

[Health Law Daily Wrap Up, LABORATORIES—CORPORATE INTEGRITY AGREEMENTS: Clinical lab settles false claims investigation with \\$3.5M, CIA, \(Jan. 26, 2018\)](#)

Health Law Daily Wrap Up

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By Robert B. Barnett, Jr., J.D.

Primex Clinical Laboratories, Inc., of VanNuys, California, has entered into a five-year Corporate Integrity Agreement (CIA) with the HHS Office of Inspector General (OIG) contemporaneously with a settlement agreement with the U.S. In return for settling the false claims investigation by agreeing to the conditions set forth in the CIA, Primex will not be excluded from federal health care programs ([Corporate Integrity Agreement](#), December 29, 2017).

False Claims action. Two whistleblowers filed a [qui tam action](#) against Primex and the owner of DNA Stat, LLC, a laboratory management company that employed sales representatives and licensed pharmacists. The relators alleged several kickback schemes, including (1) creating the appearance of paying physicians to provide clinical study data for a Primex-sponsored study related to pharmacogenetic testing when, in fact, the physicians were being paid for referring patients for the testing; (2) providing physicians with in-office medical technicians to do work related to the Primex-sponsored study in an effort to induce those physicians to order pharmacogenetic tests from Primex; and (3) that the pharmacogenetic tests were not medically necessary. After the United States chose to participate in the suit, the government added a contention that DNA Stat's agreements with Primex and with its sales representatives took into account the volume and value of referrals physicians made to Primex for pharmacogenetic tests when calculating compensation.

Settlement. To settle the claims, Primex agreed to pay \$3.5 million, and the owner of DNA Stat will pay \$270,000; the relators will receive \$754,000. [Jason Mehta](#), a partner at [Bradley](#) and former Assistant U.S. Attorney, told Wolters Kluwer that the Department of Justice will continue focusing on fraud in the context of clinical diagnostic testing. He said, "As more and more money is spent on clinical testing, these services will continue to be a growth area for health care fraud prosecutions and I expect the Department's interest, as well as whistleblowers' interest, will only continue in the coming months and years."

CIA. The agreement between Primex and the OIG contains the standard CIA provisions, including: (1) appointing a compliance officer within 90 days; (2) developing written standards and policies, including policies to ensure that Focus Arrangements do not violate the Anti-Kickback Statute or the Stark Law; (3) implementing a comprehensive employee training program; (4) retaining an independent review organization to conduct annual reviews; (5) establishing a confidential disclosure program; (6) restricting employment of ineligible persons; (7) reporting overpayments and ongoing investigations; and (8) providing an implementation report and annual reports to OIG. In the CIA, Primex also agreed to stipulated penalties for material breaches of CIA requirements imposed on Primex.

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