

BLOG



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Introduction

As we reflect on the past in order to prepare for the future, it becomes increasingly clear that 2021 will bring greater use of one of the government's most powerful civil enforcement tools—the False Claims Act ("FCA")—to root out fraud and abuse involving government funds in a myriad of industries and in novel ways. While there was a decrease in total FCA recoveries by the U.S. Department of Justice ("DOJ") in fiscal year 2020, [1] the significance of this drop must be assessed in the context of other reported statistics, as well as the global health crisis that impacted the nation during most of 2020. A careful analysis of the reported statistics offers tremendous insight into the changing nature of the DOJ's FCA enforcement activities in recent years. These insights, along with the expected impact of the many pandemic-related response and relief programs and anticipated enforcement priorities under the new administration, suggest that we will see a significant increase in FCA investigations and related litigation impacting a growing number of industries and categories of defendants, including more matters initiated by the government independent of whistleblowers.

KEY FCA TAKEAWAYS FROM FY 2020 AND EXPECTATIONS FOR FUTURE FCA ENFORCEMENT

Despite Decrease in FY 2020 FCA Recoveries, Increase in Filings and Large Recoveries Shortly After Close of FY 2020 Reveal Continued Focus on FCA Enforcement.

The approximately \$2.2 billion recovered by the DOJ in fiscal year 2020 is the lowest total recovered since 2008 and marked a decrease of over 27% from the approximately \$3.08 billion recovered in fiscal year 2019. Even recoveries from the health care industry—historically a top target for FCA enforcement and once again the leading industry for FCA recoveries in fiscal year 2020—were down to \$1.86 billion in fiscal year 2020 from \$2.6 billion in 2019. However, the significance of this decrease in total FCA recoveries must be assessed against the backdrop of the number of newly filed FCA matters, the global health pandemic that gripped the nation in 2020, and the substantial amounts recovered within two months following the close of the fiscal year.

During fiscal year 2020, there was a substantial increase in the total number of new FCA matters filed, from 786 new matters filed in 2019 to 922 new matters docketed in 2020. As in earlier years, the vast majority of new matters—672—were filed under the FCA's whistleblower, or *qui tam*, provisions that allow individuals to file lawsuits alleging false claims on behalf of the government and share in any recovery (typically between 15% and 30%). In addition, whistleblower cases continued to serve as the leading source of FCA recoveries in 2020, with approximately \$1.69 billion (approximately 76% of the total recovered) secured in *qui tam* matters, and awards to whistleblowers of more than \$309 million.

This increase in the number of new FCA matters commenced in fiscal year 2020 suggests that efforts to utilize the FCA to root out fraud against the government are steadily growing, and that 2021 will see continued vigorous FCA enforcement. It also suggests that the decrease in total FCA recoveries in fiscal year 2020 was not the result of a reduced interest in pursuing FCA enforcement initiatives. Rather, the reduced amount of recoveries was likely due primarily to challenges stemming from the global health crisis. Pandemic-related closures, delays in proceedings, and impediments to conducting investigations since March 2020 necessarily would have slowed the pace of these matters, pushing off recoveries beyond the end of the 2020 fiscal year. Further, and as discussed below, there were at least two significant FCA recoveries—totaling over \$3 billion—within 60 days following the close of the government's 2020 fiscal year. While those recoveries were not included in the fiscal year 2020 numbers, the matters giving rise to them were clearly the subject of robust DOJ enforcement activity in 2020, further suggesting that the decrease in the reported recoveries for fiscal year 2020 is not indicative of a waning of FCA enforcement initiatives.

FCA Enforcement Activities Likely to Increase Under the New Administration.

