



## **Millennium Health and DOJ Settle False Claims Act Allegations for \$256 Million**

Sara M. Lord

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On October 19, 2015, the Department of Justice (DOJ), through the United States Attorney's Office for the District of Massachusetts, announced that Millennium Health (formerly Millennium Laboratories) had agreed to resolve allegations under the False Claims Act (FCA) for \$256 million. Millennium, which is one of the largest urine drug testing laboratories in the United States was accused of billing Medicare, Medicaid, and other federal health care programs for medically unnecessary drug testing and genetic testing, and providing kickbacks to physicians to induce business. The settlement incorporates two FCA settlements between the company and the DOJ, one involving urine drug testing and one involving pharmacogenetic testing, as well as an administrative settlement between Millennium and the Department of Health and Human Services (HHS).

Under the urine drug testing settlement, Millennium has agreed to pay \$227 million to resolve allegations that were made in seven separate *qui tam* actions that it systematically billed federal health care programs for excessive and unnecessary drug testing from January 1, 2008 through May 20, 2015. The complaint filed by the United States alleges that Millennium caused physicians to order excessive numbers of urine drug tests, based, in part, on the use of "custom profiles." Rather than being customized for patients individually, these profiles functioned as standing orders for physicians to order large number of tests without an individualized assessment of each patient's needs. The government's complaint further alleges that Millennium violated the Stark Law and Anti-Kickback Statute by providing physicians with free drug test cups on the express condition that the physicians return the specimens for hundreds of dollars' worth of additional testing.

Under the pharmacogenetic testing settlement, Millennium will pay \$10 million to resolve allegations, made in another *qui tam* action, that it submitted false claims to federal health care programs for medically unnecessary genetic testing that was routinely performed without an individualized assessment of need, from January 1, 2012 through May 20, 2015.

In addition to resolving the FCA allegations, Millennium also reached an agreement with the Centers for Medicare & Medicaid Services (CMS) to pay \$19 million to resolve administrative actions regarding Millennium's claims to Medicare for certain drug test billing codes. These claims were the subject of claim denials and an overpayment action initiated by CMS and its contractors.

In connection with both FCA settlements, Millennium also has entered into a Corporate Integrity Agreement with the HHS, Office of Inspector General.

## Authors and Contributors

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**Sara M. Lord**

Partner, DC Office  
202.677.4054  
sara.lord@agg.com

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**Atlanta Office**

171 17th Street, NW  
Suite 2100  
Atlanta, GA 30363

**Washington, DC Office**

1775 Pennsylvania Avenue, NW  
Suite 1000  
Washington, DC 20006

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