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Practice Groups:

Investigations, Enforcement and White Collar

Federal, State and Local False Claims Act

Health Care and FDA

Health Care Fraud and Abuse

Policy and Regulatory Area

The False Claims Act & Health Care: 2019 Recoveries and 2020 Outlook

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In 2019, the False Claims Act[1] ("FCA") remained the federal government's ("Government") primary method of civil fraud enforcement. While the more than $3 billion in civil fraud recoveries in Fiscal Year ("FY") 2019 resulted from Government enforcement across a number of industries, health care continued to represent the most fertile ground for recoveries.[2] Indeed, as in prior years, the lion's share of the Government's civil fraud-related recoveries came in health care, which accounted for approximately eighty-five percent (85%) of recoveries in 2019.[3]

These specific recoveries were significantly bolstered during the year by major settlements with hospital systems and pharmaceutical companies, which primarily related to alleged improper relationships with health care practitioners[4] and as a civil outgrowth of efforts to address the nation's opioid epidemic.[5] Long-term care providers, including hospice, home health, and skilled nursing facilities, continued to prove to be primary targets of governmental scrutiny under the FCA in 2019.[6] Other traditional Government targets — durable medical equipment ("DME") companies and laboratories — were the focus of substantial criminal enforcement, which involved extensive parallel civil investigations.[7] The Government also demonstrated a continued willingness to pursue FCA actions against individuals, including

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[1] 31 U.S.C. § 3729 *et seq.*

[2] *See* U.S. Dep't of Just., Fraud Statistics Overview (Jan. 9, 2020), https://www.justice.gov/opa/press-release/file/1233201/download.

[3] *See id.*

[4] *See* Press Release, U.S. Dep't of Just., Medstar Health to Pay U.S. $35 Million to Resolve Allegations that it Paid Kickbacks to a Cardiology Group in Exchange for Referrals (Mar. 21, 2019), https://www.justice.gov/usao-md/pr/medstar-health-pay-us-35-million-resolve-allegations-it-paid-kickbacks-cardiology-group ("The allegations resolved in the settlement include the payment of kickbacks to MACVA under the guise of professional services agreements, in return for MACVA's referrals to Union Memorial of lucrative cardiovascular procedures, including cardiac surgery and interventional cardiology procedures, from January 1, 2006 through July 31, 2011.").

[5] *See* Press Release, U.S. Dep't of Just., Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations (June 5, 2019), https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal (resolving, through a global resolution, civil and criminal allegations of which $195 million were designated to settle allegations that Insys Therapeutics violated the FCA).

[6] *See, e.g.*, Press Release, U.S. Dep't of Just., Skilled Nursing Facility Management Company Agrees to Settle False Claims Allegations (Feb. 5, 2019), https://www.justice.gov/usao-mdtn/pr/skilled-nursing-facility-management-company-agrees-settle-false-claims-act-allegations (resolving FCA claims for approximately $9.7 million dollars for the alleged submission of "pre-admission evaluations with photocopied or pre-signed physician signatures on the required certifications for claims rendered to TennCare beneficiaries at [defendant's] associated Tennessee skilled nursing and rehabilitation facilities").

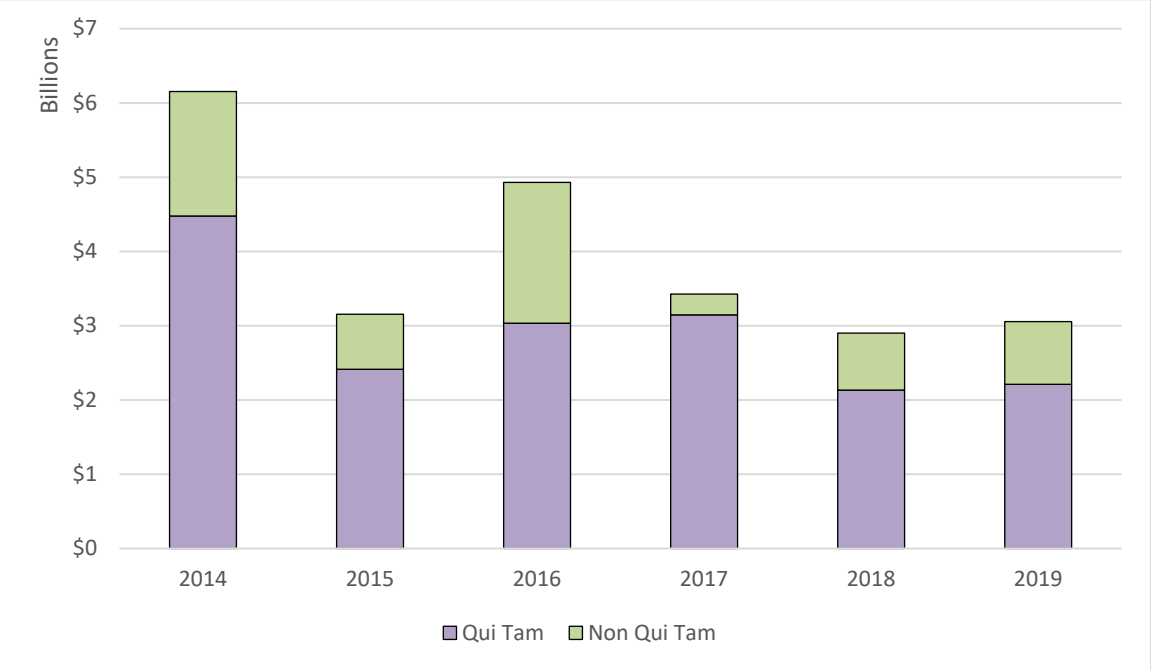
[7] *See* Press Release, U.S. Dep't of Just., Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for over $1.2 Billion in Losses (Apr. 9, 2019), https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes; Press Release, U.S. Dep't of Just., Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for over $2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged (Sep. 27, 2019), https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.