Despite the slowdowns of the past fiscal year, FCA enforcement activities are likely to increase under the new administration. As Deputy Assistant Attorney General Michael D. Granston recently commented, protecting taxpayer funds is a nonpartisan issue. Given the unprecedented federal resources made available to address the financial impact of the coronavirus pandemic, the coming years will undoubtedly see an increasing use of the FCA to uncover and redress fraud in connection with the COVID-19 relief programs, including the Paycheck Protection Program ("PPP") enacted under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). In fact, as we reported earlier, on January 12, 2021, the DOJ announced the first civil settlement resolving alleged FCA violations based on allegations of fraud against the PPP. Particularly in view of the tremendous number of individuals and entities applying for pandemic-related benefits and the substantial sums involved—which dwarf prior relief efforts following earlier crises such as Hurricane Katrina and the 2008 financial crisis [6]—COVID-19-related fraud will likely drive FCA recoveries in the years to come and outpace the FCA recoveries that followed earlier crises.

This is especially likely in view of announcements by the DOJ and various government agencies of initiatives to ferret out and redress COVID-19-related fraud schemes and the establishment of new oversight committees charged with policing the use of federal funds. [2] For example, currently pending in the Senate is the Coronavirus Oversight and Recovery Ethics Act (the "CORE Act"), a bill intended to increase government authority over the use of CARES Act and other stimulus funds. [3] The CORE Act would grant the Congressional Oversight Commission, established in the CARES Act, subpoena authority for testimony and documents and expand its jurisdiction to include all COVID-19 relief funding, and would establish whistleblower protections for government contractors and private sector workers who report waste, fraud, or abuse or are victims of misconduct. The enactment of the CORE Act thus would bolster FCA investigations scrutinizing the receipt and use of federal COVID-19 relief funds. In addition, whistleblowers motivated by the prospect of obtaining significant financial rewards in the form of relator share awards will likely file *qui tam* complaints where they believe they have evidence of wrongdoing in connection with COVID-19 relief programs. Furthermore, recent comments by newly confirmed Treasury Secretary Janet Yellen, pushing Congress to "act big" and pass a \$1.9 trillion relief package, suggest additional federal COVID-19 relief funds are on the way for individuals and businesses, expanding the universe of funds and participants to be scrutinized and policed in order to protect against fraud. [9]

In addition, the new administration appears poised to support increasingly robust FCA enforcement. President Biden, for example, previously served in an administration during which the FCA was significantly strengthened through the 2009 Fraud Enforcement and Recovery Act ("FERA") amendments to the statute. Among other things, those amendments strengthened the FCA by affording additional protections to whistleblowers. Indeed, during the

years when President Biden was Vice President, FCA recoveries averaged approximately \$3.88 billion per year. Vice President Harris has also made extensive use of California's false claims act to combat fraud, recovering enormous amounts of money in sanctions and settlements as Attorney General of California, including \$241 million from Quest Diagnostics, the largest recovery in the state's history. Similarly, Xavier Becerra, nominee for Health and Human Services Secretary and current Attorney General of California, brings a wealth of experience in taking on big corporations with the aid of whistleblowers and California's false claims act. In fact, Becerra previously sponsored legislation in California that would expand the state's FCA to further empower whistleblowers reporting tax fraud.

Significant Number of Government-Initiated Actions in FY 2020 – A Trend That Will Likely Continue in 2021.

Driving the overall increase in new FCA matters in fiscal year 2020 was a significant jump in government-initiated (non-qui tam) matters. The 250 new government-initiated matters commenced in fiscal year 2020 is the highest total since 1994. This development suggests that the government is becoming more proactive in its efforts to ferret out fraud in connection with federal funds. And it is likely that in 2021 we will see a continuation of the 2020 uptick in FCA investigations and actions initiated by the government. This will be due in large part to the expanding number of task forces, commissions, and government appointees charged with policing the federal funds being distributed under the various pandemic response and relief programs as discussed above. The expectation that 2021 is likely to see more government-initiated FCA matters is further supported by the government's development of new tools to root out fraud. Notably, DAAG Granston recently predicted that the DOJ will increasingly rely on data analytics to identify potential fraud cases and initiate investigations independent of complaints filed by whistleblowers. [11]

Diverse Array of Industries Targeted in FY 2020 - Expansion Expected in 2021.

