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Foley Hoag 2025 White Collar Year in Preview Series

FEBRUARY 2025



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Foley Hoag 2025 White Collar Year in Preview Series

February 15, 2025

FOLEY HOAG LLP

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HEALTH CARE FRAUD ENFORCEMENT IN 2025



By Caroline Donovan, David G. Lazarus, Yoni Bard, Jasmine N. Brown and Brenna M. Rosen

We kick off our annual Year in Preview series with a comprehensive look at health care fraud enforcement in 2025. This post proceeds in three parts. *First*, we explore what the second Trump administration might bring, looking at enforcement metrics from Trump’s first presidency while examining the priorities we might expect from the current nominees to key health care agencies. *Second*, we look at the hot spots – enforcement targets that, year after year, receive government scrutiny and fill the pages of DOJ press releases. *Third*, we look at the courts, recapping significant acquittals and tracking key appeals that may shape health care fraud laws for years to come.

I. ENFORCEMENT UNDER THE SECOND TRUMP ADMINISTRATION

As we close out the Biden presidency and head into the second Trump term, change is expected across the federal government. This includes a host of high-profile nominees to health care departments and agencies. However, it is unclear what their impact will be on areas of traditional health care fraud enforcement – nor should it be assumed that those nominees, if confirmed, are fully aligned on their priorities in this space. If past is prologue, we should expect continued focus on health care fraud, the single largest driver of the federal government’s recovery in the first Trump presidency, at levels largely aligned with what we’ve seen in the intervening four years.

By the Numbers

In terms of dollars recovered by the federal government in health care fraud matters, the data from the first Trump administration is in line with figures seen during the Biden administration.

Based on False Claims Act (FCA) data published annually by the Department of Justice (“DOJ”), the recoveries are roughly comparable. Under Trump, in 2017, the federal government recovered \$2.4 billion in settlements and judgments involving the health care industry (of \$3.7 billion total); in 2018, \$2.5 billion involved the health care industry (of \$2.8 billion total); in 2019, \$2.6 billion involved the health care industry (of \$3.0 billion total); and, in 2020, \$1.8 billion involved the health care industry (of \$2.2 billion total).

By comparison, under Biden, in 2021, the federal government recovered \$5.0 billion in settlements and judgments involving the health care industry, of which \$2.8 billion was attributable to one opioid-related settlement (of \$5.6 billion total); in 2022, \$1.7 billion involved the health care industry (of \$2.2 billion total); and in 2023, \$1.8 billion involved the health care industry (of \$2.68 billion total). As of the date of this publication, 2024 data had not yet been released. Adjusting for the 2021 opioid settlement, these annual recoveries all fall within a range from \$1.7 billion to \$2.6 billion, and the particular administration does not appear to drive the scale of recovery. We will look to see whether recoveries going forward depart from

this range and, if so, what might be driving any changes.

Importantly, FCA settlements are often years in the making and, therefore, are typically less impacted by changes in DOJ leadership. However, the incoming administration has expressed its intent to have more hands-on control from a central DOJ in Washington over the actions of the United States Attorney's Office. In theory, this could extend to more oversight and shaping of FCA resolutions, particularly regarding the settlement figures (as opposed to whether DOJ should pursue particular settlements).

The Nominees Speak (or Spoke)

While the data above indicates a relatively steady state for health care fraud enforcement activity between the Trump administration in 2017-2020 and the subsequent Biden administration, the current slate of nominees may be reason to expect more significant changes. That said, it is not always clear in what direction these individuals would move their respective departments and agencies – and in some instances, tensions among the nominees' positions make the predictive exercise even less certain.

One of the most significant nominees is **Dr. Mehmet Oz**, the nominated Administrator for the Centers for Medicare and Medicaid Services ("CMS"). Oz has previously called traditional Medicare "highly dysfunctional." In an editorial for *Forbes* co-authored with the former CEO of Kaiser Permanente, Oz articulated his strong support for the Medicare Advantage program run with commercial insurers, going so far as to title the article "Medicare Advantage For All Can Save Our Health-Care System" and to propose a 20 percent payroll tax (split evenly between employer and employee) to cover the expansion of Medicare Advantage. That Oz now oversees the program he proposed to eliminate would suggest a likely attempt to reduce the import and scope of traditional Medicare. Beyond his support for Medicare Advantage and antipathy for traditional Medicare, Oz's nomination will likely also focus on his investments, many of which were disclosed as part of his 2022 Senate candidacy in Pennsylvania. These include substantial investments in insurer UnitedHealth Group and investments in the pharmaceutical, agricultural, and fast-food industries, potential points of tension with the expressed views of fellow nominee Robert F. Kennedy. Historically, Oz reportedly received more than \$1.25 million in fees for serving as a speaker for device manufacturers.

At the Justice Department, Attorney General nominee **Pamela Bondi** presents a slightly more traditional background, insofar as she was formerly Attorney General for the State of Florida and in that role, oversaw various recoveries by the Medicare and Medicaid fraud units. Bondi's office was also among the first in the country to affirmatively move to dismiss an FCA action after declining to intervene, a practice that was officially embraced by DOJ in the first Trump administration in a memo issued January 10, 2018 (the Granston Memo). As always with the Department of Justice, we will watch closely not only the nomination for Attorney General but the appointment of a Deputy Attorney General, perhaps the individual most likely to impact federal policy and practice for prosecutors across the districts.

The expected impact of other significant health care nominees in the enforcement space is less clear. That includes **Robert F. Kennedy Jr.**, nominated as Secretary of the Department of Health and Human Services ("HHS"). Kennedy is perhaps most associated with vaccine skepticism/denialism, in particular, his belief in a causal link between vaccination and autism. In the weeks since his nomination, however, much of the attention has focused on his views about food safety. Kennedy has commented, "The food industry and big agriculture producers control the FDA, and so they're not worried about public health; they're worried about advancing the mercantile interests of those corporations." He said that "FDA's war on public health is about to end" and that he has been nominated expressly to root out "corruption and conflicts at the agencies," a seeming reference to pharmaceutical industry influence and a perceived revolving door between government and industry. On these issues and others – like stem cells – Kennedy

would be expected to adopt a more aggressive approach than past administrations, though details on the actual execution of that approach are still outstanding. Equally unclear is where Kennedy falls on other issues within the purview of HHS – including key legislation like the Affordable Care Act. Likewise, Kennedy’s views about the work of CMS, another agency that would report to him, are unknown. In this regard, his impact on that regulatory regime remains to be seen.

Meanwhile, **Dr. Marty Makary** is nominated as Commissioner for the FDA. Makary, a surgeon and professor at Johns Hopkins, brings to bear some recurring hallmarks of these health care nominees (i.e., a critique of the government’s response to COVID-19). Makary has critiqued the FDA for relying on misleading data in connection with certain opioids; what this means for purposes of regulatory approval if he is nominated is the question, with many expecting this to play out in connection with medication abortion.

Rarely are nominees so high-profile and prolific in their public statements before nomination. It will be interesting to see whether these individuals, if confirmed, adopt policy positions in line with what previously were personal position statements, or whether they are ultimately more constrained by their offices and the system of government and rulemaking in which they now operate.

II. THE CLASSICS: PRIORITY AREAS IN HEALTH CARE FRAUD ENFORCEMENT

Even with a new administration and potentially shifting priorities, certain areas have long been – and will remain – hot spots for health care fraud enforcement. Enforcement targets change over time (e.g., patient assistance programs no longer receive the attention they used to), but the areas below are not coming off the government’s radar anytime soon.

Labs

Clinical laboratories are a common target for health care fraud enforcement. The government scrutinizes diagnostic and genetic testing labs for allegedly medically unnecessary testing, incorrect or duplicative billing codes, improper referrals from health care providers, and other conduct. New technology that many labs rely on often outpaces regulatory guidance and is not fully understood by federal law enforcement, increasing risks for lab companies.

In the final months of 2024, the government announced (1) a \$7.2 million [settlement](#) in September by an Indiana hospital, its clinical laboratory, and various individuals to resolve alleged FCA violations based on testing – billed to Medicare, Kentucky Medicaid, and TRICARE – that the government contended was medically unnecessary or done in violation of the AKS because it was not used for medical diagnosis or treatment; and (2) health care fraud and other [charges](#) in November against the owner of a Texas laboratory for allegedly causing BioDX Labs LLC to submit more than \$79 million in fraudulent claims to Medicare and Texas Medicaid for respiratory pathogen panel tests that were not provided and were not medically necessary.

Within the first few days of 2025, there were more health care fraud resolutions involving labs, namely (1) an FCA [settlement](#) in Tennessee by LabCorp entities and University Health System, Inc. for allegedly delaying the submission of physician orders for lab tests by Caris Life Sciences, Inc. to circumvent Medicare’s “14-Day Rule” (requiring that tests performed within 14 days after a patient’s discharge be billed to the hospital); and (2) a [settlement](#) by Florida-based Physicians Toxicology Laboratory, LLC, an affiliated entity, and a few individuals to resolve alleged FCA violations in connection with orders of urine drug and hormone tests paid for by Medicare. We will continue to see labs in the government’s crosshairs throughout 2025.

Durable Medical Equipment (DME)

Medicare payments for DME and related medical supplies exceed \$7 billion annually. The government invests in controls and enforcement to stop alleged DME fraud, often involving billing, coding, medical necessity, and alleged kickbacks. In the summer of 2024, the U.S. Department of Health and Human Services, Office of the Inspector General (“HHS-OIG”), announced that it would undertake multiple reviews regarding current DME fraud schemes and safeguards. These reviews will examine issues related to [billing](#) and [overlapping claims](#), and the findings are expected to be released sometime in 2025. Enforcement against DME suppliers will surely continue, and the findings by HHS-OIG may affect the aspects of DME sales most likely to draw scrutiny going forward.

Telemedicine and Digital Health

Telemedicine and digital health have been expanding in recent years, and the government is closely watching the industry as a new target for health care fraud. In 2024, Attorney General Merrick Garland said that “addressing the rise of schemes that exploit telemedicine technology” was a DOJ priority, as he announced charges against Done Global, Inc. executives for their alleged role in a \$100 million scheme using telemedicine providers to prescribe more than 40 million Adderall pills and other stimulants to patients with no medical need for the drugs. Remote prescribing arrangements likely will not be the only fraud target in this space as digital health delivery models become more widely adopted and begin to benefit from government payment. We have already entered a new frontier in behavioral health: based on a CMS [rule](#) finalized last year, as of January 1, 2025, Medicare coverage became available for certain mental health apps authorized by the Food and Drug Administration. Even with the coming shake-up in DOJ, we expect the government to continue and perhaps expand its enforcement efforts as it tries to keep pace with the rapidly growing remote care industry.

Pharma

DOJ continues to enforce the AKS against pharmaceutical companies and distributors, with settlements for violations totaling hundreds of millions of dollars. Enforcement in the area is unlikely to slow.

In October 2024, the United States obtained a \$450 million settlement from Teva Pharmaceuticals USA Inc. and Teva Neuroscience, Inc. (“Teva”) to resolve allegations that it used charities that help cover Medicare patients’ out-of-pocket drug costs to pay kickbacks and boost sales of its multiple sclerosis drug Copaxone.^[1] The government alleged that Teva, the largest generic drug manufacturer in the United States, coordinated and conspired with two copay assistance foundations to ensure that purported donations to the foundations were used to specifically cover the copays of Medicare Copaxone patients. It allegedly engaged in this scheme for over ten years while steadily raising the drug’s price. The government’s settlement with Teva is the largest settlement of an AKS violation stemming from the alleged use of third-party foundations as conduits to pay patient copays.

Since 2017, the United States has collected over \$1 billion in similar alleged schemes, and the HHS-OIG has stated that it “remains committed to thoroughly pursuing allegations of price fixing and kickbacks that put the Medicare program at risk.” Notably, FCA actions targeting patient assistance programs were largely government-driven and not the result of relator-filed qui tam actions. This matters because government-driven FCA enforcement trends may slow (or even stop) as the enforcement priorities shift. Enforcement in this area could slow because DOJ’s apparent message to the industry through litigation has likely impacted how patient assistance programs are established and operated. Companies with patient assistance programs closely watch these litigations and adjust their programs to reduce risk.

Shortly after the Teva settlement, in December 2024, ASD Specialty Health Care LLC, doing business as

Bessee Medical, agreed to pay \$1.67 million to settle allegations that it violated the AKS and FCA by providing inventory management systems to retina practices at no cost to induce them to purchase neovascular age-related macular degeneration (wet AMD) drugs from Besse. The settlement resolved claims brought by two individual whistleblowers, who will receive roughly a quarter million dollars from the proceeds of the settlement.

Pharmacy Benefit Managers

Pharmacy benefit managers (“PBMs”) have been the subject of scrutiny and bipartisan reform efforts for the past several years due partly to their drug rebate programs. Often described as “middlemen” in the pharmaceutical industry, PBMs negotiate drug costs with pharmacies and drug manufacturers, create drug tiers, and set reimbursement rates. When manufacturers offer large rebates, PBMs will include the manufacturers’ drugs in their formularies and put them in more favorable insurance tiers. Per the PBM tiering decisions, pharmacists then charge patients the amounts that PBMs reflect are owed, and bill health plans to cover the remaining costs. The PBMs determine how much to reimburse the pharmacies and how much to charge patient health insurers for sales. Months later, when drug manufacturers submit the rebates to the PBMs to be passed along to the health insurers, PBMs receive a portion as a fee for their services.

This system raised the ire of Congress, which included several PBM reforms in the original stopgap funding bill blocked by the incoming Trump administration at the end of December 2024. Although the administration declined to support the PBM reforms contained in the bill, in a December 13, 2024 press conference, President-elect Trump referred to PBMs as “horrible middlem[e]n . . . We’re going to knock out the middleman. We’re going to get drug costs down at levels that nobody has ever seen before.” Shortly thereafter, on December 31, 2024, Elon Musk, tapped to head the forthcoming Department of Government Efficiency, tweeted, “What is a ‘pharmacy benefit manager?’” What the administration does, if anything, remains to be seen, but we expect PBM reform and enforcement activity to remain an issue in 2025. Indeed, this is some precedent here: in 2020, the Trump administration sought to make rebates to Medicare Part D plan sponsors and their PBMs illegal by removing the safe harbor protection that shields these rebates from the federal anti-kickback laws, in a rule delayed by the Biden administration until 2023 and then delayed again by Congress until 2032. Many states, including Massachusetts, have also expressed their interest in so-called PBM reform.

Should significant changes occur in the next year, manufacturers will face challenges adjusting their business practices to ensure compliance with the AKS.

Payors

Medicare advantage is front and center on enforcers’ minds. HHS-OIG is paying close attention to alleged AKS violations arising from marketing arrangements related to the Medicare Advantage Program and providers. On December 11, 2024, the OIG office issued a Special Fraud Alert focused on two types of arrangements that implicate the AKS: (1) payments from Medicare Advantage organizations, agents, brokers, and other health care professionals in exchange for patient referrals to certain Medicare Advantage plans; and (2) payments from health care professionals to agents, brokers, or others in exchange for Medicare enrollee referrals to particular health care professionals. The OIG noted that these arrangements may result in the exact harm that the AKS is designed to protect – that is, unfair competition and improper steering of Medicare enrollees to plans or providers based on lucrative incentives rather than the best interest of the enrollee.

Because the OIG has issued only six Special Fraud Alerts in the past twenty years, this alert may help predict where the OIG and DOJ will be focusing their attention in the coming months and years. Recently,

Oak Street Health agreed to pay \$60 million to settle allegations that it paid referrals to insurance agents to direct Medicare Advantage-eligible patients to Oak Street Health’s primary care clinics. This is likely just one of many enforcement actions to come related to patient choice. To that end, the OIG’s Special Fraud Alert contains a list of “Suspect Characteristics,” indicating that a marketing arrangement may violate the AKS. Parties to any such arrangements should study them carefully. Historically, prosecutions and FCA actions related to special fraud alerts become more aggressive over time, and enforcement often spreads beyond the obvious players into the fringes. For example, telemedicine enforcement moved over time from marketers and pharmacies purportedly central to the illegal schemes and, instead, began to target those further removed, such as technology platform owners and other non-providers. As enforcers run to participate in the Medicare Advantage space it will be important to follow how far afield they intend to stretch.

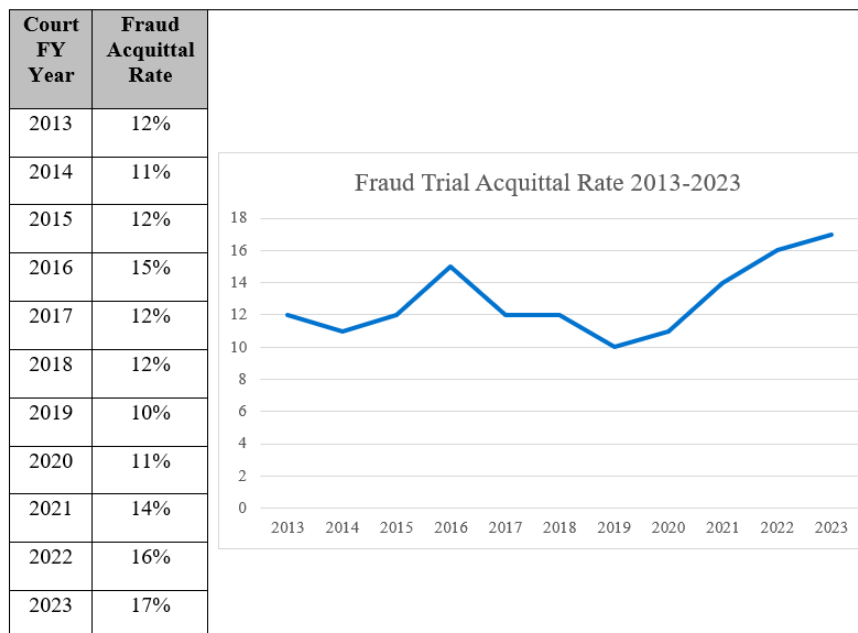
III. HEALTH CARE FRAUD LAW IN THE COURTS

Noteworthy Acquittals

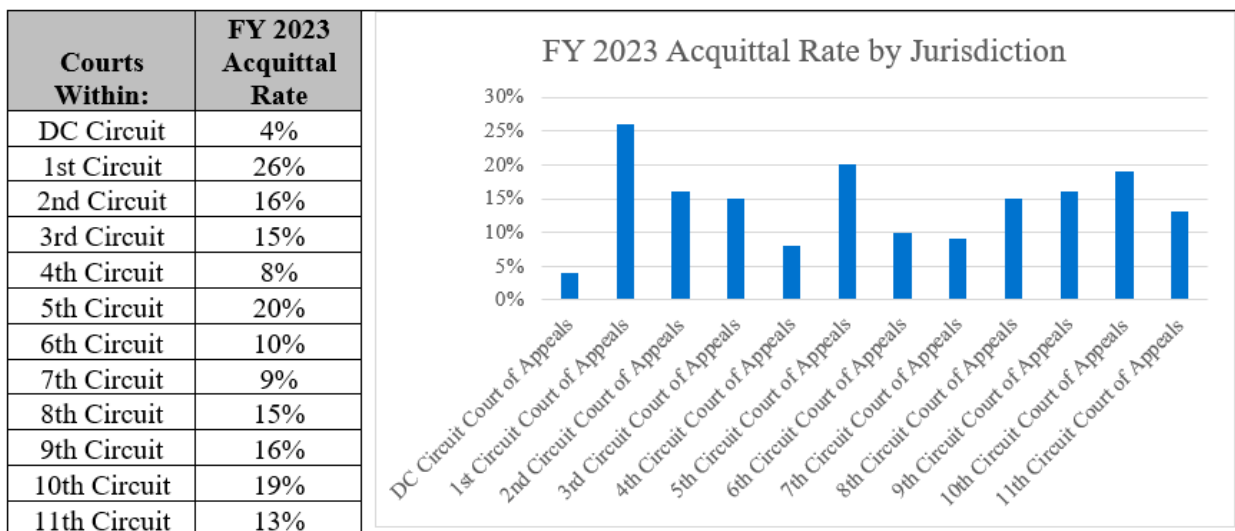
2024 was an important reminder that sometimes cases need to be tried. This is particularly true in the fraud context, where the government continues to make aggressive charging decisions – these must be tested at the motion stage, at trial, and, when appropriate, on appeal. Fraud cases, particularly health care fraud cases, often turn on fact-based questions of intent best evaluated by a jury of one’s peers. The government suffered several fraud trial acquittals in 2024.

