

## **DOJ Continues to Target Lab Sales Arrangements and Ordering Practices**

Article By:

Kurt R. Erskine

Jessica M. Andrade

Ellen H. Persons

Brea M. Croteau

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Signaling its continued scrutiny of the laboratory industry, the Department of Justice (DOJ) entered into a settlement agreement with Texas lab Genotox Laboratories Ltd. last month related to compensation Genotox paid to sales reps for recommending Genotox's urine drug tests (UDT). Specifically, the settlement agreement states that, between 2014 and 2020, Genotox paid independent contractor sales reps and marketing firms to recommend Genotox's UDTs, and then paid for those recommendations based on a percentage of the revenue it realized from its UDT billing to insurers in violation of the Anti-Kickback Statute (AKS). In 2019, Genotox began transitioning its marketing compensation structure from percentage to fixed rate over concerns with the Eliminating Kickbacks in Recovery Act (EKRA). Still, at least three sales reps continued to get paid on a percentage basis through 2022. The settlement agreement also alleges that Genotox knowingly submitted UDT claims to insurers based on a blanket or standing orders not medically necessary, another focus of DOJ enforcement in the lab space.

Under the agreement, Genotox will pay \$5.9 million to settle the claims a whistleblower brought, Genotox's former billing manager, who will receive approximately \$1 million. Genotox also agreed to enter a five-year Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General, which requires the company to maintain a compliance program, implement a risk assessment program, and hire an independent review organization to review claims Genotox submits to Medicare and Medicaid. In a parallel proceeding, Genotox entered into an 18-month Deferred Prosecution Agreement with the U.S. Attorney's Office for the Western District of Texas to resolve a criminal investigation regarding the same conduct. This highlights how these cases, depending on the U.S. Attorney's Office and the prosecutor involved, can have civil implications and criminal penalties even without patient harm.

This settlement is yet another in a string of settlements between the DOJ and labs, indicating the Department's continued and increasing interest in sales rep compensation and ordering practices.

Sales rep compensation, particularly percentage-based commission payments, implicates the AKS and the newer, less frequently utilized EKRA. Labs should ensure robust compliance programs and obtain legal advice regarding marketing compensation structures and test ordering practices to avoid potential DOJ scrutiny.

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