

## insights

# DOJ's evolving 'carrot and stick' approach to increasing health care fraud corporate compliance

The carrot or the stick ... which motivates compliance conduct more? Consider it a rhetorical question for now, but it's once again a tactic being deployed by the U.S. Department of Justice to motivate or cajole corporate compliance. In separate announcements over the past several weeks, DOJ dangled two new "carrots" in front of companies involved in fraud investigations and criminal cases. Prior to that, the Department also reminded the public about the significant consequences of finding your business weighed down by DOJ scrutiny in reporting a record year of False Claims Act ("FCA") settlements and recoveries from the federal government's previous fiscal year, ending September 30, 2022.

### DOJ wants claw back of executive comp and bonuses

Most recently, on March 2, 2023, while speaking at the ABA's annual white collar crime conference, Deputy Attorney General Lisa Monaco announced that DOJ is launching a three-year test program that will offer reduced fines to corporations that commit crimes if the company acts to claw back compensation previously paid to executives and employees responsible for the illegal conduct. Additionally, DOJ will require companies that reach a criminal resolution to restructure compensation and bonus programs to punish bad behaviors in the future. Monaco stated in her remarks: "Nothing grabs attention or demands personal investment like having skin in the game, through direct and tangible financial incentives." This announcement is an extension of the efforts previously announced by DOJ, and is also tied to the Department's recent changes to the Corporate Enforcement Policy announced in late-February 2023. TC covered those changes in another recent [Health Law Checkup post available here](#). Together, this approach is intended to prompt companies to police themselves affirmatively, rather than sit back and wait for enforcement authorities to catch bad conduct. DOJ also noted, however, that it will *not* increase punishment against companies that may be prohibited or otherwise unable to pursue claw backs based on international laws.

### False Claims Act recovery exceeds \$2 billion in fiscal year 2022

Looking back slightly, in February 2023, DOJ released its annual statistics for FY2022 FCA settlements and judgments, reporting over **\$2 billion** in recoveries. While not the highest in terms of dollar amount, it is the second-highest number of settlements and judgments under the FCA in one year. For health care companies, there can be no doubt that DOJ's enforcement eye remains squarely on them with more than 75% (over **\$1.7 billion**) of the total coming from that sector, including cases involving virtually every kind of market participant: drug and medical device manufacturers, durable medical equipment ("DME") companies, home health and managed care providers, hospitals, pharmacies, hospice organizations, and physicians. To stress the importance of this significant amount, the \$1.7 billion recovered by DOJ for health care fraud under the FCA only encompasses federal losses and does not cover any additional amounts recouped for state Medicaid programs.

Some noteworthy recoveries and other actions by DOJ in the health care sector include:

- **Drug pricing:** Drug pricing remains a hot political topic, and DOJ appears to be doing its part to address high prices as well.
- DOJ filed suit against Professional Compounding Centers of America Inc. (PCCA), a manufacturer of active pharmaceutical ingredients sold to compounding pharmacies, for allegedly reporting inflated and fraudulent Average Wholesale Price ("AWP") data. In particular, DOJ alleges that the AWP data reported by PCCA caused its pharmacy customers to submit inflated reimbursement claims to the military's TRICARE program, because PCCA's reported AWP did not reflect the actual prices at which it sold those ingredients to pharmacy customers.

- **“Classic” kickbacks:** Every year, DOJ resolves and pursues new cases against health care companies for providing “classic,” unlawful kickbacks.
  - Biogen Inc. paid **\$843.8 million** related to allegations that between 2009 and 2014 the company paid kickbacks such as speaker training and consulting fees to physicians who spoke at Biogen programs related to its multiple sclerosis drugs.
  - Respirationics, Inc. paid **\$24.75 million** relating to allegations that it knowingly provided unlawful kickbacks to DME suppliers in the form of free physician prescribing data to assist sales efforts for DME suppliers.
- **Prior authorization support:** Commercial relationships involving prior authorization support are likely to see continued, if not increased, enforcement scrutiny. Kaleo Inc. paid **\$12.7 million** for alleged false claims for directing physicians to send prescriptions to certain specialty pharmacies that submitted false prior authorization requests to insurers. DOJ also obtained a **\$1.3 million** settlement from Solera Specialty, a specialty pharmacy that allegedly submitted false and misleading prior authorizations for Kaleo’s drug.
- **Physician MSOs:** Although individual enforcement is nothing new, it seems less common that larger numbers of physicians get wrangled in the enforcement net. DOJ obtained settlements **from 32 Texas doctors totaling more than \$5 million** for allegations of improper remuneration, disguised as investment returns, from management service organizations for ordering lab tests from certain entities.
- **Qui Tam recoveries:** Finally, DOJ concluded its FY22 report noting that **over \$1.9 billion**—representing more than 86%—of the \$2.2 billion in total FCA recoveries **came from qui tam (or whistleblower) lawsuits**, and that whistleblowers filed an average of more than 12 cases per week in FY22. While the pace of *qui tams* may continue, it stands to reason that DOJ will likely spend more time harvesting more of its own investigations and prosecutions, considering how other recent press releases from DOJ touted that prosecutors have now essentially cleared their desks from cases backlogged during the Covid-19 pandemic, as court’s grappled with a virtual litigation world.

What is the ultimate takeaway for health care market participants based on all of the recent news from DOJ? First, it is usually better to avoid the scrutiny of enforcement authorities by implementing robust and active compliance programs that deter bad conduct before it happens. Those investments promote the best interests of the company, its customers, and its products and services. Second, because there is no inoculation from bad conduct, DOJ is leveraging new tactics to incentivize or compel companies to self-police and voluntarily come forward when compliance breakdowns occur. Third and finally, as some of the above news may indicate, the consequences of failing to maintain adequate compliance controls and to consider voluntary self-disclosures and other mitigation steps when gaps occur can be painful to the company’s bottom line and its reputation.

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