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Analysis

Raucous 2021 Awaits FCA Litigants After Low-Key Year

By Jeff Overley and Daniel Wilson

Law360 (January 22, 2021, 11:20 PM EST) -- False Claims Act recoveries were modest overall in 2020, but the relatively calm year seeded the clouds for a stormy 2021 by generating tremendous government spending on pandemic relief, a record number of new cases and a potentially game-changing decision in a closely watched area of Medicare fraud litigation.

Here, Law360 explores the FCA's quiet 2020 and potentially turbulent 2021 based on newly released litigation statistics and interviews with attorneys.

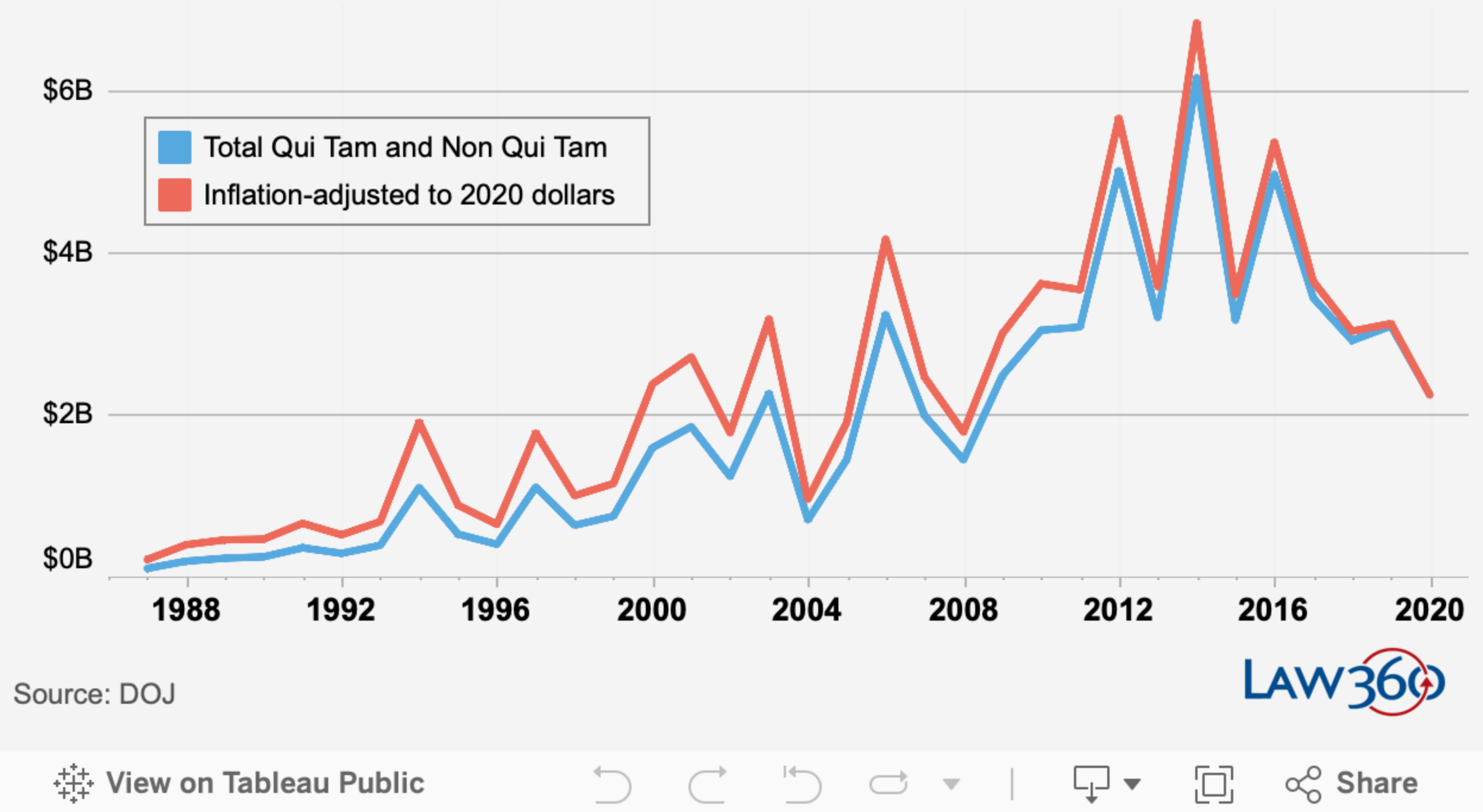
Recoveries Fall Sharply Amid COVID-19

Total FCA recoveries in fiscal year 2020 were \$2.2 billion, down from \$3.1 billion in 2019 and **lower than any year since 2008**. The coronavirus pandemic presumably contributed to the dramatic decline by shuttering courthouses and preventing in-person discussions that could have steered FCA cases toward settlements more efficiently.

"I have to think that COVID [affected] FCA investigations, and the velocity of investigations and litigation, in the same way it has, frankly, for virtually all other litigation," [Sidley Austin LLP](#) partner Scott Stein said.

Inflation-Adjusted FCA Recoveries

When historical recoveries are shown in 2020 dollars, annual hauls in the mid-2000s look more impressive, and the most recent yearly totals look more modest.



