

**GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General**



**Inspector General
April 29, 2013**

PAR PHARMACEUTICALS TO PAY \$22.5 MILLION IN SETTLEMENT

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with other states and the federal government and reached agreement with Par Pharmaceutical Companies, Inc. (“Par”) to settle allegations that Par promoted sales of the drug Megace ES for uses not approved as safe and effective by the Food and Drug Administration (“FDA”) and not covered by the state Medicaid programs.

Par will pay the states and the federal government a total of \$22.5 million dollars in civil damages to compensate Medicaid, Medicare, and various federal healthcare programs for harm suffered as a result of its conduct.

In addition, on March 5, 2013, Par pleaded guilty in the United States District Court for the District of New Jersey to an information charging Par with a criminal misdemeanor for misbranding Megace ES in violation of the Federal Food Drug and Cosmetic Act (“FDCA”), and was ordered to pay \$18 million in fines and \$4.5 million in criminal forfeiture. The FDCA requires companies such as Par to specify the intended uses of a product in its new drug application to the FDA. Once approved, a drug may not be distributed in interstate commerce for unapproved or “off-label” uses until the company receives FDA approval for the new intended uses.

The civil settlement agreement requires Par to pay \$22.5 million to the states and the federal government to resolve claims arising from its off-label marketing of Megace ES, a megestrol acetate drug product which was approved by the FDA to treat anorexia, cachexia, or other significant weight loss suffered by patients with AIDS. The civil settlement resolves allegations that Par, by promoting the sale and use of Megace ES for other uses that were not FDA-approved and not covered by Medicaid, Medicare, or other federal health care programs, caused false claims to be submitted to these programs. The states and the federal government further alleged that Par deliberately and improperly targeted sales to elderly nursing home residents with weight loss, whether or not such patients suffered from AIDS, and launched a long-term care sales force to market to this population. During this marketing campaign, Par was allegedly aware of adverse side

effects associated with the use of megestrol acetate in elderly patients, including an increased risk of deep vein thrombosis, toxic reactions in elderly patients with impaired renal function, and mortality.

The states and the federal government further alleged that Par made unsubstantiated and misleading representations about the superiority of Megace ES over generic megestrol acetate for elderly patients to encourage providers to switch patients from generic megestrol acetate to Megace ES, despite having conducted no well-controlled studies to support a claim of greater efficacy for Megace ES. Except as admitted in Par's plea agreement, the claims settled by the civil settlement agreement are allegations only, and there has been no determination of liability as to those claims.

As a condition of the settlement, Par has entered into a Corporate Integrity Agreement ("CIA") with the United States Department of Health and Human Services, Office of the Inspector General, which will closely monitor the company's future marketing and sales practices. In addition, the CIA prohibits Par from providing compensation to sales representatives or their managers based on the volume of sales of Megace ES and any branded successor megestrol acetate drug.

This settlement is based on three *qui tam* cases that were filed in the United States District Court for the District of New Jersey by private individuals who filed actions under state and federal false claims statutes. As part of the settlement, the District of Columbia has received \$59,805 in restitution and other recovery.

A National Association of Medicaid Fraud Control Units team participated in the investigation and conducted the settlement negotiations with Par on behalf of the settling states. Team members included representatives from the Offices of the Attorneys General for the states of Arizona, Florida, New York and Ohio. Inspector General Willoughby acknowledged Medicaid Fraud Control Unit attorney Elaine Block for handling this matter for the District.