The fiscal year 2020 statistics reveal that the FCA was used to combat fraud against the public fisc in a growing array of industries. [12] While there were 456 and 35 new *qui tam* (whistleblower-initiated) matters involving the health care industry and the defense industry (traditional FCA targets) filed in 2020, respectively, there were 181 new *qui tam* matters filed in other industries in 2020, which is an increase from the 148 filed in 2019. [13] In addition, recoveries in these other industries increased this past fiscal year to just under \$297 million, [14] from approximately \$207 million in fiscal year 2019. The expansion of industries targeted for FCA enforcement is reflected in the FCA recoveries secured by DOJ in cases involving the following alleged schemes: (i) bid-rigging in an auction to purchase non-performing loans from the Department of Energy, (ii) fraudulent billing of inflated labor hours and purported work performed to construct and maintain a waste treatment plant, (iii) improper reporting in connection with National Institute of Health-funded research grants for time spent on non-grant-related activities, (iv) improperly obtaining Federal Housing Administration ("FHA") insurance for a mortgage to develop a hospital and using loans in violation of FHA requirements, and (v) false claims for reimbursement by state agencies in connection with their administration of the Supplemental Nutrition Assistance Program, previously known as the Food Stamp Program. [15]

In 2021, the DOJ can be expected to expand the reach of the FCA to additional industries, imposing heightened scrutiny on a wide array of entities and individuals doing business with the government. This is especially true given the broad reach of COVID-19 relief efforts. As discussed in our previous article, [16] the CARES Act provides financial assistance and funding to individuals and organizations across many different industries. For example, the CARES Act makes billions of dollars available to passenger air carriers, cargo air carriers, and businesses critical to maintaining national security. The Act also authorizes billions of dollars in forgivable loans to small businesses, nonprofits, and certain tribal entities under the PPP, as well as emergency grants to eligible small businesses. As such, given the myriad of businesses and industries taking advantage of the COVID-19 financial relief programs, it can be expected that the FCA will be used as an anti-fraud enforcement tool across a growing number of industries beyond those that have been the primary targets of FCA enforcement in prior years, such as the health care, defense, and financial industries.

The technology industry is likely to see more FCA investigations and litigation for reasons that go beyond COVID-19 relief efforts. With the growing threat of cyberattacks, cybersecurity protections are increasingly being included as material requirements in government contracts. As a result, contractors providing cybersecurity products and services may find themselves in the government's crosshairs based on alleged false representations arising out of statements regarding the security of their products and services. [17]

Finally, we are likely to see a return of increased FCA recoveries involving the defense industry. FCA recoveries in this area have declined over the years—including a precipitous drop from 2019, when approximately \$253 million was recovered, to 2020, when only \$75 million was secured by the DOJ. However, in 2020, there were 64 new FCA matters initiated in this area (including both *qui tam* and government-initiated matters), which is the highest total since 2013.¹⁸

FCA Added to Arsenal of Weapons Used to Pursue Specific Enforcement Priorities in FY 2020 – A Trend Likely to Continue in 2021.

An analysis of FCA enforcement initiatives over the past several years suggests a growing use of the FCA as an added tool for pursuing specific enforcement priorities and objectives. [19] For example, the FCA has been used to help combat the opioid crisis, as can be seen by the October 2020 global resolution with Purdue Pharma LP ("Purdue"), which included a payment of \$2.8 billion for Purdue's alleged FCA violations arising from its unlawful promotion of its opioid drugs for improper uses and related kickback schemes to induce prescriptions of its opioids. $\frac{20}{20}$ The resolution also required Purdue's owners to pay \$225 million to resolve their individual FCA liability—the DOJ's largest FCA settlement with a non-corporate entity.[™] The government also reached a global resolution with Indivior PLC related to its marketing of the opioid addiction treatment drug Suboxone. [22] That resolution—which was agreed to in July 2020 but conditioned on the district court's acceptance of Indivior's guilty plea in November 2020—included a \$300 million payment to resolve allegations that Indivior promoted Suboxone to physicians who were writing prescriptions for uses that were unsafe, ineffective, and medically unnecessary and used false and misleading claims that Suboxone was less susceptible to diversion, abuse, and accidental pediatric exposure than other buprenorphine products. Given the Biden campaign promise to "[h]old accountable big pharma[ceutical] companies, executives, and others responsible for their role in triggering the opioid crisis" and to "[d]irect the [DOJ] to make actions that spurred this crisis a top investigative and, where appropriate, civil and criminal enforcement priority," [23] it is likely that the new administration will make aggressive use of the FCA to support its efforts to combat the opioid crisis.

