessed penalties are getting smaller and/or that FCA claims are generally less successful overall. The same trend does not appear to be the case for the healthcare industry, where both the civil fraud recoveries and the new matters filed have remained relatively stable.²⁸ These numbers demonstrate that the FCA is, and will likely continue to be, uniquely tailored to combatting alleged fraud in health care for the foreseeable future.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

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2019 Outlook

Perhaps more so than in recent years, the future of FCA enforcement and recoveries in health care is clouded with uncertainty, largely due to three factors that could reshape the FCA landscape in the coming year:

1. Changes in Department of Justice (“DOJ”) policies and leadership that may discourage the filing of *qui tam* cases and/or Government intervention in the same;
2. An ongoing split amongst federal courts regarding the interpretation of *Escobar’s* materiality standard; and
3. Shifting DOJ approaches to combatting the opioid crisis and increasing scrutiny on telemedicine arrangements, particularly those involving ancillary services.

These factors are discussed below, along with their potential effect on the FCA enforcement environment in 2019 and beyond.

Granston Memo, William P. Barr, and Changes in Enforcement Policy

On January 10, 2018, Michael Granston, Director of the Civil Fraud Section of DOJ’s Civil Division, issued a memorandum regarding circumstances in which prosecutors should consider seeking the dismissal of a *qui tam* complaint (“Granston Memo”).²⁹ Grounded in Section 3730(c)(2)(A) of the FCA—which empowers DOJ to seek dismissal of a *qui tam* action without the consent of the relator³⁰—the Granston Memo calls out “meritless” claims, “parasitic or opportunistic” claims, and those claims which might interfere with agency policies and/or programs, among others, as instances where DOJ attorneys should consider seeking dismissal.³¹

The idea that the Granston Memo signaled a major change in *qui tam* litigation has been met with skepticism—the Granston Memo even acknowledges that, “[h]istorically, the Department has utilized Section 3730(c)(2)(A) sparingly,” instead preferring to simply decline to intervene in questionable cases.³² Additionally, there are almost no reliable statistics available regarding the rate at which DOJ has attempted to dismiss *qui tam* claims, making it difficult to assess whether or not the Granston Memo has had any statistically significant effect on DOJ dismissal rates. As such, it remains unclear if the Granston Memo’s assertion that Section 3730(c)(2)(A) is “an important tool to advance the government’s interests, preserve limited resources, and avoid adverse precedent” has had any practical impact on DOJ’s dismissal activities.³³

It should be noted, however, that, on November 30, 2018, the Solicitor General filed an *amicus* brief with the Supreme Court of the United States in *Gilead Sciences Inc. v. U.S. ex rel. Campie*, a *qui tam* action in which the Government had previously declined to intervene.³⁴ In the brief, the Solicitor General recommended denial of *certiorari* and stated

²⁹ Michael D. Granston, *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)* (Jan. 10, 2018).

³⁰ 31 U.S.C. § 3730(c)(2)(A).

³¹ Michael D. Granston, *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)* (Jan. 10, 2018).

³² *Id.*

³³ *Id.*

³⁴ See Brief for the United States as Amicus Curiae, at 16, *Gilead Scis., Inc., v. United States ex rel. Campie*, No. 17-936; *United States ex rel. Campie v. Gilead Scis., Inc.*, No. C-11-0941 EMC,

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that if *Campie* was remanded to the federal district court, the Government would seek dismissal because the case threatened to “impinge on agency decision making and discretion and would dissuade the interests of the United States.”³⁵ Shortly thereafter, the Supreme Court denied *certiorari*.³⁶

The Government’s position in *Campie* serves as evidence post-Granston Memo that the Government may more actively seek dismissals under Section 3730(c)(2)(A) in the coming year and thereby reign in the number of *qui tam* lawsuits. This potential development is particularly notable because the Granston Memo follows a decade-long surge in the number of *qui tam* actions filed.³⁷ As illustrated in the graphs below, from FY 2001 to FY 2009, relators filed a total of 3,367 new *qui tam* lawsuits.³⁸ By contrast, from FY 2010 to FY 2018, relators filed 6,011 new *qui tam* matters, which amounts to a more than 175% increase from the previous nine years.³⁹ Over that same period, non-*qui tam* cases filed under the FCA increased by only 21% (from 944 to 1145).⁴⁰ In light of the Granston Memo and the renewed emphasis on the Government exercising its Section 3730(c)(2)(A) powers, 2019 may mark the year when this tide of *qui tam* actions begins to change, particularly in health care-related actions.