By way of background, trials historically favor the government, and only a small percentage of defendants choose to proceed to trial. In FY 2023 (the last year data was available), for example, only 2.5% of all federal defendants proceeded to trial.^[2] Of that small group, 85% were convicted.^[3]

Fraud cases typically proceed to trial more often than the average criminal case. In 2023, nearly 5% of fraud defendants proceeded to trial – nearly double the overall percentage. Fraud defendants fare slightly better at trial than the average with an acquittal rate in 2023 of nearly 17% (compared to ~15% overall). The percentage of fraud acquittals has risen over the past ten years:



Acquittal rates vary by jurisdiction. District-level offense-type data is not available; however, it is possible to review the overall trial acquittal rate by district for all types of offenses. The overall acquittal rate varies widely by jurisdiction. In FY 2023, for example:



Here are a few noteworthy not-guilty verdicts in 2024 that were delivered in health care fraud cases:

United States v. Jeffrey Andrews, et. al., 2:20-cr-00578

In July 2020, a grand jury in the District of New Jersey returned a sprawling 15-count indictment against Jeffrey Andrews, Chad Beene, Adam Brosius, and Robert Schneiderman. The indictment alleged that the defendants conspired to, and did, commit health care fraud and AKS violations against the government through a scheme in which they obtained medically unnecessary prescriptions for expensive topical creams, which they then billed to TRICARE, Medicare, and commercial payors for reimbursement. The government has pursued many of these alleged TRICARE compound schemes around the country.

Three defendants, Jeffrey Andrews, Adam Brosius, and Robert Schneiderman pled guilty. Only Chad Beene elected to test the government’s case at trial – and notwithstanding his co-defendants’ guilty pleas and cooperation – he won.

On October 28, 2024, Beene’s jury trial began in Newark. Both Brosius and Schneiderman testified for the government. According to the government, “[t]he trial was lengthy and complex, spanning approximately three weeks, involving approximately 30 witnesses and hundreds of documents and exhibits.” On November 22, 2024, the jury found Chad Beene not guilty on six counts of health care fraud and deadlocked on both conspiracy counts and all the AKS counts. It remains possible the government will try again at a second trial on the deadlocked conspiracy and AKS counts.

Based on a review of the docket, Beene’s defense attacked the prosecution and the proof against him. Beene argued, among other things, that when he discovered a provider was not signing prescriptions, Beene rejected the behavior and suggested a civil suit against the doctor. According to one filing “[a]t best, what the government has shown in this case is that Mr. Beene was negligent in not following up on perceived problems, many instances of which came up during trial.”

This appears to have been an aggressive prosecution. Beene was not a medical provider and, according to documents filed in the case, had no specialized health care training. Despite that, he was charged as a member of a conspiracy involving the submission of supposedly false claims for allegedly unnecessary prescriptions. This acquittal demonstrates that there is some limit to the government's ability to hold non-medical professionals responsible for the actions of medical professionals. Many or most TRICARE compound fraud prosecutions have resulted in guilty pleas, but this is another example of a jury rejecting the government theories of criminality – particularly when applied to a non-medical professional.

Interestingly, the grand jury in Newark returned the indictment in this case only months before the Mattia indictment (discussed below), which another judge dismissed as legally insufficient, and the two indictments include similar allegations and theories of culpability.

United States v. Zarobkiewicz et al., 5:22-cr-659

On August 19, 2024, a jury in the San Antonio Division of the Western District of Texas acquitted Kuba Zarobkiewicz and Anthony Fermin of all charges stemming from a sixteen-count superseding indictment. According to that indictment, Zarobkiewicz and Fermin owned and operated multiple pharmacy businesses, and Mirza owned and operated telemarketing companies. Similar to the TRICARE compound fraud scheme alleged in *Jeffrey Andrews* (above), the government alleged that the defendants conspired to pay bribes to Mirza's telemedicine company in exchange for signed prescriptions and durable medical equipment (DME) orders being sent to Zarobkiewicz and Fermin's pharmacies. The government alleged that the prescriptions and DME were medically unnecessary. Mirza pleaded guilty, but co-defendants Zarobkiewicz and Fermin chose a trial. The jury spent three days deliberating before returning a not-guilty verdict.

United States v. Muhamad Aly Rifai, 5:22-cr-390

In May 2024, a jury in the Eastern District of Pennsylvania acquitted a psychiatrist of health care fraud. According to the indictment, Dr. Muhamad Aly Rifai, who practiced largely by telemedicine, allegedly billed Medicare (1) for services not provided, (2) for services purportedly provided but to patients who were deceased, and (3) for a volume of services that could not have been provided in a given day. The defendant elected to proceed to trial and, following an 8-day trial, the jury returned a verdict of not guilty on all counts.

A few things to note about the government's trial strategy. Interestingly, the government presented two FCA whistleblowers as trial witnesses. This is a risky strategy for the government because it allows the defense, as happened here, to attack their credibility as interested parties hoping to receive a financial payout and to accuse the government of confirmation bias – investigating and charging the defendant based on the whistleblowers allegations but not based on the evidence. The government also provided one of the whistleblowers with immunity and she testified about her immunity agreement. Immunity is always risky for the government, and it needs to be carefully vetted before it is provided. At a minimum, the government should first understand what crime(s) the immunized witness believes they need protection from prosecution. Here, the immunized witness was asked this seemingly basic question on cross examination. In a worst-case scenario answer for the government, the immunized witness said she had not done anything wrong, and worse for the government, she had not done anything wrong with or at the direction of the defendant. It is somewhat surprising to see this response from the immunized witness on the stand and in front of the jury.

* * *

There is no single reason juries found these individuals not guilty. Each case is different and driven by unique facts, circumstances, and legal strategies. Most triable cases involve questions of intent versus questions about what happened. Health care fraud prosecutions rise and fall based on the government's ability to prove bad intent and the defendant's success at poking holes in that proof and/or presenting their own evidence of lawful intent. Just because most fraud cases end in guilty pleas does not mean every fraud case must. Like in 2024, we will continue seeing health care fraud cases tried to verdicts (including acquittals) in 2025.

Important Health Care Fraud Cases on Appeal

Additionally, in 2025, there are several cases and opinions to pay attention to as they will have some bearing on the reach of federal health care fraud laws, including the Anti-Kickback Statute.

Two of these cases are wire fraud cases arising from the Third Circuit.

Kousisis v. United States, 23-cr-909

The Supreme Court heard oral arguments in *Kousisis* on December 9, 2024. The case is on appeal following a jury's conviction of defendants for conspiracy to commit wire fraud (18 U.S.C. § 1349) and wire fraud (18 U.S.C. § 1343), among other things.

The government alleged that the defendants conspired to defraud, and did defraud, the U.S. Department of Transportation and the Pennsylvania Department of Transportation by skirting the disadvantaged business enterprise ("DBE") requirements – intended to promote the participation of socially and economically disadvantaged individuals – in the contracts the defendants were awarded. Although the contracted-for work was completed, the defendants received millions of dollars that would not have been paid had the government known the defendants did not satisfy the DBE requirements. The government argued that the defendants defrauded the government because they were induced into providing the grants based on fraudulent misrepresentations that the applicants satisfied the DBE requirements. The government argued that they would not have paid the defendants had they known they did not satisfy those requirements.

The defendants argued that the government's "fraudulent inducement" theory required a showing that they schemed to harm the government financially. Here, the defendants argued that the government received the full benefit of the bargain because the work was completed. The Third Circuit rejected that argument, stating that the DBE requirement was an essential part of the contract.

At oral arguments before the Supreme Court, some of the justices expressed skepticism at the defendants' argument that it is necessary to show financial harm to convict for wire fraud by pointing to the lack of statutory support for that argument. Other justices questioned whether the defendants' argument failed if the Pennsylvania Department of Transportation paid more for the DBE contract (the government conceded that it did not know if this was the case). The defendants countered that the government's fraudulent inducement theory would impermissibly stretch the fraud statutes to concert into a federal felony offense almost any conduct, including mere puffery and other statements made during ordinary business transactions. All the justices questioned how thin the line was before an action constitutes fraud. One demonstrative example explored at oral argument questioned whether it would be wire fraud if someone wanted to hire a babysitter of a particular faith and hired a teenage babysitter because the babysitter claimed to be a member of the particular religion but it turned out that was not true. Even though the babysitter took great care of the child and performed perfectly, the Court wondered whether this apparent misrepresentation would convert the babysitter's actions into a federal felony. The answer would seemingly be yes – if the government's fraudulent inducement theory is correct,

this conduct would potentially be criminal. This is an ever-present question that makes this case a significant one.

The Supreme Court's decision in *Kousis* will be one to watch in 2025 for its likely impact on health care fraud cases. The government often relies on the fraudulent inducement theory in health care fraud prosecutions and FCA actions.

Kousis v. United States, 23-cr-909

The Third Circuit also recently addressed whether the government must establish "convergence" (i.e., that the defrauded party itself – rather than some third party – was deceived) to obtain a conviction of wire fraud. The convergence defense is that fraudulent misrepresentations or similar fraudulent conduct must be directed at the party from whom financial benefits are being taken. It's a defense that is often raised but rarely prevails.

In *Porat*, a former dean of the Fox School of Business at Temple University was convicted of conspiracy to commit wire fraud (18 U.S.C. § 1349) and wire fraud (18 U.S.C. § 1343) after submitting fake data to several academic ranking services such as the U.S. News & World Reports to inflate the school's national rankings. As a result, the school saw a surge in enrollment and received almost \$40 million in tuition payments. The government alleged that because of this scheme, applicants, students, and donors of the school were defrauded under false pretenses.

On appeal from the defendant's conviction, the Third Circuit rejected defendant's argument that the government had to prove that the defendant defrauded the victims directly through his own conduct, and that it was insufficient to show that he defrauded the third-party academic ranking services. Looking to the text of the statute, the Third Circuit held that the wire fraud statute does not require "convergence." The Third Circuit stated that even if the statute did require the government to prove convergence, the evidence at trial showed that the defendant directly deceived students and recruiters through his email and marketing campaigns.

The defendant has petitioned for certiorari, so the Supreme Court might weigh in on this issue. However, to date, almost all circuits have rejected the convergence defense. The Ninth Circuit has ruled that convergence is an element the government must prove for wire fraud, see *United States v. Lew*, 875 F.2d 291, 221-22 (9th Cir. 1989), while the D.C. Circuit had held that the need to show convergence is case-dependent. See *United States v. Abou-Khatwa*, 40 F.4th 666, 675 (D.C. Cir. 2022). The Supreme Court might therefore decline to address this issue, at least for now.

* * *

Although, factually, these cases have no relation to federal health care fraud, they will be important for the existential question of what constitutes fraud. First, in essentially every case involving the AKS, the government argues that providing a kickback automatically makes a claim false, even if the care itself was medically necessary – thus the government received the benefit of the bargain notwithstanding the illegal kickback. Second, a recognition that convergence is a necessary element for fraud will necessarily impact the health care fraud statutes, which have an "intent to defraud" element but not a requirement that the defendant's conduct must be directly defraud the government. A Supreme Court decision in *Kousis* or *Porat* would impact the way that the government prosecutes, and defense attorneys defend, health care fraud cases.

There are more cases to watch even still. One such case, *United States v. Sorenson*, No. 24-1557 (7th Cir.),

addresses the impact of the Anti-Kickback Statute on marketing services or relationships. A three-judge panel heard oral arguments on December 4, 2024. The resulting decision may have widespread impacts on what is considered a “referral” under the AKS. The defendant was convicted for providing kickbacks to physicians in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2). Specifically, the government alleged that defendant paid marketing companies to find patients that needed orthopedic braces and then contact those patients’ providers to induce them to order orthopedic braces that were later fulfilled by the defendant’s company. The defendant argued that the arrangement was legal under Department of Health and Human Service guidance and that he did not fall within the scope of the statute because he was not a health care provider. The government disagreed. The government argued that the text of the AKS refers to “any person” not just health care providers. The government also argued that the defendant created an illegal referral when he paid the marketing companies to directly leverage their influence over medical decisions that are otherwise under a patient’s right to choose. How the court decides will ultimately narrow or broaden the circumstances that constitute a “referral” under the AKS.

In 2025, the courts continue to debate the pleading standard required to survive a motion to dismiss under Rule 9(b) of the Federal Rules of Civil Procedure. In 2022, Novartis won the dismissal with prejudice of a relator’s third amended complaint in the Southern District of New York. The complaint alleged that Novartis engaged in a nationwide kickback scheme that induced providers to prescribe its multiple sclerosis drug, Gilenya, through speaker events as well as other promotional and educational events. However, in a bad start to the new year, the Second Circuit reversed the district court’s decision in *US ex. Rel. Steven M. Camburn, et. al. v. Novartis Pharmaceutical Corporation*, No. 22-2708 (2d Cir. Dec. 27, 2024). The Second Circuit held that “a plaintiff adequately pleads an Anti-Kickback Statute (‘AKS’), 42 U.S.C. § 1320a-7b, violation when she states with the requisite particularity that at least one purpose of the alleged scheme was to induce fraudulent conduct (the ‘at-least-one-purpose’ rule).” While this decision follows the direction that many other circuits have taken, this is the first decision of its kind in the Second Circuit. However, the Second Circuit did not stop there. The court further held that “as a corollary, a plaintiff pleading an AKS violation as a predicate to an FCA claim need not state a quid pro quo exchange.” This decision has ultimately changed the pleading standards in the Second Circuit, making it much easier than before for plaintiffs to assert fraudulent intent under Federal Rules of Civil Procedure Rule 9(b) in health care fraud cases.

On the other hand, currently before the US Court of Appeals for the First Circuit is *U.S. v. Regeneron Pharmaceuticals, Inc.*, No. 23-2086,^[4] a major FCA case that has the potential to further a circuit split over the interpretation of the FCA’s causation element in cases where a violation of the AKS is a predicate violation for a false claim. Defendant Regeneron is accused of paying a charity to reimburse patients’ Medicare copays for one of its drugs – an allegation not dissimilar to the one at the heart of the government’s recent settlement with Teva, discussed above. Regeneron argues that the First Circuit should uphold the district court’s decision requiring but-for causation, follow the Sixth and Eighth Circuits, and apply a restrictive “but-for” causation standard, which would require the government to prove that “but for” the unlawful remuneration in violation of the AKS, the false claims would not have been submitted.

The dispute centers on the definition of “resulting from” as used in the AKS. The government and relators argue for a lax standard to prove a claim to the government results from a kickback whereas defendants, and at least two District Judges in Massachusetts, take the position that the plaintiff must prove but-for the kickback a claim would not have resulted. Regeneron cites *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828 (8th Cir. 2022) and *United States ex rel. Martin v. Hathaway*, 63 F. 4th 1043 (6th Cir. 2023) to support its theory. If the First Circuit declines to apply the but-for standard, it would align itself with the Third Circuit, which applies a more plaintiff-friendly standard, requiring only that the

government demonstrate “some connection between a kickback and subsequent reimbursement claim.” *Greenfield v. Medco Health Sols. Inc.*, 880 F.3d 89, 100 (3d Cir. 2018). Relators and the DOJ in the First Circuit, particularly Massachusetts, are very active in the FCA space and the First Circuit’s decision in *Regeneron* could have broad implications on the volume and type of cases filed there. Foley Hoag’s [White Collar Law and Investigations Blog](#) recently wrote about this topic. (Stay tuned for our upcoming False Claims Act Year in Review for much more on this and other FCA topics.)

On appeal in the Third Circuit is a case likely to influence the pleading requirements for health care fraud claims under § 18 U.S.C. 1347 and 18 U.S.C. § 1349 for false and misleading claims in 2025. In *US v. Carmine Mattia, Jr.*, No. 24-2589, defendant Carmine Mattia, an employee of a telecommunications company and a sales representative for various compounding pharmacies, allegedly bribed a colleague into obtaining “medically unnecessary” compounded medications so that Mattia would receive commissions for the sales. The government’s superseding indictment alleges that Mattia secured the signature of a doctor on prescription forms for the colleague, despite the absence of a doctor/patient relationship between the colleague and the doctor. A health plan was then billed for these “medically unnecessary” medications while Mattia received a cut of the sales. Specifically, Mattia was charged with “knowingly and intentionally conspir[ing] and agree[ing] with others to knowingly and willfully execute a scheme and artifice to defraud a health care benefit program” by causing “false and fraudulent insurance claims” to be submitted to a health care plan for “medically unnecessary” medications in violation of 18 U.S.C. § 1349 and 18 U.S.C. § 1347.

Mattia moved to dismiss the health care fraud claims, arguing that the government failed to properly allege a false or misrepresentative statement made by him to satisfy the pleading standard for health care fraud. He also challenged the term “medically unnecessary” as unconstitutionally vague. In a somewhat rare turn of events, the district court granted his motion based on the insufficiency of the superseding indictment. The court held that to prove a violation of § 1349, which prohibits attempting or conspiring to commit health care fraud, “the government must show (1) a conspiracy existed; (2) the defendant knew of it; and (3) the defendant knowingly and voluntarily joined it.” Section 1347 prohibits “knowingly and willfully execut[ing] or attempt[ing] to execute, a scheme or artifice-(1) to defraud any health care benefit program; or (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services.” The court noted that a scheme to defraud “must involve some sort of fraudulent misrepresentations or omissions reasonably calculated to deceive persons or ordinary prudence and comprehension.” (citations omitted).

Ultimately, the district court ruled that the government’s superseding indictment failed to allege (1) any misrepresentation or false or fraudulent statements or omission by Mattia; (2) how the “false and fraudulent insurance claims” were “caused” to be submitted to the Health Plan and who submitted those claims; or (3) what, if any, false or fraudulent statements or misrepresentations appeared on the insurance claims that were purportedly submitted to the company’s health plan. The court did not reach the challenges to the vagueness of medical necessity but did include a lengthy footnote challenging the strength of such claims and also stated in the opinion “there is unquestionably no singular or static definition for “medically unnecessary,” rendering it a vague term, which can have different meanings depending on context.” Defendants have long sought unsuccessfully to attack as vague the government’s use of the term “medical necessity.” Perhaps through continuing challenges, in New Jersey and elsewhere, they will ultimately prevail.