physicians and executives, as a means of achieving wider deterrence and establishing accountability for alleged corporate misconduct.[8]

This article analyzes FCA activity in 2019 by the numbers, and considers how those numbers might shift in 2020 as a result of emerging trends and governmental priorities in health care fraud enforcement.

FY 2019 Civil Fraud Recoveries

In FY 2019, the Government obtained more than $3 billion[9] in total civil fraud recoveries, in large part because of the operation and application of the FCA.[10] These recoveries amounted to an increase from the $2.9 billion collected in FY 2018.[11] As has been the case since FY 2014, however, the Government's recoveries have generally trended downward since that year's record high recoveries of $6.1 billion.[12] Since at least 2014, whistleblower or *qui tam* lawsuits remained the primary driver of these recoveries, particularly within health care.



[8] *See* Press Release, U.S. Dep't of Just., Former CEO of Hospital Chain to Pay $3.46 Million to Resolve False Billing and Kickback Allegations (Apr. 30, 2019), https://www.justice.gov/opa/pr/former-ceo-hospital-chain-pay-346-million-resolve-false-billing-and-kickback-allegations ("Gary D. Newsome, former CEO of Health Management Associates LLC (HMA), a hospital chain that was headquartered in Naples, Florida, has agreed to pay the United States $3.46 million to settle allegations that he caused HMA to knowingly submit false claims to government health care programs by admitting patients who could have been treated on a less costly, outpatient basis . . . .").

[9] U.S. Dep't of Just., Fraud Statistics Overview (Jan, 9, 2020), https://www.justice.gov/opa/press-release/file/1233201/download.

[10] U.S. Dep't of Just, Press Release, Justice Department Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.

[11] U.S. Dep't of Just., Fraud Statistics Overview (Jan. 9, 2020), https://www.justice.gov/opa/press-release/file/1233201/download.

[12] *Id.*

Figure 1: Total Civil Fraud Recoveries[13]

Recoveries in the health care industry increased slightly in FY 2019.[14] Specifically, the Government recovered $2.6 billion in civil fraud-related actions involving the health care industry in FY 2019, compared to $2.5 billion recovered in FY 2018.[15] FY 2019 recoveries in health care represented approximately eighty-five percent (85%) of all recoveries.[16] FY 2019 was the tenth consecutive year that health care fraud recoveries surpassed $2 billion.[17]

