NOLAN & AUERBACH, P.A.

Forest Whistleblower Cases Settle for Over $300 Million

Includes Latest Settlement Involving Drug Companies Selling Unapproved Drugs

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FORT LAUDERDALE – WEDNESDAY, SEPTEMBER 15, 2010 – For the second time this month, the national whistleblower law firm of Nolan & Auerbach, P.A. announces another successful whistleblower recovery by their courageous clients, whose cases are returning millions of dollars to the US Treasury for America's healthcare programs. Two weeks ago, the firm represented two of the whistleblowers in a $600 million overall settlement with Allergan, Inc. Today marks the unsealing of its client's case against pharmaceutical manufacturer Forest Laboratories, Inc., and its subsidiary Forest Pharmaceuticals, Inc., which have agreed to pay $42.5 million to resolve allegations that they illegally sold the drug Levothroid, even though the FDA had never proven the drug to be safe or effective at that time. These companies are the latest to settle allegations raised in a multi-defendant lawsuit, claiming that several drug companies have illegally marketed and sold unapproved drugs to Medicaid providers. The lawsuit was brought under the *qui tam*, or whistleblower, provisions of the False Claims Act. This settlement also settles two other *qui tam* actions, which, in total, resulted in the **$149 million** recovery. In addition, Forest has agreed to pay a **$150 million criminal fine**, to forego $14 million in disputed payments and to plead guilty to a misdemeanor charge of introducing this misbranded drug into interstate commerce.

This is the third settlement this year involving unapproved drugs originally exposed in the multi-defendant *qui tam* lawsuit. In the first settlement, EON Laboratories Inc. paid more than $3.48 million to resolve allegations concerning the sale of its unapproved Nitroglycerin extended release product. In the second settlement, Schwarz Pharma and its subsidiary Kremers Urban paid $22 million to resolve allegations concerning the sale of two drugs, Deponit and Hyoscyamine Sulfate Extended Release.

Under the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*, every drug must be approved by the FDA for safety and effectiveness before it can be marketed to the public. However, the FDA has recently acknowledged that there are thousands of unapproved drugs illegally on the market, posing serious health risks to patients, particularly Medicaid recipients, many of whom are elderly or disabled, and who have extensive healthcare needs.

Medicaid provides prescription drug reimbursement only for statutorily defined "Covered Outpatient Drugs," which are drugs that the FDA has approved for safety and effectiveness and that are dispensed by prescription. To be eligible to receive Medicaid payments, drug companies must quarterly certify to the Center for Medicare and Medicaid Services ("CMS") that each "drug" they designate as a Covered Outpatient Drug meets the statutory definition.

The whistleblowers alleged that from August 2001 through December 2005, Forest repeatedly misrepresented to CMS that its drug Levothroid met the definition of a Covered Outpatient Drug. Notably, Forest made these false representations or omissions after the FDA had announced that all oral levothyroxine sodium products, including Levothroid, needed to obtain proper FDA approval for safety and efficacy.

"When pharmaceutical companies falsify information about their drug to Medicaid, they siphon our limited healthcare dollars away from proven medicines," said managing partner **Marcella Auerbach**. "These business practices cause federal and state government health care programs to pay millions of dollars for prescriptions that are not eligible for payment."

According to the whistleblower lawsuit, Forest nearly doubled its illegal sales of Levothroid after the FDA required the phased-down distribution of all unapproved oral levothryoxine sodium products, including Levothroid. All the while, Forest submitted quarterly reports to CMS, falsely stating that Levothroid qualified as a Covered Outpatient Drug.

"When drug companies turn a blind eye to the law and a deaf ear to federal agencies, we should hold those companies responsible," said partner **Jeb White**. "Several drug companies still need to see the light of truth when it comes to the sale of unapproved drugs to Medicaid."

Federal and State False Claims Acts allow private citizens with detailed knowledge of fraud to bring an action on behalf of the governments and to assist in the recovery of the governments' stolen dollars. These statutes allow the government to recover three times the amount it was defrauded, in addition to civil penalties of $5,500 to $11,000 per false claim. Successful whistleblowers can receive between 15 and 30 percent of the governments' recovery.

In all three cases, Forest will pay the federal government $88,833,560.18, plus accrued interest, to settle the civil allegations. The participating States will receive $60,324,497.48, plus accrued interest, as a result of a Medicaid State settlement. The whistleblowers will collectively receive $14,613,070, plus accrued interest, from the federal share of the settlement amount and a yet-to-be-announced share from the States.

The settlement was achieved through the coordinated efforts of the US Justice Department, state attorneys general, and other law enforcement entities including Medicaid Fraud Control Units, and the Office of Inspector General of the US Department of Health and Human Services. Specifically, the federal government was represented by an exceptional team of government attorneys, including Assistant Director Jamie Yavelberg, US Justice Department, Civil Division, Commercial Litigation Branch; Assistant US Attorney Gregg Shapiro, US Attorney's Office for the District of Massachusetts; Senior Trial Counsel Sanjay Bhambhani and Trial Attorney Eva Gunasekera, US Justice Department, Civil Division, Commercial Litigation Branch; and Assistant Inspector General for Legal Affairs Greg Demske, Office of Inspector General of the US Department of Health and Human Services. The participating States were represented by an equally dedicated team of government attorneys, via the National Association of Medicaid Fraud

Control Unit's *Qui Tam* Subcommittee. The committee includes several state representatives, including Massachusetts Assistant Attorney General Robert Patten, Texas Assistant Attorney General Noelle Letteri, Virginia Assistant Attorney General Lelia Beck, and Florida Assistant Attorney General Carlos Rey.

This case is *United States et al., ex rel. Jim Conrad and Constance Conrad v. Forest Pharmaceuticals, Inc, et al.*, No. 02-cv-11738-NG (D. Mass.).

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