JUSTICE NEWS

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Drug Maker Forest Pleads Guilty; To Pay More Than $313 Million to Resolve Criminal Charges and False Claims Act Allegations

WASHINGTON - 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, which at the time was an unapproved new drug, and the illegal promotion of Celexa for use in treating children and adolescents suffering from depression, the Justice Department announced today. 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. Forest has agreed to pay more than $313 million to resolve criminal and civil liability arising from these matters.

Forest Pharmaceuticals Inc. agreed to plead guilty to one criminal felony count of obstructing justice, one criminal misdemeanor count of distributing an unapproved 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 combined 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. Celexa and Lexapro are anti-depressant drugs that, at the time period at issue, were 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, the 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 charges 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-out 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 at a 2003 inspection of a manufacturing plant in Cincinnati, certain company management personnel falsely advised the investigators that the portable humidifier was 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 False Claims Act complaint filed by the United States 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 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. Kickbacks allegedly included cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment. 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.

"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."

"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."

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."

Forest Laboratories has also 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 matter was handled by the U.S. Attorney's Office for the District of Massachusetts and the Civil Division of the Department of Justice. The corporate Integrity Agreement was negotiated by the Office of Inspector General of the Department of Health and Human Services (OIG-HHS). The case was investigated by agents from the FBI, the OIG-HHS, FDA's Office of Criminal Investigations and the Department of Veterans Affairs' Office of Inspector General. Assistance was also provided by FDA's Office of General Counsel, the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

This settlement is part of the government's emphasis on combating health care fraud and another step for the HEAT initiative, which was announced by Attorney General Holder and Secretary Sebelius in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid fraud through enhanced cooperation. One of the most powerful tools in that effort is the FCA, which the Justice Department has used to recover $3.391 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department's total recoveries in FCA cases since January 2009 are $ 4.4691 billion.

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Civil Division

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