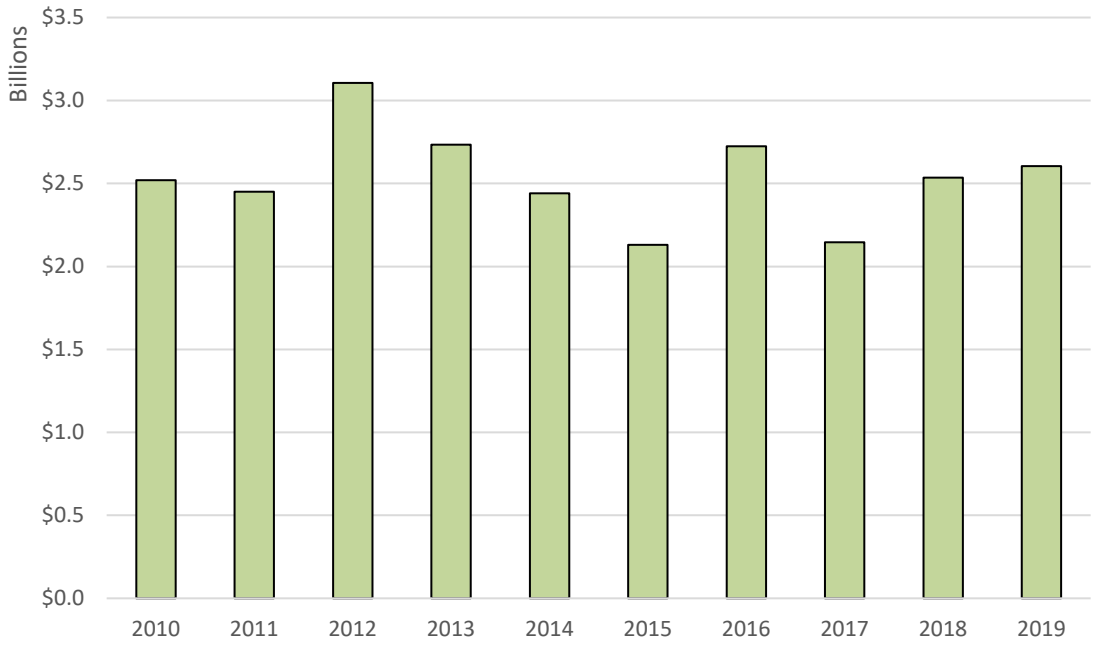


Figure 2: Civil Fraud Recoveries Related to the Health Care Industry[18]

Considering only *qui tam* actions in which the Government intervened, FY 2019 recoveries from interventions totaled $1.91 billion.[19] In stark contrast, recoveries from non-intervened cases amounted to $293.17 million. Of the $1.91 billion recovered in intervened cases, $1.63 billion — or eighty five percent (85%) — involved the health care industry.[20] As illustrated in the graph at Figure 3, from FY 2014 to FY 2019, total recoveries from actions in which the Government intervened have generally declined.[21] Recoveries in health care-related actions where the Government intervened slightly decreased from approximately $1.87 billion in FY 2018 to approximately $1.64 billion in FY 2019.[22] Despite these recent declines in recoveries,

[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*

efforts to combat fraud in health care remain robust and are currently the primary focus of FCA actions.

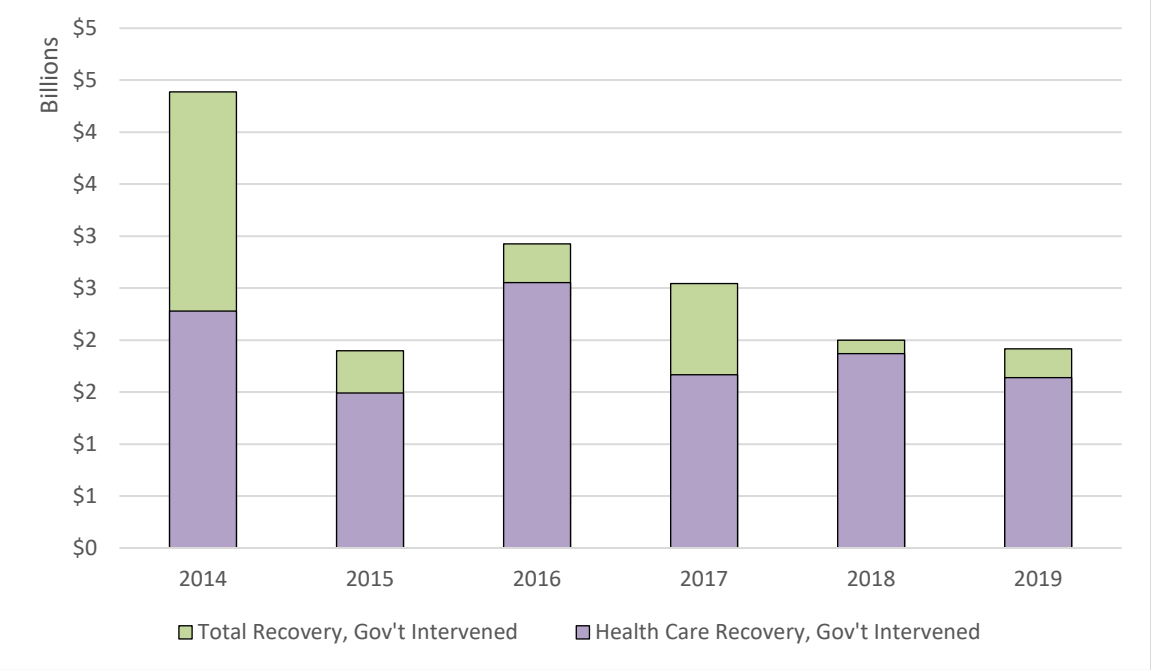


Figure 3: Civil Fraud Recoveries in Government-Intervened Matters[23]

The use of the FCA primarily in health care is also evident in the number of FCA actions filed last year.[24] In FY 2019, 782 new FCA actions were filed, 636 of which were *qui tam* or whistleblower actions (which amounts to an average of twelve (12) new *qui tam* cases per week).[25] Of the 782 new FCA actions, 505 — or sixty-five percent (65%) — were related to the health care industry.[26]

[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*

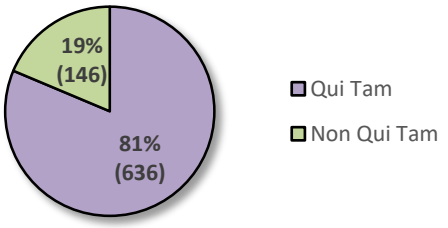


Figure 4: FCA Actions Filed in FY 2019[27]

