The United States Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE
WEDNESDAY, SEPTEMBER 15, 2010
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DRUG MAKER FOREST PLEADS GUILTY; WILL PAY MORE THAN $313 MILLION TO RESOLVE CRIMINAL CHARGES AND FALSE CLAIMS ACT ALLEGATIONS

Boston, Mass. - Forest Pharmaceuticals, Inc., a subsidiary of New York City-based Forest Laboratories, Inc., has agreed to plead guilty to charges relating to obstruction of justice, the distribution of Levothroid, an unapproved new drug used to treat hypothyroidism, and the illegal promotion of Celexa, an anti-depressant drug for use in treating children and adolescents.

The companies also agreed to settle pending False Claims Act allegations that Forest caused false claims to be submitted to federal health care programs for the drugs Levothroid, Celexa, and Lexapro, another anti-depressant drug. Forest has agreed to pay more than $313 million to resolve criminal and civil liability arising from these matters.

Tony West, Assistant Attorney General of the Justice Department's Civil Division; United States Attorney Carmen M. Ortiz; Mark Dragonetti, Special Agent in Charge of the Food and Drug Administration, Office of Criminal Investigations; Richard DesLauriers, Special Agent in Charge of the Federal Bureau of Investigation - Boston Field Office; Susan J. Waddell, Special Agent in Charge of Health and Human Services, Office of Inspector General; and Jeffrey Hughes, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of Inspector General, Office of Investigations - Northeast Field Office, announced that Forest Pharmaceuticals agreed to plead guilty to one criminal felony count of obstructing justice, one criminal misdemeanor count of distributing an unapproved new drug in interstate commerce, and one criminal misdemeanor count of distributing a misbranded drug in interstate commerce. Under the plea agreement, Forest Pharmaceuticals will pay a criminal fine of $150 million and will forfeit an additional $14 million in assets. Forest Pharmaceuticals' guilty plea and sentence is not final until accepted by the U.S. District Court. Forest also will pay over $149 million to resolve allegations under the False Claims Act, including a civil complaint filed by the United States in February 2009.

Under the Food, Drug and Cosmetic Act (FDCA), a manufacturer is required to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) and obtain the agency's approval before distributing a "new drug" in interstate commerce. In this NDA, the manufacturer is required to set forth information concerning the manufacturing processes and composition of the drug, and provide sufficient data generated in adequate and well-controlled clinical investigations to demonstrate that the drug is safe and effective for its specified use. After the FDA approves the product as safe and effective for a specified use, any promotion by the manufacturer for other uses – known as "off label" uses – renders the product misbranded.

Today's resolution concerns three drugs distributed by Forest: Levothroid, Celexa and Lexapro. Levothroid was an orally administered levothyroxine sodium drug used to treat hypothyroidism, a condition in which an individual has a thyroid deficiency. The anti-depressant drugs Celexa and Lexapro were, during the time period at issue, approved only for use in treatment of adult depression.

In the criminal information, the government alleges that Forest Pharmaceuticals began distributing Levothroid in the early 1990s without first obtaining FDA approval. Orally administered levothyroxine sodium drugs had been on the market to treat hypothroidism since the 1950s, and manufacturers had introduced these drugs into the market without first obtaining FDA approval. In 1997, however, the FDA announced that these drugs were “new drugs” under the FDCA and needed the agency’s approval. Nonetheless, because the FDA deemed the drugs to be medically necessary, manufacturers were given four years – until Aug. 14, 2001 – in which to conduct the necessary studies and obtain FDA approval. Later, in order to meet continuing patient demand, the FDA announced that, as a matter of enforcement discretion, the agency would permit manufacturers of unapproved levothyroxine sodium drugs to continue distributing their unapproved drugs after Aug. 14, 2001, on certain conditions. One of those conditions was that any manufacturer which had not obtained NDA approval for its levothyroxine sodium drug product needed to comply with a two-year, gradual distribution phase-down of its unapproved drug until it obtained FDA approval to distribute the drug.