After losing a motion for reconsideration before the district court, the government appealed to the Third

Circuit and argued that the district court applied a heightened pleading standard that is not required by the Federal Rules of Criminal Procedure. In its brief, the government described the standard applied by the district court as one “akin to requiring trial proofs or the kind of specificity that civil fraud complaints require.” It argued that under Federal Rule of Criminal Procedure 7(c)(1), an indictment is sufficient if it includes the statutory language, the elements of the statute, and the time period of the offenses. Because one of the government’s claims was for conspiracy and one was for aiding and abetting, it also argued that the district court’s finding that the superseding indictment was deficient because it failed to allege that Mattia personally made any false statements was improper. On the constitutional issue, the government argued that “medically unnecessary” is not unconstitutionally vague, and a person of ordinary intelligence would “understand that giving the false impression that a doctor legitimately prescribed a medication to obtain payment for medically unnecessary drugs was garden variety fraudulent conduct” under the health care fraud statute.

This case is pending in the Third Circuit but will have considerable impact on health care fraud pleading standards for future cases.

* * *

2024 was a busy year in and out of the courts for legal developments regarding health care fraud laws. These trends and rulings have broad impact both on conduct and on the crafting and company oversight of compliance programs and training. We will continue to monitor this area in 2025 and share our findings.

^[1] As an Assistant United States Attorney in Boston, before he entered private practice, David G. Lazarus represented the government on aspects of both the Teva and Regeneron False Claims Act cases relating to patient assistance programs. The information contained in this publication is based solely on publicly available information and reporting and is not based on that involvement.

^[2] The United States Courts’ annual report provides fiscal year data. See <https://www.uscourts.gov/data-news/reports/statistical-reports/judicial-business-united-states-courts>. The Courts’ fiscal year ends September 30th.

^[3] All percentages in this section are rounded to the nearest whole number.

^[4] See note.

FALSE CLAIMS ACT IN 2025: LOOKING BACK AND WHAT'S AHEAD



By Anthony D. Mirenda, Caroline Donovan, David G. Lazarus, Yoni Bard, Rachel Kerner, Natalie Panariello, Caroline Holliday and Shayonna Cato

The Attorney General and key Department of Justice leadership are now in place and appear to have hit the ground running. As the new administration looks to deploy the False Claims Act (FCA) aggressively and in new ways, we consider below what these changes portend. First, to the extent that past may be prologue, we provide a comparative analysis of FCA enforcement under President Trump's first term and President Biden's term. Second, we consider both historically important priorities for enforcement and areas that have become significant in the early days of the second Trump administration. We conclude with a review of some of the most watched decisions in 2024 and the early days of 2025.

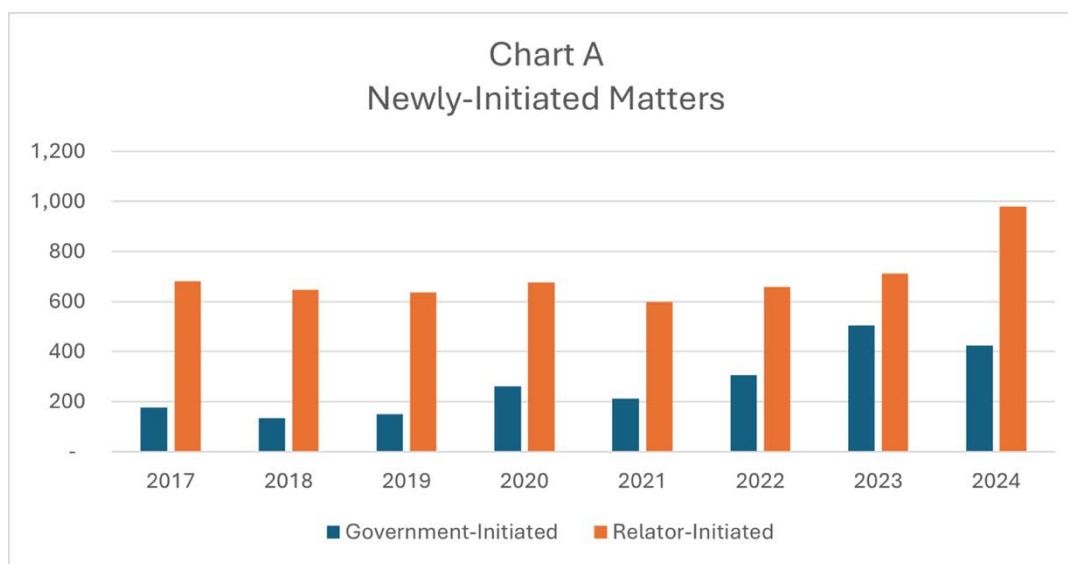
I. BY THE NUMBERS

False Claims Act enforcement is a seemingly evergreen focus of the government, with billions of dollars annually flowing to the government from resolution of these actions. And FCA cases can be brought by private parties (called Qui Tam Relators) who bring claims in the name of the government and stand to receive a substantial financial bounty if successful - those economics remain as a powerful incentive for new cases to be brought regardless of the level of government enforcement. With the second Trump term now underway, we look back at the first Trump administration and the Biden administration to understand what these precedents tell us. These are imperfect predictors, especially given the pace and extent of change already undertaken in the early days of this administration, but the historical trends show the powerful financial incentives for the government and relators to continue bringing FCA cases.

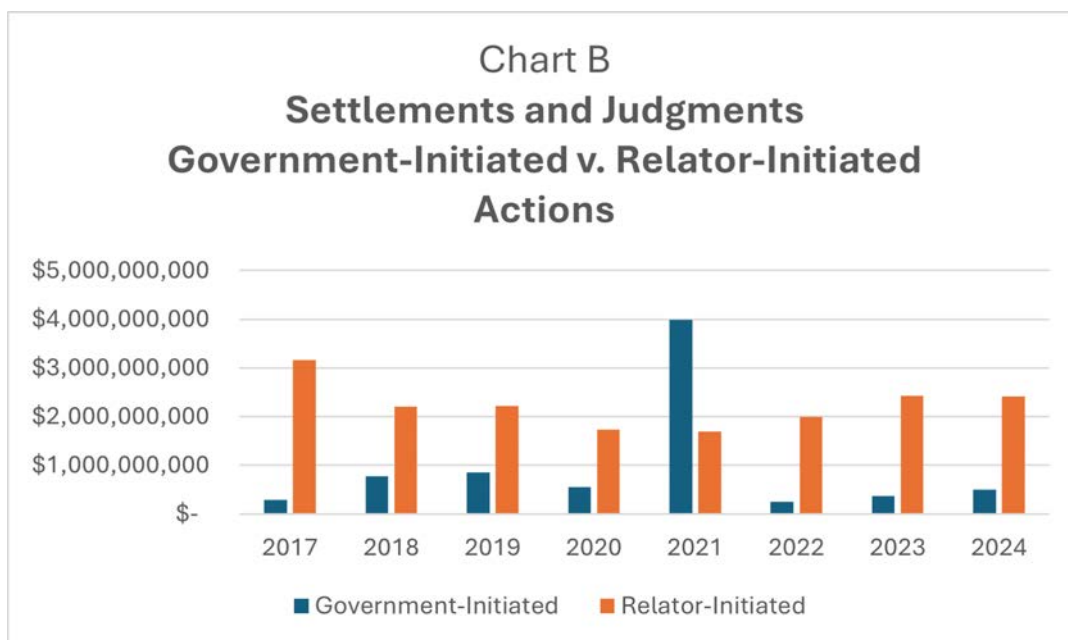
Of the newly filed FCA cases brought in 2024, 70% (979) were initiated by a relator and only 30% (423) were initiated by the government. Looking at all FCA cases that were resolved in 2024 (which would include many cases brought in prior years) there was a total of \$2.9 billion recovered. Of that \$2.9 billion, just over \$500 million is attributable to cases initiated by the government, while \$2.4 billion was recovered in relator-initiated cases, with the vast majority of those recoveries (\$2.2 billion) coming in relator-initiated cases in which the government intervened (elected to participate as a plaintiff). These numbers represent a high-water mark for newly-initiated FCA matters, though the total amount recovered sits squarely in line with median recoveries of late.

So now with data closed for the last full year of Biden's term, are there relevant differences between the Justice Department's False Claims Act focus under Biden versus Trump? Based solely on the numbers, not necessarily.

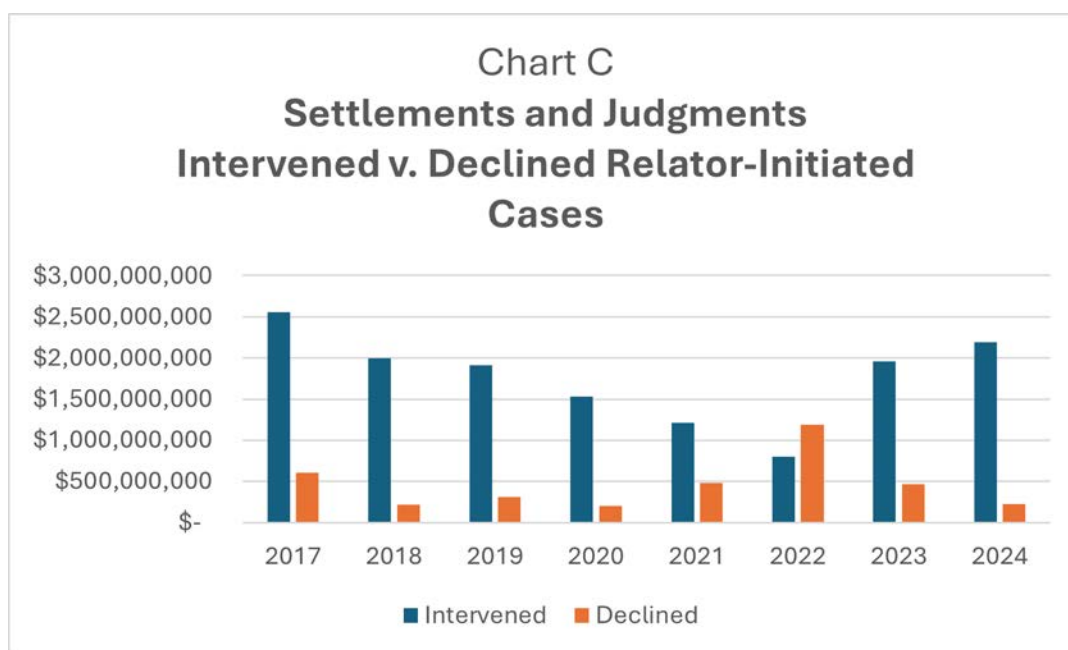
There were a roughly comparable number of new matters brought in the first two years of the Biden presidency as there were throughout the first Trump presidency. See Chart A below. In 2023 and 2024, we saw a noticeable uptick in new cases, in both non-qui tam FCA and qui tam FCA actions, with 1,218 new cases in 2023 and 1,402 new cases in 2024. Before 2023, annual new cases had approached but not exceeded the 1,000 mark. One distinction worth noting between the first Trump term and Biden's term concerns the breakdown between government-initiated FCA and relator-initiated FCA matters: In all but the first year of Biden's term, there was a greater percentage of relator-initiated FCA matters than in any year of Trump's first term. Indeed, growth in relator-initiated FCA matters has been driving the overall increase in FCA matters.



Looking at the size of the aggregated recoveries year to year, as shown in Chart B, the government realized generally larger settlements in the first Trump term than in Biden's term, with a significant exception in 2021. Thus in 2017, the government recovered over \$3.4 billion; in 2018, nearly \$3 billion; in 2019, just over \$3 billion; and in 2020, over \$2.2 billion. Meanwhile, in 2021, the government realized over \$5.6 billion in recoveries, attributable to a significant opioid settlement; in 2022, approximately \$2.2 billion; in 2023, nearly \$2.8 billion; and in 2024, approximately \$2.9 billion. In each administration - the first Trump term and Biden's term - government-initiated FCA actions drove the substantial majority of the totals recovered (excepting for 2021).



Within those qui tam recoveries, intervened matters were responsible for the lion's share of recoveries in all but 2022, as reflected in Chart C. Here too, there is not a seismic difference between the first Trump administration and the Biden administration, and thus we see the highest annual recovery in intervened matters in the first year of Trump's first term and the second highest in the last year of Biden's term.



II. PRIORITY AREAS OF FCA ENFORCEMENT

Health Care

As discussed in our recent post on [Health Care Fraud Enforcement in 2025](#), health care will continue to be a focus of FCA enforcement under the second Trump administration.

2024 and early 2025 have seen FCA settlements in the health care space ranging from the hundreds of thousands to hundreds of millions of dollars. These included settlements from pharmaceutical companies, pharmacies and pharmacy benefit managers, clinical laboratories, skilled nursing facilities, and substance use disorder treatment clinics, among others. The settlements have involved a variety of alleged unlawful activity, including the following:

- Issuing (in the case of prescribers) and dispensing (in the case of pharmacies) opioid prescriptions without a legitimate medical basis;
- Marketing opioids to high-volume prescribers for non-medically accepted indications;
- Billing for prescriptions that were processed but never picked up by beneficiaries;
- Billing for treatment services that were unreasonable, unnecessary or unskilled, or simply were not provided;
- Failing to properly discharge patients who no longer needed inpatient treatment;
- Billing for medically unnecessary tests;
- Paying unlawful kickbacks to physicians and insurance agents;
- Submitting false average sales price reports to Centers for Medicare and Medicaid Services (CMS) that excluded certain price concessions; and
- Failing to accurately report rebates from drug manufacturers.

In one particularly sizable set of settlements, Teva Pharmaceuticals USA Inc. and Teva Neuroscience Inc. ("Teva") agreed to pay \$425 million and \$25 million to resolve two matters involving alleged violations of the Anti-Kickback Statute ("AKS") and the FCA. The larger of the two matters stemmed from a complaint filed in the U.S. District Court for the District of Massachusetts in 2020 alleging that Teva coordinated and conspired with a specialty pharmacy and various copay assistance foundations to cover Medicare patients' copays for the multiple sclerosis drug Copaxone over a period of more than 10 years. The second matter came out of the U.S. District Court for the Eastern District of Pennsylvania and involved allegations that Teva violated the AKS by conspiring with competing generic drug manufacturers to fix prices and allocate markets for generic drugs. The distinct conduct at issue in these two matters serves as a powerful example of how diversely the FCA can be used against companies in the health care space, and we do not expect the government to quell its attempts at creativity in this regard in the near term.

Government Contracting and DEI

Government and defense contracting will also continue to be a focus of FCA enforcement in the coming years.

Since the start of 2024, there have been FCA settlements in the government contracting space ranging from the hundreds of thousands to tens of millions of dollars. These settlements involved companies of various sizes and specialties, including aerospace companies Sikorsky Support Services Inc. and Derco Aerospace Inc., ship manufacturer Austal USA LLC, and Booz Allen, an advanced technology company. The settlements involved a variety of alleged unlawful activities, including the following:

- Overcharging the U.S. military for spare parts and materials needed to repair and maintain military aircraft;
- Supplying valves for combat ships that did not meet military specifications;
- Using illegally divulged confidential government contracting and budget information to obtain government contracts;
- Billing the government for hours not actually worked.

Sikorsky Support Services Inc. and Derco Aerospace Inc. paid \$70 million to resolve allegations that they had overcharged the U.S. Navy for aircraft parts, while Austal USA LLC paid almost \$812,000 to resolve allegations that it had supplied inadequate valves for U.S. Navy combat ships.

Given President Trump's commitment to the recently launched DOGE-initiative, as well as statements by the Secretary of Defense and other Cabinet officials, emphasizing a need to find a perceived "billions" in fraud and waste, we can expect that the second Trump administration will continue using the FCA to combat fraud in all areas of government contracting, grants, and payments.

Over the course of the next year, we are also likely to see a new target of FCA enforcement in the government and defense contracting space: contractors who continue to maintain diversity, equity, and inclusion (DEI) and other affirmative action programs, given Trump's January 21, 2025 executive order targeting affirmative action and DEI initiatives in the federal government.

The executive order (EO), titled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," revoked several prior active executive orders, including dating back to 1965. The DEI Executive Order broadly deems DEI programs and policies illegal, and it specifically addresses higher education institutions, stating an intention to root out all race- and sex-based preferences used by higher education institutions (among many other "critical and influential institutions of American society"). The DEI Executive Order also creates new compliance obligations for all government contractors and grant recipients, heightening risk under the FCA.

Key provisions of the EO include:

- i. A requirement that any federal government contract or grant award contain terms requiring that the contracting party or grant recipient agree that its compliance with federal anti-discrimination laws is material to the government's payment decisions for purposes of the False Claims Act.
- ii. A prohibition on federal contractors and subcontractors being able to consider "race, color, sex, sexual preference, religion, or national origin in ways that violate the Nation's civil rights laws" in their employment practices.
- iii. A requirement that all contractors or grant recipients affirmatively "certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws."

As detailed in another [Foley Hoag post](#), government contractors or grant recipients who maintain DEI policies contrary to new terms and restrictions read into the law by the new Administration will risk liability under the FCA. In practice, this will likely result in private individuals bringing cases challenging companies' DEI activities and/or policies, which the government has indicated may constitute illegal discrimination. Based on the newly required certification language and the materiality designation of those certifications by the government, the FCA can now be used by those on either side of this issue. What have historically been largely individualized employment-law-based claims of workplace discrimination can now potentially also be pursued as FCA matters.

Qui tam relators and President Trump's DOJ are highly likely to capitalize on this expansion of FCA liability. Of special interest here is the impact this EO will have on private companies with federal contracts, which comprise some of the nation's largest employers. In addition, a recent Supreme Court decision may also further embolden qui tam relators and the DOJ. On February 21, 2025, the United States Supreme Court decided *Wisconsin Bell, Inc. v. United States ex. rel. Heath*, No. 23-1127, 604 U.S. ___ (2025). There, the Supreme Court confirmed an expansive reading of "claims" under the FCA. Wisconsin Bell moved to dismiss the qui tam FCA action and argued, in part, that because the money it received was largely money private carriers paid to a non-profit to administer based on government regulations, it did not submit any "claim" for government funds. The district court and U.S. Court of Appeals for the Seventh Circuit rejected this argument, as did the Supreme Court. The Supreme Court held that because the government provided at least some of the money in the fund, claims to the fund fell under the FCA. The Court stated: "And all the statute requires is that [federal money] provide 'any portion'-not the whole-of the sums requested." While not groundbreaking, this decision is a reminder that the FCA has a broad reach and provides an expansive definition of federal funding.

Finally, the DEI EO states that contractors may continue to comply with the existing regulatory scheme until April 21, 2025, which suggests that the relevant government offices, including the Office of Management and Budget, as well as the Federal Acquisition Regulatory Council, will be issuing guidance to procuring agencies in the coming months. Accordingly, there will be much uncertainty in the coming months, so government and defense contractors should be vigilant to ensure that they are complying with all government regulations and rules. See our prior [post](#) for a list of initial action items that should help government contractors and grant recipients begin to adapt to this changing environment.

Cybersecurity

Using the FCA as a tool for cybersecurity enforcement was an innovation of former President Biden's DOJ, which in 2021 launched its Civil Cyber-Fraud Initiative to use the FCA to pursue cybersecurity-related fraud by government contractors and grant recipients. Since its inception, the initiative has settled seven cybersecurity-related FCA matters, including four in 2024:

1. In May 2024, the DOJ announced a \$2.7M settlement with the staffing company Insight Global LLC to resolve a qui tam lawsuit alleging that the company, which was hired by the Pennsylvania Department of Health using funds from the U.S. Centers for Disease Control and Prevention, failed to implement adequate cybersecurity measures to protect health information obtained during COVID-19 contact tracing.
2. In June 2024, the DOJ announced settlements totaling \$11.3M with consulting companies Guidehouse Inc. and Nan McKay and Associates to resolve a qui tam lawsuit alleging that the companies failed to meet cybersecurity requirements in a federally-funded state contract to facilitate online applications for federal rental assistance during the COVID-19 pandemic.
3. In October 2024, the DOJ announced a settlement of approximately \$1.18M total value with Virginia-based contractor ASRC Federal Data Solutions LLC resolving FCA allegations related to storage of unsecured personally identifiable information of Medicare beneficiaries.
4. Also in October 2024, the DOJ announced a \$1.25M settlement with Pennsylvania State University to resolve a qui tam lawsuit alleging non-compliance with cybersecurity requirements in defense and aerospace contracts.

