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Practice Groups:

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The False Claims Act and Health Care: 2022 Recoveries and 2023 Outlook

By John H. Lawrence, Mark A. Rush, Anderson M. Shackelford, Nora E. Becerra, and Natalia A. Nino

On 7 February 2023, the US Department of Justice (DOJ) publicly reported the statistics for federal civil fraud recoveries in Fiscal Year (FY) 2022.[1] While the DOJ emphasized in its accompanying press release that "the government and whistleblowers were party to 351 settlements and judgments" which comprised "the second-highest number of settlements and judgments in a single year,"[2] the numbers illustrate that FY 2022 continues a years-long trend—FY 2021 aside[3]—of diminishing False Claims Act[4] (FCA) civil fraud recoveries.[5] Indeed, FY 2022's US$2.2 billion in total recoveries was the lowest total in 14 years.[6] Fascinatingly, for the first time since the DOJ began tracking FCA statistics in FY 1987, aggregate recoveries in non-intervened *qui tam* actions outpaced that in *qui tam* matters in which the DOJ intervened or otherwise pursued recovery.[7] This held true both for health care matters and overall.[8]

At US$1.8 billion, the health care industry again accounted for the lion's share of recoveries in FY 2022 (80% of the aggregate total).[9] However, this was the lowest amount for health care-related[10] recoveries since FY 2009.[11] As in the past, the government pursued a wide array of health industry entities and providers with its civil fraud enforcement efforts in FY 2022. Over the course of the year, it targeted pharmaceutical manufacturers,[12] health

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[1] U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW (Feb. 7, 2023), https://www.justice.gov/opa/press-release/file/1567691/download. This sum reflects only federal recoveries; Medicaid recoveries are not accounted for in this figure. *Id.*

[2] Press Release, U.S. Dep't of Just., False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022 (Feb. 7, 2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022

[3] *See* John H. Lawrence et. al, *The False Claims Act and Health Care: 2021 Recoveries and 2022 Outlook*, K&L GATES (Apr. 7, 2022), https://www.klgates.com/The-False-Claims-Act-and-Health-Care-2021-Recoveries-and-2022-Outlook-4-7-2022 ("The US$5.6 billion in recoveries reported by the United States Department of Justice (DOJ) in its 1 February 2022 press release is more than double the US$2.2 billion recovered in FY 2020, and is the second largest total recovery ever recorded.").

[4] 31 U.S.C. §§ 3729-33.

[5] Setting aside FY 2021, civil fraud recoveries have dropped from US$5 billion in FY 2016 to US$2.2 billion in FY 2022. U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW, *supra* note **Error! Bookmark not defined.**

[6] In FY 2008, recoveries totaled US$1.4 billion. *Id.*

[7] *Id.*

[8] *Id.*

[9] *See id.*

[10] References herein to "health care-related" statistics refer to those matters in which the Department of Health and Human Services (HHS) was the primary government agency benefitting from a fraud settlement/recovery. *See id.* Those statistics are reported in the DOJ's "Fraud Statistics Overview." *Id.* at 4-6.

[11] *Id.*

[12] *See, e.g.*, Press Release, U.S. Dep't of Just., Mallinckrodt Agrees to Pay $260 Million to Settle Lawsuits Alleging Underpayments of Medicaid Drug Rebates and Payment of Illegal Kickbacks (Mar. 7, 2022), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-260-million-settle-lawsuits-alleging-underpayments-medicaid-drug#:~:text=The%20settlement%20provides%20for%20Mallinckrodt's,to%20resolve%20the%20kickback%20allegations.

plans,[13] nursing homes and long-term care management companies,[14] home health companies,[15] hospices,[16] health care systems,[17] hospitals,[18] durable medical equipment companies,[19] pharmacies,[20] individual practitioners,[21] physician groups,[22] and clinical laboratories,[23] to name a few. As predicted last year,[24] Medicare Advantage-related enforcement prove d a governmental focus in FY 2022, as evidenced by the DOJ's announced intervention in one such case[25] and continued participation in several others.[26] The government also highlighted its enforcement priorities in Medicaid program FCA cases and COVID-19-related fraud,[27] among other areas. The DOJ signaled its intent to continue

[13] *See, e.g.*, Press Release, U.S. Dep't of Just., California County Organized Health System and Three Health Care Providers Agree to Pay $70.7 Million for Alleged False Claims to California's Medicaid Program (Aug. 18, 2022), https://www.justice.gov/opa/pr/california-county-organized-health-system-and-three-health-care-providers-agree-pay-707.

[14] *See, e.g.*, Press Release, U.S. Dep't of Just., Justice Department Sues American Health Foundation and Its Affiliates for Providing Grossly Substandard Nursing Home Services (June 15, 2022), https://www.justice.gov/opa/pr/justice-department-sues-american-health-foundation-and-its-affiliates-providing-grossly.

[15] *See, e.g.*, Press Release, U.S. Att'y's Off., W. Dist. Ky., Home Health Company Operating in Florida Pays $2.1 Million to Resolve False Claims Allegations (May 5, 2022), https://www.justice.gov/usao-wdky/pr/home-health-company-operating-florida-pays-21-million-resolve-false-claims-allegations.

[16] *See, e.g.*, Press Release, U.S. Dep't of Just., Crossroads Hospice Agrees to Pay $5.5 Million to Settle False Claims Act Liability (Nov. 23, 2021), https://www.justice.gov/opa/pr/crossroads-hospice-agrees-pay-55-million-settle-false-claims-act-liability.

[17] *See, e.g.*, Press Release, U.S. Att'y's Off., E. Dist. Wash., Providence Health & Services Agrees to Pay $22.7 Million to Resolve Liability From Medically Unnecessary Neurosurgery Procedures at Providence St. Mary's Medical Center (Apr. 12, 2022), https://www.justice.gov/usao-edwa/pr/providence-health-services-agrees-pay-227-million-resolve-liability-medically.

[18] *See, e.g.*, Press Release, U.S. Dep't of Just., Flower Mound Hospital to Pay $18.2 Million to Settle Federal and State False Claims Act Allegations Arising from Improper Inducements to Referring Physicians (Dec. 2, 2021), https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations.

[19] *See, e.g.*, Press Release, U.S. Dep't of Just., Hearing Aid Company Eargo Inc. Agrees to Pay $34.37 Million to Settle Common Law and False Claims Act Allegations for Unsupported Diagnosis Codes (Apr. 29, 2022), https://www.justice.gov/opa/pr/hearing-aid-company-eargo-inc-agrees-pay-3437-million-settle-common-law-and-false-claims-act.

[20] *See, e.g.*, Press Release, U.S. Atty's Office, E.D. Wis., Milwaukee Pharmacy Chain to Pay Over $2 Million to Resolve Allegations It Violated the False Claims Act (Jan. 28, 2022), https://www.justice.gov/usao-edwi/pr/milwaukee-pharmacy-chain-pay-over-2-million-resolve-allegations-it-violated-false.

[21] *See, e.g.*, Press Release, U.S. Dep't of Just., United States Files False Claims Act Complaint Against Chiropractor, Modern Vascular Office-Based Labs and Modern Vascular Corporate Entities (Dec. 13, 2022), https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-chiropractor-modern-vascular-office. *See also* Press Release, U.S. Dep't of Just., Fifteen Texas Doctors Agree to Pay over $2.8 Million to Settle Kickback Allegations (June 28, 2022), https://www.justice.gov/opa/pr/fifteen-texas-doctors-agree-pay-over-28-million-settle-kickback-allegations.

[22] *See, e.g.*, Press Release, U.S. Dep't of Just., Physician Partners of America to Pay $24.5 Million to Settle Allegations of Unnecessary Testing, Improper Remuneration to Physicians and a False Statement in Connection with COVID-19 Relief Funds (Apr. 12, 2022), https://www.justice.gov/opa/pr/physician-partners-america-pay-245-million-settle-allegations-unnecessary-testing-improper.

[23] *See, e.g.*, Press Release, U.S. Att'y's Off., D. Mass., MD Labs and its Co-Founders Agree to Pay Up to $16 Million to Resolve Allegations of Fraudulent Billing (Oct. 20, 2021), https://www.justice.gov/usao-ma/pr/md-labs-and-its-co-founders-agree-pay-16-million-resolve-allegations-fraudulent-billing. *See also* Press Release, U.S. Att'y's Off., D. Mass., Radeas LLC Agrees to Pay $11.6 Million to Resolve Allegations of Fraudulent Billing (Mar. 31, 2022), https://www.justice.gov/usao-ma/pr/radeas-llc-agrees-pay-116-million-resolve-allegations-fraudulent-billing.

[24] *See* Lawrence, *supra* note **Error! Bookmark not defined.** ("[I]ndustry participants should expect the DOJ to accelerate its pursuit of fraud in the Medicare Advantage arena against both insurers and providers.").

[25] *See, e.g.*, Press Release, U.S. Att'y's Off., S. Dist. N.Y., United States Files Civil Fraud Lawsuit Against Cigna For Artificially Inflating Its Medicare Advantage Payments (Oct. 17, 2022), https://www.justice.gov/usao-sdny/pr/united-states-files-civil-fraud-lawsuit-against-cigna-artificially-inflating-its.

[26] U.S. Dep't of Just., False Claims Act Settlements, *supra* note **Error! Bookmark not defined.** ("This past year, the department . . . continued to litigate a number of other cases, including actions against [several Medicare Advantage insurers].").