According to the criminal charges, Forest Pharmaceuticals made a deliberate decision to continue distributing its unapproved Levothroid product in quantities far exceeding the amounts permitted by the FDA’s distribution phase-down plan. The criminal information further alleges that, on Aug. 7, 2003, the FDA sent a Warning Letter advising that Forest Pharmaceuticals was no longer entitled to distribute its unapproved Levothroid product because the company had made a deliberate decision not to comply with the FDA’s distribution phase-down plan. After receiving the warning letter, Forest Pharmaceuticals directed its employees at its St. Louis distribution center to work overtime until approximately 1:00 a.m. the following morning and, during that time, to continue shipping as much of its unapproved Levothroid as possible.

The criminal charges further allege that Forest Pharmaceuticals submitted inaccurate information to the FDA as part of its NDA submission for Levothroid and that Forest Pharmaceuticals obstructed an FDA regulatory inspection concerning the data submitted in the Levothroid NDA. Specifically, when FDA inspectors saw a portable humidifier in a testing room at a 2003 inspection of a manufacturing plant in Cincinnati, certain company management personnel falsely advised the investigators that the portable humidifier was merely being stored in the room and had not been used for humidity control, when in fact it had been.

The company also has resolved civil False Claims Act allegations for its continued distribution of unapproved Levothroid after August 14, 2001, and for failing to advise the Centers for Medicare and Medicaid Services that the drug no longer qualified for coverage by government health care programs, thereby causing false claims to be submitted to those programs.

Forest Pharmaceuticals halted its commercial distribution of its unapproved version of Levothroid as of Aug. 9, 2003. Since the fall of 2003, Forest Pharmaceuticals has been commercially distributing a different orally administered levothyroxine sodium drug, also called Levothroid, in accordance with a supply agreement with Lloyd Pharmaceuticals. This resolution does not involve that product.

Regarding Celexa, the criminal information and the United States’ False Claims Act complaint allege that Forest Pharmaceuticals promoted the drug for unapproved pediatric use. Despite a limited approval only for adult depression, Forest Pharmaceuticals promoted Celexa for use in treating children and adolescents suffering from depression. The government alleges that, in conjunction with this off-label promotion, Forest Pharmaceuticals publicized and circulated the positive results of a double-blind, placebo-controlled Forest study on the use of Celexa in adolescents while, at the same time, Forest Pharmaceuticals failed to discuss the negative results of a contemporaneous double-blind, placebo-controlled European study on the use of Celexa in adolescents.

The government further alleges that Forest Pharmaceuticals’ off-label promotion consisted of

various sales techniques, including directing its sales representatives to promote pediatric use of Celexa in sales calls to physicians who treated children and adolescents, and hiring outside speakers to talk to pediatric specialists about the benefits of prescribing Celexa to children and teens. The False Claims Act complaint also alleges that Forest engaged in such marketing conduct in connection with Lexapro, which, at that time, also lacked any approvals for pediatric use.

The civil complaint further alleges that Forest used illegal kickbacks to induce physicians and others to prescribe Celexa and Lexapro. The kickbacks allegedly included expensive meals, lavish entertainment, and cash payments disguised as grants or consulting fees. The civil complaint alleges that, as a result of the foregoing conduct, Forest caused false claims to be submitted to federal health care programs.

Lexapro was approved for use for acute and maintenance treatment of Major Depressive Disorder in adolescents, 12 - 17 years of age, on March 19, 2009, years after the conduct at issue in the government investigation.

“Forest Pharmaceuticals deliberately chose to pursue corporate profits over its obligations to the FDA and the American public,” said Carmen Ortiz, U.S. Attorney for the District of Massachusetts. “The company knew that it did not have FDA approval to distribute Levothroid. Instead of complying with the FDA’s phase-down schedule, which would have permitted the company to continue to distributing a limited amount of its unapproved drug, Forest Pharmaceuticals instead decided to flout the law rather than lose sales. This was completely unacceptable.”

“We will not tolerate any company that obstructs justice and illegally promotes drugs that were not approved to treat children,” said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. “Forest Pharmaceuticals has pled guilty to breaking the law. The Justice Department will continue to ensure that taxpayers do not foot the bill when such unlawful and improper conduct occurs.”