But attorneys also cautioned against pinning too much blame on COVID-19, saying the [U.S. Department of Justice](#) quickly found its footing amid the pandemic's workplace upheaval.

"Parties working to finalize FCA settlements with the government in the midst of the pandemic really had no idea what the next day would bring from an operational standpoint," [Bass Berry & Sims PLC](#) member Matthew M. Curley told Law360. "Fortunately, the government showed an understanding of those concerns and demonstrated some real flexibility in working to finalize FCA settlements, which helped move them along to completion."

In addition, the small haul in 2020 represented the continuation of a trend during the Trump administration, which generally captured fewer FCA dollars than the Obama administration. One factor in that Trump-era trend could be the so-called Granston memo, a 2018 directive that led DOJ lawyers to more frequently seek dismissal of disfavored FCA cases filed by whistleblowers, [McCarter & English LLP](#) associate Cara Wulf said. Some of those dismissals affected cases with the potential for multibillion-dollar damages and penalties.

Attached Documents

- [Statistics - 1987-2020](#)
- [Opinion - Sutter Health](#)

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Case Information

Case Title
United States of America et al v. Sutter Health et al

Case Number
3:15-cv-01062

Court
California Northern

Nature of Suit
Other Statutes: False Claims Act

Judge
Laurel Beeler

Date Filed
March 06, 2015

Law Firms

- [Bass Berry](#)
- [Constantine Cannon](#)
- [King & Spalding](#)
- [McCarter & English](#)
- [PillieroMazza](#)
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Companies

- [DaVita Inc.](#)
- [Gilead Sciences Inc.](#)
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- [Pfizer Inc.](#)
- [Practice Fusion Inc.](#)
- [Purdue Pharma LP](#)
- [Regeneron Pharmaceuticals Inc.](#)
- [ResMed Inc.](#)
- [Sutter Health](#)
- [Teva Pharmaceutical Industries Ltd.](#)

Government Agencies

- [U.S. Department of Defense](#)
- [U.S. Department of Health and Human Services](#)
- [U.S. Department of Justice](#)