[27] *See id.* (highlighting efforts to combat "Fraud and Abuse in the Medicaid Program" and "COVID-Related Fraud").

pursuing health care fraud wherever it may be found, emphasizing yet again its view that "enforcement of the [FCA] deters others who might try to cheat the system for their own gain, and in many cases, also protects patients from medically unnecessary or potentially harmful actions."[28]

In this article, K&L Gates highlights three areas worthy of the health care industry's attention in the year ahead and beyond. First, all eyes are on the Supreme Court of the United States (SCOTUS) as it addresses two hotly contested FCA issues: (1) the contours of the government's dismissal authority in non-intervened cases, and (2) the extent to which defendants can escape FCA liability by relying on objectively reasonable interpretations of governing regulations (even where they subjectively doubt those interpretations). Second, providers should pay close attention to the government's growing use of the "High Risk – Heightened Scrutiny" list, which the government has demonstrated an increased willingness to use for providers the government does not wish to exclude from the federal health care programs, but who refuse to enter into Corporate Integrity Agreements (CIAs) despite signing an FCA settlement agreement. Lastly, COVID-19-related fraud enforcement will likely gain momentum as the government devotes resources toward investigating and prosecuting fraud stemming from the pandemic. This article will analyze these topics in depth, but will first delve into the FY 2022 statistics in detail.

FY 2022 Civil Fraud Recoveries

At US$2.2 billion, overall civil fraud recoveries were down significantly in FY 2022 as compared to FY 2021.[29] However, the prior fiscal year can fairly be characterized as an outlier due to a disproportionately large settlement with Purdue Pharma in connection with the opioid crisis.[30] Even so, while recoveries in FY 2022 were only marginally less than in FY 2020, they were at their lowest since FY 2008.[31] And FY 2022's US$2.2 billion total is even more notable considering that US$843.8 million—over 38%—came from a single FCA settlement with Biogen, Inc.[32] As shown in Figure 1, the general downward trend in FCA recoveries dating back to FY 2016 is clear. As Figure 2 illustrates, the trend becomes even more apparent when removing the large resolutions with Purdue Pharma and Biogen, Inc. from the statistics for FY 2021 and FY 2022, respectively. In a reversal from FY 2021, *qui tam* matters drove the bulk of the recoveries in FY 2022, accounting for just under US$2 billion—nearly 89% of the total.[33] Whistleblower and *qui tam*-related recoveries added an additional US$245.6 million in recoveries.[34]

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[28] *Id.*

[29] U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW, *supra* note **Error! Bookmark not defined.**.

[30] *See Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family*, U.S. DEP'T OF JUST. (Oct. 21, 2020), https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid [hereinafter *Purdue Pharma*].

[31] U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW, *supra* note **Error! Bookmark not defined.**.

[32] *See* Press Release, U.S. Dep't of Just., Biogen Inc. Agrees to Pay $900 Million to Settle Allegations Related to Improper Physician Payments (Sept. 26, 2022), https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments#:~:text=Biogen%20Inc.,Payments%20%7C%20OPA%20%7C%20Department%20of%20Justice [hereinafter U.S. Dep't of Just., Biogen]. Note that, while the press release indicates that Biogen agreed to pay US$900 million, US$56.2 million of this amount was nonfederal recovery. *Id.*

[33] U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW, *supra* note **Error! Bookmark not defined.**.

[34] *Id.*

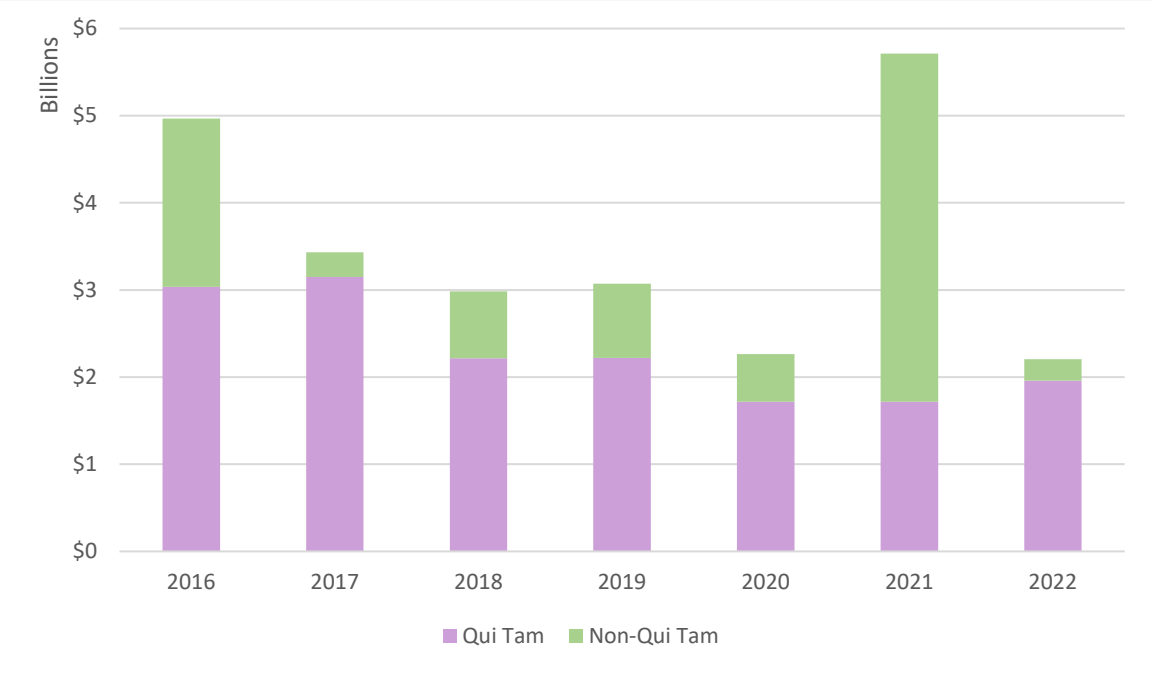

Figure 1: Total Civil Fraud Recoveries[35]

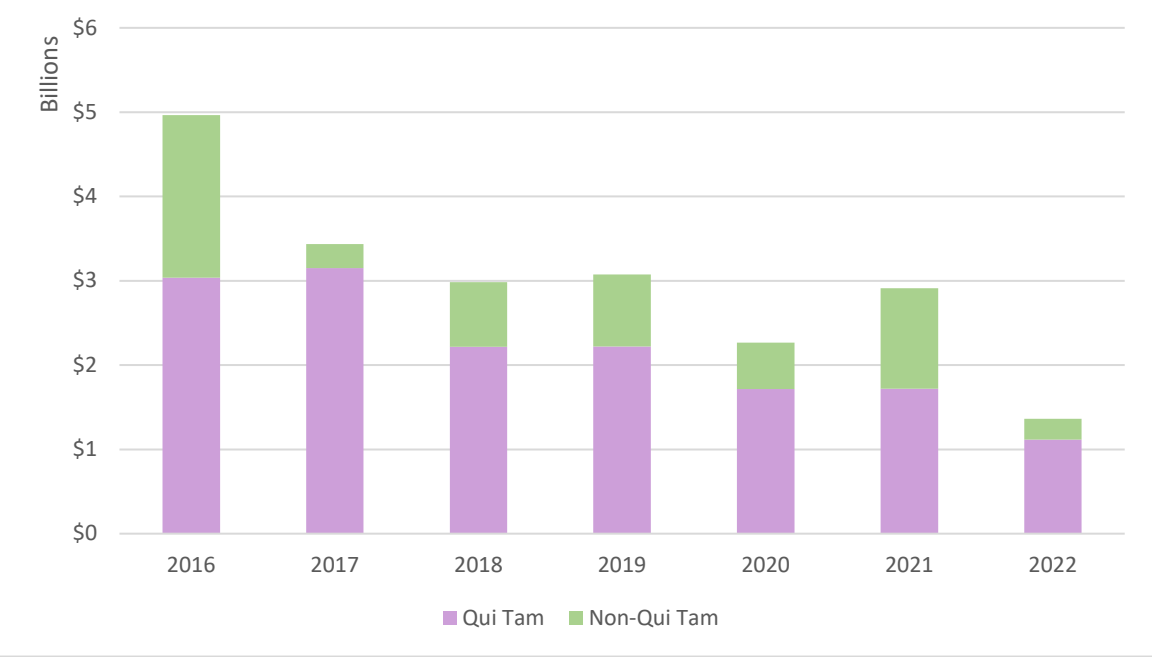

Figure 2: Total Civil Fraud Recoveries (Excluding FY 2021 Resolution With Purdue Pharma and FY 2022 Resolution With Biogen, Inc.)[36]

[35] *See id.*

[36] *See id.*; *Purdue Pharma*, *supra* note **Error! Bookmark not defined.**; U.S. Dep't of Just., Biogen, *supra* note **Error! Bookmark not defined.**.

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Turning to health care-related civil fraud recoveries, FY 2022's US$1.8 billion in total recoveries—while dwarfed by the US$5.1 billion recorded in FY 2021—was likewise only slightly less than FY 2020's US$1.9 billion in recoveries.[37] As demonstrated in Figure 3, recoveries in health care-related FCA cases since 2016 have not followed any discernible pattern. However, as Figure 4 shows, when removing the aforementioned larger settlements in each of the past two fiscal years, a slight downward trend emerges.

