

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
August 19, 2010



**ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC TO PAY MORE
THAN \$50 MILLION TO STATE MEDICAID PROGRAMS TO SETTLE
CLAIMS OF OFF-LABEL MARKETING**

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with the states in reaching an agreement in principle with Ortho-McNeil-Janssen Pharmaceuticals, Inc. to settle allegations that the company engaged in off-label marketing of its anticonvulsant drug, Topamax. Ortho-McNeil-Janssen will pay the state Medicaid Programs a total of \$50,688,483.52, which will be allocated to the states, D.C., and the federal government based on their joint funding of Medicaid.

The state settlement is part of the recent \$75,370,000 million settlement between the company and the United States that was announced by the United States Attorney's Office for the District of Massachusetts on April 29, 2010. The remainder of the settlement, \$24,106,000, is allotted for federal programs such as Medicare, TRICARE, and the Department of Veterans Affairs.

Ortho-McNeil-Janssen Pharmaceuticals is settling allegations that it engaged in a company-wide scheme to improperly market Topamax for unapproved uses. Topamax is a drug that is approved by the Food and Drug Administration (FDA) to treat epileptic symptoms and to aid in the prevention of migraine symptoms. Despite Topamax's limited indication, it is alleged that Ortho-McNeil-Janssen marketed the drug to physicians for a variety of psychiatric conditions (including, but not limited to, bipolar disorder and drug and alcohol dependency), and that as a result government healthcare programs such as Medicaid paid for more Topamax prescriptions than they should have.

As part of the settlement, Ortho-McNeil-Janssen Pharmaceuticals has entered into a Corporate Integrity Agreement 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.

This settlement is based on two *qui tam* cases that were filed in the United States District Court for the District of Massachusetts by relators – private parties who filed actions under state and federal false claims statutes.

The National Association of Medicaid Fraud Control Units Ortho-McNeil-Janssen Pharmaceuticals Negotiating Team participated in the investigation and represented the interests of the states during negotiations with Ortho-McNeil-Janssen Pharmaceuticals, Inc. Team members included representatives from Michigan, Massachusetts, California, and Virginia. Mr. Willoughby acknowledged the Department of Health Care Finance for its assistance with providing data. In addition, he recognized auditor LaShawn Brooks and attorney Dangkhwa Nguyen of the Office of Inspector General Medicaid Fraud Control Unit who worked on the data analysis for the District's claim.