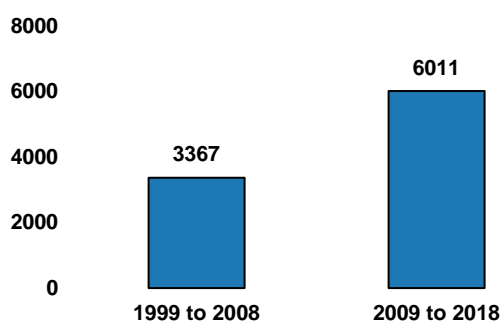


Figure 7: Qui Tam Cases Filed⁴¹

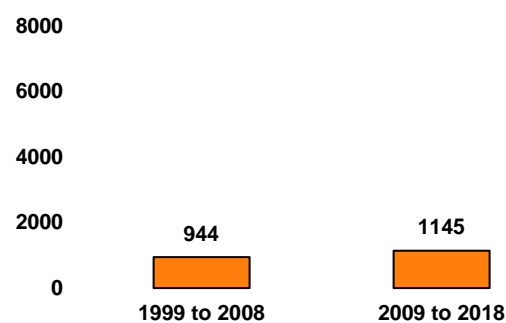


Figure 8: Non Qui-Tam Cases Filed⁴²

Importantly, the Granston Memo is not the only source of uncertainty in 2019 surrounding FCA actions. William P. Barr, who was recently confirmed as the Attorney General of the United States, has described the FCA as an “abomination,” and previously stated that its *qui tam* provisions were designed to exploit the worst “mercenary motives of private bounty hunters.”⁴³ While he made these statements several years ago, Mr. Barr’s position on the FCA has garnered renewed attention in light of his recent confirmation. During the 2019

2015 WL 3659765 (N.D. Cal. June 12, 2015), *rev’d and remanded sub nom. United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017).

³⁵ See Brief for the United States as Amicus Curiae, at 16, *Gilead Scis., Inc., Petitioner v. United States ex rel. Jeffrey Campie, et al.*, No. 17-936.

³⁶ *Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936, 2019 WL 113075, at *1 (U.S. Jan. 7, 2019).

³⁷ U.S. Dep’t. of Justice, *Fraud Statistics Overview* (December 21, 2018), https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ U.S. Dep’t. of Justice, *Constitutionality of the Qui Tam Provisions of the False Claims Act*, Opinion Of The Office Of Legal Counsel, 13 Op. O.L.C. 249 (1989).

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confirmation process, Mr. Barr was asked about his position on the FCA and “unnecessary dismissals of meritorious *qui tam* cases,” and he responded by vowing to “diligently enforce the” FCA, but he did not offer any further substantive details.⁴⁴

While it is unclear what Mr. Barr specifically meant by diligent enforcement of the FCA, such a statement does not necessarily mean sustaining the record-breaking numbers of FCA-related recoveries and actions in recent years. Mr. Barr’s apparent skepticism of the FCA and its *qui tam* provision could shape DOJ’s approach during his tenure to declining to intervene in, or seeking dismissal of, these actions. It also potentially dovetails with the Granston Memo’s emphasis on discouraging and dismissing meritless *qui tam* complaints.⁴⁵ Taken together, Mr. Barr’s views and the Granston Memo suggest that *qui tam* actions may face more scrutiny than in previous years, which may lead to a decline in the number of *qui tam* actions filed or allowed to proceed in 2019.

Escobar and Supreme Court Intervention

The United States Supreme Court’s landmark 2016 opinion in *Escobar*⁴⁶ continued to have an impact on FCA litigation in 2018 and is primed to have further impact in 2019. The Supreme Court stated in *Escobar* that FCA “liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement.”⁴⁷ However, because the FCA is a fraud statute, the analysis focuses on whether the noncompliance was “material” to the payment.⁴⁸ According to *Escobar*, “[w]hat matters is not the label that the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.”⁴⁹ As such, *Escobar* aimed to reinforce that only material noncompliance can lead to FCA liability.

A critical aspect of *Escobar* is that “implied false certification”—the violation of a statutory, regulatory, or contractual requirement with which an entity impliedly certified compliance by submitting a claim for payment—is a valid basis for FCA liability.⁵⁰ In light of its focus on materiality, however, *Escobar* reaffirms that an “implied false certification” must be “material,” meaning that it has “a natural tendency to influence, or be capable of influencing, the

⁴⁴ Letter from William P. Barr, Nominee for Attorney General of the United States, to Hon. Lindsay Graham, United States Senator, and Hon. Diane Feinstein, United States Senator enclosing written responses to Questions for the Record (Jan. 27, 2019) at 10-11, <https://www.judiciary.senate.gov/imo/media/doc/Barr%20Responses%20to%20QFRs.pdf>.