The FCA was also used to combat fraudulent schemes contributing to the rising costs of prescription drug prices. For example, the DOJ secured several FCA settlements involving schemes related to the Medicaid rebate program and pharmaceutical companies' improper use of foundations as conduits for the payment of patient copayments. [24] In addition, the DOJ has utilized the FCA to help root out fraud targeting the Medicare Part C program. This is an area that is likely to see increasing focus—and resulting recoveries—in the years ahead, particularly given the number of Medicare beneficiaries covered under the Medicare Part C program and the substantial amount of government funds involved. Indeed, DAAG Granston recently identified investigating fraud related to the Medicare Part C program as one of the DOJ's important priorities.

In short, the FCA has been used effectively to combat a widening variety of unlawful schemes and that trend is expected to continue. The FCA's lower burden of proof (preponderance of the evidence) as compared to the higher burden of proof in criminal matters (beyond a reasonable doubt) and the fact that the FCA does not require proof of a specific intent to defraud make the FCA a highly effective tool in the DOJ's arsenal of weapons to combat fraud. As such, the new administration can be expected to make robust use of the FCA to help achieve its various enforcement priorities and objectives.

Increasing Number of Individuals Held Accountable for FCA Violations in FY 2020 – Expected for 2021 Too.

The DOJ once again devoted a section of its press release to highlighting significant settlements with individuals, underscoring its commitment to use the FCA to redress and deter fraud against the government committed by individuals. [28] The DOJ is likely to continue this trend of holding individuals accountable for wrongdoing under the FCA. Indeed, fiscal year 2021 has already seen the record-setting \$225 million FCA settlement with the owners of Purdue. Further, as discussed above, significant resources are being devoted to combatting fraud against pandemic-related government programs. Accordingly, there will be greater scrutiny of the many certifications required from

companies and their management in order to participate in those programs. Keeping in mind that FCA liability may be imposed based on actual knowledge as well as acting in deliberate ignorance or reckless disregard of the truth or falsity of the required certifications, the conduct of individuals preparing and filing those certifications will become critical to determining whether there were related FCA violations. Holding individuals involved in the preparation and submission of false certifications accountable for FCA violations would send a strong message of deterrence. In fact, such a message has already been sent by the recent announcement of alleged FCA violations committed by SlideBelts Inc. and its president and CEO in connection with PPP loan applications. The agreement noted that the government had FCA and FIRREA claims in the amount of \$4,196,992, but agreed to settle at a far lower amount due "solely" to the financial conditions of the bankrupt company and its president and CEO.

Expanding Categories of FCA Defendants in FY 2020 - A Trend That Is Likely to Continue in 2021.

In 2019 and 2020, the government brought FCA cases against a new category of defendants—the private equity owners of companies alleged to have violated the FCA. Specifically, in November 2020, the DOJ announced that a Johnson & Johnson subsidiary and a private equity firm agreed to pay a total of \$11.5 million to resolve FCA claims. The claims stemmed from a whistleblower complaint alleging that another former Johnson & Johnson subsidiary, Therakos, Inc., promoted a medical procedure for the treatment of a form of cancer on children when the procedure was not approved by the Food and Drug Administration for use in the pediatric population. [30] The private equity firm agreed to pay \$1.5 million of the total settlement amount to resolve allegations that Therakos continued the alleged improper sales and promotion practices after the private equity firm acquired Therakos. Earlier, in September 2019, the DOJ announced a \$21.36 million settlement of alleged FCA violations stemming from a purported kickback scheme with a compounding pharmacy, two of its executives, and the private equity firm that managed the compounding pharmacy on behalf of its investors. [31] The DOJ alleged that the private equity firm knew of and agreed to the plan to pay outside marketers to generate prescriptions for the compounding pharmacy and financed the kickback payments paid by the compounding pharmacy to the marketers.