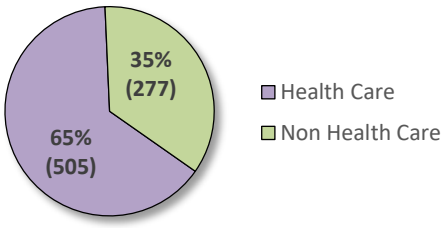


Figure 5: Health Care-Related FCA Actions Filed in FY 2019[28]

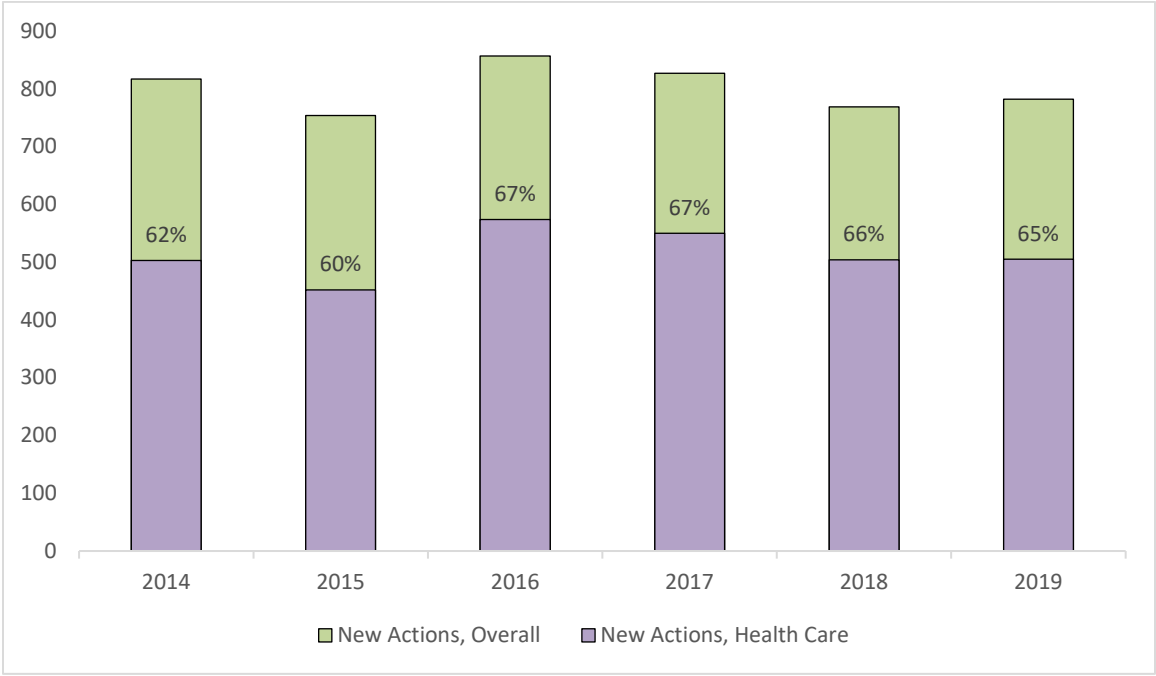


Figure 6: Percentage of New Health Care-Related FCA Actions[29]

Neither the number of new FCA actions per year nor the number of new FCA health care-related actions per year have changed significantly since 2014.[30] The consistency in the number of actions filed each year is remarkable in light of the significant decrease in civil fraud recoveries overall. These numbers may suggest that the average settlement amounts or assessed damages/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 health care industry, where both the civil fraud recoveries and the new matters filed have remained relatively

[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.*

stable.[31] 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.

2020 Outlook

FCA-related actions in health care in 2020 are likely to continue the substantial trend of recoveries that has helped define the last decade of Government enforcement. In particular, 2020 will likely see increased relator and Government enforcement activities in three diverse areas:

1. Physician compensation arrangements, especially those that potentially implicate the practice "loss" theory advanced in *United States ex rel. Bookwalter v. UPMC*;[32]
2. Academic institutions and alleged falsified research reported in grant applications and progress reports as a result of the $112.5 million settlement with Duke University in 2019;[33] and
3. Parallel civil enforcement efforts against a range of defendants, including physicians, charged as part of recent U.S. Department of Justice ("DOJ") takedowns surrounding marketing and telehealth arrangements involving DME companies and laboratories.[34]

These areas are discussed in detail below, along with their potential effect on FCA recoveries and the overall enforcement environment in 2020 and beyond.

Increased Focus on Physician Compensation

Developments at the end of 2019 suggest the Government and relators alike may specifically target health care providers for alleged violations of the Stark Law[35] under the practice "loss" theory in 2020.[36] The practice loss theory suggests that hospitals would not compensate a physician above fair market value unless the hospital expected the physician to make up the difference in referrals.[37] As a result, proponents of the practice loss theory believe that compensation agreements out of line with fair market value must include improper remuneration for physician referrals.[38]

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[31] *Id.*

[32] 938 F.3d 397 (3d Cir. 2019), *reh'g granted, judgment vacated*, 944 F.3d 965 (3d Cir. 2019), *and on reh'g*, No. 18-1693, 2019 WL 7019394 (3d Cir. Dec. 20, 2019).

