

Record Year for False Claims Act Settlements

WRITTEN BY

Abigail A. Hazlett | Christen Tuttle | Jennifer Onka

In 2021, the Department of Justice (DOJ) [obtained more than \\$5.6 billion in False Claims Act settlements and judgments](#) — the largest amount since 2014 and the second largest amount recorded. This number is inflated by the massive \$2.8 billion Purdue settlement related to its opioid promotion. But even after discounting the recovery amount by \$2.8 billion, that leaves [approximately \\$1.1 billion in non *qui tam* claims](#), far exceeding previous recovery amounts under the Trump administration. Moreover, while falling slightly below pre-pandemic levels, *qui tam* recoveries remained consistent with 2020 numbers. In addition, the U.S. Securities and Exchange Commission's (SEC) whistleblower program [announced a record-breaking year](#) in terms of number of awards, dollars awarded, and number of whistleblower tips received.

The health sciences industry should take note: Both the DOJ and SEC are stepping up enforcement action, and there are several indications this trend will only continue.

First, as noted above, the number of non-*qui-tam* actions rose dramatically under the Biden administration. Recent statements from Biden administration officials confirm that the administration is committed to making it easier to prosecute wrongdoers and to incentivize whistleblowers to come forward.

In his March 3 [remarks](#) to the ABA Institute on White Collar Crime, Attorney General Merrick Garland affirmed that “prosecution of corporate crime is a Justice Department priority.” This commitment is not merely lip service, but it is backed by a FY 22 budget increase that will allow the DOJ to hire 120 attorneys, in addition to the 34 attorneys the Criminal Division’s Fraud Section hired in 2021.

And in February 2022, SEC Chair Gary Gensler issued a [statement](#) on proposed amendments to rules governing the SEC’s whistleblower program. The amendments seek to undo [previous amendments](#) adopted by the Trump administration in September 2020, which some feared would discourage whistleblower activity. With these new amendments, the SEC seeks to “ensure that whistleblowers are both incentivized and appropriately rewarded” for reporting potential violations of the law.

Second, both AG Garland’s remarks and the DOJ’s press release focused on pandemic-related fraud as a primary area of interest, particularly fraud related to Paycheck Protection Program (PPP) loans. AG Garland stated that he will soon name a chief prosecutor to lead specialized teams dedicated to pandemic fraud. We also anticipate seeing an increased focus on telehealth, which grew exponentially during the pandemic. As our colleagues discussed [here](#), telehealth fraud has been an area of significant focus for the DOJ for the past several years. As the pandemic has highlighted the important role telemedicine plays in increasing health care accessibility and affordability, particularly for traditionally underserved communities, it is presumably here for the foreseeable future. In light of its anticipated permanence and massive scope, enforcement activity is unlikely to

abate.

Finally, a return to in-person activities means the reemergence of potentially high-risk activities, particularly speaker programs. As evidenced by a November 2020 HHS OIG [Special Fraud Alert](#), highlighting the “inherent fraud and abuse risks associated with … company-sponsored speaker programs,” enforcement agencies have long viewed these programs with a skeptical eye. In-person detailing is another area of potential risk because it may increase the risk of off-label promotion or improper remuneration.

Focusing on compliance heads off potential violations and encourages would-be whistleblowers to raise their concerns internally by fostering a culture of ethics and compliance. Failure to demonstrate to employees that their concerns will be taken seriously and addressed appropriately could lead those employees to take their concerns elsewhere. Such was the case in 2018, when James Landolt, a former Mallinckrodt director, took his allegations to a whistleblower firm after he believed that his internal reporting failed to yield corrective action. Per court documents, there was a “years-long internal compliance failure,” which led Landolt to lack “confidence” that senior leadership would do the right thing. It was [recently reported](#) that Landolt will receive more than \$40 million of the recent \$233.7 million settlement between DOJ and Mallinckrodt to resolve allegations that Mallinckrodt knowingly underpaid Medicaid rebates for its drug Achtar.

According to Landolt, the whistleblower laws made him feel like he had “a voice and the power to do something about wrongdoing.” Effective compliance programs can also be an effective tool to empower employees and give them a voice. That is why it is so crucial for companies to invest in a well-designed, well-resourced, and well-functioning compliance program. As 2021 has shown us, it is certain that enforcement agencies are making that investment and welcoming would-be whistleblowers with open arms.

As companies decide what will be their employees’ “new normal,” we recommend reviewing policies on high-risk areas, such as speaker programs and in-person detailing. We also recommend conducting refresher trainings on these policies.

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