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ENDO HEALTH SOLUTIONS AND ENDO PHARMACEUTICALS OF MALVERN, PA TO PAY $171.9 MILLION TO RESOLVE CIVIL FALSE CLAIMS ALLEGATIONS

PHILADELPHIA -- Specialty pharmaceuticals company Endo Health Solutions, Inc. and its subsidiary Endo Pharmaceuticals Inc. (Endo), which is headquartered in Malvern, Pennsylvania, have agreed to pay $171.9 million to resolve civil allegations of off-label marketing of their adhesive pain patch Lidoderm. The civil resolution is the result of whistleblower allegations filed in the Eastern District of Pennsylvania and was announced today by the Department of Justice and United States Attorney Zane David Memeger. Separately handled and announced today by the Department of Justice and the Office of the United States Attorney for the Northern District of New York is Endo Pharmaceuticals Inc.'s additional deferred prosecution agreement to pay $20.8 million in criminal forfeiture and fines to resolve related criminal liability. The criminal resolution is discussed at http://www.justice.gov/opa/pr/2014/February/14-civ-187.html.

Civil Settlement in Eastern District of Pennsylvania. Lidoderm was FDA approved only for relief of pain associated with post-herpetic neuralgia ("PHN"), a painful condition that affects some individuals with a history of shingles. The civil settlement resolves allegations under the False Claims Act that, between March 1999 and December 2007: (1) Endo knowingly promoted Lidoderm for treatment of non-FDA-approved (off-label) conditions, including lower back pain and chronic pain; (2) because uses of the product for those conditions were not medically accepted indications, federal health care programs did not cover such uses; and (3) Endo's off-label promotion caused providers to submit false reimbursement claims for such non-covered uses to Medicare, Medicaid, and other federal health care programs. Of the $171.9 million that Endo has agreed to pay to resolve these civil claims, the company will pay $137,700,172 to the United States and $34,209,981 to various States and the District of Columbia.

Under *qui tam* (whistleblower) provisions of the federal False Claims Act, certain private citizens may bring civil actions on behalf of the United States and may share in any recovery. The settled Lidoderm civil allegations include those originally brought by whistleblower Peggy Ryan in the first of three *qui tam* lawsuits now pending in federal court in the Eastern District of Pennsylvania. Ms. Ryan is a former Endo sales representative whose sales territory included upstate New York. The whistleblower share of the settlement has not yet been determined.

"Off-label marketing can undermine the doctor-patient relationship and adversely influence the clear and honest judgment of doctors that their patients rely on and trust. Pharmaceutical companies have a legal obligation to promote their drugs for only FDA-approved uses. This obligation takes precedence over the company's bottom line," said Memeger.

"FDA's drug approval process is designed to ensure that companies market their products for uses that are proven to be safe and effective," said Stuart F. Delery, Assistant Attorney General for the Civil Division of the United States Department of Justice. "We will hold accountable those who circumvent that process in pursuit of financial gain."

Corporate Integrity Agreement. As part of the settlement, Endo Pharmaceuticals Inc. agrees to enter into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS"). The CIA requires Endo to implement measures designed to avoid or promptly detect conduct similar to that which allegedly gave rise to this matter, including measures requiring: (1) an internal risk assessment and mitigation program; (2) numerous internal and external reviews of promotional and other practices; (3) key executives and individual Board members to sign compliance certifications; and (4) public reporting of information about Endo's financial arrangements with physicians.

"By marketing Lidoderm for uses not covered by Federal health care programs, Endo profited at the expense of taxpayers and could have put patients at risk," said Daniel R. Levinson, the HHS Inspector General. "Under our CIA Endo agrees to promote its products legally, while board members and top executives are specifically held accountable for compliance."

Investigating these matters were the Federal Bureau of Investigation; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; and the respective Inspector Generals' Offices for HHS, the U.S. Postal Service, and the U.S. Office of Personnel Management.

The civil settlement was jointly handled: in the Eastern District of Pennsylvania, by Civil Chief Margaret L. Hutchinson, Deputy Chief Mary Catherine Frye, and Assistant U.S. Attorney Gerald B. Sullivan, with analysis by Auditors Denis J. Cooke and Dawn Wiggins; and at the Commercial Litigation Branch of the U.S. Department of Justice's Civil Division, by Trial Attorney Brian McCabe. Assistance was provided by the HHS Office of Counsel to the Inspector General; the FDA's Office of Chief Counsel; and the National Association of Medicaid Fraud Units.

The settled civil claims are allegations only. There has been no determination of civil liability. The civil lawsuits are docketed in the Eastern District of Pennsylvania as *U.S.A. et al. ex rel. Ryan v. Endo Pharmaceuticals Inc.*, No. 05-cv-3450; *U.S.A., et al. ex rel. Weathersby, et al.*, No. 10-cv-2039; and *U.S.A. ex rel. Dhillon v. Endo Pharmaceuticals*, No. 11-cv-7767.

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