Richard DesLauriers, Special Agent in Charge of the FBI’s Boston Field Division said, “The completion of this investigation, and those ongoing, reflect law enforcement's cooperative efforts to identify individuals and companies who seek to line their pockets at the expense of the health care system and the safety of each of us. This year alone, the Boston Division of the FBI and its law enforcement partners obtained eight convictions and recovered $2.45 billion in fines, restitution, forfeitures, civil settlements and seizures from such investigations.”

Department of Veterans Affairs Inspector General George J. Opfer said, “Our office is committed to protecting those veterans from harm done intentionally or indirectly by pharmaceutical companies who promote off label marketing for profit and distribute unapproved drugs to not only our nation’s heroes, but our fellow Americans.”

The civil settlement covers various lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which allows private citizens with knowledge of fraud to bring civil actions on behalf of the United States and share in any recovery. As part of the civil settlement, more than $88 million will be distributed to the federal government and more than $60 million will be distributed to and shared by the states. As part of today’s resolution, the private whistleblowers will receive approximately $14 million from the federal share of the settlement amount. The cases resolved by the civil settlement are United States ex rel. Christopher R. Gobble, et al. v. Forest Laboratories, Inc. & Forest Pharmaceuticals, Inc.; United States ex rel. Joseph Piacentile, et al. v. Forest Laboratories, Inc.; and United States ex rel. Constance Conrad v. Forest Pharmaceuticals, Inc., et al.

“Today’s announcement demonstrates the government’s commitment to targeting companies

that choose to disregard their regulatory obligations and pursue profits over the public's health," said FDA Commissioner Margaret M. Hamburg, MD. "The FDA applauds the hard work of the Department of Justice and our law enforcement counterparts in bringing about this successful result."

"This combined resolution reflects this Office's continuing emphasis on pursuing pharmaceutical companies that fail to meet their commitment to be law-abiding corporate citizens," said U.S. Attorney Ortiz. "Congress has created a drug-approval system to protect the American public by ensuring that only those drugs that have been proven to be safe and effective are on the market. Patients have a right to receive only drugs that satisfy this requirement, and doctors and patients have a right to receive accurate and complete information about drugs so that they can make fully informed treatment decisions."

Forest Laboratories also has signed a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). This five-year agreement requires Forest to implement a compliance program that addresses promotional activities and regulatory functions. Among other things, the CIA requires that the Board of Directors (or a committee of the Board) annually review the company's compliance program with the help of an outside expert and certify its effectiveness; that certain senior executives annually certify that their departments or functional areas are compliant; that Forest send doctors a letter notifying them about the settlement; and that the company post on its website information about payments to doctors, such as honoraria, travel or lodging. Forest is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches.

"The safety of the public depends upon a process that approves drugs for specific uses. Forest Pharmaceuticals' off-label marketing and marketing an unapproved drug undermined that protection and potentially put public safety at risk. We cannot and must not tolerate this corporate behavior," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "OIG will oversee an agreement that will increase the company's accountability for its marketing practices and will make its actions more transparent."

This settlement is part of the United States Attorney's Office ongoing emphasis on combating health care fraud. Since January 2009, Ortiz's Health Care Fraud Unit in Boston has recovered more than $2.8 billion in criminal fines, forfeiture and civil recoveries. These recoveries account for a significant portion of all the nationwide recoveries in health care fraud cases since January 2009.

The criminal case was investigated and prosecuted by Assistant United States Attorney James E. Arnold of the United States Attorney's Office for the District of Massachusetts and Trial Attorney Jeffrey I. Steger of the Justice Department's Office of Consumer Litigation. The civil investigation and settlement were handled by Assistant United States Attorney Gregg Shapiro of the United States Attorney's Office for the District of Massachusetts and Trial Attorneys Sanjay M. Bhambhani and Eva U. Gunasekera of the Commercial Litigation Branch of the Justice Department's Civil Division. The CIA was negotiated by Mary Riordan and Geeta Kaveti of HHS-OIG. The case was investigated by agents from the Federal Bureau of Investigation, the Office of Inspector General of the Department of Health and Human Services, the Food and Drug Administration's Office of Criminal Investigations, and the Department of Veterans Affairs' Office of Inspector General. Assistance was also provided by Steven Tave, Associate Chief Counsel of FDA's Office of General Counsel, the Office of Personnel Management, the National Association of Medicaid Fraud Control Units, and the offices of various state Attorneys General.

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