In addition, in August 2024, the United States intervened in a qui tam lawsuit against the Georgia Institute of Technology and Georgia Tech Research Corp. alleging that the defendants failed to follow cybersecurity

rules purportedly incorporated in two Department of Defense contracts when performing on-campus research. *United States ex rel. Craig v. Ga. Tech Rsch. Corp., et al.*, No. 1:22-cv-02698 (N.D. Ga.). The defendants have moved to dismiss the United States' complaint-in-intervention, and the motion is currently pending. This is the first cybersecurity-related FCA case in which a defendant has elected to defend the claims in court rather than pursue pre-litigation settlement. As such, it will be the first time that the government's theory that one can violate the FCA by failing to comply with cybersecurity regulations will be tested.

Looking ahead, we do not expect the second Trump administration to embrace a cybersecurity strategy that entails more regulation of the American private sector, including through FCA enforcement. Rather, we expect this administration to focus its cyber efforts on computer intrusions and attacks from abroad, as was the case during President Trump's first administration. Nevertheless, compliance with federal cybersecurity regulations should remain a priority for government contractors, particularly academic institutions that handle sensitive government data.

We also do not expect the second Trump Administration to abandon ongoing FCA investigations and litigations. As one example, on February 18, 2025, the Department of Justice settled FCA allegations against Health Net Federal Services Inc. (HNFS) and its corporate parent, Centene Corporation for \$11,253,400. According to the DOJ press release, the settlement resolves allegations that HNFS falsely certified compliance with cybersecurity requirements in a contract with the U.S. Department of Defense to Administer the Defense Health Agency's TRICARE health benefits program.

State Attorneys General

Nearly every state has its own version of the FCA and state Attorneys General will likely remain, or become increasingly, active in the FCA space across a broad spectrum of industries. State legislatures are also increasingly active in enacting legislation directed at strengthening or expanding the breadth of FCA statutes.

For example, Massachusetts recently enacted a new law requiring private equity companies, real estate investment trusts (REITS), and management services organizations (MSOs) doing business with Massachusetts healthcare providers to timely disclose their portfolio companies' FCA violations or face FCA liability themselves. The law exempts "venture capital firms exclusively funding startups or other early-stage businesses" from the new requirements. Foley Hoag recently discussed these new changes in a post on our White Collar Law and Investigations Blog found [here](#).

House Bill 5159, which was signed into law on January 8, 2025, amended the Massachusetts False Claims Act to impose liability on owners and investors that "know[] about" and fail to disclose FCA violations to the Commonwealth within 60 days of identifying the violation. The law also codifies the Attorney General's authority to issue civil investigative demands to health care investors.

The law applies to those with an "ownership or investment interest" in a covered entity, with "ownership or investment interest" broadly defined as "(1) direct or indirect possession of equity in the capital, stock or profits totaling more than 10 per cent of an entity; (2) interest held by an investor or group of investors who engages in the raising or returning of capital and who invests, develops or disposes of specified assets; or (3) interest held by a pool of funds by investors, including a pool of funds managed or controlled by private

limited partnerships, if those investors or the management of that pool or private limited partnership employ investment strategies of any kind to earn a return on that pool of funds."

When exactly a health care investor "knows about" an FCA violation such that it must disclose that violation to the Commonwealth is not defined in the new law, creating uncertainty for companies seeking to comply with the 60-day reporting deadline. We recommend that investors proactively consult with FCA counsel regarding oversight of their health care portfolio companies and seek guidance from counsel about potentially reportable incidents as soon as possible.

III. DEVELOPMENTS IN THE COURTS

***Zafirov* (holding: the qui tam provisions of the FCA are unconstitutional)**

One 2024 case out of the U.S. District Court for the Middle District of Florida - U.S. ex. rel. *Zafirov v. Florida Medical Associates LLC* - raises the question of whether there will even be a qui tam vehicle to enforce the topics discussed above going forward. In September 2024, the Middle District of Florida held that the FCA's qui tam provision - which has allowed individuals to sue on behalf of the government since the law was enacted in 1863 - is unconstitutional under the Appointments Clause of the Constitution. More about the decision can be found [here](#).

Zafirov was appealed in late October 2024 and the government, which had initially declined to intervene, but subsequently intervened for the limited purpose of defending the constitutionality of the FCA qui tam provisions, filed its appellant brief on January 6, 2025. The government's leading argument is that relators are "private litigants pursuing private interests" and so do not exercise executive power under the FCA. ECF 39 at 7. According to the government, qui tam suits "are distinct from the government's enforcement efforts[;]" they "supplement" rather than supplant them. Relators, they say, are therefore not enforcing federal law in a manner inconsistent with the Vesting and Take Care Clauses and need not be appointed in the manner required by the Appointments Clause. *Id.*

While the government's argument is not new - indeed, it quotes Supreme Court and circuit precedent for this point - the collection and emphasis of these cases in the government's brief may have unintended, defendant-friendly implications, even if the qui tam provisions ultimately survive constitutional challenge. It has long been argued that a relator steps into the government's shoes in a *qui tam* action and that the government is the real party in interest. This principle yields many policy-based holdings that now may be ripe for challenge. Just to mention a few examples, on the theory that it would harm the real party in interest, i.e., the government, courts have found that a defendant may not rely on an unclean hands defense against a relator. As another example, courts have held that res judicata is improper as to a relator because the relator is not the "party" to the case. And joint prosecutorial privilege has been found to exist in *qui tam* actions on the grounds that the government and relator are essentially the same party. But in *Zafirov*, the government moves away from this line of thinking and instead uses the relator's distinct identity to its advantage. With such a spotlight on *Zafirov*, it may be challenging for the government to continue to have it both ways going forward. To be fair, however, the government's *Zafirov* brief seemingly recognizes this contradiction. It walks a fine line, including the arguments noted above along with acknowledging that "relator's suit may also vindicate a federal interest in remedying and deterring fraud on the United States." ECF 39 at 7. This may be enough to avoid the government's positioning in *Zafirov* being used against it in different contexts.

On the other hand, this ruling could have negative implications for defendants, too. It may mean the DOJ increasing resources dedicated to FCA cases in order to timely investigate and intervene to avoid dismissal under *Zafirov*'s holdings. Attorney General Pam Bondi has signaled as much. During her confirmation hearings, she testified that under her leadership, the DOJ will devote sufficient resources to FCA enforcement and will defend the constitutionality of the FCA's qui tam provisions.

In the meantime, qui tam litigants may be wondering what this means for their litigation strategy. Few cases have weighed in on the constitutionality of the qui tam provisions since *Zafirov*. Those that have do not credit the argument. Despite this, defendants are raising the constitutionality defense in just about every procedural vehicle they can, so we may soon have a fuller picture of how other courts approach this argument. To preserve their rights, defendants should amend their affirmative defenses to add that the qui tam provisions of the FCA are unconstitutional, and, if the timing is appropriate, raise such an argument in any motion to dismiss or similar briefing.

Loper Bright (holding: courts may not defer to an agency's own interpretation of an ambiguous law)

In *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), the Supreme Court abrogated the longstanding Chevron deference to agency interpretation of silent or ambiguous statutes, making clear that “[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority” and “may not defer to an agency interpretation of the law simply because a statute is ambiguous.” *Id.* at 412-13.

In the FCA enforcement context, in which falsity often turns on questions of statutory interpretation, *Loper Bright* may prove a boon to defendants. *Loper Bright* offers defendants facing an enforcement action an avenue to advance their own interpretations of ambiguous statutes and requires the courts to consider such arguments without deference to the relevant agency's interpretation. For example, where a defendant is charged with falsely certifying that it complied with a regulation interpreting a silent or ambiguous statute, that defendant can now argue the regulation is invalid per the statute's plain text or otherwise exceeds an agency's statutory authority.

A handful of cases have considered the impact of *Loper Bright* in the FCA enforcement context. In *United States ex rel. Sheldon v. Forest Laboratories, LLC*, No. ELH-14-2535, 2024 U.S. Dist. LEXIS 129331 (D. Md. July 23, 2024), for example, the U.S. District Court for the District of Maryland addressed a motion to dismiss FCA claims arising from alleged violations of the Medicaid Drug Rebate Statute. After supplemental briefing from the parties addressing the impact of *Loper Bright* on their positions, the court granted the defendant's motion to dismiss, finding that the relator had failed to adequately plead falsity or scienter as required under the FCA. In doing so, as instructed by *Loper Bright*, the court independently interpreted the Medicaid Drug Rebate Statute and declined to rely on the CMS' interpretation.

Loper Bright provides no guarantee for defendants in FCA cases – in fact, it may yield greater unpredictability for those defendants because courts have more flexibility (variability) when interpreting an ambiguous statute. *Loper Bright* does not preclude courts from considering agency guidance to help them decide FCA cases. Still, *Loper Bright* is likely to increase the chances of success for a defendant in an FCA enforcement action predicated on violation of an ambiguous statute because Courts are no longer permitted to simply defer to the agency interpretation in that instance. *Sheldon* previews the new opportunities *Loper Bright* may create for such defendants.

Regeneron (holding: plaintiff must prove an anti-kickback statute violation was the but-for cause of a false claim when relying on the "resulting from" language in the statute)

A key case to watch in 2024 was *U.S. v. Regeneron Pharmaceuticals*, and on February 18, 2025, the U.S. Court of Appeals for the First Circuit Court held that the AKS requires the government to prove that an AKS violation was the but-for cause of any false claims submitted to federal healthcare programs to give rise to FCA liability. The Third, Sixth, and Eighth Circuits have already weighed in on this question, reaching varying conclusions and setting up a split ripe for resolution by the Supreme Court. Members of Foley Hoag's White Collar Crime and Government Investigations practice group shared their analysis of the decision here.

Under the Third Circuit's view, the government must merely show that a patient is "exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018). That is, the government need not prove that the alleged false claims would not have been submitted but for the alleged unlawful kickback. The government favored this less demanding causation standard, and it advanced this position before the First Circuit in *Regeneron*.

The standard adopted by the Sixth and Eighth Circuits is the more stringent but-for causation standard, which requires the government to prove that but for the unlawful kickback in violation of the AKS, the false claims would not have been submitted. See *U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 834 (8th Cir. 2022); *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023). This was the position adopted by the district court in *Regeneron* and ultimately accepted by the First Circuit on appeal.

* * *

2024 was a busy year for the False Claims Act, and there are no signs of slowing down as we head into 2025. We recommend any company or individual that received federal money - of any kind - closely monitor unfolding events and seek qualified legal counsel when appropriate.



HIGHER EDUCATION IN 2025: FOCAL POINTS FOR COMPLIANCE AND INVESTIGATIONS

By Emily Nash, David G. Lazarus, Howard Weiss, Kenny Peralta

Colleges and universities have been operating under a microscope for the past few years, and as 2025 begins, there is no sign of that scrutiny abating, albeit with a different focus under the current presidential administration. As this new administration begins, higher education is understandably, and appropriately, on high alert.

Looking ahead at 2025, we address what we expect to be the key areas of government investigation, oversight, and prosecution this year. We focus on the “what” and the “how”: addressing first the issues that we anticipate being the target of government activity and then the tools that may be employed to effectuate this oversight.

I. THE FOCUS AREAS: PROGRAMS AND INITIATIVES LIKELY TO FACE ONGOING OR INCREASED SCRUTINY

Higher education has become ground zero for some of the most heavily politicized issues in recent months. The first days of the Trump administration have also brought a barrage of activity affecting or even targeting colleges and universities. The following is a list of issues we view as points of significant concern for government enforcement this year within this ever-evolving environment.

Race and DEI

President Trump’s criticism of race-conscious initiatives and diversity, equity, and inclusion programming (“DEI”) was a focal point of his campaign, and it appears to remain a focal point during the opening weeks of his second term. Within 48 hours of his inauguration, President Trump issued a flurry of Executive Orders, including the [“Ending Illegal Discrimination and Restoring Merit-Based Opportunity”](#) Executive Order (“DEI Executive Order”), which revoked several prior active executive orders, including dating back to 1965. The DEI Executive Order broadly deems DEI programs and policies illegal, and it specifically addresses higher education institutions, stating an intention to root out all race- and sex-based preferences used by higher education institutions (among many other “critical and influential institutions of American society”).

Admissions and Race-conscious Programming

Race-conscious programming has been an area of significant risk for higher education institutions since before the second Trump administration began. The Supreme Court’s 2023 [decision](#) in *Students for Fair Admissions (“SFFA”) v. Harvard College and SFFA v. University of North Carolina* (together referenced herein as “SFFA”) declared race-conscious admissions programs unlawful. SFFA has also spurred challenges to all

aspects of higher education institutions' operations. As our prior [client alert](#) explained, throughout 2024, universities confronted challenges to their procurement policies, scholarship and fellowship programs, and employment decisions. Although some courts have relied on *SFFA* in reviewing such challenges, many cases are still working their way through the courts.

But the Trump administration's view on the matter is clear: *SFFA* applies broadly. The DEI Executive Order denounces "institutions of higher education [that] have adopted and actively use" race-based preferences. It states that all such policies could violate Federal civil rights laws, and it does not use any language limiting its opinion to admissions policies. The DEI Executive Order instructs the Attorney General and Secretary of Education to issue guidance to higher education institutions "regarding the measures and practices required to comply with [*SFFA*]." This guidance will be provided by May 21, 2025.

DEI Programming

In 2024, DEI programming was a focus for Republicans in Congress and Republican-controlled state legislatures around the country. This past year, three states—[Alabama](#), [Iowa](#), and [Utah](#)—prohibited universities from maintaining DEI offices. Many other state legislators introduced a variety of legislation targeting DEI in higher education, and although these laws were not ultimately enacted, institutions in these states still acted quickly to comply. For example, the University of Kentucky voluntarily [closed](#) its "Office for Institutional Diversity" after questioning from the state legislature. At the Federal level, members of Congress have vocally criticized DEI programming. In March, the House Subcommittee on Higher Education and Workforce Development had a [hearing](#), "Divisive, Excessive, Ineffective: The Real Impact of DEI on College Campuses." Rep. Burgess Owens, the Chairman of the Subcommittee, opened the hearing by calling DEI "a long-growing cancer that resides at the heart of American academic institutions." This year, one Arkansas senator has already [announced](#) his intention to introduce legislation targeting these programs in higher education institutions.

The Trump administration has signaled its intent to challenge higher education institutions' DEI policies directly. In his DEI Executive Order, President Trump "order[ed] all agencies to enforce our longstanding civil-rights laws and to combat illegal private-sector DEI preferences, mandates, policies, programs, and activities." President Trump has already dismantled DEI programs throughout the Federal Government through his "[Ending Radical And Wasteful Government DEI Programs And Preferencing](#)" Executive Order. And, in his DEI Executive Order, President Trump instructed federal agencies to create a "plan of specific steps or measures to deter DEI programs or principles (whether specifically denominated 'DEI' or otherwise) that constitute illegal discrimination or preferences." We thus expect challenges to race-conscious and DEI policies and programs to continue, and likely increase, in 2025.

Sex and Gender Identity

The Trump administration has also prioritized issues involving sex and gender identity in higher education. One of President Trump's first acts in his second term was to issue the "[Defending Women From Gender Ideology Extremism And Restoring Biological Truth To The Federal Government](#)" Executive Order ("Sex/Gender Executive Order") to proclaim that "[s]ex" is not a synonym for and does not include the concept of "gender identity," and direct agencies to enforce "sex-protective laws" as excluding gender and sexual orientation. The Sex/Gender Executive Order specifically targets higher education through Title IX, including instructions to rescind prior Title IX guidance, and instructions to the Attorney General to issue guidance that *Bostock v. Clayton County*, which held that Title VII's ban on discrimination based on sex also

prohibits discrimination based on gender identity and sexual orientation, does not apply to Title IX. It further directs “the Attorney General, the Secretary of Labor, the General Counsel and Chair of the Equal Employment Opportunity Commission, and each other agency head with enforcement responsibilities under the Civil Rights Act [to] prioritize investigations and litigation to enforce” the Executive Order’s policies.

This position is a direct reversal of the Biden administration’s policy, particularly with respect to Title IX. In 2024, the Department of Education finalized a rule amending Title IX regulations to, among other things, interpret “sex” to include sexual orientation and gender identity. On January 9, 2025, a Kentucky federal district court vacated the 2024 Title IX rule in full, and on January 31, the Department of Education’s Office for Civil Rights (“OCR”) issued a [Dear Colleague letter](#) confirming that it had no intention of reviving the 2024 rule. OCR stated it would enforce Title IX under the 2020 rule instead of the “recently invalidated 2024 Title IX Rule.” In support of this position, OCR cited both the Kentucky decision and the Sex/Gender Executive Order.

Beyond this recent Title IX activity, there has been and will likely continue to be significant focus on transgender students, especially in college athletics. Last year, Ohio and New Hampshire joined a list of states banning transgender girls and women from girls’ and women’s sports teams at both the K-12 and collegiate level. The National Association of Intercollegiate Athletics, which oversees collegiate sports for smaller colleges, approved a policy barring most transgender women from competition. And the House recently passed a bill that would prohibit transgender girls and women from playing on K-12 and college teams that align with their gender identity.

Finally, we note that the Supreme Court may weigh in again on this topic in 2025. In October, the Supreme Court granted a certiorari petition to review the Sixth Circuit’s [decision](#) in a reverse discrimination sexual orientation case, *Ames v. Ohio Dep’t of Youth Services*. Although this is again a Title VII case, the Supreme Court will be addressing what standard to apply in reverse discrimination cases. Many circuits now require “background circumstances to support the suspicion that the defendant is that unusual employer who discriminates against the majority” (e.g., that a member of the relevant minority group made the decision at issue). If the Supreme Court reverses the Sixth Circuit, reverse discrimination claims are likely to significantly increase in the coming year.

Free Speech and the First Amendment

Student protests. In 2024, free speech and the First Amendment remained hot topics as the ongoing Israel-Palestine conflict created uniquely challenging enforcement issues for universities across the country. Pro-Palestinian protests on college campuses escalated in April 2024, following the arrests at Columbia University, where more than 100 students were [arrested](#). This dismantling of the initial encampment at Columbia sparked similar actions nationwide, leading [students](#) at over 100 colleges across the United States to set up protest encampments demanding that their schools divest from companies supporting Israel. The dismantling of these encampments resulted in numerous OCR investigations and settlements with universities involving claims of harassment following the protests.

The Trump administration has, in its first days in office, taken a clear position on this issue. First, among the many Executive Orders President Trump signed on his first day in office was the Executive Order “[Protecting the United States from Foreign Terrorists and Other National Security and Public Safety Threats](#),” which appears to target foreign students and staff who participated in pro-Hamas protests. The Executive Order called for the removal of these foreign visa holders, stating “the United States must ensure that admitted

aliens and aliens otherwise already present in the United States do not bear hostile attitude towards its citizens, culture, government, institutions, or founding principles, and do not advocate for, aid, or support designated foreign terrorists and other threats to our national security.”

