Government of the District of Columbia OFFICE OF THE INSPECTOR GENERAL $\star \star \star$



Inspector General October 30, 2014

ORGANON TO PAY \$31 MILLION TO SETTLE ALLEGATIONS OF FALSE BILLINGS TO STATE MEDICAID PROGRAMS

Interim Inspector General Blanche L. Bruce announced today that the District of Columbia has joined with other states and the federal government to settle allegations that drug manufacturer Organon underpaid rebates to the D.C. Medicaid program, offered improper financial incentives to nursing home pharmacy companies, promoted its antidepressants for unapproved uses, and misrepresented its drug prices to the D.C. Medicaid program. The settlement, valued at \$31 million, resulted from two whistleblower lawsuits filed in the United States District Court for the District of Massachusetts and the United States District Court for the Southern District of Texas, and resolves four separate allegations:

- Underpaid Rebates: The government alleged that Organon did not include rebates and discounts in its best price reporting and, therefore, underpaid rebates owed to the DC Medicaid Program. The federal Medicaid Drug Rebate Program requires that all drug manufacturers that supply products to Medicaid recipients, provide Medicaid programs the benefit of the "best price" available for that product.
- **Kickbacks:** The government alleged that Organon offered nursing home pharmacy companies market share discounts and rebates to encourage the use of antidepressants Remeron and Remeron SolTab over competing antidepressants, which violated the federal Anti-Kickback Statute, and resulted in the submission of false claims to the D.C. Medicaid program.
- **Off-Label Promotion:** The government alleged that Organon promoted the sale and use of Remeron and Remeron SolTab for conditions that were not approved as safe and effective by the Food and Drug Administration. Specifically, Organon marketed drug side effects as possible benefits and promoted the use of Remoron in children and adolescents.
- **Pricing Misrepresentations:** The government alleged that Organon reported false and inflated prices to the D.C. Medicaid program, then offered the drugs at a lower cost as a financial inducement to nursing home pharmacy companies by increasing the "spread" between the actual cost of the drug to pharmacies versus the amount that the Medicaid program reimburses for the drugs.

Organon was headquartered in Oss, Netherlands. The company's assets are now owned by Merck.

A National Association of Medicaid Fraud Control Units team participated in the settlement negotiations with Organon on behalf of the states and included representatives from the Offices of the Attorneys General for the states of California, New York, Ohio, and Texas. Ms. Bruce commended the efforts of Medicaid Fraud Control Unit attorney Marcus A. Weeks on this matter.