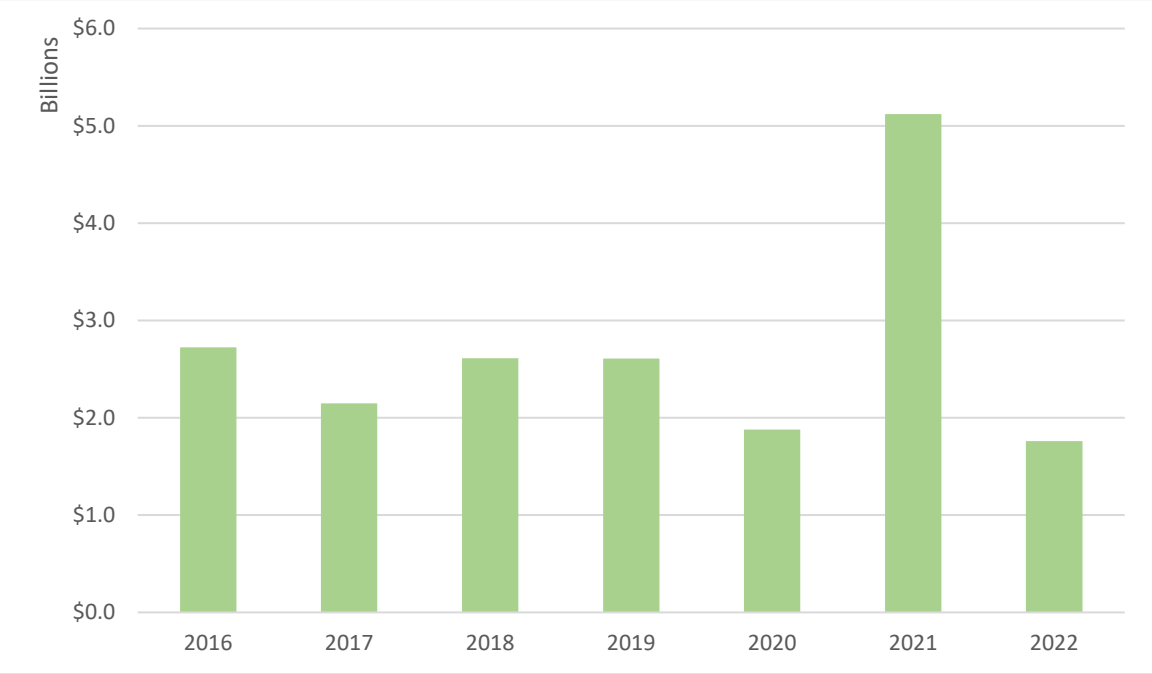

Figure 3: Civil Fraud Recoveries Related to the Health Care Industry[38]

[37] U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW, *supra* note **Error! Bookmark not defined.**.
[38] *Id.*

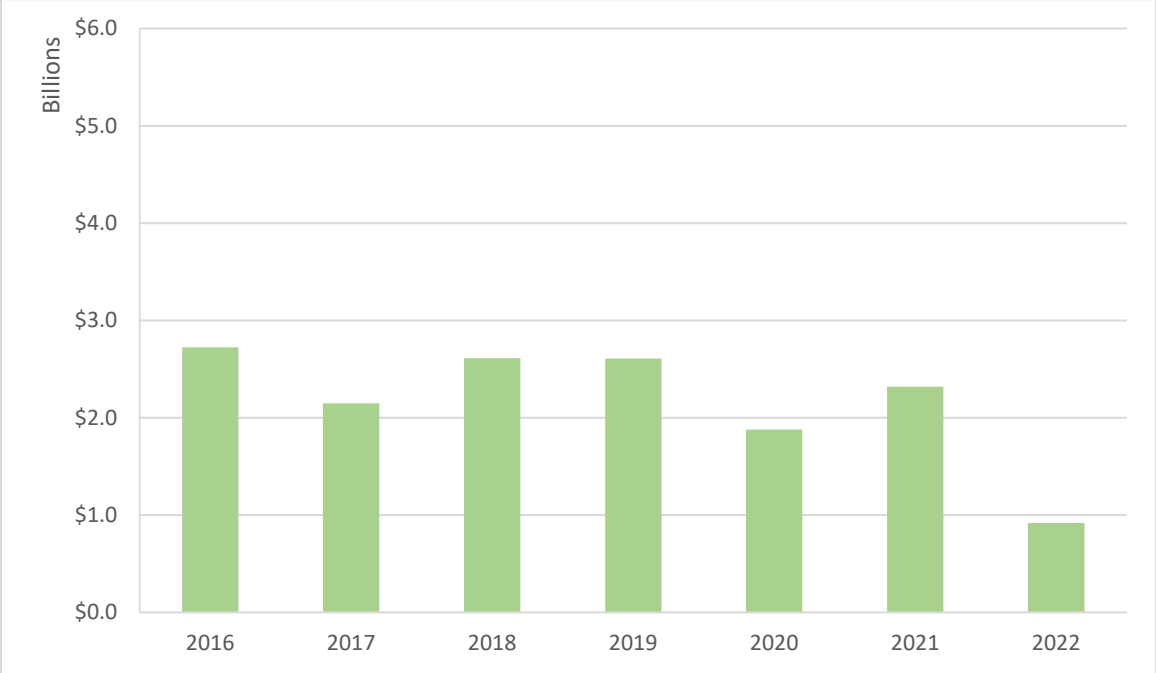

Figure 4: Civil Fraud Recoveries Related to the Health Care Industry (Excluding FY 2021 Resolution With Purdue Pharma and FY 2022 Resolution With Biogen, Inc.)[39]

Looking at *qui tam* actions specifically, FY 2022 appears to have been an anomalous year in several respects. First, in government-intervened *qui tam* actions settled/resolved in FY 2022, recoveries totaled just US$776.8 million, the lowest in 18 years.[40] The same was true for government-intervened health care-related *qui tam* actions, where the US$641.7 million recovered was also the lowest in 18 years.[41] Second, while history has shown that government intervention drives the vast majority of civil fraud recoveries both inside and outside of health care, this was not so in FY 2022. For the first time since the DOJ began tracking FCA statistics in FY 1987, *qui tam* matters in which the government declined to intervene resulted in a higher aggregate recovery than government-intervened matters.[42] Overall, non-intervened matters yielded US$1.2 billion in settlements/judgments, accounting for 60.4% of all *qui tam* recoveries.[43] For health care-related *qui tam* actions, non-intervened matters yielded US$1 billion, 61.2% of that category's total.[44] Still, by any measure—as shown in Figure 5—total recoveries in intervened actions have declined notably over the past few years. This is so for *qui tam* matters overall and for health care-related *qui tam* matters. Nevertheless, K&L Gates expects that the government will vigorously pursue health care FCA cases in the year ahead. In fact, anecdotally, K&L Gates has heard from various government officials that

[39] *See id.*; *Purdue Pharma*, *supra* note **Error! Bookmark not defined.**; U.S. Dep't of Just., Biogen, *supra* note **Error! Bookmark not defined.**.

[40] U.S. DEP'T OF JUST., FRAUD STATISTICS OVERVIEW, *supra* note **Error! Bookmark not defined.**.

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

the government may be stepping up the urgency of its enforcement actions, precisely because of how low the recoveries were in FY 2022.

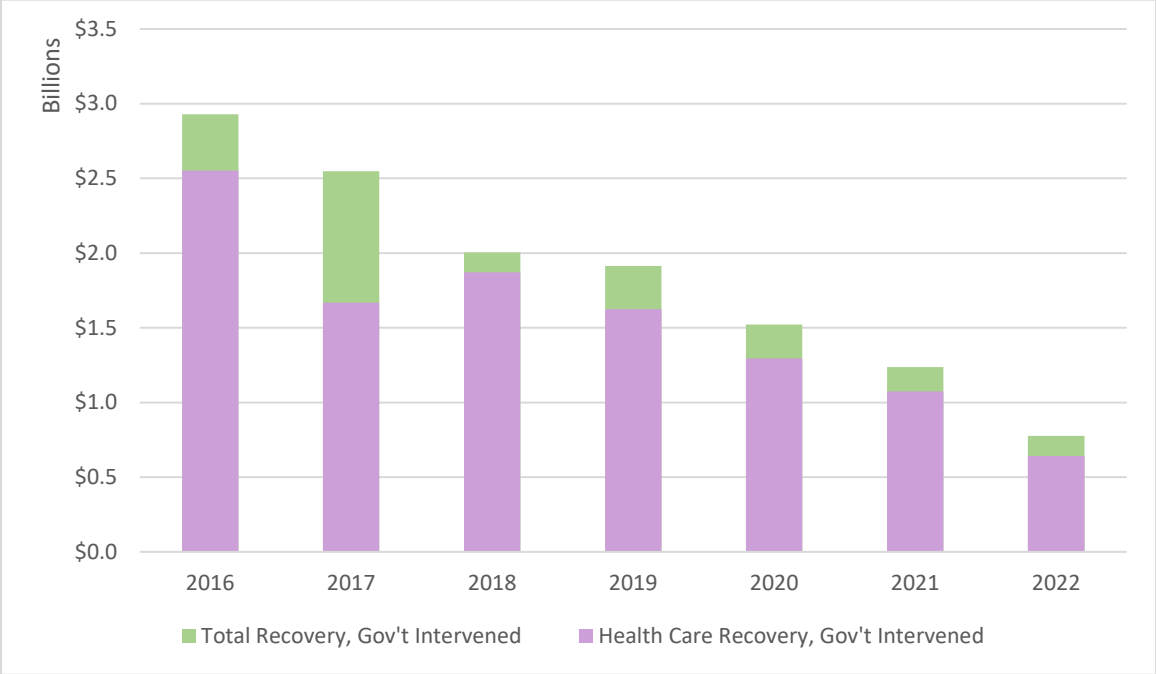

Figure 5: Civil Fraud Recoveries in Government-Intervened Matters

Even as FY 2022 saw the lowest aggregate total recovery in 14 years, it had the second-highest number of FCA settlements and judgments on record.[45] As Figure 6 shows, there were 652 *qui tam* actions filed during this period, compared with 296 non-*qui tam* actions. As illustrated in Figure 7, there were 371 new health care-related *qui tam* actions filed in FY 2022, along with 93 non-*qui tam* actions.