[33] Press Release, U.S. Dep't of Just., Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct (Mar. 25, 2019), https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related. *See also* Complaint, *United States ex rel. Booze v. Univ. of S.C. et al.*, No. 3:16-cv-183 (W.D.N.C. Apr. 22, 2016) (regarding unsealed *qui tam* complaint accusing university of violating the FCA by providing falsified research results in federal grant reports and applications).

[34] *See* Operations Brace Yourself and Double Helix*, supra* note 7.

[35] 42 U.S.C. § 1395nn.

[36] *See* United States *ex rel.* Bookwalter v. UPMC, 938 F.3d 397 (3d Cir. 2019), *reh'g granted, judgment vacated*, 944 F.3d 965 (3d Cir. 2019), *and on reh'g*, No. 18-1693, 2019 WL 7019394 (3d Cir. Dec. 20, 2019).

[37] *See, e.g.,* Relator's Third Amended Complaint Under Federal False Claims Act at 8, *United States ex rel. Reilly v. North Broward Hospital District et al.*, No. 10-60590 (alleging that "Broward Health and its physicians know that referrals are driving factors in the excessive compensation" and contending that,"[i]f no referrals were made by the physicians and if referrals were not considered, then Broward Health has compensated its physicians to generate losses in excess of approximately 160 million dollars over the last 8 years").

[38] *See United States ex rel. Parikh v. Citizens Medical Center*, 977 F.Supp.2d 654, 671 (S.D. Tex. 2013) ("Even if the cardiologists were making less than the national median salary for their profession, the claims that they began making substantially more money once Citizens employed them is sufficient to allow an inference that they were receiving improper

At the beginning of FY 2019, the Government relied on this practice loss theory in securing a $24 million settlement agreement with Montana-based Kalispell Regional Healthcare System, along with six subsidiaries and related entities (collectively, "KRHS"), to resolve allegations that KHRS violated the Stark Law, Anti-Kickback Statute[39], and FCA by paying excessive full-time compensation to physicians, many of whom worked "far less than full time."[40] The government alleged that KHRS "conspired to violate the Anti-Kickback Statute by paying excessive compensation to physicians employed by [KHRS] to induce referrals to" a related entity, and "by providing administrative services to" the related entity "at below fair market value to reduce expenses and increase profits distributed to physician investors" at the related entity.[41] Additionally, the relator alleged that, although physicians' personal productivity was commonly less than the 10th or 25th national percentiles, KRHS generally compensated them in excess of the 90th percentile.[42] KHRS did not admit any wrongdoing.[43]

In September 2019, the Third Circuit Court of Appeals expressly endorsed the practice loss theory in its opinion in *United States ex rel. Bookwalter v. UPMC*, which reversed and remanded the U.S. District Court for the Western District of Pennsylvania's dismissal of the relators' complaint.[44] UPMC compensated its surgeons with a base salary and required that they meet a particular quota of work units ("wRVUs"); surgeons who exceeded their quota earned an additional $45 per wRVU, but surgeons who failed to meet their quota could have their future base salaries docked.[45] The relators alleged that this arrangement violated the Stark Law, and, therefore, the FCA, because the physicians' compensation varied with, or took into account, the value or volume of the physicians' referrals to UPMC.[46] The Third Circuit found that the relators met their pleading burden by plausibly alleging a "common sense" causal connection between the physicians' pay and their referrals because of the disparity between what UPMC collected based on the physicians' services and what UPMC paid the physicians.[47] Additionally, adopting the same logic used by the Fourth Circuit Court of Appeals in the landmark physician compensation case, *United States ex rel. Drakeford v. Tuomey*,[48] the Third Circuit held that the very structure of the UPMC physicians' contracts was enough to plead that the physicians' compensation structure varied with the volume and value of the surgeons' referrals to UPMC hospitals through correlation alone.[49]

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remuneration. This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals").

[39] 42 U.S.C. § 1320a-7b.

[40] Press Release, U.S. Dep't of Just., Kalispell Regional Healthcare System to Pay $24 Million to Settle False Claims Act Allegations (Sept. 28, 2018), https://www.justice.gov/opa/pr/kalispell-regional-healthcare-system-pay-24-million-settle-false-claims-act-allegations [hereinafter, "KRHS Press Release"].

[41] *Id.*

[42] *See* Amended Complaint at *7–8, United States *ex rel.* Mohatt v. Kalispell Regional Healthcare, No. CV-16-125 (D. Mont. May 1, 2017).

[43] KRHS Press Release, *supra* note 40.

[44] *See* United States *ex rel.* Bookwalter v. UPMC, 938 F.3d 397 (3d Cir. 2019), *reh'g granted, judgment vacated*, 944 F.3d 965 (3d Cir. 2019), *and on reh'g*, No. 18-1693, 2019 WL 7019394 (3d Cir. Dec. 20, 2019).