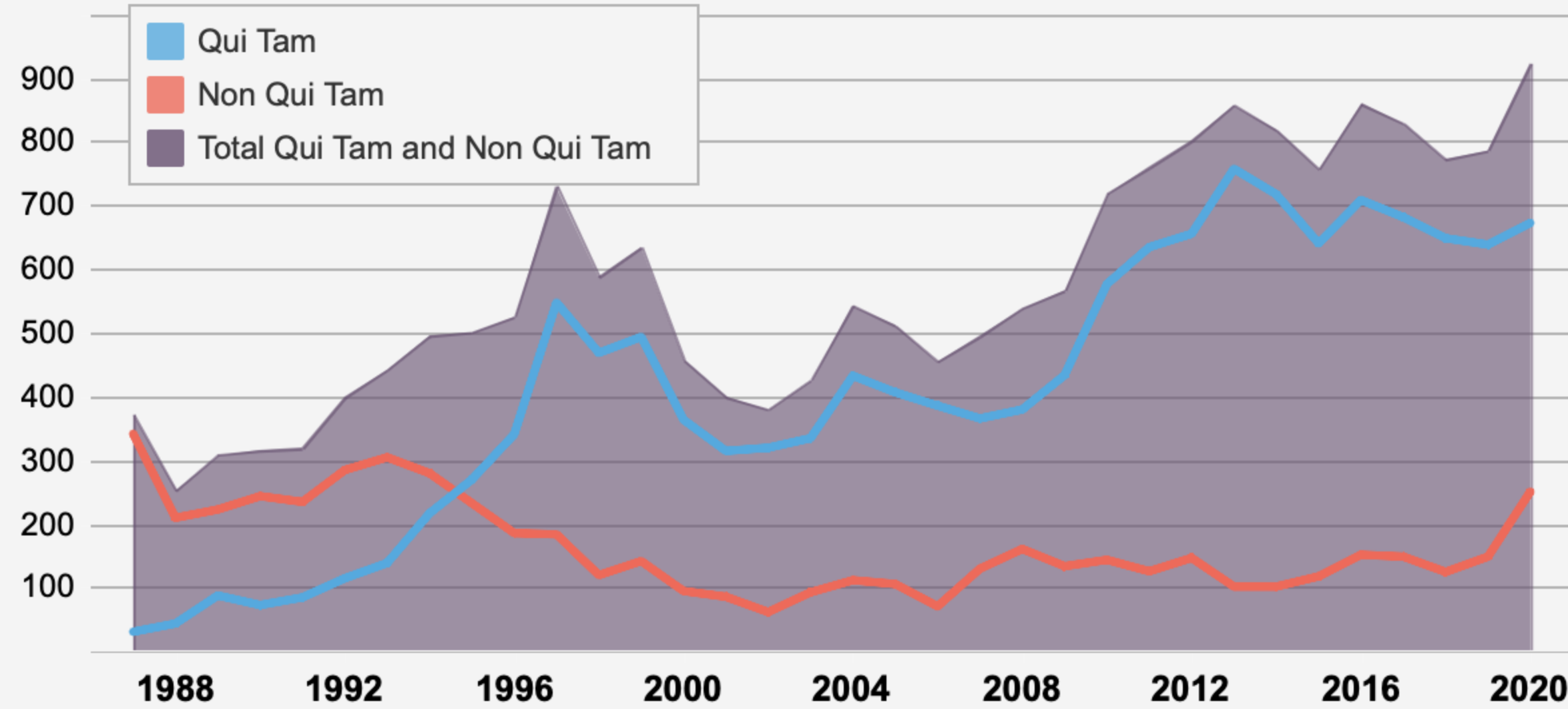
New DOJ-Filed Cases Surge

Even if FCA settlements took longer to finalize because DOJ attorneys were working from home, it doesn't mean they were twiddling their thumbs while waiting to hear back from defense lawyers. Instead, DOJ attorneys may have ended up with more free time to spend on audits and referrals from federal agencies, said Matt Feinberg, chair of [PiliroMazza PLLC's FCA team](#).

That could help explain why the DOJ opened 250 FCA cases and investigations in 2020, a 70% jump from 2019 and the most since 1994. The agency did not respond to questions about why its new filings rose, and its announcement of the 2020 recoveries did not provide any explanation.

New Suits Surge

2020 saw a record number of new FCA suits. The record was fueled by strong whistleblower activity and the biggest tally of new DOJ cases since 1994.



Source: DOJ

[View on Tableau Public](#)

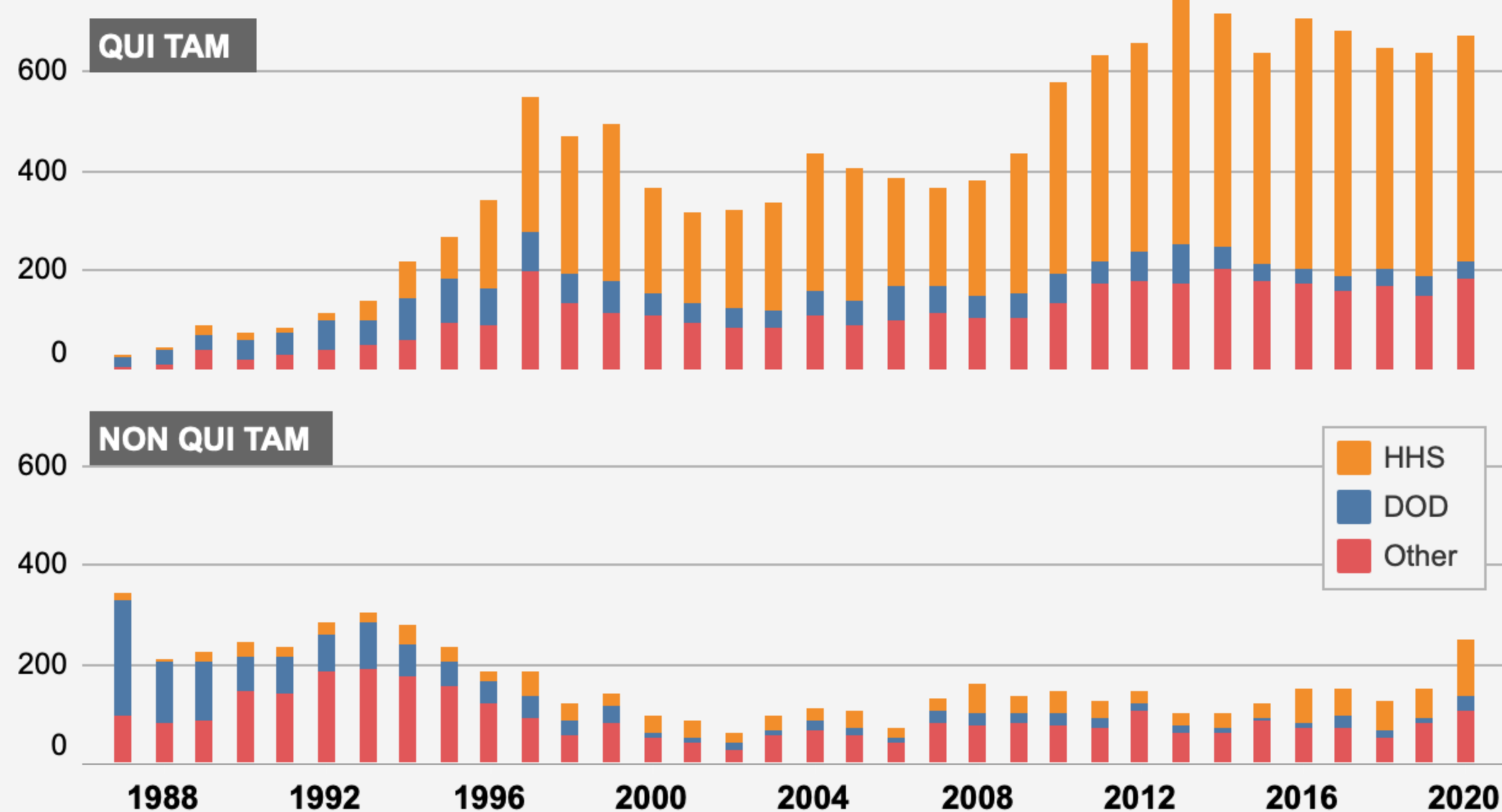
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Some of the new cases probably relate to more than \$1 trillion doled out under COVID-19 stimulus legislation. Whenever there's a gusher of government spending — as seen during the Iraq and Afghanistan wars and the 2007-2008 financial crisis — a spike in FCA cases usually follows.