On January 29, 2025, President Trump issued his Executive Order, [“Additional Measures to Combat Anti-Semitism”](#) (“Anti-Semitism Executive Order”), outlining the administration’s plan to combat antisemitism in the United States following a reported rise in antisemitism incidents after the October 7 attack by Hamas in Israel. The Anti-Semitism Executive Order specifically addresses a “failure” to protect students on campuses, citing a December 2024 House Committee report on antisemitism (addressed in greater detail below). It directs the Department of Education to prepare a report that includes an inventory and analysis of all Title VI complaints and administrative actions related to antisemitism after October 7, 2023. The order also directs the Attorney General to prosecute antisemitism under the Conspiracy Against Rights statute, 18 U.S.C. § 241, and instructs the Secretary of State, the Secretary of Education, and the Secretary of Homeland Security to coordinate on recommendations for monitoring and reporting activities by alien students and staff that may warrant removal under immigration law.

Since the ceasefire announcement, college protests have subsided, and it remains unclear if the [Trump administration](#) will use the order to identify students from 2024 protests. Following the 2024 protests, Steve Scalise, House majority leader, has [discussed](#) plans to punish universities that allow pro-Palestine protests by revoking their accreditation.

[Academic freedom.](#) Universities’ ability to rely on traditional First Amendment protections for curriculum and scholarship is likely to be tested under the second Trump administration. In a section entitled “Scope,” the [DEI Executive Order](#) includes the following provision: “This order does not prohibit individuals teaching at federally funded institutions of higher education, as part of a broader course of academic instruction, from advocating for, endorsing, or promoting unlawful employment or contracting practices that are prohibited by this order.” The implications of this provision remain unclear, but the Scope provisions are likely included to protect against First Amendment challenges to the Executive Order.

President Trump [promised](#) during his campaign to eliminate “wokeness” in education and intends to use federal funds as leverage to achieve this goal. He has [promised](#) to cut federal funding to any schools that promote “Critical Race Theory, transgender issues, and other inappropriate racial, sexual, political content on our children.” In contrast, the Trump administration has taken steps to promote “patriotic education.”

The administration’s early actions in this realm have focused on K-12 schooling, but they reveal a broader position toward academic freedom that implicates higher education. For example, the January 29, 2025 Executive Order, [“Ending Radical Indoctrination in K-12 Schooling,”](#) directs schools to cease promoting “discriminatory equity ideology” and instead promote “patriotic education.” On January 24, 2025, the Department of Education dismissed all pending complaints about [book bans](#), rejecting the notion that removal of “racially divisive” books could amount to a Title VI violation.

Critical race theory took center stage a few years ago, but Republicans have vowed to focus on this in the new year. In December, Republican members of the U.S. House Subcommittee on Early Childhood, Elementary, and Secondary Education discussed what they refer to as “woke” curricula in schools. This topic remains a significant concern for lawmakers, especially in light of a Florida Senate Bill passed in 2023, which has already impacted schools in Florida this past year (e.g., Florida International University’s Board of

Trustees voted to drop 22 courses from the core curriculum, including Anthropology of Race & Ethnicity, Introduction to LGBTQ+ Studies, and Sociology of Gender).

Foreign Influence and the China Initiative

China Initiative II. The Trump administration will likely restart, if not expand, the China Initiative, which was terminated by President Biden. Under the China Initiative in his first term, President Trump pursued individuals and institutions for alleged undisclosed ties to China. The China Initiative led to multiple criminal prosecutions, many of them resulting in dismissals, and a number of investigations of research facilities and institutions. Project 2025, believed to be a significant influence on President Trump's likely agenda, explicitly called for the restart of the China Initiative. The first China Initiative was largely viewed as a failure and the new administration may modify its approach accordingly. The first China Initiative mainly targeted Chinese researchers alleged to have undisclosed ties to China and programs in China. The Second China Initiative will likely be more institution and laboratory focused. For example, the inquiries may focus on sanctions, export control, supply chain prohibitions, and international collaborative efforts. Data privacy requirements and cybersecurity controls are other mechanisms the government may use to pursue institutions dealing with foreign entities.

In 2024, the research compliance landscape saw significant updates, particularly in the realm of research security training. The Office of Science and Technology Policy issued new guidelines mandating that covered institutions, including certain higher education and nonprofit research entities, implement comprehensive research security training programs. These programs are designed to address cybersecurity, foreign travel security, research security, and export control. Institutions can meet these requirements by certifying that their personnel have completed federal research security training modules or by deploying their own training programs. This move aligns with broader efforts to enhance national security and protect sensitive research from foreign interference, underscoring the critical importance of robust cybersecurity measures in academic and research settings.

II. ENFORCEMENT: AGENCIES AND THEIR TOOLS

The federal government wields a significant number and type of tools it might leverage to obtain policy-oriented results. On an individual basis, for example, as discussed above, Homeland Security and other federal agencies, perhaps in conjunction with university campus safety departments, may investigate and target individual student visa holders and seek to rescind or revoke their permissions based on participation in protests. Law enforcement can use administrative subpoenas, voluntary requests for information, search warrants (in appropriate circumstances), and other tools to investigate and identify students for further scrutiny and enforcement. Historically, the Department of Justice ("DOJ") has prosecuted visa holders or other non-citizens for conduct while in the United States or before arriving here by alleging those individuals lied on immigration paperwork by either certifying they had not violated any laws in the past or certifying they would abide by all laws while in the United States. The government has broad discretion in this area, including an expansive definition of materiality governing information provided during the application process: "A fact is considered material...[if] had the truth been known, [the individual] would not have been eligible to receive a visa or enter the United States." Visa fraud can be a criminal offense, and investigators often utilize the entire law enforcement toolkit, including grand jury subpoenas and testimony, search warrants, surveillance, and more.

Institutions are also likely to undergo significant scrutiny in the coming year. First, they may be the recipient of government requests (or lawful demands) for information about individual students, faculty, facilities, residences, and more. These inquiries will range from targeted to broad, and we recommend each inquiry be carefully scrutinized for lawfulness as well as any statutory or policy-based notice requirements. We recommend institutions review their internal policies on responding to lawful process, consult internal or external counsel upon receipt of any such process, and undertake a review of institutional document/information preservation and destruction policies. Second, institutions may themselves be targeted for investigation in connection with any number of potential violations. For example, research misconduct and undeclared conflicts of interest, discrimination and harassment complaints, and newly required certifications of compliance with federal law and policy related to DEI programs can serve as the basis for federal investigations. Institutions should review their existing programs and existing grant and contract processing procedures.

False Claims Act

Many government investigations will begin with whistleblower tips or whistleblower lawsuits (*qui tams*). In addition to the broad reward component of the False Claims Act (“FCA”), many DOJ components have implemented jurisdiction-specific whistleblower reward programs, and many existing programs already provide bounties to tipsters. Given the politically charged nature of these policies and directives, institutions should expect to see an increase in tipster activity. Institutions should evaluate existing programs and procedures for employees, academics, and students to raise concerns of all types and should ensure those programs provide mechanisms for reporting back—in some manner—the outcome of those concerns. Many whistleblowers report that they attempted to solve the perceived problem at the institution level before resorting to becoming a tipster. Good stakeholder communication is important while being mindful to protect any attorney-client or otherwise privileged information.

A claim to the government may be false if it contains material misrepresentations or omissions. Institutions may be liable for contract certifications and other paperwork if the government or relator (whistleblower) can prove that the institution had actual knowledge about the false information, was deliberately ignorant, or acted with reckless disregard to the truth or falsity of the information. The FCA provisions are incredibly broad and carry tremendous treble damages plus statutory penalties per claim.

2024 FCA Cases – cybersecurity. In 2024, a series of high-profile FCA cases placed colleges and universities under scrutiny, with allegations of failing to meet cybersecurity requirements. DOJ efforts to combat cybersecurity threats include its Civil Cyber Fraud Initiative. This initiative is dedicated to using the FCA to promote cybersecurity compliance amongst government contractors and grantees, holding them accountable when they knowingly violate applicable cybersecurity requirements. On October 22, 2024, following a *qui tam* action filed by a whistleblower and former employee, Pennsylvania State University reached a settlement with the DOJ, agreeing to pay the U.S. Government \$1.25M for alleged cybersecurity compliance violations under the FCA. As another example, on February 19, 2024, the DOJ intervened under the *qui tam* or whistleblower provisions of the FCA in a claim against the Georgia Institute of Technology (“Georgia Tech”) and Georgia Tech Research Corp. (“GTRC”). The allegations state that these defendants knowingly did not comply with cybersecurity requirements associated with the Department of Defense (“DoD”) contracts. The whistleblower suit was initiated by current and former members of Georgia Tech’s Cybersecurity team. The complaint alleges that a research lab at Georgia Tech failed to develop and implement a system security plan, as required by the DoD cybersecurity regulations, and submitted a false cybersecurity assessment score to DoD for the Georgia Tech campus. The complaint also alleges that the

lab failed to install, update or run anti-virus or anti-malware tools on desktops, laptops, servers, and networks at the lab. The case is still being litigated in the Northern District of Georgia.

Anticipated FCA liability - DEI programs. The DEI Executive Order, discussed above, establishes new compliance obligations for all government contractors and grant recipients. Most notably, the Order introduces a new mandatory contract certification. The inclusion of mandatory contract certification is directly linked to the Trump administration's desire to use the FCA to enforce its policy vision, as certifications are "claims" to the government and can therefore be the basis of a FCA claim.

To expand and make plain the FCA's application to contract and grant documents, the DEI Executive Order includes a requirement that every contract or grant award include a "term requiring the contractual counterparty or grant recipient to agree that its compliance in all respects with all applicable Federal anti-discrimination laws is material to the government's payment decisions for purposes of section 3729(b)(4) of title 31, United States Code." Moreover, a contractor or grant recipient must also affirmatively "certify that it does not operate any programs promoting DEI that violate any applicable Federal anti-discrimination laws." This means that, when implemented, any government contractor or grant recipient or institution who continues to engage in prohibited discrimination or maintains certain affirmative action programs or DEI policies—contrary to the new contract terms and affirmative certifications—will risk liability under the FCA by virtue of submitting invoices to the government for payment. As discussed above, this risk is especially high because of the FCA's *qui tam* relator provisions, which incentivize employees through bounty payment to bring FCA suits on behalf of the government. Government investigation in this space may begin with the institution's receipt of a Civil Investigative Demand from DOJ seeking testimony and/or documents, a subpoena, investigators appearing on campus or at the institution, an administrative subpoena, or other form of inquiry.

Given the large role whistleblowers play in the origination of these investigations, institutions should be mindful of their document retention policies particularly in connection with departing employees and contractors. Institutions should both ensure compliance with internal preservation policies (both keeping and destroying) and ensure that departing employees and contractors do not retain any institution-owned information, documents, or messages.

Congressional Inquiry

The focus on higher education is not limited to the executive branch. In 2024, Congress continued turning its attention toward colleges and universities with highly publicized inquiries into universities' handling of protests and antisemitism in connection with the Israel-Palestine conflict. This scrutiny also went well beyond public hearings, including requesting and subpoenaing documents from institutions on the topic. On December 18, 2024, the U.S. House of Representatives released a [Staff Report on Antisemitism](#) ("Staff Report") condemning universities for failing to sufficiently combat antisemitism on campuses. The report criticizes several universities' conduct in great detail, such as providing data regarding disciplinary action taken (or not taken) by universities toward students. The report makes several recommendations, including that universities "impose meaningful discipline in response to antisemitic conduct violations" and more broadly "increase academic rigor and viewpoint diversity," and that the executive branch "aggressively enforce" Title VI and the Clery Act and withhold funding or issue fines for noncompliant universities.

Congress has also directed its attention toward the other key focal points of President Trump's campaign and the first days of his second administration, such as gender. For example, in December, the Senate

Judiciary Committee held a hearing on federal regulations around sports gambling that ended up shifting focus toward transgender athletes, with several committee members grilling NCAA president Charlie Baker on the NCAA's policies, which do not ban transgender athletes from participating in college sports.

Congressional attention on higher education is likely to continue in this first year of the second Trump administration. Focus on colleges and universities aligns with the goals and initiatives of the executive branch. It has yielded quick results: Following highly public congressional hearings, multiple presidents of prominent universities resigned. Given the recent political momentum and the Staff Report's emphasis on holding universities accountable, higher education institution can expect congressional subpoenas and other forms of congressional inquiry to continue.

Agency Investigation and Activity

President Trump's various Executive Orders promised regulatory action against entities engaging in conduct contrary to the Administration's policies, including those engaging in DEI programing and promoting "gender ideology." The DEI Executive Order also expressly directs each agency to identify up to nine potential civil compliance investigations of certain categories of organizations, including "institutions of higher education with endowments over 1 billion dollars." The Trump administration has several tools it could use to push its agenda.

An attack on higher education institution's funding will be, and already has been, at the center of efforts to compel compliance with the Administration's policies. During his campaign, President Trump pledged to cut federal funding to educational institutions "pushing Critical Race Theory, transgender insanity, and other inappropriate racial, sexual, or political content on our children." Following through on these commitments, on January 27, 2025, Matthew Vaeth, the acting director of the Office of Management and Budget ("OMB"), issued a memorandum directing all federal agencies to "temporarily pause all activities related to obligation or disbursement of all Federal financial assistance, and other relevant agency actions that may be implicated by the executive orders, including, but not limited to, financial assistance for foreign aid, nongovernmental organizations, DEI, woke gender ideology, and the green new deal." Two lawsuits were immediately filed to enjoin the implementation of this [memorandum](#). In one case, the court entered an administrative stay preventing OMB from enforcing the memorandum, but the stay is only in effect until 5:00 p.m. on February 3, 2025 and it only affects the "pause [on] disbursement of Federal funds under all open awards." After this order, OMB rescinded the directive (although while seemingly moving forward with the underlying policy). The court in the other case thereafter also issued a temporary restraining order enjoining the funding suspension. Although—as we explained in a recent [client alert](#)—the funding suspension is likely unlawful, recipients of federal funding remain in a state of uncertainty as these cases proceed and the administration's policies continually shift.

Regardless of how this funding suspension plays out, the Trump administration will likely continue to target higher education institutions' funding, specifically as it relates to NIH and other federal research grants.

Department of Health & Human Services (HHS). In 2024, the House Committee on Energy and Commerce and the House Committee on Education and the Workforce sent a [joint letter](#) to HHS Secretary inquiring, in light of the student protests related to the Israel-Palestine conflict, how HHS and NIH were "ensuring that [NIH-funded] institutions [were] fostering and maintaining an environment free from harassment and discrimination." The letter also states that "HHS's OCR is responsible for ensuring that institutions that receive Federal financial assistance comply with Title VI as well as other civil rights laws" and argues that "[c]olleges

or universities that violate Title VI can ultimately lose Federal funding.” HHS OCR did not engage with the House Committees on the issue. In September, however, HHS OCR did initiate a Title VI investigation into Cleveland Clinic because of an allegation that “Cleveland Clinic treats white individuals differently from certain racial and ethnic minorities in the tailoring and provision of services provided through its Minority Stroke Program and Minority Men’s Health Center.”

We expect HHS OCR to only become more active in this space under the Trump administration. Indeed, in its Staff Report mentioned above, the House foreshadowed what steps HHS and NIH may take this year. For example, the Staff Report notes that “[i]f NIH is not satisfied with the actions taken by the grantee institution because of [an HHS OCR and HHS OGC] investigation, it may recommend further actions” and “[f]ailure to implement said actions may result in suspension or reconsideration of the grant.” The Report also suggests “[a]ll NIH-funded institutions should create a task force or commission of external experts in civil rights—including an expert in antisemitism—to review their curriculums for bias, discrimination, indoctrination, etc., to ensure that students are not being subjected to politicized or biased educations.” These suggestions are even more important to consider because of the newly mandated certification required in all grant and contract applications certifying that the institution is in compliance with DEI rules. Significantly, institutions that do undertake a task force or commission process should be mindful of the recommendations and findings of those groups and ensure they are either implemented or considered and rejected based on sound (and well documented) reasoning. Alternatively, ignoring those findings could heighten the potential argument that a certification on a contract or grant form is false because the institution writ-large utilized a commission but ignored its advice.

Department of Education. The Department of Education’s Office of the Inspector General (“DOE OIG”) may also play a role in enforcing the Trump administration’s agenda. President Trump recently fired the Inspector General for the Department of Education and is likely to appoint a new one favorable to his positions. The DOE OIG investigates whether federal funds provided to higher education institutions are being used in permissible ways. That may extend to funds being used in connection with race-conscious or sex-conscious programs, DEI programs, certain curricula, and other operations that may not comply with the Administration’s new policies.

Lastly, as is no surprise, we expect the Department of Education’s OCR will be an active participant in these regulatory actions. In 2024, OCR was particularly active with respect to universities’ handling of student protests and allegations of antisemitism and discrimination targeting students of Palestinian, Arab, South Asian, or Muslim descent. OCR entered into dozens of resolution agreements with institutions resolving Title VI investigations into such conduct, and it also published a fact sheet and a number of letters clarifying schools’ obligations under Title VI. One such [letter](#) provided several examples illustrating how OCR could apply Title VI standards to allegations of discrimination arising from student protests or comments directed towards Jewish, Arab, Muslim, or Israeli students. This activity has continued into 2025, with seven universities entering into Title VI resolution agreements with OCR in January alone.

We also flag that one organization, the Equal Protection Project, has filed dozens of complaints with OCR, alleging universities’ “diversity” scholarship, fellowship, and other programs impermissibly restrict eligibility to students based on race, color and national origin. We anticipate OCR will become much more active in investigating these and other similar complaints



YEAR IN PREVIEW: REVIEW OF AND INSIGHTS INTO INVESTIGATIONS BY THE 119TH CONGRESS

By Daniel Levin, Adam Safwat, Anthony D. Mirenda, Nicholas Alejandro Bergara, Matthew E. Miller, Jasmine N. Brown and Eli Greenspan

The 119th United States Congress began on January 3, 2025. With a narrow majority in both the House of Representatives and the Senate, the Republicans control every committee, ensuring that congressional investigations will support the Republican policy agendas. In this Congress, we expect that congressional committees will seek information and testimony from private sector entities, particularly U.S. companies leveraging technology, social media, and artificial intelligence, companies and firms that have publicly announced diversity, equity, and inclusion (“DEI”) or environmental, social, and governance (“ESG”) policies or practices, green or alternative-energy companies, as well as continuing to investigate fraud related to and the source of the COVID-19 pandemic. We detail the features and tools of a congressional investigation and outline these several investigative priorities below.

CONGRESSIONAL INVESTIGATIONS V. AGENCY INVESTIGATIONS

There are several features that separate congressional investigations from agency or Department of Justice investigations. Although Congress’s power to investigate is not explicitly stated in the Constitution, it is inherently found under their power to legislate. This makes the scope of Congress’s investigatory powers quite broad and limited only to the extent that the investigation is not furthering a valid legislative purpose.

Congress’s power to investigate is generally pursued through its various committees and subcommittees. This makes committees, such as the House Committee on Oversight and Government Reform and the Permanent Subcommittee on Investigations (part of the Senate Committee on Homeland Security and Government Affairs), each of which has some of the broadest investigative authority in Congress, important to focus on. Committee majorities can direct investigations based on several largely unchecked factors, including their own political agenda, public opinion, alleged or perceived wrongdoings or unethical practices, public attention on company actions, and proposed legislation.