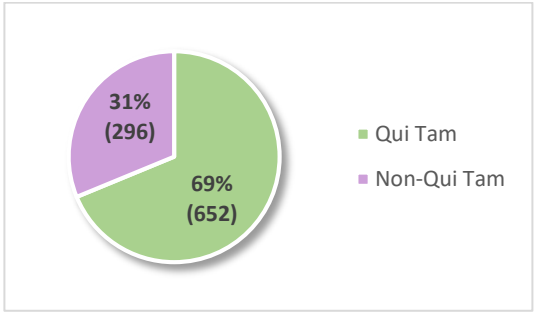

Figure 6: FCA Actions Filed in FY 2022[46]

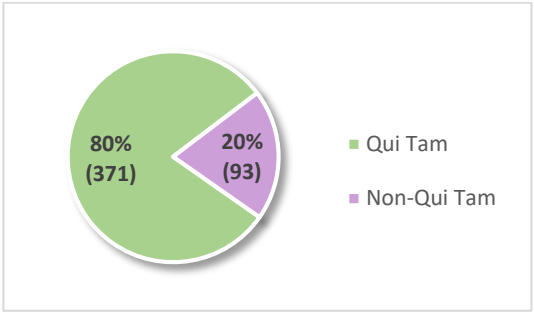

Figure 7: Health Care-Related FCA Actions Filed in FY 2022[47]

[45] *Id.*
[46] *Id.*
[47] *Id.*

As referenced, health care-related FCA matters continue to comprise the bulk of settlements and recoveries, as they have for quite some time.[48] This is a reflection of relators' and the DOJ's prolific use of the FCA in the health care industry. But, as Figure 8 shows, in FY 2022, health care-related actions constituted only 49% of all new matters filed. This is the first time since FY 2007 that new non-health care-related actions have outpaced new health care-related actions.[49]

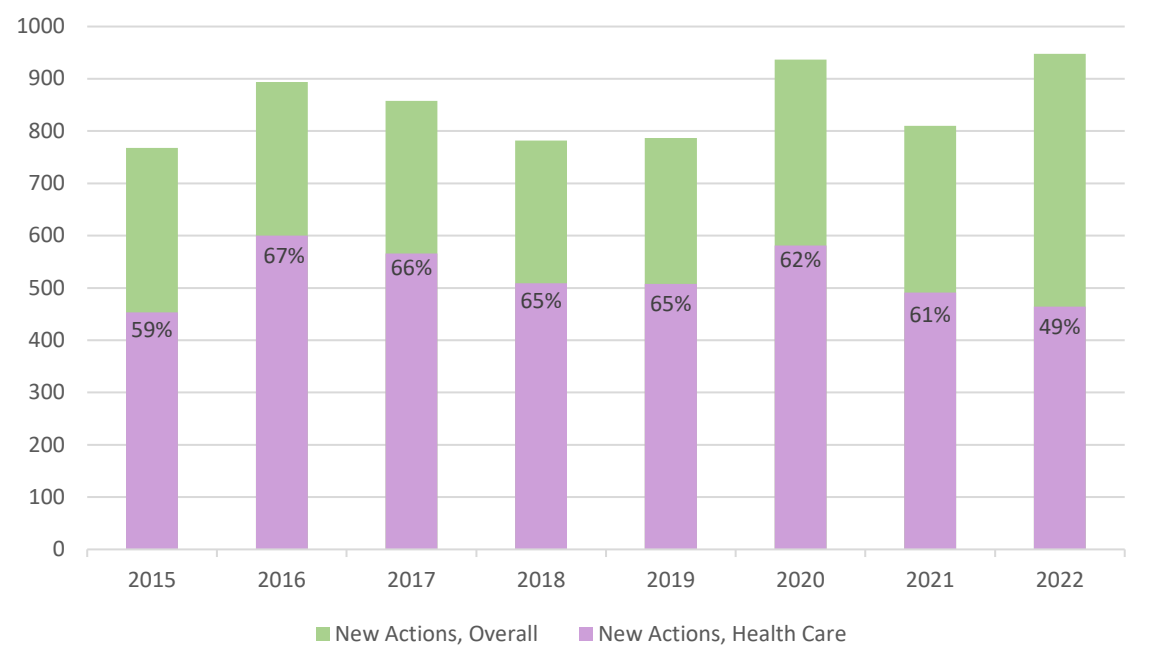

Figure 8: Percentage of New Health Care-Related FCA Actions[50]

2023 Outlook

Even while FY 2022 comprised "the second-highest number of settlements and judgments in a single year,"[51] health care-related recoveries were the lowest since FY 2009. Health care industry FCA actions thus continued the downward trend of diminishing civil fraud recoveries dating back to FY 2016. The past year was also atypical in that non-health care-related cases constituted the bulk of newly filed actions, and settlements/resolutions in non-intervened cases outpaced intervened cases in aggregate recovery (both overall and for health care-related matters).

Despite these surprising trends, K&L Gates still expects government enforcement activity in the healthcare space to be robust in the year ahead. To that end, we believe that the following topics are worthy of monitoring in FY 2023:

[48] *Id.*
[49] *See id.*
[50] *Id.*
[51] U.S. Dep't of Just., False Claims Act Settlements, *supra* note **Error! Bookmark not defined.**.

1. SCOTUS' forthcoming decisions in United States ex rel. Polansky v. Executive Health Resources; United States ex rel. Schutte v. SuperValu, Inc.; and United States ex rel. Proctor v. Safeway, Inc.;
2. The Office of Inspector General's (OIG) continued use of the "High Risk – Heightened Scrutiny" list; and
3. COVID-19-related fraud enforcement.

This article discusses these areas in detail below, along with their potential impact on FCA recoveries and the overall enforcement environment in the upcoming year and beyond.

FCA Cases on SCOTUS' 2023 Docket

While it is not possible to say for certain, it is likely that the pendency of two important FCA cases before SCOTUS had some impact on FCA recoveries in FY 2022. Due to the substantial effects that rulings in these cases might have, litigants may well have adopted a wait-and-see approach, electing to account for how these cases are resolved before weighing whether to settle or proceed to trial. In the year ahead, it will be prudent to monitor SCOTUS' decisions in *Polansky* and *Supervalu/Safeway*, as these weighty cases will significantly influence FCA litigation going forward. We discuss each of these cases below.

Polansky

In December 2022, SCOTUS heard argument in *Polansky*, a case concerning the government's authority to dismiss FCA *qui tam* actions after initially declining to intervene.[52] As K&L Gates referenced last year,[53] the government's dismissal authority in FCA cases is the subject of a circuit split, with at least three different standards governing such authority.[54] *Polansky* will identify the contours of the government's dismissal authority in initially declined *qui tam* actions.

In *Polansky*, a relator filed a *qui tam* action in 2012 alleging that the defendant, a "physician advisor" company that provides review and billing certification services to hospitals and physicians that bill Medicare, began "systematically enabling its hospital clients to over-admit patients by certifying inpatient services that should have been provided on an outpatient basis."[55] The relator's complaint remained under seal for the next two years while the government investigated the FCA allegations, but the government ultimately declined to intervene.[56] Under the FCA, "[i]f the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action."[57] Given the

[52] *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 142 S. Ct. 2834 (June 21, 2022).

[53] Lawrence *supra* note **Error! Bookmark not defined.**.

[54] The D.C. Circuit has held that the government has an "unfettered right to dismiss" a qui tam action under § 3730(c)(2)(A). *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003). In contrast, the Seventh Circuit requires that the government establish "good cause" to intervene, and then satisfy the voluntary dismissal standards under Rule 41 of the Federal Rules of Civil Procedure in order to dismiss over a relator's objection. United States ex rel. CIMZNHCA, LLC v. UCB, Inc., 970 F.3d 835, 849-50 (7th Cir. 2020). And the Ninth Circuit mandates that the government identify "a valid government purpose" and "a rational relation between dismissal and accomplishment of the purpose" to effectuate dismissal, after which the burden shifts to the relator "to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *United States ex rel., Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998).

[55] *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 17 F.4th 376 (3d Cir. Oct. 28, 2021), *cert. granted*, 142 S. Ct. 2834 (June 21, 2022).

[56] *Id.*, at 381.