"I don't think there's ever been a period in our memory, or even potentially our history, where there has been so much immediate infusion of federal dollars into the economy," McCarter & English partner Matt Wright said of the government's pandemic-era largesse.

Broad-Based Climb in Cases

The record number of new cases in 2020 didn't stem from a rise in any single area — suits ticked up almost across the board. The only decline occurred in whistleblower cases involving the U.S. Department of Defense.



Source: DOJ

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The new cases and new spending in 2020 meant that the DOJ entered the 2021 fiscal year — which started on Oct. 1 — with lots of ore to mine for FCA enforcement. But the government also kicked off 2021 by cementing massive FCA settlements. They included deals worth \$3 billion with [Purdue Pharma LP](#) and its owners, and a deal worth \$300 million with [Indivior PLC](#).

Those deals alone pushed 2021 halfway toward the record of nearly \$6.2 billion in FCA recoveries in 2014, when massive settlements related to the housing and mortgage crisis boosted the overall haul.

2025 AI Survey

The 2025 AI Survey

Law firms are actively looking for ways to incorporate artificial intelligence into their workflow as it becomes ever more common. More than half of surveyed attorneys at U.S. law firms use generative AI for some purpose — up significantly from less than a third of attorneys who participated in the Law360 Pulse AI Survey last year.

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When the DOJ announced the latest FCA numbers, it seemed to simultaneously defend its 2020 efforts and forecast a robust 2021. It specifically singled out "settlements totaling billions of additional dollars that are not yet final or did not become final before the end of the fiscal year."

Qui Tams Steady Despite Controversial Dismissals

Critics of the Granston memo have often warned of a potential chilling effect. U.S. Sen. Chuck Grassley, R-Iowa, a key architect of the modern FCA, wrote to then-U.S. Attorney General William Barr in 2019 and complained that the directive "could undermine the purpose of the False Claims Act by discouraging whistleblowers."

But those fears haven't come to fruition: There were 672 new qui tam suits in 2020, the most since 2017 and more than all but four prior years.

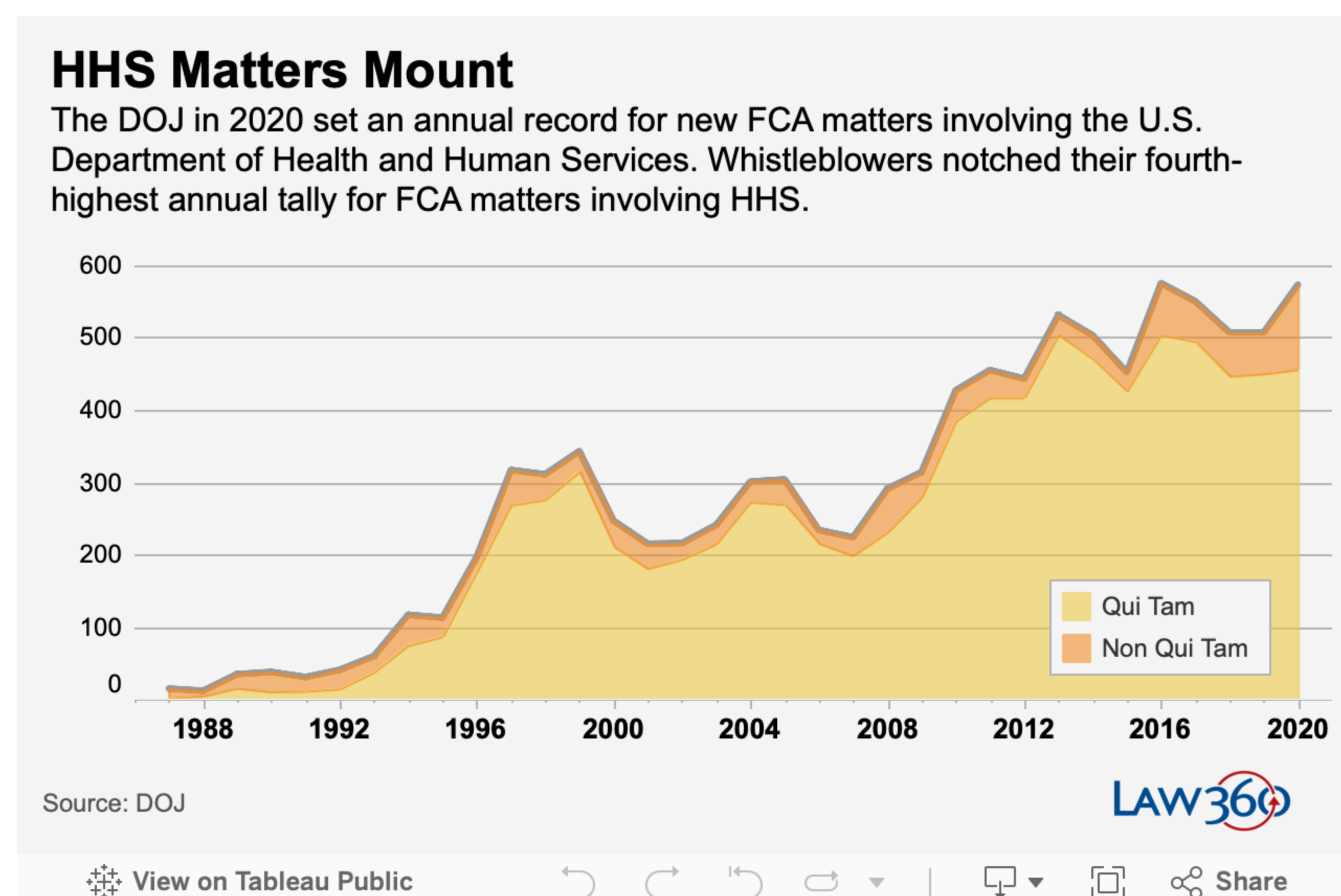
And there are reasons to think those fears will never be realized. The DOJ has torpedoed more than 50 whistleblower cases since 2018, exceeding all such dismissals in the prior 30 years combined.