[45] *Id.* at 403.

[46] *Id.* at 410.

[47] *Id.* at 411.

[48] 976 F. Supp. 2d 776 (D.S.C. 2013).

[49] *Id.* at 408.

The *Bookwalter* decision immediately sent shockwaves through the health care industry, creating concern that a relator's complaint could survive a motion to dismiss as long as the relator alleged that a physician was compensated, in part, for his or her productivity.[50] In response to the Third Circuit's finding regarding this correlation, UPMC requested a rehearing and was supported by an amicus curiae brief filed from several industry groups, including the American Hospital Association, the Association of American Medical Colleges, and the Federation of American Hospitals.[51] On December 20, 2019, the Third Circuit granted the rehearing.[52] Upon rehearing, the Third Circuit upheld the portion of its opinion regarding causation, but reversed its holding that the relators could establish that an indirect compensation arrangement violated the Stark Law simply by alleging that the surgeons' compensation correlated with the volume or value of their referrals to UPMC.[53]

Qui Tams and the Practice Loss Theory in 2020

In 2020 and beyond, relators and the Government are likely to view the Third Circuit's apparent endorsement of the practice loss theory as a viable method for alleging claims against hospitals and/or physicians participating in compensation models perceived as out of line with the value of the services provided by the physicians.[54] Given the almost ubiquitous nature of wRVUs in physician compensation determinations and the frequency with which physician compensation forms the foundation of *qui tam* actions, 2020 is likely to see increased relator activity and governmental scrutiny surrounding wRVU compensation models nationwide. Consequently, hospitals and physicians should ensure that compensation models are closely vetted through robust fair market value studies and are reinforced by clearly articulated and reasonable justifications.

Enhanced Scrutiny of Academic Institutions

In March 2019, DOJ announced a $112.5 million settlement with Duke University ("Duke") to resolve allegations that the University violated the FCA by submitting applications and progress reports that contained falsified research on federal grants to the National Institutes of Health ("NIH") and to the Environmental Protection Agency ("EPA").[55] A former employee originally filed the *qui tam* lawsuit against Duke in May 2013.[56] On August 8, 2016, the

[50] *See, e.g.*, *id.* at 423 (Ambro, J., concurring) ("Today's decision suggests, therefore, that any hospital that pays its affiliated physicians according to some metric of the work they personally perform at the hospital falls under suspicion of violating the Stark Act, and it can only restore its good name by pleading one of the statutory exceptions—presumably at the summary judgment stage at the earliest, i.e., after discovery has already taken place.")

[51] *See* Brief of Amici Curiae American Hospital Association, Association of American Medical Colleges, Federation of American Hospitals, Hospital and Healthsystem Association of Pennsylvania and New Jersey Hospital Association in Support of Petitioners; *United States ex rel. Bookwalter v. UPMC*, No. 18-1693, 2019 WL 5618125 (3d. Cir. Oct. 22, 2019).

[52] *See United States ex rel. Bookwalter*, 944 F.3d 965.

[53] *See United States ex rel. Bookwalter*, 2019 WL 7019394.

[54] For example, Cookeville Regional Medical Center Authority recently entered into a $4.1 million settlement agreement with the government over allegations that its payments to physicians violated the FCA and Stark Law because the payments allegedly "were over fair market value and resulted in substantial and consistent losses on physician practices." Verified False Claims Act Complaint at 2, *United States ex rel. Seabury v. Cookeville Regional Medical Center Authority et al.*, No. 2:15-cv-00065 (M.D. Tenn. Nov. 10, 2015); *See* Press Release, U.S. Dep't of Just., Cookeville Hospital Settles False Claims Act Allegations (Feb. 14, 2020), https://www.justice.gov/usao-mdtn/pr/cookeville-hospital-settles-false-claims-act-allegations.

[55] Press Release, U.S. Dep't of Just., Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct (Sept. 28, 2018), https://www.justice.gov/opa/pr/duke-university-agrees-pay-us-1125-million-settle-false-claims-act-allegations-related [hereinafter "Duke Press Release"].

[56] Complaint, *United States ex rel. Thomas v. Duke University et al.*, No. 4:13-cv-00017 (W.D. Va. May 17, 2013).