The tools that Congress can use to pursue their investigations are equally broad and do not necessarily follow the same rules and structure as an agency or Department of Justice investigation. These tools include:

- Public Letters
- Requests for Information
- Interviews and Depositions
- Hearings (Public and “Closed-Door”)
- Subpoenas

While Congress primarily relies on their investigative subjects to voluntarily comply with its requests for information or its interview requests, Congress can also compel disclosure of information or testimony by issuing a subpoena.

Below are the main initiatives we anticipate from the 119th Congress:

Diversity, Equity, and Inclusion (“DEI”) Practices

Congressional investigations into corporate and higher education practices related to Diversity, Equity, and Inclusion (DEI) are expected to continue this year, especially in light of President Trump’s recent executive actions limiting access to federal funds to advance DEI and attempting to restrict the advancement of DEI in higher education and the private sector.

We expect increased scrutiny into private sector industries regarding their use of DEI. In December, Representative James Comer (R-Ky.), who will remain the chair of the House Committee on Oversight and Government Reform, published an [op-ed in the Washington Times](#) confirming that the Committee’s work will align with the Trump administration’s priorities. In the article, Rep. Comer states that “[m]any of President[] Donald Trump’s key priorities align with the Oversight Committee’s jurisdiction,” and “[w]e will actively work with [President] Trump and his administration to hold the federal bureaucracy accountable and ensure taxpayer dollars are spent wisely.” According to a [press release](#) from Representative Comer (R-Ky.) on behalf of the Committee, this also includes DEI. The press release applauded President Trump’s executive orders related to DEI¹ and affirmed the position that the “federal government must stop wasting money on woke DEI programs.”

We also anticipate continued scrutiny from congressional committees regarding the use of federal funding through government contracts and grants to advance DEI programs and practices, including in higher education. The 118th Congress² was highly focused on DEI spending and practices in government, launching inquiries and investigations into the Department of Defense, the military, and the Pentagon. The Committee on Oversight and Government Reform under the 118th Congress, held a hearing on the Equal Employment Opportunity Commission’s (EEOC) requirement to enforce Title VII of the Civil Rights Act of 1964, and its alleged failure to do so by pushing and failing to investigate allegedly “unlawful [DEI] programs.” The Senate was also involved in similar investigations. In October, Senator Ted Cruz (R-Tx) released a [report](#) detailing and criticizing federal spending by the National Science Foundation for academic research into categories such as “status,” social justice, gender, race, and environmental justice.

In 2024, Congressional efforts to investigate various DEI-related issues also extended to institutions of higher education receiving federal funding, partially in response to the October 2023 attacks in Israel and the rise in reports of antisemitic incidents on some campuses. We expect Congress to carry these efforts forward into 2025, and to expand investigative efforts into other DEI-related issues on campus, including gender and sports. We covered investigations into DEI on university campuses earlier in our Year in Preview series; for more information about what we can expect from Congress related to higher education, read [here](#).

Environmental, Social, and Governance (“ESG”) Practices

Throughout 2024, Congress indicated that addressing environmental, social, and corporate governance (“ESG”) considerations, in connection with investment decisions, is a priority. On one hand, in 2024, the U.S. House of Representatives Committee on the Judiciary (“Committee”) focused on ESG practices connected to climate, involving a so-called “climate cartel.” After [starting](#) an antitrust investigation in December 2022,

where it sent numerous letters and issued multiple subpoenas, the Committee released interim staff reports in [June](#) and [December](#) 2024, respectively.

The Committee has shown no signs of letting up. It sent letters, in [July 2024](#), to over 130 U.S. entities due to their involvement in Climate Action 100+. Then, as recently as [December 2024](#), the Committee sent letters to more than 60 entities based on their participation in the Net Zero Asset Managers initiative, suggesting it plans to continue its investigation throughout 2025.

Congress also sought to overturn the U.S. Department of Labor’s “Final Rule on Prudence and Loyalty in Selecting Plan Investments and Exercising Shareholder Rights” (“[Rule](#)”), which took effect on January 30, 2023. This Rule allows fiduciaries, under the Employee Retirement Income Security Act of 1974, to consider ESG factors when determining retirement investments and exercising stockholder rights, including proxy voting.

Former President Biden’s veto, in March 2023, stopped Congress’ efforts to overturn the Rule. But with President Trump previously [indicating](#)—when campaigning—he would “immediately ban ESG investments through executive order and work with Congress to enact a permanent ban,” we expect the Rule to be overturned in 2025, further increasing the threat of congressional investigations in the ESG space as the year progresses. .

Green/Alternative Energy Infrastructure Projects

The 118th Congress made green and alternative energy a blockbuster topic for investigation in 2024. We can expect continued focus on this area during the 119th Congress as well. The Inflation Reduction Act, signed into law by President Biden in 2022, invested over \$360 billion for clean energy, reducing greenhouse gas emissions, and environmental justice projects. Since then, the House Committee on Energy and Commerce, the House Committee on Natural Resources, the Senate Commission on Energy and Natural Resources, and the Senate Committee on Environment and Public Works have been paying close attention to the issues.

On February 11, 2025, the Chair for the Subcommittee on Energy and Mineral Resources (part of the House Committee on Natural Resources) went on record saying that “[f]or 4 years, President Biden ignored the livelihoods and energy needs of hardworking Americans by waging war on domestic energy” and committed to work with President Trump to start “unleashing offshore oil and gas production.” This position on green and alternative energy is consistent with fellow Representatives Congresswoman Carol Miller (R-WV) and Congressman Lance Gooden’s (R-TX) February 7, 2025 letter to Attorney General Pamela Bondi calling for her to investigate why the DOJ under the Biden administration dismissed a qui tam False Claims Act lawsuit against Tonopah Solar Energy, LLC, which they call an example of “other failed ‘green energy’ initiatives” in the letter and a “glaring example of reckless green energy crusades” in a corresponding press release.

But this is not just a “Republican issue,” and more committees have shown interest in this issue in years past. For example, last year, we saw the conclusion of an almost three-year long investigation and a report by the Democrats on the House Committee on Oversight and Accountability and the Senate Budget Committee into “Big Oil’s decades-long deception campaign.” The investigation focused on ExxonMobil Corporation, Chevron Corporation, Shell USA Inc., BP America Inc., the American Petroleum Institute, and the Chamber of Commerce’s alleged crusade to deceive the public and their investors about the effects that oil and other fossil fuel products had climate change and to undermine efforts by green and alternative energy companies to reduce carbon emissions. Under the present Congress, we can expect inquiries into the action

of the oil majors to respond to previous shareholder campaigns regarding investments in alternative energies.

Technology

Technology was a significant area of focus for the 118th Congress, and the 119th Congress is likely to take a similar approach. Indeed, Congressional Republicans will probably keep targeting internet and social media companies for supposedly discriminating against conservative media outlets, as well as with respect to data privacy and related national security concerns pertaining to China. As outlined below, other areas to watch include artificial intelligence (“AI”), online exploitation of children, and digital assets.

Targeting Chinese Tech Companies Raising National Security Concerns

The Select Committee (“Select Committee”) on the Strategic Competition Between the United States and the Chinese Communist Party (“CCP”) has been [renewed](#) for the 119th Congress, after being put on hold during the 118th Congress. The Select Committee’s primary focus in 2024 was banning TikTok, a popular social media app headquartered in Singapore and the United States, but often believed to be subject to the influence of the Chinese Communist Party through its Chinese-based parent company, ByteDance. It also issued reports critiquing the manner in which U.S. entities might have mistakenly supported Chinese Communist Party military and technological goals—such as [financial institutions’](#) financing surveillance technology in support of the CCP and [universities’ and research institutions’](#) providing technological and military research assistance to the CCP.

In 2025, the Select Committee is likely to follow a similar approach and will continue targeting other entities or industries that pose national security risks due to their connections with the Chinese government or economic sectors.

A Possible New Approach to AI

Congress will likely keep investing substantial resources in researching the risks and benefits of different forms of AI and how this emerging technology could impact other priority investigation areas. While Congress’ approach to AI policy is still left to be determined, a December 2024 [press release](#) and [report](#) by the Bipartisan Task Force on Artificial Intelligence is instructive. This report identifies a few critical areas where Congress plans to concentrate its efforts, including intellectual property, consumer protection, and healthcare.

Senator Ted Cruz, who has publicly [voiced](#) his critiques of the Biden administration’s alleged protectionist approach to AI, now heads the Senate Committee on Commerce, Science, and Transportation. This committee is expected to dedicate significant bandwidth to issues connected to AI, so Senator Cruz could have substantial influence when it comes to congressional investigations in this area.

Preventing the Online Exploitation of Children by Big Tech

Both houses of Congress, and their respective committees, will probably maintain their efforts to investigate online dangers to children. The Senate Committee on the Judiciary—during the previous Congress—held a broadly publicized [hearing](#) regarding preventing the online exploitation of children by Big Tech. It is probable that, in addition to continuing to investigate, Congress will pass legislation directed at these issues, especially considering efforts to introduce such legislation have already started. For example, Senator Cruz has recently proposed a [resolution](#) that would terminate a Biden-era order that increased the availability of subsidized wi-fi for schoolchildren.

Limiting Scrutiny on Digital Assets³

Compared to previous years, the blockchain and cryptocurrency space is poised to receive less scrutiny from Congress, whose recent actions tend to demonstrate a more welcoming stance. Indeed, on February 11, 2025, the House Committee on Financial Services held a [hearing](#) entitled “A Golden Age of Digital Assets: Charting a Path Forward.” The hearing addressed proposed legislation, which tends to support Congress’ promotion of, and investment into, research and development of blockchain and cryptocurrency.

Nevertheless, appointments of new leaders to critical congressional committees demonstrate that both houses of Congress expect to keep tabs on stablecoin and cryptocurrency. Rep. French Hill, the new chair of the U.S. House of Representatives Financial Services Committee, was the former chair of the subcommittee that handled these digital assets. He is, thus, expected to bring these issues to the forefront before the full committee.

Similarly, Senator Tim Scott, who recently became chair of the Senate Banking Committee, was the founder of the first-of-its-kind subcommittee on digital assets. This subcommittee is set to be chaired by Senator Cynthia Lummis and will be focused on addressing cryptocurrency issues. Notably, as soon as she took her post, Senator Lummis encouraged her peers “to urgently pass bipartisan legislation establishing a comprehensive legal framework for digital assets that strengthens the U.S. dollar with a strategic bitcoin reserve.”

It remains to be seen how these committees will approach congressional investigations related to digital assets going forward.

COVID-19

Over the last five years, Congress has provided \$4.45 trillion in emergency funds to mitigate the impacts of the COVID-19 pandemic. At the beginning, several agencies responsible for disbursing payments and other forms of relief lacked robust fraud risk controls to safeguard against improper payments. This, coupled with pressure to spend federal funds quickly, increased the risk of fraud and overpayments.

In September 2024, the House Committee on Oversight and Accountability released a [staff report](#) noting that the U.S. Government Accountability Office estimates 11 to 15 percent of total benefits paid during the pandemic were fraudulent. While the staff report could signal the end of an investigation, it is possible that that Congressional Republicans will continue to probe unemployment insurance programs. One of the key recommendations in the report was to extend the statute of limitations for fraud associated with the pandemic unemployment insurance programs.

Separate from fraudulent payment investigations, both chambers have scrutinized the origins of the COVID-19 pandemic and research conducted at the Wuhan Institute of Virology, which previously received funding from the National Institutes of Health (NIH). Sen. Rand Paul (R-KY), Chair of the Senate Homeland Security and Governmental Affairs Committee, subpoenaed 14 agencies in January 2025 for more information on the research conducted at the Wuhan Institute of Virology.

As 2025 unfolds, Congressional Republicans are expected to further probe the origins of the pandemic and continue investigating fraud pertaining to COVID-19 relief programs.

Closing Thoughts

Companies, investors, scientific and educational institutions and non-profit organizations should expect the current 119th Congress to aggressively use its investigatory powers to help forward the Republican agenda and the priorities of the Trump Administration in the areas we discuss above. We will continue to follow the activities of various congressional activities as the year progresses.

¹"Ending Radical and Wasteful Government DEI Programs and Preferencing," Exec. Order No. 14151 (Jan. 20, 2025);
"Ending Illegal Discrimination and Restoring Merit-Based Opportunity," Exec. Order No. 14173 (Jan. 21, 2025)

²Called the Committee on Oversight and Accountability.

³The U.S. Securities and Exchange Commission has also signaled a more accommodating approach to the crypto asset industry. For more information, click [here](#).

SEC EXPECTED TO SHIFT PRIORITIES AND ADOPT A MORE BUSINESS-FRIENDLY APPROACH IN 2025



By Anthony D. Mirenda, Matthew E. Miller, Adam Safwat, Rachel Kerner, Christian Garcia, Marilyn Icsman, Kian Azimpoor

The U.S. Securities and Exchange Commission (the “SEC” or the “Commission”) is undergoing substantial changes following the reelection of Donald J. Trump in November 2024. From an overhaul in the Commission’s leadership to the flurry of executive orders signed by President Trump implicating the Commission’s regulatory and enforcement priorities, we expect the SEC to pursue different priorities in 2025 than it did under the direction of former Chairman Gary Gensler, which we discuss in this White Collar Year in Preview. We also highlight key Supreme Court cases that will have a substantial impact on the SEC’s enforcement efforts moving forward. And we conclude by looking back at the SEC Enforcement Division’s (“Enforcement” or the “Division”) performance in fiscal year 2024.

I. CHANGES AT THE TOP

Following the reelection of President Trump, two SEC Commissioners, including its Chair, [announced](#) their departures. Meanwhile, then-President Elect Trump nominated [Paul Atkins](#) to replace former Chair Gensler as SEC Chair. Atkins, a financial services adviser and former SEC Commissioner during the George W. Bush Administration, has been a vocal critic of the Commission’s enforcement activities, including by [arguing](#) that corporate fines unfairly penalize shareholders and that enforcement efforts should focus on individual violators. He has criticized what he characterized as the practice of pursuing minor securities law infractions to boost enforcement statistics. While Atkins’s Senate confirmation is pending, President Trump has [appointed](#) Commissioner Mark Uyeda as Acting Chair.

The Commission is typically overseen by five commissioners. Currently, the Commission is composed of two Republicans, Acting Chair Uyeda and Commissioner Hester Peirce, and one Democrat, Commissioner Caroline Crenshaw. The current composition of the SEC signals a shift away from the heavy regulatory hand during the Gensler era. Acting Chair Uyeda [emphasized](#) recently that this transition will permit the SEC to “focus [its] efforts ... on capital formation and ensuring companies aren’t impeded by ineffective regulation.” Commissioner Peirce likewise commented that the SEC would be promoting “a regulatory environment that protects investors, facilitates capital formation, fosters market integrity, and supports innovation.” These comments indicate a move away from the climate and social regulatory agenda advanced by former Chair Gensler to refocus more on traditional enforcement concerns such as material misstatements, deficient internal controls, and gatekeeper failures. In another signal of shifting priorities, on February 10, 2025, the Trump Administration issued an [executive order](#) that directs Attorney General Pam Bondi to effectively pause the Justice Department’s enforcement of the Foreign Corrupt Practices Act (“FCPA”). While the Executive Order was silent as to the SEC—and the SEC retains its own authority to conduct investigations and

enforce the [FCPA](#), particularly for violations of the books-and-records and internal-controls provisions—the new leadership of the agency will very likely re-align its FCPA enforcement efforts to reflect the administration’s expressed priorities although there has been no clear directive to that effect yet.

III. NEW PRIORITIES SHIFTING AWAY FROM SOME HIGH-PROFILE 2024 ACTIVITIES

a. Crypto Assets at the Forefront

On January 21, 2025, Acting Chair Uyeda [announced](#) that the SEC was launching a task force spearheaded by Commissioner Peirce in an effort to develop a comprehensive and clear regulatory framework governing crypto assets. Commissioner Peirce has been a [longstanding critic](#) of the agency’s approach to crypto assets, which has primarily relied on enforcement actions. In a recent speech, she [noted](#) that the task force would be focused on determining whether various crypto assets constitute “securities” under the securities laws; potentially recommending the Commission to provide temporary or retroactive relief from registration requirements for coin or token offerings following the issuing entity’s provision of information regarding the asset; and working with investment advisers to establish a framework within which advisers can legally and practically custody crypto assets on behalf of their clients.

The SEC’s newly-minted crypto task force dovetails with President Trump’s [January 23, 2025 executive order](#) promoting the advancement of cryptocurrencies in the United States. The executive order touts the importance of the digital asset industry to the innovation and economic development of the United States and establishes a working group to consider a national digital asset stockpile. The executive order also outlines other priorities, including protecting individuals and companies that use blockchain networks and developers and miners who develop crypto assets.

b. Insider Trading

The SEC has long been focused on combatting insider trading. The Commission brought 35 insider trading actions in 2024, representing 6% of all actions brought and a slight increase from the prior year. While many of the insider trading cases brought were the “bread and butter variety,” in the previous administration’s final year, the SEC continued to stretch just how far insider trading law can be pushed.

For example, the SEC secured a victory in its first “shadow trading” enforcement action in *SEC v. Panuwat*. Shadow trading is a novel theory of insider trading that involves an investor possessing material non-public information about Company A, who trades in the securities of Company B, another company with which Company A shares some connection in the market (such as competitor or comparable company). In *Panuwat*, the SEC alleged that Panuwat, the then-head of business development at Medivation (a mid-sized, oncology focused biopharma company), purchased short-term, out-of-the-money stock options in Incyte Corporation (another mid-sized, oncology focused biopharma company), just days before the August 22, 2016 announcement that Pfizer would acquire Medivation at a significant premium. According to the complaint, when he did so, Panuwat knew that investment bankers had cited Incyte as a comparable company in discussions with Medivation and he anticipated that the acquisition of Medivation would likely lead to an increase in Incyte’s stock price. In April 2024, Panuwat was found liable for insider trading based on the novel shadow trading theory. The case was appealed in November 2024, so the shadow trading theory is headed for review in the appellate courts. Moreover, on the heels of this decision, final judgment by consent was entered in another shadow trading case pending in the Northern District of California.

It is of course difficult to predict where incoming Chair Atkins will choose to focus his efforts in leading the agency, but it seems most likely that he will pick up where President Trump's last administration left off: staple SEC cases rather than cases based on new theories of liability, and fewer insider trading cases overall. This does not mean that SEC enforcement of insider trading is going away. Indeed, data from SEC enforcement during the previous Trump Administration reveals insider trading cases were pursued, but not to the same degree as in other administrations. For example, in 2019, the SEC pursued the lowest number of insider trading enforcement actions since 1996 and charged the lowest number of defendants since the Reagan Administration. More still, it seems doubtful the new administration will continue to push the envelope on what insider trading law covers. And the record-breaking penalties seen in 2024 are unlikely to persist in 2025. The SEC is instead expected to take a more conservative approach, seeking smaller penalties from corporations so as not to inadvertently punish shareholders.

c. Recordkeeping/Off-Channel Requirements

In the past year, the SEC continued to bring enforcement actions against regulated entities—such as broker-dealers and investment advisers—that failed to comply with recordkeeping requirements. Under the Investment Advisers Act of 1940 and other relevant statutes and regulations, registered investment advisors must maintain certain books and records. In particular, the SEC pursued actions where entities failed to ensure that “off-channel communications,” such as those taking place via employees’ text messages and messaging apps, were maintained as required by the Investment Advisers Act.