⁴⁵ Moreover, Mr. Barr’s skepticism potentially aligns with Deputy Attorney General Rod Rosenstein’s late 2018 statement regarding DOJ’s “piling on” policy that “prosecutors and civil enforcement attorneys prize the Department’s reputation for fairness” and “understand the importance of protecting [DOJ’s] brand.” U.S. Dep’t. of Justice, Deputy Attorney General Rod Rosenstein Delivers Remarks to the New York City Bar White Collar Crime Institute (May 9, 2018), <https://www.justice.gov/opa/speech/deputy-attorney-general-rod-rosenstein-delivers-remarks-new-york-city-bar-white-collar> (“Our new policy discourages ‘piling on’ by instructing Department components to appropriately coordinate with one another and with other enforcement agencies in imposing multiple penalties on a company in relation to investigations of the same misconduct . . . In highly regulated industries, a company may be accountable to multiple regulatory bodies. That creates a risk of repeated punishments that may exceed what is necessary to rectify the harm and deter future violations.”).

⁴⁶ *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016).

⁴⁷ *Id.* at 1995.

⁴⁸ *Id.* at 2003.

⁴⁹ *Id.* at 1996.

⁵⁰ *Id.* at 1995–96.

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payment or receipt of money or property.”⁵¹ This is so because materiality “look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.”⁵² In so stating, the Supreme Court asserted that the materiality standard was “rigorous” and “demanding.”⁵³

Since *Escobar* was decided, federal courts have struggled to apply its materiality standard in a consistent and clear manner, particularly regarding the specific showing required to satisfy the standard. For example, some federal courts have held that complaints sufficiently pleaded materiality where there was “more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations.”⁵⁴ In contrast, other federal courts have emphasized past action or inaction in the Government’s payment of a claim as central to the materiality analysis, as such action or inaction can show actual Government behavior as opposed to behavior in the abstract.⁵⁵ Currently pending before the Supreme Court is at least one petition for *writ of certiorari* urging the Court to resolve this split and further clarify *Escobar*’s materiality standards.⁵⁶

It remains to be seen whether the Supreme Court will consider the materiality standard in 2019 and provide any clarification. Without it, the FCA will likely continue to be defined by inconsistent application of the materiality standard by federal courts, which may lend itself to potential shifts in FCA recoveries across federal circuits.

Telemedicine, Ancillary Services, and Increased Enforcement

Health care arrangements involving telemedicine are likely to draw increased scrutiny and enforcement activity in 2019, including through the FCA. Telemedicine “allows health care providers to evaluate, diagnose, and treat patients remotely—without the need for an in-person visit—by interacting with a patient using telecommunications technology, such as the internet or telephone.”⁵⁷ The use of telemedicine in health care has substantially increased in recent years largely because telemedicine allows health care providers to expand the populations of patients with which the providers can connect. Such expanded coverage enhances providers’ ability to generate business and associated revenue. For patients, telemedicine services offer the potential to more conveniently connect with a range of providers who may be able to provide more effective clinical care and at a potentially lower cost.

⁵¹ 31 U.S.C. §3729(b)(4).

⁵² *Escobar*, 136 S. Ct. at 2002.

⁵³ *Id.*

⁵⁴ *United States ex. rel. Campie v. Gilead Scis., Inc.*, No. C-11-0941 EMC, 2015 WL 3659765 (N.D. Cal. June 12, 2015), *rev’d and remanded sub nom. United States ex. rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017). *See also United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018), *petition for cert. filed*, No. 18-699, Nov 20, 2018 (affirming a similar position).

⁵⁵ *See, e.g., United States ex. rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (maintaining that relator’s failure to plead that “CMS ‘consistently refuses to pay’ claims” alleged and relator’s concession “that CMS consistently reimburse[d]” the “claims with full knowledge of the purported noncompliance” effectively “militates against finding a materiality”).

⁵⁶ *United States v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018), *petition for cert. filed*, No. 18-699, Nov 20, 2018.

⁵⁷ U.S. Dep’t. of Justice, Press Release, Burlington, New Jersey, Doctor Arrested for Role in \$20 Million Telemedicine Compounded Medication Scheme (Nov. 16, 2018), <https://www.justice.gov/usao-nj/pr/burlington-new-jersey-doctor-arrested-role-20-million-telemedicine-compounded-medication>.