[57] 31 U.S.C. § 3730(c)(3).

government's declination, the court unsealed the relator's complaint and the relator, "for himself and for the United States Government," continued the action.[58]

Over the next several years, the parties participated in significant litigation surrounding the relator's FCA claims.[59] However, in February 2019—after the case had been litigated for more than six years—the government notified the parties that it intended to dismiss the entire action pursuant to 31 U.S.C. § 3730(c).[60] Under that provision, a relator's ability to continue a *qui tam* FCA action that the relator initiates is limited "[i]f the Government proceeds with the action."[61] Moreover, "[t]he Government may dismiss the action notwithstanding the objections of the [relator]," provided the relator receives notice and an opportunity to be heard on the Government's motion to dismiss.[62] Ultimately, upon the government's motion to dismiss the *Polansky* relator's case, the district court dismissed the action.[63] The relator appealed.[64]

On appeal, the Third Circuit recognized that there was a circuit split regarding whether the government must intervene before moving to dismiss.[65] Adopting the standard in the Sixth and Seventh Circuits, the Third Circuit held that "the Government must intervene before it can move to dismiss, but it can seek leave to intervene at any point in the litigation upon a showing of good cause."[66] Further, the Third Circuit held that the government, once it intervenes, must satisfy the standard set forth in Rule 41(a) of the Federal Rules of Civil Procedure to win a voluntary dismissal over the relator's objection.[67] The court held that Rule 41(a) "establishes different standards for a motion to dismiss depending on the procedural posture of the case."[68] It further held that "[i]f the motion is filed before the defendant files an answer or summary judgment motion, 'the plaintiff may dismiss an action without a court order' simply by filing a 'notice of dismissal.'"[69] However, "once the action has passed the point of no return, . . . then 'an action may be dismissed . . . only by court order, on terms that the court considers proper.'"[70]

On June 21, 2022, SCOTUS granted certiorari in *Polansky* to resolve the circuit split[71] regarding the parameters of the government's dismissal authority.[72] The High Court's ruling will articulate the circumstances under which the government—following an initial declination—may nevertheless seek to dismiss FCA actions over a relator's objection, and how it must undertake to do so. The Court's resolution of this important question will likely dictate how often the government exercises its dismissal authority. If armed with absolute discretion to dismiss FCA cases, the government may seek to dismiss cases more frequently

[58] *Polansky*, 17 F.4th at 381 (cleaned up) (quoting 31 U.S.C. § 3730(b)(1)).
[59] *Id.*
[60] *Id.*
[61] 31 U.S.C. § 3730(c)(1).
[62] *Id.* § 3730(c)(2)(A).
[63] Polansky, 17 F.4th at 382.
[64] *Id.*
[65] *Id.* at 385.
[66] *Id.*
[67] *Id.* at 389.
[68] *Id.*
[69] *Id.* (quoting Fed. R. Civ. P. 41(a)(1)(A)).
[70] *Polansky*, 17 F.4th at 389 (cleaned up) (quoting Fed. R. Civ. P. 41(a)(2)).
[71] *See supra* note **Error! Bookmark not defined.**.
[72] *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 142 S.Ct. 2834 (June 21, 2022).

to guard against the establishment of wayward precedent and the consumption of significant government resources in order to monitor ongoing cases of questionable merit, among other considerations. Conversely, if SCOTUS reins in the government's ability to dismiss initially declined cases, the government may intervene in a higher number of *qui tam* matters to ensure more effective control over FCA cases. In either case, in the year ahead, it will be critical to monitor the extent to which *Polansky* affects FCA litigation.

Supervalu and Safeway

In January 2023, SCOTUS granted certiorari in two other FCA cases—*SuperValu*[73] and *Safeway*[74]—to address what constitutes a "knowing" violation of the FCA.

SuperValu concerned a large grocery store chain with over 800 in-store pharmacies, which from 2006 to 2016, billed a number of insurers, including Medicare Part D (the prescription drug arm of Medicare) and Medicaid.[75] During that time, the grocery store devised a price-match program whereby, upon a customer's request, it would match lower prescription drug prices offered by local competitors.[76] However, the grocery store then billed its "usual and customary" price to insurers, rather than the discounted, price-matched amounts it had agreed to accept from its customers upon request.[77] In 2011, relators filed a FCA complaint alleging that the grocery store "price-matched to avoid losing customers to competitors with lower drug prices . . . and made up the difference by charging the government healthcare programs its higher, retail price."[78]

The district court granted partial summary judgment against the defendant grocery store on the falsity prong of the FCA.[79] However, applying the holding in *Safeco Insurance Co. of America v. Burr*[80]—a Seventh Circuit Fair Credit Reporting Act case—the district court ultimately entered summary judgment in favor of the grocery store on the scienter prong of the FCA,[81] which requires that the defendant act "knowingly" in order for FCA liability to attach.[82] "Knowingly," as defined in the FCA, means having "(i) actual knowledge of the information; (ii) acting in deliberate ignorance of the truth or falsity of the information; or (iii) acting in reckless disregard of the truth or falsity of the information."[83] The district court held that, under *Safeco*, the defendant's understanding of the "usual and customary" price, while ultimately incorrect, was objectively reasonable at the time the defendant relied upon it, and that there was no authoritative guidance to warn the defendant away from its interpretation.[84]

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[73] *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. Aug. 12. 2021), *cert. granted*, 143 S.Ct. 644 (Jan. 13, 2023).

[74] *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. Apr. 5, 2022), *cert. granted*, 143 S.Ct. 643 (Jan. 13, 2023).

[75] *SuperValu*, 9 F.4th at 461.

[76] *Id.*

[77] *Id.*

[78] *Id.* at 462.

[79] *Id.*

[80] *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007).

[81] *SuperValu*, 9 F.4th at 462.

[82] 31 U.S.C. § 3729(a)(1)(A).

[83] *Id.* § 3729(a)(1)(B).

[84] *SuperValu*, 9 F.4th at 462–63.

Thus, applying *Safeco*, the district court entered summary judgment in favor of the defendant on all FCA claims.[85]

On appeal, the Seventh Circuit Court of Appeals affirmed and, likewise applying *Safeco*, held that an FCA "defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it."[86] Thus, the Seventh Circuit relied on the common law definition of "knowingly"—as articulated in *Safeco*—to affirm the entry of summary judgment in favor of the defendant.[87] Importantly, the Seventh Circuit held that this was so even where—as relators alleged—the defendant subjectively did not believe its interpretation was correct.[88] This, according to the court, is because there is "nothing in the language of the FCA [that] suggests that a defendant's subjective intent is relevant" for determining scienter, as long as the defendant's interpretation of the law or regulation in question is objectively reasonable.[89]

Alongside *SuperValu*, SCOTUS will also resolve another FCA scienter case: *Safeway.*[90] In *Safeway*, the defendant was likewise a grocery retailer accused by a relator of failing to account for various types of discounts in reporting its "usual and customary" price to government payors, allegedly reaping a windfall to which it was not entitled.[91] As in *SuperValu*, the district court in *Safeway* relied on the Seventh Circuit's *Safeco* opinion to grant summary judgment to the defendant.[92] On appeal, the Seventh Circuit affirmed the district court's opinion on the strength of its analysis in *SuperValu*.[93] The court noted that, "[i]n doing so, [it] joined every other circuit to address the issue."[94]

On January 13, 2023, SCOTUS granted certiorari—both in *Supervalu*[95] and in *Safeway*[96]—to address whether the FCA defines "knowingly" to incorporate the common law standards of actual knowledge, deliberate indifference, and reckless disregard. Oral arguments took place on April 18 and a decision is expected by the end of June.[97]

SCOTUS' anticipated decisions in *SuperValu* and *Safeway* will be momentous in the world of FCA litigation. In granting summary judgment in favor of defendants in those cases, the Seventh Circuit has essentially held that a defendant can evade FCA liability so long as it

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[85] *Id.* at 463.

[86] *Id.* at 464.

[87] *Id.* at 463 ("The FCA defines 'knowingly' as encompassing three common law standards—actual knowledge, deliberate indifference, and reckless disregard—but is silent as to what those standards mean in the context of this statute. Supreme Court precedent teaches that 'a common law term in a statute comes with a common law meaning, absent anything pointing another way." (quoting *Safeco*, 127 S.Ct. at 2209)).

[88] *Id.* at 466 ("In the absence of textual indicia in the FCA supporting that subjective intent matters here, we apply Supreme Court precedent to interpret the same common law terms addressed in *Safeco.*").

[89] *Id.*

[90] Safeway, 30 F.4th 649.

[91] *Id.* at 654-57.

[92] *Id.* at 657.

[93] *Id.*

[94] *Id.* at 657-58 (citing *United States ex rel. Streck v. Allergan*, 746 F. App'x 101, 106 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 284 (D.C. Cir. 2015); *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 344 (4th Cir. 2022)).

[95] 143 S.Ct. 644.

[96] 143 S.Ct. 643.

[97] *See U.S. ex rel. Proctor v. Safeway, Inc. Consolidated with U.S. ex rel. Schutte v. SuperValu Inc.*, SCOTUSblog, https://www.scotusblog.com/case-files/cases/united-states-ex-rel-thomas-proctor-v-safeway-inc/.

can proffer an "objectively reasonable" interpretation of the requirement it allegedly violated, even if it subjectively did not subscribe to that interpretation at the time of the allegedly fraudulent conduct. There are competing views on this holding. The relator's bar and the DOJ claim that this precedent—if allowed to stand—will create a loophole through which unscrupulous entities can escape FCA liability in the face of knowingly fraudulent conduct. This view is colorfully reflected in the dissenting opinion in *SuperValu*, where Judge Hamilton characterized the majority's holding as "creat[ing] a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a *post hoc* legal rationale that can pass a laugh test."[98] On the other hand, the defense bar contends that these cases recognize a potent—and bona fide—defense for FCA defendants, which prevents FCA liability from attaching in the face of ambiguous regulatory requirements.

In what will be a boon to either relators or defendants, SCOTUS' resolution of *Supervalu* and *Safeway* will make or break many cases that hinge on the proper application of the FCA's scienter standard. Indeed, SCOTUS' decision will operate as a judicial referendum on the viability of a potential "ambiguity" defense in FCA cases, pursuant to which defendants can avoid liability by denying the presence of the requisite scienter. It is highly likely that a number of FCA cases in which scienter is at issue have remained dormant, waiting on guidance from SCOTUS before proceeding further into settlement discussions or discovery and to trial . Litigants who adopted this "wait and see" approach may have contributed to FY 2022's modest recovery statistic. Depending on how the Court rules on this issue, future aggregate FCA recoveries could be much higher—or much lower—in the years to come.