Government submitted notice that it would not intervene at that time.[57] However, in 2017, the Government filed a statement of interest in the case[58] and later combined the case with ongoing litigation in the Middle District of North Carolina.[59]

The Government alleged that, between 2006 and 2018, Duke submitted claims to the NIH and EPA that contained falsified or fabricated data or statements in thirty (30) grants, causing the NIH and EPA to pay out grant funds they otherwise would not have.[60] In particular, the Government contended that the results of certain research related to mice conducted by a Duke research technician in its Airway Physiology Laboratory, as well as statements based on those research results, were falsified and/or fabricated.[61] The scope of the alleged false claims compounded year after year as the researchers authored "numerous scientific publications based on [allegedly] fraudulent research funded by public grants," which were "used to justify future grant awards, money which would then be spent on more fraudulent research."[62]

FCA, *Qui Tam*s, and Academic Research in 2020

Upon announcement of the Duke settlement, representatives from the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") and EPA suggested that similar enforcement would continue, commenting, "OIG and our law enforcement partners will continue to hold such grantees fully accountable regardless of the length or complexity of the investigations," and "[t]his settlement sends a strong message that fraud and dishonesty will not be tolerated in the research funding process. We will continue to take appropriate legal measures to ensure a fiscally sound system that protects grant funds."[63]

The Government's warning to academic institutions surrounding potential enforcement activity related to federal research grants/funding was underscored on January 28, 2020, when DOJ announced that it had charged, among others, the Chair of Harvard University's Chemistry and Chemical Biology Department for making "a materially false, fictitious and fraudulent statement" in connection with NIH and Department of Defense ("DOD") grants.[64] "These grants require disclosure of significant foreign financial conflicts of interest, including financial support from foreign governments or foreign entities," and the Government alleges that the Harvard Chair "lied about his involvement" with a Chinese talent program alleged to "reward individuals for stealing proprietary information" from the United States.[65] While DOJ maintains that Harvard was unaware of its Chair's foreign connections and alleged misrepresentations

[57] Notice of the United States that it is Not Intervening at this Time, *United States ex rel. Thomas v. Duke University et al.*, No. 4:13-cv-00017 (W.D. Va. Aug. 8, 2016).

[58] Statement of Interest, *United States ex rel. Thomas v. Duke University et al.*, No. 4:13-cv-00017 (W.D. Va. Feb. 10, 2017).

[59] Order granting Motion to Transfer Case, *United States ex rel. Thomas v. Duke University et al.*, No. 4:13-cv-00017 (W.D. Va. Mar. 28, 2017).

[60] Duke Press Release, *supra* note 55.

[61] *Id.*

[62] Amended Complaint, *United States ex rel. Thomas v. Duke University et al.*, No. 4:13-cv-00017 (W.D. Va. Nov. 13, 2015).

[63] Duke Press Release, *supra* note 55.

[64] Press Release, U.S. Dep't of Just., Harvard University Professor and Two Chinese Nationals Charged in Three Separate China Related Cases (January 28, 2020), https://www.justice.gov/opa/pr/harvard-university-professor-and-two-chinese-nationals-charged-three-separate-china-related.

[65] *Id.*

on NIH and DOD grants, the case is demonstrative of another type of fact pattern in which an academic institution might have been exposed to FCA liability.[66]

Moreover, given the way research projects build upon each other, the possibility of a false or fraudulent claim early in the research project could result in significant liability for multiple tainted projects. Additionally, in the Duke case, the relator's share of recoveries was over $33 million;[67] a healthy incentive for prospective relators to file *qui tam* lawsuits against research universities that receive federal funding. For these reasons and those discussed above, 2020 is likely to see significant Government and relator FCA activity in the research grant space.

Continued Focus on Telehealth Arrangements

In 2019, the Government clearly communicated its intention to target telehealth arrangements designed to bilk federal health care programs out of federal funds through fraudulent conduct. While it remains a burgeoning and promising form of patient care, telehealth services continue to represent health care's "Wild West" due to the relative infancy of telehealth's use in the industry. As a result, 2019 was, in part, defined by the Government's intense scrutiny of arrangements at the intersection of telehealth and ancillary services, particularly DME sales and genetic testing. This scrutiny manifested itself in two sweeping nationwide Government "takedowns" that involved billions of dollars in claims billed to Medicare, hundreds of defendants/potential defendants, and a myriad of federal criminal charges. While these takedowns were primarily criminal enforcement actions, they have involved and triggered parallel civil proceedings under the FCA that have the potential to substantially impact FCA recoveries in 2020.

Operation Brace Yourself

On April 9, 2019, the DOJ announced charges against twenty four (24) individuals — three (3) prescribing medical professionals and twenty one (21) owners and corporate executives associated with DME and telemedicine companies — in an investigation spearheaded by the DOJ, the Federal Bureau of Investigation ("FBI"), and OIG.[68] Dubbed as "Operation Brace Yourself," officials described the takedown as focused on "[a]n international fraud ring [that] allegedly bilked Medicare out of more than $1 billion by billing it for unnecessary medical equipment — mainly back, shoulder, wrist, and knee braces" that involved over 100 companies.[69]

The DME companies involved allegedly paid national and international marketing companies tens of millions of dollars to arrange for Medicare beneficiaries (via television and online advertising) to receive medically unnecessary orthotic bracing.[70] According to the Government, the marketing companies arranged for Medicare beneficiaries to consult with

[66] *Id. See also* Press Release, U.S. Dep't of Just., Department of Justice Reaches $5.5 Million Settlement with Van Andel Research Institute to Resolve Allegations of Undisclosed Chinese Grants to Two Researchers (December 19, 2019) (stating that "Van Andel Research Institute (VARI) has agreed to pay $5,500,000.00 to resolve allegations that it violated the False Claims Act by submitting federal grant applications and progress reports to the National Institutes of Health (NIH) in which VARI failed to disclose Chinese government grants that funded two VARI researchers").