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As telemedicine is relatively new, largely unregulated, and becoming exponentially more popular with both providers and patients, it is also a burgeoning area for health care fraud. This reality is particularly apparent at the intersection of telemedicine and ancillary services—such as pharmaceutical prescriptions, clinical laboratory testing, and durable medical equipment (“DME”) sales—which have independently been fertile grounds for Government enforcement over the last several years. The introduction of a telemedicine component into these arrangements seems to heighten concerns that the arrangements may be structured in a manner that targets Medicare, Medicaid, and TRICARE beneficiaries, and/or involve kickbacks to health care providers.

The likelihood of increased scrutiny on telemedicine in 2019 is also based on a handful of notable enforcement efforts in late 2018, including those described below.

1. “On October 12, 2018, the District Court for the Eastern District of Tennessee unsealed a 32-count indictment charging four individuals and seven companies in a \$1 billion health care fraud scheme.”⁵⁸ The defendants were charged with conspiracy to commit health care fraud, mail fraud, and introducing misbranded drugs into interstate commerce, based upon “an elaborate” telehealth “scheme” with several of the defendant-pharmacies.⁵⁹ At the center of the alleged fraud scheme was a telehealth company and its Chief Executive Officer.⁶⁰ Specifically, the telehealth company was alleged to have fraudulently solicited “insurance coverage information and prescriptions from consumers across the country for prescription pain creams and other similar products.”⁶¹ According to the indictment, 100 physicians hired by the telehealth company approved the prescriptions without knowing that the defendant-pharmacies “were massively marking up the prices of the invalidly prescribed drugs, which the defendants then billed to private insurance carriers.”⁶² The Government specifically “alleges that the defendants submitted not less than \$931,000,000 in fraudulent claims for payment.”⁶³
2. On November 16, 2018, a physician in New Jersey was charged with one count of conspiracy to commit health care fraud.⁶⁴ He is alleged to have been “paid by various telemedicine companies to prescribe exorbitantly expensive compounded medications, such as pain creams, scar creams, migraine creams, and metabolic supplements/wellness capsules, regardless of whether they were medically necessary for the patient.”⁶⁵ Specifically, the telemedicine company paid the physician on a per prescription basis.⁶⁶ The physician “signed the prescriptions without having established any prior doctor-patient relationship, speaking with the patient, or conducting any kind of medical evaluation.”⁶⁷ The physician’s alleged “participation in the conspiracy caused a

⁵⁸ U.S. Dep’t. of Justice, Press Release, Four Men and Seven Companies Indicted for Billion-Dollar Telemedicine Fraud Conspiracy, Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes (October 15, 2018), <https://www.justice.gov/opa/pr/four-men-and-seven-companies-indicted-billion-dollar-telemedicine-fraud-conspiracy>.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ U.S. Dep’t. of Justice, Press Release, Burlington, New Jersey, Doctor Arrested for Role in \$20 Million Telemedicine Compounded Medication Scheme (November 16, 2018), <https://www.justice.gov/usao-nj/pr/burlington-new-jersey-doctor-arrested-role-20-million-telemedicine-compounded-medication>.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

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loss to health care benefit programs of more than \$20 million, at least \$3 million of which was sustained by TRICARE.”⁶⁸

3. On November 27, 2018, the U.S. Attorney's Office for the Southern District of California announced that a Tennessee-based nurse practitioner pled guilty for participating “in a health care fraud scheme that bilked TRICARE ... out of more than \$65 million. As part of her guilty plea, [the nurse practitioner] admitted to conducting sham ‘telemedicine’ evaluations that resulted in the prescription of exorbitantly expensive compounded medications to patients that she never saw or examined in person.”⁶⁹ Specifically, as part of the scheme, current and former Marines and their family members were paid “to obtain compounded medications that would be paid for by TRICARE.”⁷⁰ Their information was sent to the Tennessee medical clinic that employed the nurse practitioner, who “then conducted phone calls with the TRICARE beneficiaries, and recommended that they be prescribed compounded medications despite never examining the patients in person.”⁷¹ These prescriptions were then signed by doctors employed by the Tennessee medical clinic.”⁷² The prescriptions were then allegedly “sent directly to particular pharmacies controlled by co-conspirators, which filled the prescriptions and billed TRICARE at exorbitant prices.”⁷³

While these cases are criminal in nature, they are harbingers of an area of health care that may be ripe for FCA action in 2019 and beyond because telemedicine arrangements are often used to facilitate the submission of claims to federal health care programs. As such, 2019 may be the year when these arrangements become a focus of FCA-related enforcement.