OIG's Apparent Increased Use of the "High Risk - Heightened Scrutiny" List

The OIG's strict adherence to the Independent Review Organization (IRO) component of modern-day Corporate Integrity Agreements (CIAs)—under which providers face stringent outside monitoring—and OIG's use of "form" CIAs may cause a shift in the way health care providers seek to resolve FCA claims. Providers facing FCA investigations and *qui tam* actions must weigh the benefits of litigating or settling such claims. However, providers who decide to settle must negotiate not only with the DOJ, but also with OIG as to whether a CIA will be required.

Federal law allows the Secretary of the United States Department of Health and Human Services (HHS) to permissively exclude entities from participation in federal health programs under a variety of enumerated circumstances.[99] These circumstances fall into two categories: "derivative exclusions" and "non-derivative exclusions." Derivative exclusions result in the exclusion of "an individual or entity . . . based on an action previously taken by a court, licensing board or other agency."[100] In contrast, non-derivative exclusions are "based on determinations of misconduct that would originate with determinations made by the OIG," requiring "the OIG, if challenged, to make a prima facie showing that the improper behavior did occur."[101] Thus, while a provider may enter into a settlement with the DOJ in which the provider does not admit fault, the OIG may still permissibly exclude such providers from federal health care programs.[102] In settling FCA claims, the OIG will typically classify each

[98] Supervalu, 9 F.4th at 473 (Hamilton, J., dissenting).
[99] 42 U.S.C. § 1320a-7(b); 42 C.F.R. §§ 1001.201 - .1701.
[100] 55 Fed. Reg. 12,206.
[101] *Id.*
[102] *See id.*

provider under one of five categories on its "risk spectrum:" (1) Highest Risk - Exclusion, (2) High Risk - Heightened Scrutiny, (3) Medium Risk - CIAs, (4) Lower Risk - No Further Action, and (5) Low Risk - Self-Disclosure.[103]

In order to retain participation in federal health care programs, providers may negotiate and enter into CIAs with the OIG. CIAs generally last five years and include various requirements such as hiring a compliance officer, developing policies and training programs, providing reports to OIG, and most notably, retaining an independent and objective IRO to conduct various reviews.[104] In exchange for a provider entering into a CIA, the OIG refrains from seeking the provider's exclusion from federal health care programs.[105] However, the CIA requirements can be both costly and vastly invasive. In particular, under the IRO component of CIAs, providers are subject to third-party review of the provider's arrangements and claims, systems, processes, policies, procedures, and practices.[106] OIG has continued to stringently enforce the IRO component in the CIA context and there is no indication of its willingness to forgo it. Moreover, OIG often adheres to a "form" CIA and will rarely negotiate many of its material terms and provisions.

Providers who settle and sign CIAs fall under the "Medium Risk" category of the OIG's risk spectrum.[107] However, on some occasions, providers refuse to enter into CIAs. Such refusals may arise when, for example, providers enter into settlement agreements with the DOJ that include corrective action plans and audits for the claims in question.[108] Additionally, other providers may desire to resolve litigation with DOJ, but do not consider a CIA to be warranted under the conduct alleged. In cases where providers refuse to enter into CIAs, OIG views them as posing "a significant risk to Federal healthcare programs and beneficiaries"[109] and "considers persons that have refused to enter into CIAs a greater continuing compliance risk to the programs than persons that have entered into CIAs."[110] Those providers who decide not to enter into CIAs may nonetheless retain their right to participate in federal health programs if the OIG determines that excluding such provider would "not be in the best interests of Medicare or its beneficiaries."[111] Where the OIG believes a CIA is necessary but the entity refuses to enter into one, the OIG "evaluates whether to pursue exclusion or whether other administrative actions, such as use of its

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[103] *Fraud Risk Indicator,* U.S. DEP'T OF HEALTH AND HUM. SERVS. OFF. OF INSPECTOR GEN., https://oig.hhs.gov/fraud/fraud-risk-indicator/ (last visited Apr. 25, 2023).

[104] *Corporate Integrity Agreements*, U.S. DEP'T OF HEALTH AND HUM. SERVS. OFF. OF INSPECTOR GEN., https://oig.hhs.gov/compliance/corporate-integrity-agreements/ (last visited Apr. 25, 2023).

[105] *Id.*

[106] *See, e.g.,* Synthes, Inc. Corporate Integrity Agreement (Mar. 3, 2023), https://www.justice.gov/archive/usao/pae/News/2010/Oct/synthes_cia.pdf; *see also Corporate Integrity Agreement Documents*, U.S. DEP'T OF HEALTH AND HUM. SERV. OFF. OF INSPECTOR GEN. (Apr. 7, 2023), https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.

[107] *See Fraud Risk Indicator, supra* note **Error! Bookmark not defined.**.

[108] Kris B. Mamula, *UPMC Waves Off Agreement that Would Bring 5 Years of Federal Tracking*, PITTSBURGH POST-GAZETTE, Mar. 23, 2023, https://www.post-gazette.com/business/healthcare-business/2023/03/23/upmc-whistleblower-lawsuits-office-inspector-general-settlement-neurosurgeons/stories/202303210096.

[109] *High Risk - Heightened Scrutiny*, U.S. DEP'T OF HEALTH AND HUM. SERVS. OFF. OF INSPECTOR GEN. https://oig.hhs.gov/compliance/corporate-integrity-agreements/high-risk.asp (last visited Apr. 25, 2023).

[110] OFF. OF INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUM. SERVS., CRITERIA FOR IMPLEMENTING SECTION 1128(B)(7) EXCLUSION AUTHORITY 2, https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf [hereinafter OFF. OF INSPECTOR GEN., CRITERIA].

[111] *"Unilateral Monitoring" Is New OIG Strategy; Audits of Hospitals Continue at Full Tilt*, 21 REPORT ON MEDICARE COMPLIANCE, no. 37, Oct. 2012, https://assets.hcca-info.org/Portals/0/PDFs/Resources/Rpt_Medicare/2012/rmc102212.pdf [hereinafter *Unilateral Monitoring*].

authorities under the Inspector General Act, are appropriate to monitor the person's compliance with Federal health care programs . . . ."[112]

One such monitoring program includes placing the provider on the OIG's public "High Risk - Heightened Scrutiny" list.[113] Starting September 27, 2018, OIG began "adding information to its website about its assessment of the future risk presented by the defendants in [FCA] settlements . . . ."[114] OIG also noted that the new information would "identify FCA defendants that refused to enter into CIAs with OIG" because "OIG views these defendants as posing a heightened risk."[115] As it is currently stated on the OIG's website, the OIG reserves this list for providers that it "determined . . . needed additional oversight, [but] refused to enter [CIAs] sufficient to protect Federal healthcare programs."[116]

Currently, the effects of appearing on the "High Risk" list are largely unknown given the lack of guidance that OIG has published surrounding this monitoring and the small number of providers currently on the High Risk list. The OIG, however, indicates that under the Inspector General Act, it can use administrative actions that constitute "unilateral monitoring."[117] Such unilateral monitoring can take the form of the OIG making referrals to CMS for claims reviews, as well as subjecting the entity (and/or individuals) to audit and investigation.[118]

To date, OIG has used the High Risk list sparingly. For example, out of the 351 FCA settlements and judgments in 2022,[119] the OIG's website shows that it placed only two providers on the High Risk list.[120] As of 2022, the providers on the list included only small, specialized providers, such as an orthopedic center, a dental practice, and a rehab and nursing center.[121] On February 23, 2023, however, OIG added the University of Pittsburg Medical Center (UPMC) to the list after it declined to sign a CIA to resolve a Medicare billing dispute.[122] UPMC—the largest non-government employer in Pennsylvania—is now the largest provider on the High Risk list, with approximately 92,000 staff members, 40 hospitals, and 4,900 employed doctors.[123] In discussing UPMC's decision not to enter into a CIA, spokesman Paul Wood stated that a "settlement was negotiated in good faith and agreed to by UPMC, Department of Justice and OIG, which put in place a carefully tailored corrective action plan for" the provider and conduct at issue.[124] Despite the recent addition of UPMC,

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[112] OFF. OF INSPECTOR GEN., CRITERIA, *supra* note 110, at 2, https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf.

[113]. *Unilateral Monitoring*, *supra* note **Error! Bookmark not defined.** at n.9.

[114] Letter from Daniel Levinson, Health and Hum. Servs. Inspector Gen., to Sens. McCaskill and Wyden (Sept. 27, 2018), https://www.skadden.com/-/media/files/publications/2019/01/hhs-oig-closes-2018-with-new-fraud-risk/fn112hhs-oig-ltr-to-mccaskill-re-corporate-integri.pdf?rev=ce66e887e4d04ae0b7afeda82aa28250&hash=6182CB0B183A4B056AAE802A1290C3BB.

[115] *Id*.

[116]*High Risk - Heightened Scrutiny*, *supra* note **Error! Bookmark not defined.**.

[117] OFF. OF INSPECTOR GEN., CRITERIA, *supra* note 110, at 2.

[118] *Id.*

[119] Dep't of Just., False Claims Act Settlements, *supra* note **Error! Bookmark not defined.**.

[120] *See High Risk - Heightened Scrutiny*, *supra* note **Error! Bookmark not defined.**.

[121] *See id.*

[122] Mamula, *supra* note **Error! Bookmark not defined.**.

[123]*UPMC Facts and Stats*, UPMC, https://www.upmc.com/about/facts#:~:text=About%20UPMC&text=The%20largest%20nongovernmental%20employer%20in,medical%20insurer%20in%20western%20Pennsylvania (last visited Apr. 25, 2023).