We can expect that the government and whistleblowers will continue to use the FCA to seek recovery against additional categories of defendants whose conduct can be proven to have facilitated the alleged violations of the FCA. In particular, the government is likely to pursue FCA claims against third parties such as investors, auditors, and private equity firms that the government views as having sufficient knowledge of misconduct, oversight, or control over an alleged wrongdoer. Expanding the types of defendants against which the FCA is used serves to increase the government's ability to recover from what may be "deeper pockets." In addition, efforts to combat the opioid crisis may be strengthened by targeting health care industry participants beyond providers and drug manufacturers. Indeed, DAAG Granston recently remarked that the DOJ may focus on supply chain participants who contributed to the crisis or those who seek to take advantage of the crisis, such as labs engaged in excessive drug testing. Expenditure of the crisis or those who seek to take advantage of the crisis, such as labs engaged in excessive drug testing.

Conclusion

A thorough analysis of the DOJ's FCA recoveries in fiscal year 2020, considered against the backdrop of the increasing amounts of federal funds available to address the global health crisis, heightened government scrutiny of related programs, growing threats stemming from the opioid crisis and cybersecurity risks, as well as the significant recoveries already obtained by the DOJ in fiscal year 2021, reveals that 2021 will likely see a marked increase in FCA enforcement initiatives and related recoveries. As discussed above, this expectation is strenghtened by certain stated enforcement priorities of the new administration, along with the apparent historical support of our various new leaders for aggressively using state and federal false claims acts to root out fraud and strengthen whistleblower protections.

The robust FCA enforcement initiatives expected in 2021 will likely include investigations targeting both companies and individuals in a widening array of industries, the use of the FCA in pursuing diverse law enforcement priorities, and the increase in the number of government-initiated actions independent of whistleblower complaints. Thus, companies and individuals must remain vigilant in order to minimize the risk of finding themselves the target of FCA investigations and related litigation, which include the potential for substantial financial consequences, including steep penalties, treble damages, and possible exclusions from federal programs. It is critical for all organizations and individuals doing business with the government to ensure that they have appropriate safeguards in place both to

prevent FCA violations in the first instance, as well as put them in the best position for defending against such allegations should they arise.

If you have additional questions or need further assistance, please reach out to <u>Suzanne Jaffe Bloom</u>, Co-Chair - White Collar, Regulatory Defense, and Investigations Practice; <u>Benjamin Sokoly</u>, Of Counsel – Litigation; <u>Zain Maredia</u>, Litigation Associate, or your Winston relationship attorney.

View all of our FCA Playbook perspectives <u>here</u>. View all of our COVID-19 perspectives <u>here</u>. Contact a member of our COVID-19 Legal Task Force <u>here</u>.