The Opioid Epidemic

The fight against opioid abuse will remain a top priority for the Government in 2019.⁷⁴ According to a February 28, 2018 statement from Deputy Associate Attorney General Stephen Cox, the Government considers the FCA to be “a powerful tool to pursue all of those in the opioid distribution chain that are responsible for the improper marketing, distribution, prescription and diversion of opioids—from pharmaceutical manufacturers to physicians, and everyone in between.”⁷⁵ Following this statement, on May 15, 2018, DOJ announced that it had intervened in five *qui tam* lawsuits that alleged illegal kickback schemes and fraud on federal health programs “in connection with the marketing of Subsys, an opioid painkiller”⁷⁶ United States Attorney Nicola T. Hann said in the announcement:

⁶⁸ *Id.*

⁶⁹ U.S. Dep’t. of Justice, Press Release, Tennessee Nurse Practitioner Pleads Guilty for Role in \$65 Million TRICARE Fraud (November 28, 2018), <https://www.justice.gov/usao-sdca/pr/tennessee-nurse-practitioner-pleads-guilty-role-65-million-tricare-fraud-0>.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ U.S. Dep’t. of Justice, Deputy Associate Attorney General Stephen Cox Delivers Remarks at the Federal Bar Association Qui Tam Conference (Feb. 28 2018), <https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-delivers-remarks-federal-bar-association>.

⁷⁵ *Id.*

⁷⁶ U.S. Dep’t. of Justice, Press Release, U.S. Intervenes in ‘Whistleblower’ Lawsuits Alleging Insys Therapeutics Paid Illegal Kickbacks to Promote Subsys (May 15 2018), <https://www.justice.gov/usao-cdca/pr/us-intervenes-whistleblower-lawsuits-alleging-insys-therapeutics-paid-illegal-kickbacks>.

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“Our intervention in these cases is just one part of the Justice Department’s multi-pronged efforts to combat the opioid crisis.”⁷⁷ DOJ has since intervened in similar *qui tam* lawsuits in which drug makers are alleged to have improperly marketed the opioid addiction treatment Suboxone.⁷⁸

The Government coupled these FCA enforcement efforts during the past year with the creation of various strike and task forces designed to help identify and combat fraudulent activity in the prescribing and dispensing of opioids. According to the Government, the Prescription Interdiction & Litigation (PIL) Task Force is designed to “aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufacturers and distributors.”⁷⁹ Similarly, the Government created the Appalachian Regional Prescription Opioid Strike Force (“ARPO Strike Force”) in an effort to stem the tide of the opioid epidemic in five states hit the hardest by the crisis.⁸⁰ “The mission of the ARPO Strike Force is to identify and investigate health care fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids.”⁸¹

These task and strike forces have central criminal enforcement elements and operate to ferret out and combat fraudulent activities viewed as contributing to the ongoing opioid crisis. These initiatives, coupled with the Government’s FCA enforcement activities in the space in 2018, are expected to generate substantial FCA-related activity in 2019 as the Government continues to seek to combat the crisis.

Conclusion

It remains to be seen what the FCA landscape will look like in 2019 by the numbers and in light of both consistent and shifting Governmental priorities. As discussed above, all indications are that 2019 will be a particularly active year for the Government and relators alike in a variety of areas across the health care industry. As a result of continued scrutiny and enforcement activities, it is essential for those operating in health care—particularly those that bill federal and state health care programs—to ensure their financial arrangements and billing activities are compliant with applicable federal and state health care fraud and abuse laws. In addition, those operating in health care should work with health care regulatory counsel to design, implement, and enforce properly functioning compliance programs and other efforts to best avoid FCA exposure, costly litigation, and penalties.

⁷⁷ *Id.*

⁷⁸ See, e.g., U.S. *ex rel.* Williams v. Reckitt Benckiser Inc., No. 13-cv-00036 (W.D. Va. 2013) (notice of election to partially intervene by United States of America, filed Aug. 1, 2018).

⁷⁹ U.S. Dep’t. of Justice, Press Release, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (February 27, 2018), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force>.

⁸⁰ U.S. Dep’t. of Justice, Press Release, Justice Department’s Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions (October 25, 2018), <https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid>.

⁸¹ *Id.*

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Authors:

Mark A. Rush

mark.rush@klgates.com

+1.412.355.8333

Mary Beth Johnston

marybeth.johnston@klgates.com

+1.919.466.1181

John H. Lawrence

john.lawrence@klgates.com

+1.919.466.1112

Samuel P. Reger

samuel.reger@klgates.com

+1.412.355.6258

Jared A. Kephart

jared.kephart@klgates.com

+1.412.355.7436

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