[124] Mamula, *supra* note **Error! Bookmark not defined.**.

the High Risk list remains small, with only six providers as of April 2023.[125] However, the OIG has made clear that it will "continue to use various tools, including unilateral monitoring and providing information to the public, to mitigate these compliance risks."[126]

Looking ahead to FY 2023, when providers weigh whether to settle FCA cases when the OIG insists on a CIA, they should anticipate that OIG will enforce the IRO component of CIAs regardless of whether the conduct at issue warrants a claims review. In light of such enforcement, we suspect providers may more seriously consider litigating FCA claims or opting for placement on the High Risk list, as opposed to settling and entering into CIAs with the OIG. After all, if the OIG will unilaterally impose enhanced monitoring on providers regardless, providers may question what incentive exists to memorialize such terms in a CIA. Providers who are subject to corrective action plans and auditing under a settlement agreement with DOJ may be even less inclined to execute CIAs and instead opt for litigation or placement on the High Risk list. Additionally, as more providers—including larger hospital systems—acquiesce to placement on the list, the "public shaming" effect of the list may become less impactful. In response, OIG may "ramp up" its unilateral monitoring, subjecting providers to audits and investigations as a dissuasive tactic. However, it is unclear whether such monitoring will match the invasiveness that CIAs currently impose. If it does not, it is possible that an increase in providers' refusal to execute CIAs in FY 2023 might increase, with a concomitant increase in the number of providers on the High Risk list.

COVID-19 Related Fraud Enforcement Under the FCA

The COVID-19 pandemic and associated relief efforts—including the 2020 CARES Act, the Consolidated Appropriations Act of 2021, and the American Rescue Plan Act of 2021—will likely continue to generate increased civil and criminal enforcement activity in years to come.[127] Despite the notable decline in recoveries outlined above, the government's near record-high volume of settlements and judgments in FY 2022 is not likely to decrease in the near future given recent developments, the most notable of which is President Biden's March 2023 announcement outlining a sweeping pandemic anti-fraud proposal.[128] This announcement follows other initiatives that demonstrate the government's heightened emphasis on COVID-19 related fraud, including increasing the statute of limitations for acts involving the primary COVID-19 loan programs to 10 years.[129] These efforts may ultimately result in a similarly large number of enforcement matters in the years ahead, as well as a potential increase in FCA recoveries.

The unprecedented speed with which the government distributed Provider Relief Funds (PRF) and Paycheck Protection Program (PPP) funds under the CARES Act—and the attendant shifting regulatory guidance under those programs—unfortunately generated a

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[125] *See High Risk - Heightened Scrutiny*, *supra* note **Error! Bookmark not defined.**.

[126] OFF. OF INSPECTOR GEN., CRITERIA, *supra* note 110, at 2.

[127] *See* Mark A. Rush et al., COVID-19: Looming False Claims Act Liability For Paycheck Protection Program Loans (Apr. 9, 2020), https://www.klgates.com/COVID-19-Looming-False-Claims-Act-Liability-for-Paycheck-Protection-Program-Loans-04-09-2020.

[128] Statement and Press Release, White House, FACT SHEET: President Biden's Sweeping Pandemic Anti-Fraud Proposal: Going After Systemic Fraud, Taking on Identity Theft, Helping Victims (Mar. 2, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/02/fact-sheet-president-bidens-sweeping-pandemic-anti-fraud-proposal-going-after-systemic-fraud-taking-on-identity-theft-helping-victims/.

[129] COVID-19 EIDL Fraud Statute of Limitations Act of 2022, H.R. 7334, 117th Cong. (2021–2022), https://www.congress.gov/bill/117th-congress/house-bill/7334; PPP and Bank Fraud Enforcement Harmonization Act of 2022, H.R. 7352, 117th Cong. (2021–2022), https://www.congress.gov/bill/117th-congress/house-bill/7352/text.

landscape ripe with opportunities for fraud. The government acknowledged this threat early on, and in March 2021, the DOJ announced that it had publicly charged nearly 500 defendants with criminal offenses connected to COVID-19 relief efforts, including attempts to fraudulently obtain over US$569 million from the U.S. government and individuals through alleged PPP fraud, Economic Injury Disaster Loans (EIDL) fraud, and Unemployment Insurance (UI) fraud.[130] Shortly thereafter, on May 17, 2021, U.S. Attorney General Merrick Garland announced the establishment of the COVID-19 Fraud Enforcement Task Force ("Task Force") which represented a large-scale coordination and pooling of resources in order to enhance enforcement efforts against COVID-19 related fraud.[131] The Task Force is comprised of several entities within the DOJ, including the Criminal and Civil Divisions, the Executive Office for United States Attorneys, and the Federal Bureau of Investigation.[132]

These efforts only increased in 2022. For example, on March 10, 2022, the DOJ announced the appointment of Associate Deputy Attorney General Kevin Chambers as Director for COVID-19 Fraud Enforcement.[133] At the time of his appointment, the government had already amassed criminal charges against over 1,000 defendants with alleged losses exceeding US$1.1 billion, seized over US$1.0 billion in EIDL proceeds, and commenced over 240 civil investigations into more than 1,800 individuals and entities for alleged misconduct in connection with pandemic relief loans totaling more than US$6.0 billion.[134] Then, on September 12, 2022, the DOJ announced the establishment of three Strike Force teams that would operate out of the Southern District of Florida, the District of Maryland, and the Central and Eastern Districts of California.[135] U.S. Attorney General Merrick Garland underscored the government's resolve in fighting pandemic-related fraud, stating that "[t]he Department remains committed to using every available federal tool—including criminal, civil, and administrative actions—to combat and prevent COVID-19 related fraud . . . [and] will continue to hold accountable those who seek to exploit the pandemic for personal gain, to protect vulnerable populations, and to safeguard the integrity of taxpayer-funded programs."[136]

Despite this increased focus and coalescing of resources to stamp out COVID-19 related fraud, the DOJ continues to prioritize what appears to be alleged blatant fraudulent activity over technical violations. The DOJ has continued to reflect the sentiment captured in the remarks that DOJ's former Principal Deputy Assistant Attorney General delivered to the U.S. Chamber of Commerce's Institute for Legal Reform in 2020. In that speech, DOJ maintained, "you can rest assured that the Civil Division will not pursue companies that made immaterial

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[130] Press Release, U.S. Dep't of Just., Justice Department Takes Action Against COVID-19 Fraud: Historic Level of Enforcement Action During National Health Emergency Continues (Mar. 26, 2021), https://www.justice.gov/opa/pr/justice-department-takes-action-against-covid-19-fraud.

[131] Press Release, U.S. Dep't of Just., Attorney General Announces Task Force to Combat COVID-19 Fraud (May 17, 2021), https://www.justice.gov/opa/pr/attorney-general-announces-task-force-combat-covid-19-fraud.

[132] *Id.*

[133] Press Release, U.S. Dep't of Just., Justice Department Announces Director for COVID-19 Fraud Enforcement: Criminal and Civil Enforcement Actions Alleging Fraud Related to Over $8 Billion in Pandemic Relief (Mar. 10, 2022), https://www.justice.gov/opa/pr/justice-department-announces-director-covid-19-fraud-enforcement.

[134] *Id.*

[135] Press Release, U.S. Dep't of Just., Justice Department Announces COVID-19 Fraud Strike Force Teams: Strike Force Team Locations Include Los Angeles, Sacramento, Miami, and Baltimore (Sept. 14, 2022), https://www.justice.gov/opa/pr/justice-department-announces-covid-19-fraud-strike-force-teams.

[136] Press Release, U.S. Dep't of Just., Attorney General Merrick B. Garland Delivers Remarks at COVID-19 Fraud Enforcement Task Force Roundtable (Mar. 10, 2022), https://www.justice.gov/opa/speech/attorney-general-merrick-b-garland-delivers-remarks-covid-19-fraud-enforcement-task-force.

or inadvertent technical mistakes in processing paperwork, or that simply and honestly misunderstood the rules, terms and conditions, or certification requirements."[137] Notably, the majority of COVID-19 related enforcement efforts to date have focused on egregious instances of fraud, such as identity theft schemes premised as COVID relief efforts, consumer price gouging related to items in demand during the height of the pandemic, unauthorized administration of vaccines, telehealth fraud schemes for sham telemedicine visits or medically unnecessary genetic tests, selling fake COVID-19 vaccination cards, and obtaining PPP loans for nonexistent companies, which ultimately funded luxury sports cars, vacations, and jewelry to name a few.[138] That said, there is always the possibility that relators could bring qui tam cases against companies that made honest mistakes based on a misunderstanding of fast-changing guidelines or that opinions as to what constitutes "inadvertent technical mistakes" may vary widely between the government and industry standards.