But the DOJ did so during the tenure of Barr, who in 2019 [walked back previous comments](#) about the FCA's whistleblower provisions being an "abomination" and unconstitutional. With that in mind, it seems unlikely that future DOJ leadership would go to even greater lengths to wipe out whistleblower cases.

"We just got past an attorney general who is known for his hostility to the False Claims Act," [Constantine Cannon LLP](#) partner Eric R. Havian, who represents whistleblowers, told Law360. "And if we didn't see a tidal wave of dismissals under this past attorney general, I don't expect we're going to see one in the future."

Kickbacks Fuel Recoveries – And a New Defense Strategy

Fraudulent health care billing has become such an overwhelming source of FCA payouts that the law's acronym sometimes seems like it could stand for the False Care Act.

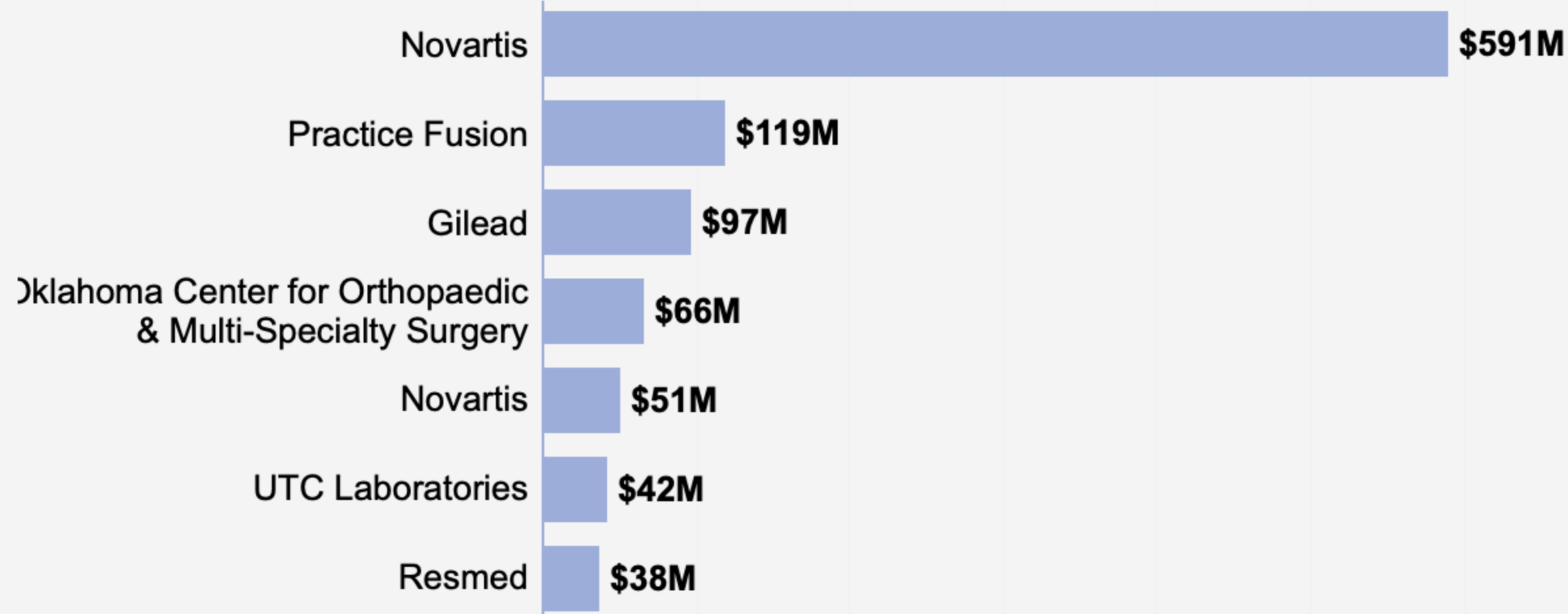


Health care's dominance persisted in 2020, when almost 85% of FCA proceeds involved billing of the [U.S. Department of Health and Human Services](#). But the dominance also became even more narrowly focused on billing of HHS that was tainted by kickbacks.