- [1] see DOJ Press Release, "Justice Department Recovers Over \$2.2 Billion from False Claims Act Cases in Fiscal Year 2020," (Jan. 14, 2021), available at https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020 ("2020 FCA Recoveries Press Release"); see also DOJ Fraud Statistics, October 1, 1986 September 30, 2020, available at https://www.justice.gov/opa/press-release/file/1354316/download ("DOJ Fraud Statistics").
- $\stackrel{\square}{=}$ see DOJ Fraud Statistics.
- See DOJ Fraud Statistics.
- see Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute (December 2, 2020), available at https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act ("Granston Remarks").
- [5] See "DOJ Announces First Settlement To Resolve Alleged FCA Violations By A PPP Borrower And Its CEO," Mondaq, January 22, 2021, available at https://www.mondaq.com/unitedstates/insolvencybankruptcy/1028784/doj-announces-first-settlement-to-resolve-alleged-fca-violations-by-a-ppp-borrower-and-its-ceo.
- As noted by DAAG Granston in recent remarks, the total disbursements under the Troubled Asset Relief Program in the wake of the 2008 financial crisis is estimated to be only one-sixth of the government's \$2.6 trillion in loans and other economic support—before the most recent stimulus—provided in response to the COVID-19 crisis. See Granston Remarks.
- For additional information, see our earlier articles "Mitigating FCA Liability Risks from Covid-19 Relief Programs," Bloomberg Law, May 2020, available at https://www.winston.com/images/content/2/0/v2/204436/MitigatingFCALiabilityRisksECO49129.pdf. "Inside the First Paycheck Protection Program Fraud Charges," Law360, May 15, 2020, available at https://www.law360.com/tax-authority/articles/1273295/inside-the-first-paycheck-protection-program-fraud-charges.
- see Coronavirus Oversight and Recovery Ethics Act of 2020, S.3855, 116th Cong., available at https://www.congress.gov/bill/116th-congress/senate-bill/3855.
- see "Yellen Readies Big Changes for Treasury," The N.Y. Times, Jan. 18, 2021, available at https://www.nytimes.com/2021/01/18/us/politics/janet-yellen-treasury.html.
- [10] See "Incoming HHS Secretary Becerra will be a Champion for Whistle-blowers," San Francisco Chronicle, Jan. 20, 2021, available at https://www.sfchronicle.com/opinion/openforum/article/Incoming-HHS-Secretary-Becerra-will-be-a-champion-15883208.php.
- see Granston Remarks.
- see 2020 FCA Recoveries Press Release.
- see DOJ Fraud Statistics.
- $[\underline{14}]$ see DOJ Fraud Statistics.
- see 2020 FCA Recoveries Press Release.
- see "Mitigating FCA Liability Risks from Covid-19 Relief Programs," *Bloomberg Law*, May 2020, *available at* https://www.winston.com/images/content/2/0/v2/204436/MitigatingFCALiabilityRisksECO49129.pdf.

- see "Key Takeaways from DOJ's 2019 FCA Recovery Stats," Law360, March 31, 2020, available at https://www.law360.com/articles/1254852/key-takeaways-from-doj-s-2019-fca-recovery-stats; Granston Remarks.
- [<u>18]</u> see DOJ Fraud Statistics.
- see Granston Remarks.
- [20] see DOJ Press Release, "Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family" (October 21, 2020), available at https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.
- These settlements were reached after the DOJ's 2020 fiscal year ended on September 30, 2020, and thus are not included in the \$2.2 billion recovered in fiscal year 2020.
- see DOJ Press Release, "Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay \$600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution" (July 24, 2020), available at https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million; 2020 FCA Recoveries Press Release.
- [23] See "The Biden Plan to End the Opioid Crisis," available at https://joebiden.com/opioidcrisis/.
- see Granston Remarks; 2020 FCA Recoveries Press Release.
- see DOJ Press Release, "Medicare Advantage Provider to Pay \$270 Million to Settle False Claims Act Liabilities" (October 1, 2018), available at https://www.justice.gov/opa/pr/medicare-advantage-provider-pay-270-million-settle-false-claims-act-liabilities.
- [26] see Granston Remarks.
- [<u>27</u>] see Granston Remarks.
- see 2020 FCA Recoveries Press Release.
- see "DOJ Announces First Settlement To Resolve Alleged FCA Violations By A PPP Borrower And Its CEO," Mondaq, January 22, 2021, available at https://www.mondaq.com/unitedstates/insolvencybankruptcy/1028784/doj-announces-first-settlement-to-resolve-alleged-fca-violations-by-a-ppp-borrower-and-its-ceo; Settlement Agreement between United States and Brigham Taylor and SlideBelts Inc. (Jan. 12, 2021), available at https://www.justice.gov/usao-edca/press-release/file/1352931/download.
- see DOJ Press Release, "Former Owners of Therakos, Inc. Pay \$11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients" (November 19, 2020), available at https://www.justice.gov/usao-edpa/pr/former-owners-therakos-inc-pay-115-million-resolve-false-claims-act-allegations.
- see DOJ Press Release, "Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay \$21.36 Million to Resolve False Claims Act Allegations" (September 18, 2019), available at https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million.

[<u>32]</u>
See Granston Remarks.
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