For example, on June 30, 2022, the DOJ announced that MorseLife Health System Inc. ("MorseLife"), a not-for-profit nursing home health system, agreed to pay US$1.75 million to resolve its potential liability under the FCA for facilitating COVID-19 vaccinations for hundreds of individuals ineligible to participate in the CDC Pharmacy Partnership for Long-Term Care Program ("LTC PPP").[139] The LTC PPP was a program specifically designed to vaccinate long-term care facility ("LTCF") residents and staff, whom represented a high-risk population, when doses of COVID-19 vaccine were in limited supply.[140] MorseLife is located in West Palm Beach, Florida and oversees health care facilities on its campus, including a nursing home and an assisted living facility which were eligible for vaccination under the LTC PPP.[141] MorseLife allegedly knew that the LTC PPP covered only LTCF residents and staff, but nevertheless invited and administered the vaccination of hundreds of ineligible persons at the clinic by mischaracterizing them as "staff" and "volunteers," many of whom MorseLife targeted for donations.[142]

There have also been some notable FCA cases involving improper payments under the PPP, which Congress enacted to provide loans guaranteed by the U.S. Small Business Administration (SBA) to eligible small businesses for payroll, rent, utility payments, and other

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[137] Speech to the Inst. for Legal Reform, U.S. Chamber of Com. (June 26, 2020), https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

[138] *See, e.g.*, Press Release, U.S. Att'y's Off., N. Dist. of Tex., Coppell Man Pleads Guilty to $24 Million COVID-Relief Fraud Scheme (Mar. 24, 2021), https://www.justice.gov/usao-ndtx/pr/coppell-man-pleads-guilty-24-million-covid-relief-fraud-scheme; Press Release, U.S. Dep't of Just., MorseLife Nursing Home Health System Agrees to Pay $1.75 Million to Settle False Claims Act Allegations for Facilitating COVID-19 Vaccinations of Ineligible Donors and Prospective Donors (June 30, 2022), https://www.justice.gov/opa/pr/morselife-nursing-home-health-system-agrees-pay-175-million-settle-false-claims-act [hereinafter U.S. Dep't of Just., MorseLife]; Press Release, U.S. Dep't of Just., Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat Health Care-Related COVID-19 Fraud: Criminal Charges Brought Against Owners and Executives of Medical Businesses, Physicians, Marketers, and Manufacturers of Fake COVID-19 Vaccination Record Cards with Losses Exceeding $149 Million (Apr. 20, 2022) https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-health-care; Press Release, U.S. Dep't of Just., Laboratory Owner Sentenced to 82 Months in Prison for COVID-19 Kickback Scheme (Nov. 9, 2021), https://www.justice.gov/opa/pr/laboratory-owner-sentenced-82-months-prison-covid-19-kickback-scheme.

[139] U.S. Dep't of Just., MorseLife, *supra* note **Error! Bookmark not defined.**.

[140] *Id.*

[141] *Id.*

[142] *Id.*

business-related costs.[143] The DOJ has pursued borrowers that improperly received duplicate or inflated PPP loans or were otherwise not eligible to receive any PPP loan.[144] Over the last year, the department resolved 35 FCA matters, recovering over US$6.8 million and avoiding more than US$1.5 million in losses for SBA in the form of federal guarantees on improper loans.[145]

Notably, the DOJ has also increased the scope of targeted activity, evidencing a more aggressive approach to the types of COVID fraud cases they pursue.[146] For example, the government has demonstrated a willingness to bring FCA actions for PPP fraud even before a borrower seeks forgiveness of the loan, and even based on relatively low damages.[147] Initially, it was unclear whether the government was interested in pursuing less egregious instances of fraud, such as pre-forgiveness PPP loan matters, since a FCA claim requires an allegation that the defendant either made—or caused to be made—false claims for payment from the federal government.[148] In these scenarios, it is the lenders, not the government, who provide the funding before the PPP loans are forgiven. This makes the damages to the government under a FCA theory relatively small in pre-forgiveness cases.[149]

Governmental efforts to set examples in such cases—pursuing FCA cases regardless of an individual's financial status or the amount at issue—are likely to continue to build momentum. This is particularly true in light of President Biden's recent announcement, in which he previewed a plan to request US$1.6 billion in new funding from Congress to tackle fraud tied to U.S. pandemic relief programs and in March announced a three-part historic pandemic anti-fraud proposal.[150] As part of this initiative, President Biden proposed tripling the number of COVID-19 Strike Force Teams, creating a permanent data analytics platform to support investigatory efforts long term, and apportioning at least US$300 million to support investigative staff on the Pandemic Response Accountability Committee and select offices working on COVID fraud.[151] The US$300 million for the DOJ would support adding at least

[143] *See Paycheck Protection Program*, U.S. DEP'T OF TREAS., https://home.treasury.gov/policy-issues/coronavirus/assistance-for-small-businesses/paycheck-protection-program (last visited Apr. 25, 2023).

[144] U.S. Dep't of Just., False Claims Act Settlements, *supra* note **Error! Bookmark not defined.**.

[145] *Id*.

[146] For example, DOJ pursued lenders who improperly disbursed PPP funds, and on September 13, 2022, it obtained the first ever FCA settlement with a bank that allegedly made a PPP loan to a customer it knew was ineligible because its sole owner was facing criminal charges at the time of the loan; this led Prosperity Bank, a regional bank in Texas and Oklahoma, to pay US$18,673 to resolve the allegations. Press Release, U.S. Att'y's Off. N. Dist. of Tex., First-ever False Claims Act Settlement Received from Paycheck Protection Program Lender (Sept. 13, 2022), https://www.justice.gov/usao-sdtx/pr/first-ever-false-claims-act-settlement-received-paycheck-protection-program-lender.

[147] On January 12, 2021, the U.S. Attorney's Office for the Eastern District of California had announced the first ever civil settlement of a PPP fraud case for violations of the FCA and the Financial Institutions Reform, Recovery and Enforcement Act, which stemmed from false statements made to federally insured banks in order to fraudulently obtain a US$350,000 PPP loan. That case led to a settlement in which SlideBelts Inc., an internet retail company and debtor in bankruptcy, and Brigham Taylor, the company's president and CEO, agreed to pay a combined US$100,000 in damages and penalties in addition to agreeing to repay the PPP funds fraudulently received. Press Release, U.S. Att'y's Off. E. Dist. of Cal., Eastern District of California Obtains Nation's First Civil Settlement for Fraud on Cares Act Paycheck Protection Program (Jan. 12, 2021), https://www.justice.gov/usao-edca/pr/eastern-district-california-obtains-nation-s-first-civil-settlement-fraud-cares-act.

[148] *See* 31 U.S.C. § 3729(a).

[149] In the case of SlideBelts, the government used the US$17,500 in loan processing fees the SBA (a government entity) had paid to the lender as the basis for its FCA allegations. *Id.*

[150] White House, *supra* note **Error! Bookmark not defined.**.

[151] *Id*.

10 "strike forces" to target criminal syndicates and major fraudulent actors.[152] These strike forces would combine investigative, prosecutorial, and analytical capacities and include a Supervisory Assistant U.S. Attorney and a team of Assistant U.S. Attorneys, along with investigative support analysts and law enforcement agents.[153] In filling these positions, the government would leverage existing resources and utilize other federal law enforcement partners such as the Federal Bureau of Investigation, Homeland Security Investigations, Internal Revenue Service Criminal Investigation, and the U.S. Secret Service, among others. Mechanisms exist for non-DOJ agency reimbursements, such as through the DOJ's Organized Crime Drug Enforcement Task Forces.[154] This effort will also include funds to hire 30-45 additional prosecutors in order to create a Forfeiture Task Force, which—when combined with efforts to raise the administrative claims cap—is likely to drive an uptick in enforcement by increasing the cap from US$150,000 to US$1 million to ensure that all remedies are available to recapture large, six figure alleged fraud that might otherwise fall below the prioritization threshold for prosecution.[155]

This sweeping anti-fraud proposal follows President Biden's statements during his State of the Union address in early 2023, where he emphasized that: "[a]s we emerge from this crisis stronger, [we've] got to double down [on] prosecuting criminals who stole relief money meant to keep workers and small businesses afloat," and referenced his 2022 warning that "the watchdogs are back."[156] This proposal marks a major funneling of resources toward strengthening the government's efforts and backs up the myriad indications of heightened scrutiny on COVID-19 fraud.[157] The impact of these efforts will likely be felt for years to come, and the government is likely to use the FCA to spearhead civil fraud recoveries in these areas.

Conclusion

Like FY 2021, FY 2022 was an unprecedented year in terms of FCA recovery, but in a much different way. As referenced, last year coupled record-high numbers of new cases with the lowest civil fraud recovery total in quite some time, and non-intervened cases resulted in higher recoveries than intervened cases. Even so, the DOJ exercised its enforcement authority against a litany of health care providers, and there is no indication that enforcement activity will significantly slow in the year ahead.

Those operating in the health care space should closely monitor developments from SCOTUS in FY 2023, as well as the extent to which the government employs its "High Risk – Heightened Scrutiny" list to box in what it considers to be uncooperative entities. Moreover,

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[152] *Id*.

[153] *Id*.

[154] *Id*.

[155] *Id*.

[156] Joseph R Biden, President, U.S. of Am., White House State of the Union Address, Remarks of President Joe Biden – State of the Union Address as Prepared for Delivery (Feb. 7, 2023), https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/02/07/remarks-of-president-joe-biden-state-of-the-union-address-as-prepared-for-delivery/.

[157] The DOJ recently announced criminal charges against 18 defendants for their alleged participation in various fraud schemes involving health care services that exploited the COVID-19 pandemic and allegedly resulted in over $490 million in COVID-19 related false billings to federal programs and theft from federally funded pandemic programs; concurrently, the Center for Program Integrity of the Centers for Medicare & Medicaid Services (CPI/CMS) separately announced that it took adverse administrative actions in the last year against 28 medical providers for their alleged involvement in COVID-19 schemes. *See* Press Release, U.S. Dep't of Just., Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud (April 20, 2023), https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-covid-19

there is likely to be a continued emphasis by the government on pursuing COVID-19-related fraud. Depending on how these topics evolve, FCA litigation activity may be greatly affected. Consequently, health care entities and providers should regularly consult their counsel to implement best efforts to avoid FCA exposure, costly litigation, and penalties.

K&L Gates's Health Care Fraud and Abuse (U.S.) practice group is comprised of over 40 partners/counsel/of counsel and associates that routinely assist private equity firms, health systems, hospitals, and other providers and suppliers with legal advice regarding FCA, Anti-Kickback Statute, and Stark Law compliance, including internal compliance reviews, transactional due diligence, external and internal investigations, and general strategic considerations.

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