[67] Duke Press Release, *supra* note 55.

[68] News, FBI, Billion-Dollar Medicare Fraud Bust: FBI Announces Results of Operation Brace Yourself (Apr. 9, 2019), https://www.fbi.gov/news/stories/billion-dollar-medicare-fraud-bust-040919.

[69] *Id.*

[70] *Id.*

telemedicine physicians — who were not the beneficiaries' primary care providers — and paid kickbacks to these physicians in exchange for medical orders prescribing the bracing.[71] Telemedicine physicians purportedly prescribed the braces at issue, despite having only brief telephonic encounters with the patients or no encounters at all.[72] The over $900 million in Medicare proceeds paid to defendants as a result of the alleged scheme, in some cases, were purportedly "laundered through international shell corporations and used to purchase exotic automobiles, yachts, and luxury real estate in the United State and abroad."[73] As a result of this operation, over one-hundred and thirty (130) DME companies had their Medicare payments suspended.[74]

Operation Double Helix

On September 27, 2019, the DOJ announced charges against thirty five (35) individuals, including nine (9) medical professionals and six (6) laboratory owners, who used marketing and telehealth arrangements to allegedly drive the medically unnecessary and high-dollar genetic cancer ("CGx") testing of Medicare beneficiaries.[75] "Operation Double Helix" involved the alleged payment of kickbacks and bribes from CGx testing laboratories to marketing and telehealth companies for the referral of Medicare beneficiaries.[76] As a result of these arrangements, the Government claimed that CGx testing laboratories submitted over $2.1 billion in claims to Medicare for the fraudulent tests.[77]

As was the case with Operation Brace Yourself, marketing companies allegedly targeted seniors through extensive marketing efforts, including at health fairs, and arranged for "consults" between the telehealth physicians and the Medicare beneficiaries.[78] However, telehealth physicians allegedly had little to no interaction with the Medicare beneficiaries for whom they ordered CGx testing, which often commands approximately $6,000 to $10,000 in reimbursements from Medicare.[79] The Government also asserted that the results of the CGx tests were often not provided to the Medicare beneficiaries and/or were "worthless" to the beneficiaries' primary care providers.[80]

Parallel Civil Enforcement in 2020

Since it announced Operation Brace Yourself and Operation Double Helix, the Government has criminally charged other principals of DME, laboratory, marketing, and telehealth companies for their involvement in the alleged schemes. Moreover, the Government appears

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] Press Release, U.S. Dep't of Just., 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), https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

[75] Press Release, U.S. Dep't of Just., Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for over $2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged (Sep. 27, 2019), https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.*

poised in 2020 to conduct additional waves of enforcement against telehealth physicians for their purported central role in ordering medically unnecessary bracing and laboratory testing. The coming year is also likely to see criminal enforcement actions against other ancillary services, such as pharmaceutical sales, that have employed the marketing and telehealth model at issue.

The Government's criminal enforcement in the telehealth arena in 2019 will also likely result in sizeable recoveries in 2020, due to the Government's application of the FCA in parallel civil actions tied to Operation Brace Yourself and Operation Double Helix. As is common practice in criminal health care fraud matters, DOJ and various U.S. Attorneys' Offices nationwide are also investigating the defendants civilly for the alleged filing of false claims in connection with Medicare reimbursements for bracing and/or CGx testing. Consequently, as many defendants involved in the alleged marketing and telehealth schemes plead guilty, the Government is likely to seek substantial sums from defendants through application of the FCA and its significant penalties and damages. Assuming that at least some of the defendants charged as a part of Operation Brace Yourself and Operation Double Helix are not judgment proof, FCA recoveries in FY 2020 could be extensively buoyed. Moreover, to the extent certain DME and lab testing companies have yet to be charged for their operation of the marketing and telehealth model, 2020 is likely to see increased relator activity in this area.

Conclusion

The year 2019 marked the end of an incredibly active decade of FCA enforcement nationwide. Indeed, following the FCA's statutory changes at the start of the decade, 2010 through 2019 resulted in over $38 billion in recoveries under the FCA. While FCA recoveries have remained relatively flat over the last few years, and the number of *qui tam*s per year has recently declined, it remains true that the Government and relators alike continue to actively seek to apply the FCA in diverse areas and ways. This reality is particularly evident in health care, where FCA enforcement has remained remarkably consistent in terms of the number of actions per year and the amounts of recoveries per year. This consistency has remained while the areas of FCA recoveries within health care have largely varied year to year. 2020 is likely to be no different, as the FCA seems likely to take center stage in health care enforcement once again.

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.

The False Claims Act & Health Care: 2019 Recoveries and 2020 Outlook

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