According to the SEC, compliance with these requirements is necessary for protecting investors and ensuring well-functioning markets. In fiscal 2024, the SEC brought recordkeeping cases that resulted in over \$600 million in civil penalties assessed against over 70 firms. Most of the firms admitted to the facts presented in their respective SEC orders and agreed to undertake remedial measures such as retaining an independent compliance consultant. These recordkeeping cases included the SEC bringing standalone actions against investment advisors for the first time. Since December 2021, the SEC has charged over 100 firms and levied over \$2 billion in penalties for record keeping failures.

The Trump Administration will change course with the agency's initiatives given that President Trump has tapped Acting Chair Uyeda, and Atkins as incoming Chair. On September 24, 2024, Acting Chair Uyeda issued a joint [statement](#) with Commissioner Peirce urging reconsideration of the enforcement approach to off-channel communications given that “...even well-intentioned firms could find themselves in the Commission's enforcement queue time and again.” Their statement calls for the development of “...a pragmatic and privacy-respecting approach that enables firms and the Commission to have the records they need for compliance, examination, and enforcement at a reasonable cost in both financial and privacy terms.” Notably, Incoming Chair Atkins has expressed support for overhauling the SEC's enforcement methods and [noted](#) off-channel communications investigations is an area where the agency has overstepped its bounds.

Looking ahead, we expect the SEC's enforcement activity regarding off-channel communications will diminish relative to other enforcement priorities and the agency will no longer continue to conduct industry sweeps for record keeping violations. The SEC may also provide more clarity on the types of record-keeping cases it considers as meriting enforcement action.

d. Individual Accountability

Individual accountability remained a pillar of the SEC's enforcement program in 2024, and is expected to remain a focus into 2025. The SEC obtained 124 orders barring individuals from serving as officers and directors of public companies, the second highest number in a decade. In one specific case, it obtained a verdict against an individual for over \$200 million in disgorgement and civil penalties. And there are signs that holding individuals accountable will become even more of a focus in 2025. Incoming Chair Atkins has consistently suggested it is more appropriate to pursue individuals responsible for the securities violations rather than firms for oversight issues that may have led to such harm, based on his belief that pursuing the firms doubly harms investors. Industry analysts have commented that unlike Gensler, who was willing to go after firms for negligence, incoming Chair Atkins thinks there should be willful intent for the SEC to get involved. This suggests that the SEC's focus will be on serious cases in which there is both injury to investors and evidence of conduct involving at least recklessness by individual executives rather than the failure of a company to follow policies or procedures.

Further, as noted above, incoming Chair Atkins and the Trump Administration have expressed concern about large penalties imposed on companies because such penalties are ultimately passed on to shareholders who were not responsible for the company misconduct. We expect the SEC in 2025 to continue vigorously pursuing individuals who have committed violations of securities laws.

e. Artificial Intelligence

As artificial intelligence continues to rapidly increase in wide-spread usage and capability, the SEC continues to focus on AI-related misrepresentations by regulated entities. This emerging area of enforcement targets so-called "AI washing," or overstatements or other misrepresentations regarding the use or capabilities of artificial intelligence to promote a product or service.

In 2024, the SEC [charged](#) China-based investment adviser QZ Asset Management for allegedly falsely claiming that the company would use proprietary AI-based technology to generate "extraordinary" weekly returns, while also promising "100% protection" for client funds. The case is currently pending in the U.S. District Court for the District of South Dakota.

The SEC also [settled](#) charges against two investment advisers: one firm, Delphia, claimed to have an AI tool that could predict which companies and trends were "about to make it big and invest in them before everyone else," but did not actually have such AI capabilities. The other adviser, Global Predictions, falsely claimed to be the "first regulated AI financial adviser" and misrepresented that its platform provided "AI-driven" forecasts. Another [settlement](#) involved charges against the company Rimar Capital, its owner and CEO, and a board member. The SEC alleged that Rimar and the individuals "lured" investors and clients using fabrications and "buzzwords" regarding the use of AI.

In 2025, the SEC has already [settled](#) charges against yet another company, Presto Automation. The company allegedly made false and misleading statements about its flagship AI product Presto Voice, which uses AI-assisted speech recognition to automate certain aspects of drive-through ordering, in SEC filings and public statements. Specifically, the company failed to disclose that the AI technology used in Presto Voice for a period of time was actually owned and operated by a third party. It also falsely claimed that its product eliminated the need for human intervention in order-taking.

We expect “AI washing” to continue to be at the forefront of the Commission’s enforcement efforts, given the pervasiveness of artificial intelligence across all industries.

f. Climate Disclosures

On March 6, 2024, the SEC adopted the Enhancement and Standardization of Climate-Related Disclosures for Investors rule. This rule requires information about a registrant’s climate-related risks that have materially impacted, or were likely to materially impact, its business strategy, results of operations, or financial condition. Now, nearly a year later, the rule is likely no more. On February 11, 2025, acting SEC Chairman Uyeda released a [statement](#) criticizing the rule as deeply flawed and capable of inflicting significant harm on capital markets and the economy, and directed the agency to request a pause in litigation concerning the rule currently pending in the Eighth Circuit. As a result, we expect that aggressive regulation and enforcement activity related to climate disclosures will no longer go forward.

Nevertheless, readers should not rule out the possibility of continued “greenwashing” cases. In late 2024, the SEC continued to charge companies and individuals for making misstatements related to environmental and sustainability factors. While incoming Chair Atkins may not be as focused on enforcement of Environmental, Social, and Governance rules directly, his SEC may still bring enforcement actions in the right circumstances where companies fraudulently tout their environmental credentials.

g. Proactive Compliance Mitigates Penalties

In fiscal 2024, the SEC demonstrated that it would reward market participants for self-reporting, promptly undertaking remedial measures, and meaningfully cooperating with the agency. Public companies, investment advisors, and broker dealers that promoted a culture of proactive compliance were credited by the Division. In fact, the SEC approved multiple resolutions imposing reduced or even no civil penalties for entities that took these steps in matters involving a broad array of alleged violations such as fraud, recordkeeping violations, and material misstatements. In one case involving Cloopen Group Holding Limited, a Chinese cloud-based communications provider, the SEC chose not to impose civil penalties after the company proactively self-reported accounting matters, meaningfully cooperated with the agency during the investigation, and undertook remedial measures. In response to Cloopen Group Holding Limited’s measures, Gurbir Grewal—the former Director of the Division—highlighted how this demonstrated the “real benefits to companies that self-report their potential securities law violations, assist during [an] investigation, and undertake remedial measures.” Further, the SEC announced that several defendant firms that self-reported their violations received significantly lower civil penalties. In fact, in December 2024, the SEC refrained from imposing civil penalties against a publicly traded biotechnology company that self-reported, proactively remediated, and meaningfully cooperated with the Division.

It remains to be seen whether the SEC will continue to provide substantial incentives to companies who self-report securities violations in 2025. Former Chair Gensler fostered a culture of self-reporting and cooperation throughout his tenure with the SEC. The new Administration promises to be more business friendly, suggesting that the change in Commissioners is unlikely to cause the Commission to pull back on efforts to provide incentives to companies that self-report violations.

IV. SCOTUS CURBS THE SEC'S ENFORCEMENT POWER THROUGH TWO MONUMENTAL DECISIONS

Two Supreme Court decisions from the last term loom large over the SEC's enforcement powers entering 2025. In *SEC v. Jarkesy*, the Supreme Court held that the Seventh Amendment entitles defendants to a jury trial in cases where the SEC seeks civil penalties. And in *Loper Bright Enterprises v. Raimondo*, the Supreme Court overruled courts' longstanding deference to agencies in their interpretation of federal statutes. Both cases signal a trend of reduced agency authority and present significant challenges to the SEC's expansive view of its regulatory power regarding what it can require companies to disclose in financial statements to how it interprets its authority to prosecute and settle cases.

a. *Jarkesy*

In *Jarkesy*, the Supreme Court agreed that the SEC's in-house adjudication process violated defendants' right to a jury trial where the SEC pursued civil penalties designed to punish or deter the wrongdoer. This decision calls into serious question the SEC's ability to pursue financial remedies and disbarments in its in-house administrative proceedings customarily used by the SEC to adjudicate enforcement actions. Requiring that more enforcement actions be filed in federal court will require additional resources, potentially limiting the total volume of enforcement actions the SEC will bring in 2025.

Jarkesy's ramifications may be even more daunting for the Public Company Accounting Oversight Board ("PCAOB"). The PCAOB, a creature of the 2002 Sarbanes-Oxley Act, conducts investigations and brings disciplinary proceedings against registered public accounting firms and associated persons. Unlike the SEC, however, the PCAOB has no statutory authority to commence enforcement proceedings in federal court, resulting in the PCAOB conducting its disciplinary proceedings in-house. Despite *Jarkesy* concerning just the SEC, its holding seems equally applicable to the PCAOB's in-house disciplinary proceedings. In fact, targets of PCAOB in-house disciplinary proceedings have already commenced constitutional challenges against the Board, seeking to enjoin those proceedings from moving forward.

b. *Loper Bright*

In the *Loper Bright* case, the Supreme Court overruled the long-standing Chevron doctrine, which required judicial deference to agency interpretations of ambiguous statutes, ruling instead that courts must engage in their own independent statutory construction of ambiguous statutes. This decision represented a major blow to agencies' authority, including the SEC. Indeed, while *Loper Bright* involved a different federal agency's actions, its holding is broad enough to implicate the SEC's enforcement powers. Under the *Loper Bright* holding, which requires courts to undertake an independent assessment of an agency's interpretation of a statute, all agency action is far more vulnerable to review, and, ultimately, reversal. As a result, agencies like the SEC might engage in a slower rule promulgation process to develop a fuller record on which the agency can defend its actions in the face of challenge.

V. A LOOK BACK AT FISCAL YEAR 2024

Despite the sea change expected at the Commission in 2025, it is nevertheless worthwhile to take stock in how Enforcement performed in fiscal year 2024. The Division announced that it initiated 583 total enforcement actions in fiscal year 2024 (a 26% decline from fiscal year 2023), while obtaining orders for \$8.2 billion in financial remedies. Of the total enforcement actions filed, the Commission filed 431 "stand alone" actions (i.e., enforcement actions excluding those brought against issuers for delinquent filings and "follow-on" administrative proceedings seeking bars against individuals, a 14% decrease from fiscal 2023); 59 actions

against issuers for delinquent filings (a 51% decrease from fiscal year 2023); and 93 “follow-on” administrative proceedings (a 43% decrease from fiscal year 2023). The \$8.2 billion collected represents the highest amount recorded in SEC history and consists of \$6.1 billion in disgorgement and prejudgment interest and \$2.1 billion in civil penalties. More than half of that \$8.2 billion came from the monetary judgment the SEC secured following its jury trial win against Terraform Labs and Do Kwon, its principal, who were both charged with one of the largest securities frauds in U.S. history. The SEC returned \$345 million to harmed investors in fiscal year 2024, marking more than \$2.7 billion returned to investors since the start of fiscal year 2021.

The SEC [reported](#) receiving 45,130 tips, complaints, and referrals in fiscal year 2024, the most the SEC has ever received in one year. This figure includes more than 24,000 whistleblower tips. The SEC, in turn, issued whistleblower awards totaling \$255 million. The Commission also authorized a series of settled enforcement actions to address violations of the Dodd-Frank whistleblower protection rule, which prohibits market participants from taking retaliatory actions against whistleblowers for contacting the SEC.

While 2024 was a robust year for enforcement, we expect that 2025 will still be a busy year for the SEC. We anticipate the SEC will shift toward other enforcement priorities and potentially signal new substantive guidance in areas such as crypto enforcement while recalibrating in other areas, such as financial statement disclosure requirements and record keeping requirements. We also expect the SEC to continue to look at individual conduct in financial fraud and insider trading cases. We will continue to provide updates as the year progresses.



REVIEW OF INTERNATIONAL TRADE ENFORCEMENT IN THE U.S., E.U., AND UK IN 2024 AND WHAT TO EXPECT IN 2025

By Luciano Racco, Anthony D. Mirenda, Olivier Dorgans, Paul Charlot, Nicholas Alejandro Bergara, Aleksis Fernandez Caballero, Chawkat Ghazal, Camille Mayet, Zihan Mei, and Pauline Montaldier

Throughout 2024, enforcement of international trade laws continued to gather pace while the primary targets of enforcement were familiar ones: China, Russia, and Iran. Numerous government agencies issued enforcement regulations and guidance. With the new administration in the U.S., however, there appear to be new priorities. On one hand, the Trump administration may use sanctions and export controls as a tool to broker a resolution to Russia's war on Ukraine. If successful, however, we could see a rapid reduction in enforcement with respect to Russia-related actions. In the interim, a previously unified Western position on Russia is fracturing, increasing the prospect that enforcement risks for companies operating in Russia will be greater under EU and UK laws than under U.S. law. On the other hand, the Trump administration has shown signs that it intends to more closely focus on China and Iran—which could result in potential increased enforcement related to those jurisdictions. Initial indications also clearly demonstrate that, under the Trump administration, the enforcement environment for non-U.S. companies may be more challenging than for U.S. companies, especially for companies in jurisdictions that the Trump administration targets for trade-related countermeasures (such as tariffs).

On the EU side, the EU is likely to stay focused on steadily and consistently applying sanctions against Russia, as it did throughout 2024. But the intensity may depend on each Member State's respective approach to Russian sanctions—given some tend to be more aggressive in this regard than others. Nonetheless, the UK is likely to continue working closely with the EU on its efforts to sanction Russia. The UK will also likely try to keep coordinating with U.S. agencies, such as OFAC, to enforce international trade regulations.

In the accompanying paper linked below, we review international trade enforcement in the U.S., EU, and UK in 2024, and our expectations for 2025. We describe key 2024 developments in enforcement guidance and important enforcement activity involving the U.S. agencies responsible for export controls, sanctions, antiboycott, forced labor, and CFIUS enforcement. We also discuss the transition to, and shifting priorities of, the new Administration.

[Click here to view the full white paper.](#)

ANTICORRUPTION AND FCPA ENFORCEMENT: TAKEAWAYS AND LESSONS HEADING INTO 2025



By Anthony D. Mirenda, Adam Safwat, Shrutih Tewarie, Luciano Racco, Jack C. Smith, Nicholas Alejandro Bergara

With active regulators around the globe, 2024 was a busy year for anticorruption enforcement and policy. In the U.S., we saw multiple high-profile new policies and updated guidance from the U.S. Department of Justice (“DOJ”), while regulators worldwide picked up on trends to issue guidance on their key or newly available enforcement tools. We also learned lessons from significant enforcement activity at home and abroad. Below, we unpack the key trends from the past year with a look ahead to impacts in 2025.

For anticorruption trends and developments in France and the European Union, see [today’s companion piece](#) from our colleagues in Paris.

U.S. POLICY DEVELOPMENTS TO INFORM 2025 ACTIVITY

DOJ issued several policy pronouncements, primarily throughout the latter half of 2024, concerning its corporate and FCPA enforcement policies. Below are our key takeaways from these developments.

Corporate Whistleblower Awards Pilot Program

On August 1, 2024, DOJ [announced](#) the start of the Corporate Whistleblower Awards Pilot Program (“Whistleblower Program”). This program gives whistleblowers, who provide DOJ with original and truthful information regarding corporate wrongdoing—which results in a forfeiture, a chance to receive a reward.

The potential reward is contingent on specifications provided in the Whistleblower Program [guidance](#) (e.g., the forfeiture must be over \$1 million), and consists of a percentage of the forfeiture. To be eligible for compensation, the information the whistleblower provides needs to relate to one or more of the areas described below:

- Certain crimes involving financial institutions, from traditional banks to cryptocurrency businesses
- Foreign corruption involving misconduct by companies
- Domestic corruption involving misconduct by companies
- Health care fraud schemes involving private insurance plans.

Notably, entities that self-disclose voluntarily within 120 days of the submission of a whistleblower’s report may receive a presumption of a declination of prosecution, under DOJ’s [Corporate Enforcement and Voluntary Self-Disclosure Policy](#). This only occurs, however, if an entity reports before DOJ comes knocking.

The Whistleblower Program closes a loophole in FCPA enforcement. Under the Dodd-Frank whistleblower program, only referrals leading to enforcement actions against public companies listed on the U.S. stock exchanges would result in a reward. The DOJ program also applies to referrals resulting in enforcement actions against non-public companies under the FCPA (and other laws). The Whistleblower Program has the potential to increase DOJ corporate investigations in 2025 and beyond.

Likewise, as pointed out by DOJ's former Principal Deputy Assistant Attorney General ("PDAAG"), Nicole Argentieri, in her September 17, 2024 [speech](#), the Whistleblower Program will apply to violations of the Foreign Extortion Prevention Act—covered in a [previous alert](#)—which DOJ plans to "vigorously enforce."

Compensation Incentives and Clawbacks Pilot Program

On September 23, 2024 PDAAG Argentieri spoke about initial results of a DOJ initiative, the Compensation Incentives and Clawbacks Pilot Program, that DOJ [announced](#) in March 2023 ("Clawback Program"). The Clawback Program has two parts. Regarding the first, every Division corporate resolution now requires that the subject entity provide "clear metrics" regarding how its compensation and bonus systems promote compliance.

Since the inception of the Clawback Program, as PDAAG Argentieri reports, nine corporate resolutions have included this requirement. Examples comprise entities agreeing to:

- Mandate that their annual review process account for reporting of wrongdoing and compliance standards.
- Add a performance review metric assessing whether the employee acts in accordance with the entity's core values.

The second part of the Clawback Program concerns a penalty reduction for entities that either withhold or recover compensation from employees and their respective supervisors who are found to be responsible for the misconduct at issue. So far, only two entities have obtained fine reductions, solely in FCPA cases. Only one—an enforcement action against SAP SE ("SAP"), a German-based international software company—took place in 2024. SAP received a 40% fine reduction, in part because it withheld compensation from liable employees.

Evaluation of Corporate Compliance Programs (ECCP)

In September 2024, DOJ announced [several updates to the ECCP guidance](#) critical to practitioners in this space. DOJ will now include an assessment of the efficacy of a corporate enforcement program the following factors:

5. Risks of AI and Other Disruptive Technologies – The updates include considering how companies assess and manage risks from these emerging technologies.
6. Encouraging Whistleblowers – Building on DOJ's recent whistleblower program, the ECCP now explicitly assesses whether companies encourage internal whistleblowers.
7. Data Access – The revised ECCP emphasizes the subject compliance program's access to sufficient and appropriate data to be effective.
8. Lessons Learned – The updates indicate that companies' compliance programs and training should build on their own prior incidents and those of other companies.
9. Post-Transaction Integration – Following 2023's announced Safe Harbor for Voluntary Self-Disclosures Related to Mergers & Acquisitions, the ECCP updates reinforce the need for compliance involvement in acquisitions, including the target company's post-merger integration into the acquirer's business environment.

Blue Dot Network

In addition to the above-described policy pronouncements, the U.S. partnered with other countries in a joint effort to battle corruption at the international level. On April 9, 2024, in coordination with partner countries and the Organization for Economic Cooperation and Development, the U.S. Department of State announced the Blue Dot Network (“BDN”).

The BDN provides a globally recognized certification for infrastructure projects’ quality and sustainability across all major sectors (e.g., water, energy, and transport). It is based on 10 elements, including, in relevant part, promoting “protections against corruption, while encouraging transparent procurement and consultation processes.”

