Department of Justice

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United States Files Complaint Against Forest Laboratories for Allegedly Violating the False Claims Act

Pharmaceutical Company Allegedly Marketed Drugs for Unapproved Pediatric Use and Paid Kickbacks

WASHINGTON – A Complaint was unsealed today in U.S. District Court in Massachusetts against a New York pharmaceutical company for alleged False Claims Act violations arising from the company's marketing the drugs Celexa and Lexapro for unapproved pediatric use and for paying kickbacks to induce physicians to prescribe the drugs.

Acting Assistant Attorney General Michael F. Hertz; United States Attorney Michael J. Sullivan; Warren T. Bamford, Special Agent in Charge of the Federal Bureau of Investigation - Boston Field Division; Susan J. Waddell, Special Agent in Charge of Health and Human Services - Office of Inspector General, Office of Investigations; Mark Dragonetti, Resident Agent in Charge of the Food and Drug Administration, Office of Investigations - Office of Inspector General; and Jeffrey Hughes, Special Agent in Charge of the Northeast Field Office of the Veterans Affairs Office of the Inspector General, announced that the civil Complaint against Forest Laboratories Inc., of New York, New York, alleged that the company's illegal promotional practices surrounding its antidepressant drugs Celexa and Lexapro caused thousands of false and fraudulent claims to be submitted to federal health care programs.

The Complaint alleges that a double-blind, placebo-controlled, pediatric trial found Celexa no more effective than the placebo for pediatric use and that, in the study, more patients taking Celexa attempted suicide or reported suicidal thoughts than those in the group taking the placebo. The negative efficacy data led the FDA to deny Forest's request to approve Celexa for pediatric use. It is further alleged that, despite the FDA's denial of a pediatric indication, Forest actively promoted pediatric use of the drugs and misled physicians and the public by failing to disclose the results of the negative study. The same study was among those later considered by the FDA when it mandated that Forest add a "black box" warning to both the Celexa and Lexapro labels.

The Complaint alleges that Forest sought to induce physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment and other valuable goods and services, all in violation of the federal anti-kickback statute.

Neither Medicaid nor TRICARE ordinarily cover drugs for off-label uses unless the off-label use is for a medically accepted indication. The United States alleges that federal health care programs have paid thousands of false and fraudulent claims for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use and/or were ineligible for payment as a result of illegal kickbacks paid by Forest.

Prior to filing its Complaint, the government had intervened in two separate whistleblower actions against Forest that had been commenced under the qui tam provisions of the False Claims Act. The False Claims Act allows for private persons to file whistleblower suits to provide the government information about wrongdoing. Under the statute, if it is established that a person has submitted or caused others to submit false or fraudulent claims to the United States, the government can recover treble damages and $5,500 to $11,000 for each false or fraudulent claim filed. If the Government is successful in resolving or litigating its claims, a proper whistleblower can receive a share of between 15 percent and 25 percent of the amount recovered.

This investigation was conducted by the U.S. Attorney's Office for the District of Massachusetts, the Civil

Division of the U.S. Department of Justice, the Federal Bureau of Investigation, the Office of Inspector General of the Department of Health and Human Services, the Office of Criminal Investigations of the Food and Drug Administration and the Office of Inspector General of the Department of Veteran's Affairs.

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