

**Government of the District of Columbia**  
**OFFICE OF THE INSPECTOR GENERAL**



Inspector General  
March 3, 2014

**ENDO PHARMACEUTICALS TO PAY \$172.9 MILLION TO RESOLVE OFF LABEL  
MARKETING ALLEGATIONS**

Inspector General Charles J. Willoughby announced today that the District of Columbia has joined with other states and the federal government in a global settlement with Endo Pharmaceuticals, a wholly owned subsidiary of Endo Health Solutions (Endo), a manufacturer of pharmaceutical products. The settlement resolves civil allegations of unlawful marketing practices aimed at promoting the drug Lidoderm for conditions not approved by the Food and Drug Administration (FDA). According to the *qui tam*, or whistleblower lawsuit, Endo unlawfully marketed Lidoderm for use in connection with lower back pain or chronic pain. The FDA approved Lidoderm only for the treatment of pain associated with post-herpetic neuralgia, more commonly known as “shingles.”

Under the terms of the civil settlement, Endo will pay \$172,916,967 to the states and federal governments and a \$20,800,000 criminal fine. Endo will also enter into a Deferred Prosecution Agreement with the Northern District of New York and a Corporate Integrity Agreement with the Department of Health and Human Services Office of the Inspector General. The lawsuit was filed in the Eastern District of Pennsylvania under the provisions of the federal False Claims Act and analogous state false claims statutes.

Between March 1999 and December 2007, Endo knowingly promoted the sale and use of Lidoderm for use in connection with lower back and chronic pain, which were not medically accepted indications and were not covered by the state Medicaid program. Endo’s alleged unlawful conduct caused false and/or fraudulent claims to be submitted to the District Medicaid program, causing the program to pay Endo more than \$140,000 to which it was not entitled.

A team from the National Association of Medicaid Fraud Control Units worked with the federal government on the investigation and conducted settlement negotiations with Endo on behalf of the states. Team members included representatives from the Offices of the Attorneys General for the states of New York, Texas, Florida, and Oregon.