"This past year, as you looked at the big health care cases, they almost all seemed to be kickback cases or have a kickback element to them," Havian said.

Kickbacks Are King

Health care cases in general fueled 2020 recoveries, but health care cases specifically involving kickbacks were especially vital. About half of the \$2.2 billion haul was connected to kickbacks; the biggest cases are shown here.



Note: The two Novartis settlements shown here cover separate kickback allegations.
Source: DOJ

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The largest FCA settlement of 2020 saw Novartis Pharmaceuticals Corp. pay roughly \$590 million for allegedly wheedling doctors into writing prescriptions by regaling them with wine tastings, golf course outings and haute cuisine at numerous high-end restaurants, including Commander's Palace in New Orleans and Le Bernardin in New York City.

Novartis' alleged kickbacks were voluminous but also fairly traditional in the context of unlawful pharmaceutical industry freebies. Other FCA cases, however, illustrated how kickbacks come in many different forms.

[Practice Fusion Inc.](#), for example, struck a \$119 million kickbacks settlement for allegedly rigging its medical software in favor of Purdue Pharma's OxyContin. An Oklahoma hospital reached a \$66 million settlement for allegedly offering sweetheart deals on investments and office space in exchange for patient referrals. And medical equipment maker [ResMed Corp.](#) inked a \$37 million settlement for luring customers with free telephone call center services and interest-free loans.

All told, the federal government's announcement of last year's FCA recoveries identified kickback settlements collectively worth more than \$1 billion, or roughly half of the entire 2020 haul. The enforcement blitz may help to explain a recent lobbying campaign seeking latitude from Anti-Kickback Statute liability in certain circumstances.

"You can tell how badly the industry is wounded by how loudly they squeal. And they've been squealing about kickback reform — so-called reform — for a while now," Havian said. "And looking at the past year's recoveries, you can understand why."

That so-called reform emerged in late 2020 when the Trump administration finalized new safe harbors and exceptions under the AKS and a sister statute known as the Stark Law, which also covers financial conflicts of interest in health care. Widely described as industry friendly and highly technical, the safe harbors are likely to introduce uncertainty into future FCA cases involving kickbacks.

"They could complicate enforcement efforts because the new rules are, as always, dense and complex," Adam Law LLC founder Lynn Adam, a former FCA defense lawyer at [King & Spalding LLP](#) who now represents whistleblowers, told Law360.

In another potential complication for kickback enforcement, [Pfizer Inc.](#), [Regeneron Pharmaceuticals Inc.](#) and [Teva Pharmaceuticals USA Inc.](#) have recently **started raising free-speech challenges** to restrictions on purportedly charitable assistance with pharmaceutical copayments. That assistance led to FCA settlements in 2020 with Novartis, [Gilead Sciences Inc.](#) and several copay foundations.

Pfizer and Regeneron have been represented by [Ropes & Gray LLP](#), one of the main law firms that spent much of the past decade **waging free-speech attacks** against restrictions on off-label drug promotion. The efficacy of those attacks is debatable, but they came too late to prevent some of the biggest FCA settlements in history, and some observers are getting a sense of déjà vu.

Edward Baker, of counsel at Constantine Cannon, told Law360 that there's "a parallel here between the defensive strategy used by the pharmaceutical companies in the earlier off-label marketing cases and now the charitable foundation copay assistance cases."

"The pharma companies only achieved limited success using this strategy to curtail DOJ's enforcement of off-label marketing," Baker said. "I expect that they will achieve even less success with respect to the fraudulent use of charities to increase drug sales."

Sluggish Medicare Cases Poised for a Breakthrough

The DOJ and the plaintiffs bar are always delving into unexplored sectors and sniffing around for fishy business practices in search of enticing new fodder for FCA litigation. One of the most appetizing targets to emerge in recent years is Medicare Advantage, an industry of privately administered Medicare plans that received nearly \$275 billion from Uncle Sam in 2019.

But at the end of 2020 — more than six years after companies [began facing public allegations](#) of exaggerating patient illnesses to boost "risk adjustment" revenue in Medicare Advantage — the DOJ's report on FCA recoveries did not mention a single dollar involving the program.

"One thing that's notably absent in the recoveries this past year, at least as far as I can tell, is any indication that you have Medicare Advantage recoveries," Baker said.

Whistleblowers started filing suits alleging Medicare Advantage fraud soon after the risk adjustment's full implementation in 2007. The DOJ began joining some of those suits in 2017, and top government lawyers last year singled out Medicare Advantage when discussing FCA priorities.

But the litigation wave has so far produced only a handful of notable settlements. And perhaps the largest settlement — [a \\$270 million deal](#) with health care giant DaVita Inc. — dates back to 2018.