TAKEAWAYS FROM 2024 FCPA ENFORCEMENT ACTIONS

Below, we summarize some trends that emerge from the DOJ Fraud Section’s FCPA Unit activity in 2024.

Continued Emphasis on the Commodities Trading Sector in Collaboration with CFTC

Oil and gas commodities cases continue to yield corporate and individual actions from the FCPA Unit. In March, the unit announced two corporate resolutions in this space, with trading firms [Gunvor, S.A.](#) and [Trafigura Beheer B.V.](#) Another firm, [Freepoint Commodities LLC](#), reached a separate resolution with DOJ, announced in December 2023. Notably, while these cases also concerned what may be considered more traditional FCPA allegations—the payment of bribes to a state-owned entity in exchange for oil contracts—the cases against Trafigura and Freepoint featured additional and somewhat different allegations. As with the landmark 2022 resolution with [Glencore](#) and the 2020 resolution announced with [Vitol Inc.](#), the government alleged that bribes or kickback payments were made in exchange for *confidential trading information* from the state-owned entities, in violation of the FCPA. The Commodity Futures Trading Commission (“CFTC”) also pursued parallel investigations in these cases and secured parallel resolutions of allegations that the conduct resulted in violations of the Commodities Exchange Act through either manipulation of commodities benchmark prices or trading on material nonpublic information. These cases follow the CFTC’s 2019 launch of its [Foreign Corrupt Practices Initiative](#), which it expressly conceived as a collaborative effort with DOJ’s FCPA investigations.

In individual prosecutions arising from these corporate resolutions, the FCPA unit in 2024 prevailed at trial twice against individual traders of oil and gas commodities. [Javier Aguilar](#) was a former trader with Vitol, while [Glenn Oztemel](#)’s case stemmed from conduct relating to his work for Freepoint and another U.S.-based commodities trading firm, Arcadia Fuels Ltd.

Cooperation – Some Better than None, but Best to Be Quick

Several actions announced in 2024 provided continuing color on that critical factor in engagement with DOJ: cooperation. Some recent corporate resolutions suggest that even less-than-fulsome cooperation may receive some credit, but the highest credit is available only to corporations that can bring resources to bear on the cooperation effort with alacrity.

In several cases this year, DOJ penalized companies by giving less than full cooperation credit for companies that had failed to preserve and produce evidence in a timely manner during the early phases of DOJ’s investigation. At the low end of credit received, DOJ agreed to reduce the penalty imposed on Trafigura by just 10%. DOJ likewise cited [Raytheon Company](#) and [Telefonica Venezolana C.A.](#) for similar

shortcomings in their cooperation.

Telefonica Venezolana fared only slightly better by agreeing to a 20% reduction off the low end of the guidelines, with the government again noting that the company's initial response to the investigation did not identify and produce certain records the government deemed important. Nonetheless, the government did credit the company's many other cooperation efforts, including making non-U.S. employees available for interviews and producing (translated) documents from abroad.

Raytheon resolved separate criminal and civil investigations being conducted by DOJ by agreeing to pay a \$950 million combined penalty, entering two separate Deferred Prosecution Agreements and a civil False Claims Act settlement, and agreeing to the imposition of a compliance monitor. While the U.S. Attorney's Office in Massachusetts resolved an investigation related to alleged procurement fraud, the FCPA Unit resolved its case relating to violations of the FCPA and the export controls found in the International Traffic in Arms Regulations ("ITAR"). Focusing on the FCPA resolution, for which Raytheon received a 20% discount off of the guidelines, the government specifically noted that Raytheon was, in its view, "slow to respond to the government's requests" in the early phases of the investigation, and, perhaps most significantly, that the company failed to affirmatively provide information relating to the ITAR violations during the government's FCPA investigation. The announcement conveys a clear signal to practitioners: cooperate early and cooperate fully. If the prosecutors learn of another undisclosed category of misconduct partway through the investigation, negotiations will surely become more difficult.

Finally, DOJ saved its most critical commentary for a comparatively smaller case, resolved with [BIT Mining Ltd.](#) in November 2024. There, the government recognized credit for cooperation but characterized that cooperation as "reactive and limited in degree and impact." Ultimately, the criticism did not translate to a particular guidelines discount because the resolution separately recognized an inability-to-pay concession.

Voluntary Self-Disclosure Credit – The Need for Speed

Two corporate resolutions announced this year illustrate that DOJ has significant criteria for awarding credit under its Voluntary Self-Disclosure ("VSD") Policy, an approach that shows no signs of relenting in 2025.

In December, DOJ announced a non-prosecution agreement had been reached with [AAR Corp.](#) The resolution arose from a self-disclosure, and the company ultimately received a reduction of 45% from the applicable guidelines range in consideration of its cooperation. Nonetheless, the Department expressly noted that AAR's disclosure did not qualify for the VSD policy because (1) prior "English-language articles had been published in media outlets in Nepal and South Africa" that described potential irregularities and (2) 12 days before the self-report, another source reported some of the allegations to DOJ. This demonstrates that when the government says the [self-reporting company](#) must come forward "prior to the misconduct being publicly disclosed or otherwise known to the government," it means what it says. The possibility of a significant cooperation credit or even a declination is a substantial carrot, but it requires that a company be first in the door to report on itself: A reporting difference of less than a fortnight, and public articles that might not capture all of the conduct, may otherwise have a dramatic impact on the penalty a company receives at the conclusion of an investigation.

Demonstrating the point, on August 27, 2024, the Department issued a [declination letter](#) stating that it would not prosecute Boston Consulting Group, Inc. ("BCG") for its former employees' alleged violation of the FCPA involving bribes to Angolan officials. PDAAG Argentieri highlighted this action in her September 2024 remarks as an example of what is required to obtain declination under the Corporate Enforcement Policy and VSD

Policy, including, of course, timely and voluntary disclosure of evidence of a potential FCPA violation, as well as termination of personnel, clawing back equity from partners, and denying severance packages and bonuses.

SEC Resolutions – Reinforcing Compliance Needs in Foreign Subsidiaries

In addition to its joint resolutions with DOJ in several of the criminal cases noted above (including AAR Corp., Raytheon, and BIT Mining, LTD.), the SEC also settled several FCPA cases on a purely civil basis without DOJ. These cases, including against **Moog, Inc.** and **Deere & Company**, resolved allegations regarding the books and records provision of the FCPA, as opposed to the substantive bribery provision. Such cases did not appear to involve allegations of any knowing participation by the U.S. parent entities—only the failure of the companies’ internal controls to properly detect and account for bribery conduct occurring entirely in foreign subsidiaries. These actions highlight the need for acquiring and parent companies to implement sufficiently rigorous compliance and accounting controls in their foreign subsidiaries in light of the SEC’s broad jurisdictional reach to investigate books and records violations.

BROADER TRENDS AROUND THE WORLD

Offering Guidance and Seeking Whistleblowers

Heading into 2025, practitioners should be mindful of key developments in the EU and France, as our colleagues in Paris recapped in their [companion piece](#).

Beyond the developments recapped there, regulators across the globe have picked up on growing trends toward offering formal compliance guidance to regulated entities and encouraging whistleblowers to step forward through formal government programs.

United Kingdom

The UK and its Serious Fraud Office (“SFO”), including Director Nick Ephgrave, picked up on both trends in 2024. On the guidance front, in November 2024, the UK’s Home Office published [guidance](#) on the new corporate criminal offense of failure to prevent fraud, which goes into effect on September 1, 2025.

Meanwhile, [on four different occasions](#) in 2024, Nick Ephgrave appeared to call for the implementation of a whistleblower award program in the UK, which would represent a significant new tool in the SFO’s enforcement toolbox. The steady drumbeat of calls for such a program makes this an area to watch in 2025.

In addition to these trends, the UK also saw several notable anticorruption enforcement actions. In May 2024, former Chief of Staff to President Andry Rajoelina of Madagascar, Romy Andrianarisoa, became the first foreign official tried and convicted under the [UK Bribery Act](#). Later, in August 2024, the SFO [charged](#) five Glencore executives—and a sixth [in September 2024](#)—based on their alleged involvement in a conspiracy whereby they made corrupt payments to benefit Glencore’s West African oil operations. According to the SFO’s [release](#), the Glencore unit involved in this conduct was based in London. This case may be worth monitoring as 2025 progresses.

Australia

In line with the above, on August 28, 2024, the Australian government [published guidance](#) detailing, for the first time, the “adequate procedures” that companies can take to establish an effective anti-bribery compliance program.

China

On October 11, 2024, China's State Administration for Market Regulation issued the [Draft Compliance Guidelines for Healthcare Companies to Prevent Commercial Bribery Risks](#). This represents a notable step toward increased clarity from regulators through an approach similar to that of the U.S. DOJ's FCPA Resource Guide in the wake of an ongoing multi-agency anticorruption push in China's healthcare and life sciences sectors launched in July 2023 (as we [discussed](#) last year).

Concurrently with the Draft Compliance Guidelines, the National Medical Products Administration in China also announced its own landmark development in the first healthcare-specific whistleblower program in the country through the Draft Rule on Rewarding Internal Whistleblowers for Reporting on the Quality and Safety Issues of Drugs and Medical Devices.

The draft compliance guidelines and the draft whistleblower rule both suggest that Chinese regulators may be looking to examples from other jurisdictions in pursuing their own fight against corruption.

2024 IN REVIEW: KEY ANTICORRUPTION DEVELOPMENTS IN THE EU AND FRANCE, WITH INSIGHTS FOR 2025

By Olivier Dorgans, Paul Charlot, Camille Mayet and Pauline Montaldier

2024 was a particularly busy year in the European Union (EU) in the fight against corruption, marked by significant publications and enforcement actions from both European and Member State authorities. It's important to note that, pending the potential adoption of the proposal for a Directive on combating corruption from May 3, 2023, the EU still lacks a unified regulatory framework. As a result, some Member States have implemented their own national regulations regarding corruption prevention, which, aside from protections for whistleblowers, remain largely unharmonized. Similarly, when it comes to enforcement, while each EU Member State's national laws address criminal offenses related to bribery in both the public and private sectors, the definitions of these offenses and their penalties are not standardized. In this context, our report provides an overview of key publications and enforcement actions in 2024 and expected developments in 2025, both at the EU level (1) and at the national level in France (2).

For trends and developments related to anticorruption in the U.S., see [today's companion piece](#) from our U.S. colleagues.

ANTICORRUPTION IN THE EU - 2024 KEY DEVELOPMENTS

Key Updates from the European Public Prosecutor's Office ("EPPO")

EPPO's Annual Report Corruption-Related Key Takeaways

Published in March 2024, the [EPPO's annual report](#) comprises some key takeaways regarding the EPPO's enforcement actions. Notably, regarding corruption, the Report indicates that passive and active corruption on public officials (i.e., both the receipt of bribes and the offering and giving of bribes) represents 3% of the EPPO's investigated criminal offenses, with a total of 131 investigations. Italy, Bulgaria, Croatia and Romania are the top four countries where corruption investigations occurred.

The report also highlights some examples of common patterns regarding corruption offenses, such as:

- bribery of public officials in exchange for the awarding of EU funds to specific projects or service proposals;
- bribery of public officials in exchange for the approval of ineligible and inflated additional costs during the project execution phase; and
- bribery of a public official in return for influencing an ongoing EPPO investigation.

EPPO's Tendencies in 2024 Key Corruption Investigations

During 2024, several key investigations by the EPPO point to a trend in favor of public corruption investigations. Indeed, six key cases were related to corruption in the context of public projects, using

European funds (e.g. the Recovery and Resilience Facility and the European Regional Development Fund), and involving the corruption of public officials: customs officers in Malta, mayors in Romania and Italy, and the general manager of a hospital in Czechia. In each of these investigations, both individuals (a minimum of five in each investigation) and entities (two companies specialized in clothing retail, companies active in earthquake-proofing and public infrastructure safety improvements and a company working in the field of sports center construction) were found to be involved.

European Commission's Report on Corruption Risk in the EU

This [in-depth study](#) published by the European Commission on November 4th, 2024, identifies the following sectors as the most exposed regarding the risk of corruption within the EU: healthcare, finance, public procurement, defense and security, construction and infrastructure, and sports.

The report provides for each the character (forms of corruption and actors), the causes and the consequences of corruption in each at-risk sector. For instance, in the healthcare sector, one form of corruption might be the inappropriate approval of products (character). This corruption risk may be emphasized by six main driving factors (citizens' great dependence on health services, complex governance structures with multiple stakeholders, extensive funds and resources, information asymmetry, regulatory weakness and limited transparency) and might have severe consequences: affected access to health services, compromised quality of healthcare, impact on equity (imposing a major burden on poorer and marginalized households), etc.

ANTICORRUPTION IN FRANCE - 2024 KEY DEVELOPMENTS AND WHAT TO KNOW HEADING INTO 2025

Updates from France's AFA (Agence Française Anticorruption)

Reorganization of the AFA

In December 2024, the AFA created two sub-departments responsible for both advisory and control missions dedicated to:

- Public-sector players, in particular, to address the growing risks affecting regalian functions, sometimes in conjunction with organized crime;
- Economic players to support the diversity and maturity of anticorruption measures in the private sector.
- The AFA's restructuring included strengthening support, legal and communication functions, and European and international relations through the creation of a dedicated mission and unit.

As part of the restructuring, the AFA also launched an observatory on corruption, a new integrated body whose mission is to centralize and analyze data on breaches of probity, disseminate information and studies on these offences to public players, researchers and the public, and stimulate research on this subject. Therefore, the new observatory will produce in-depth analyses of corruption phenomena and promote exemplary initiatives to support the collective effort.

The AFA's New Practical Guide to Corporate Sponsorship Operations and Patronage Activities

In the context of an increase in sponsorship and patronage operations, the AFA published a non-binding practical guide that describes the situations and risk factors that companies may face when engaging in such operations. In terms of risk factors, the guide notably highlights beneficiary-related risk factors (e.g., *geographical risk, dealings with public-sector entities, etc.*) and transaction-related risk factors (e.g., *public exposure, competitive environment, urgency, etc.*). The guide also lists various risk-based approaches guided prevention (e.g., *"strengthening governance and the role of senior management"* and *"mapping sponsorship-*

and patronage-related corruption risk") and detection measures (e.g., "opening up the internal whistleblowing system to the beneficiaries of sponsorship and patronage activities" and "anticorruption accounting controls in sponsorship and patronage activities") that companies should take into account for addressing the risks associated with sponsorship and patronage operations.

Key Takeaways From the Most Recent AFA Activity Report (July 2024) and National Diagnosis of Anticorruption Measures in French Companies (October 2024)

The AFA's last activity report underlines the agency's continued commitment to work alongside public and economic players to help them fight corruption, as the following numbers show:

- 37 new controls (i.e., administrative controls stemming from the AFA's administrative control power, enabling it to verify the reality and efficiency of anticorruption compliance mechanisms) were opened in 2023, including 22 on companies and 15 on public bodies;
- Six new judicial public interest agreements, "Conventions judiciaires d'intérêt public" (hereinafter, the "CJIP"), were concluded in 2023, including 5 for corruption and 1 for influence peddling, providing for an AFA compliance program;
- 435 external reports were received by the agency in 2023 (an increase of 40% in one year), a sign of growing public concern about breaches of probity.

Noteworthy 2024 Enforcement Actions from France's PNF (Parquet National Financier)

The CJIP - the "French DPA"

Introduced by the Sapin II Act, CJIPs are alternative measures to prosecution applicable to legal entities accused of corporate criminal offenses, including bribery. These measures allow the PNF to impose, notably, public interest fines, compliance programs monitoring (of maximum 3 years) and/or damages pursuant to Article 41-1-2 of the French code of criminal procedure.

In 2024, two CJIPs have been granted by the PNF for alleged bribery:

- The PNF entered a CJIP with SOTEC on July 1, 2024, for the infraction of the complicity of bribery of foreign public officials, resulting in a fine of ,€ 520,000;
- The PNF entered a CJIP with AREVA SA on December 2, 2024, for the infraction of bribery of foreign public officials, resulting in a fine of ,€ 4,800,000 and the mandatory implementation of a 3-year audit within the ORANO Group and its subsidiaries (which includes ex-ARENA mining activities).

Key Cases Before French Jurisdictions

In 2024, three key cases were brought before the French jurisdictions at the stage of investigation or resulting in the condemnation of the involved parties:

- On February 8, 2024, the Paris Criminal Court ("*Tribunal correctionnel de Paris*") sentenced Laurent de Gourcuff (founder of the hospitality company "Paris Society") for active corruption to a 2-year suspended prison sentence, a ,€ 150,000 fine, a 5-year ban on running a business and an ineligibility penalty for one year.
- In July 2024, the PNF initiated an investigation into THALES (a French group specializing in aerospace, defense and security technologies) for suspicions of corruption of foreign public officials; the company incurs a 10-year prison sentence and a ,€ 150,000 fine.
- On December 18, 2024, the French Supreme Court upheld the conviction against Nicolas Sarkozy (former French President) in the "Wiretapping Case"; the latter was sentenced for active corruption with a senior judge of the French Supreme Court to a 3-year prison sentence, including one year under electronic monitoring and an ineligibility penalty for three years.

AFA's Analysis of First-Instance Court Rulings on Breaches of Probity

The AFA's analysis of probity-related criminal offenses is based on 504 decisions handed down by French first-instance courts between 2021 and 2022. It reveals that bribery is the most frequent criminal offense, accounting for 36.9% of all offenses (with a majority of public officials' bribery). Moreover, in 13.29% of cases, several corruption offenses were prosecuted simultaneously, reflecting a global approach by criminal judges. Notably, 51.6% of the legal decisions analyzed involve the public sector, particularly local authorities, which account for almost half of all cases. Concerning the modes of operation, on average, 2.7 people are involved per case. Furthermore, regarding the court rulings, 92.4% of defendants are individuals, most of whom are public officials and company directors.

PNF's Major Cases to Watch in 2025

The Ghosn-Dati Case (PNF Final Indictment in November 2024)

Rachida Dati (former European deputy and current Ministry of Culture) was indicted in 2021 for passive corruption and passive influence peddling in the judicial case concerning Carlos Ghosn (former CEO of Renault Nissan, under international arrest warrant). The PNF suspects Rachida Dati received almost €900,000 between 2010 and 2012 for consultancy services without any actual work in return. A subsidiary allegedly made these payments of the Nissan group. On November 15, 2024, the PNF requested in its final indictment that Rachida Dati and Carlos Ghosn should be referred to the French criminal court. It is now up to the investigating judge to decide whether there will be a trial.

Opening of the Trial For Corruption and Illegal Campaign Financing (Sarkozy) in January 2025

Nicolas Sarkozy will be tried again before the Paris Criminal Court from January 6 to April 10 in the case of the Libyan financing of his 2007 presidential campaign. After a 10-year investigation, Nicolas Sarkozy is being prosecuted for several offenses, notably passive corruption for which he is accused of having solicited Libyan public funds to finance its 2007 election campaign in return for performing acts in his official capacity or acts facilitated by his position as President (the counterparties were of a diplomatic, economic and judiciary nature).

BROADER TRENDS AROUND THE WORLD

Heading into 2025, practitioners should be mindful of key developments in the EU and France. Beyond the developments recapped there, regulators across the globe and notably in the U.S., have picked up on growing trends towards offering formal compliance guidance to regulated entities and encouraging whistleblowers to step forward through formal government programs.

For further information regarding anticorruption trends and developments in the U.S. and worldwide, see [today's companion piece](#) from our colleagues in the U.S.

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