That being said, there are signs that 2021 could be a breakthrough year. The D.C. Circuit, for example, is weighing the DOJ's appeal of a 2018 ruling that threatened to [wreck a central premise of many FCA suits](#) against Medicare Advantage insurers. At oral arguments in November, at least one D.C. Circuit judge [appeared to be leaning in the government's favor](#).

In addition, a California federal judge in March issued a sweeping decision that refused to dismiss a major FCA case accusing [Sutter Health](#), one of the nation's largest health care systems, of [obtaining and keeping Medicare Advantage money](#) for bogus diagnoses.

The 104-page decision refused to accept Sutter Health's premise — also at issue in the D.C. Circuit appeal — that Medicare Advantage participants are being underpaid relative to traditional Medicare and therefore improperly punished under the FCA.

And even if the government were underpaying, that fact "is not a defense to an FCA claim," U.S. Magistrate Judge Laurel Beeler wrote. "Possibly underpaying [Medicare Advantage] participants does not entitle [those] participants to correct that supposed wrong by submitting false diagnosis codes and failing to report or return payments predicated on the codes."

In a joint motion last month to pause proceedings, the parties announced they had "reached an agreement in principle with defendants to resolve defendants' False Claims Act liability for conduct occurring between 2010 and 2016."

Constantine Cannon's Baker told Law360 that Judge Beeler's decision contained "outstanding analysis," and he predicted that it's a sign of things to come in similar cases.

"It's a matter of time before the law gets settled there," Baker said. "We are, at the moment, in the eye of the hurricane with respect to those cases. And I think we're going to start seeing some very significant recoveries."

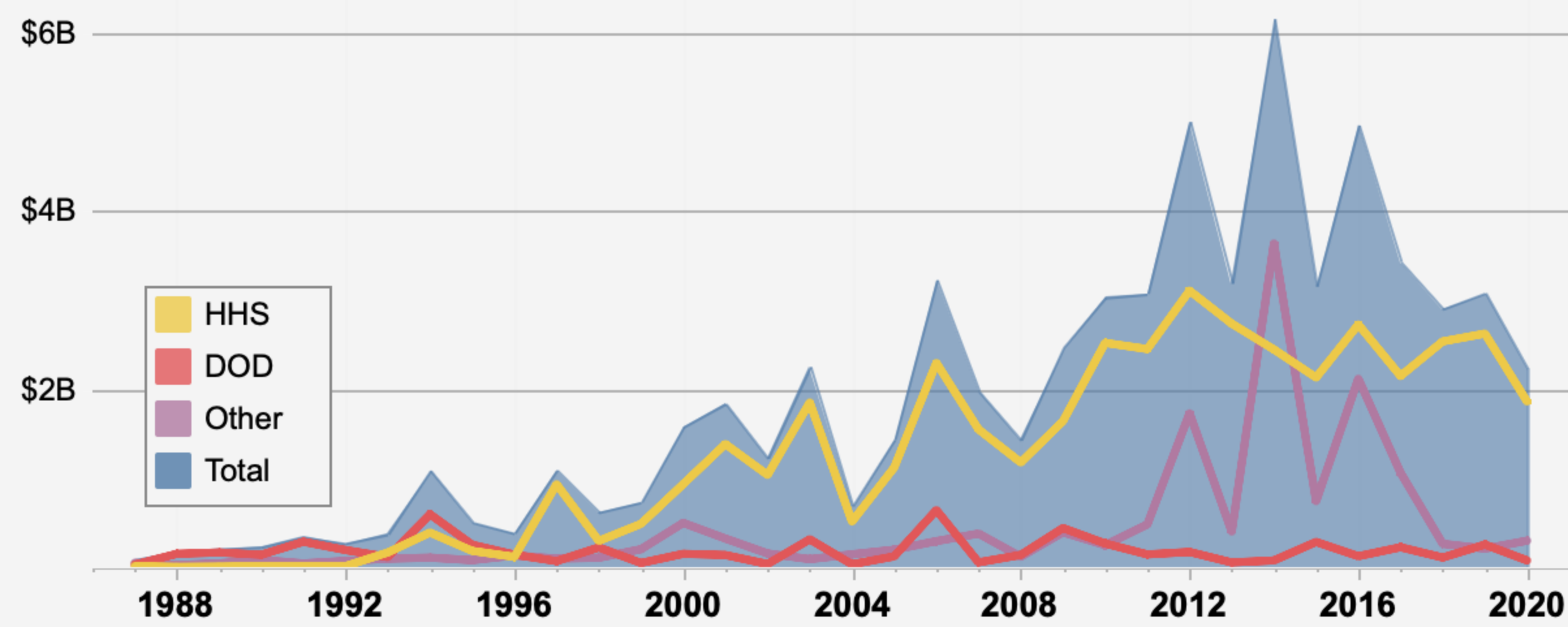
Defense Industry Recoveries Hit a New Low

The FCA debuted during the Civil War and has long been associated with fighting fraud in defense contracts. But enforcement with military connections has plummeted steadily over the years, and in 2020 it constituted only about 3% of recoveries, or \$75 million.

The \$75 million was down from \$253 million in defense recoveries the prior year and marked the puniest defense recovery since 2014. Several FCA settlements involving health care in 2020 were larger than all defense recoveries combined.

Health Is Hot, Defense Is Dwindling

As usual, FCA payouts were overwhelmingly tied to improper health care billing. Payouts linked to defense contracts — once a major component of FCA enforcement — constituted only about 3% of total recoveries.



Source: DOJ

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Since the FCA's modernization in 1986 to encourage whistleblowing, only eight years have produced smaller total recoveries from the defense sector — and that's before even accounting for inflation.

In addition, whistleblower cases involving the [U.S. Department of Defense](#) were the only FCA area where fewer suits emerged in 2020 compared to 2019. And only six of the past 34 years generated fewer defense-related qui tams than 2020.

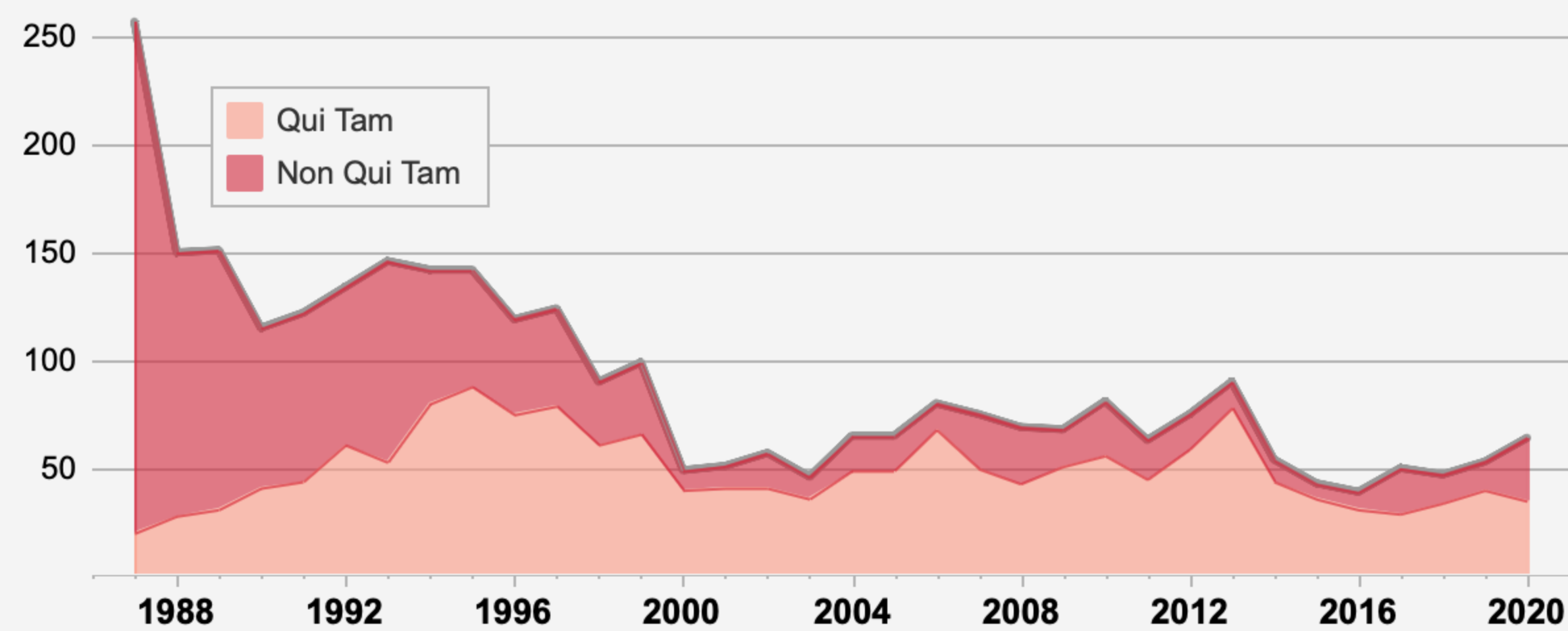
One possible explanation is that defense spending, despite being a huge part of the federal discretionary budget, hasn't risen as much as health care spending over the years, McCarter & English's Wright said.

"[It's] the law of big numbers," he said. "As health care continues to grow at a massive rate in proportion to the economy and the federal contributions of federal dollars to that sector of the economy grows, then naturally there are more opportunities for either accounting errors or outright fraud or mischief."

And while there may be hundreds or thousands of major defense contracts, there are tens of millions of patients in Medicare and Medicaid, presenting far more opportunities for relators or the government to file cases. Further, health care delivery and payments are in constant flux, while in defense, many of the contracting vehicles in common use haven't changed significantly in decades, McCarter & English's Wulf said.

DOD Caseload Rebounds

Federal prosecutors last year brought their highest number of cases involving the U.S. Department of Defense since 1999. Whistleblower cases involving the DOD were the only area where new cases dipped.



Source: DOJ

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For all of its diminished importance to FCA litigation, the defense industry could see more scrutiny in 2021, given that 64 new defense cases were filed in 2020, the most since 2013.

--Editing by Breda Lund and Emily Kokoll.

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