Department of Justice

U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE Thursday, August 17, 2017

Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability

Mylan Underpaid Medicaid Rebates on EpiPen

BOSTON – The U.S. Attorney's Office announced today that pharmaceutical companies Mylan Inc. and Mylan Specialty L.P. have agreed to pay $465 million to resolve allegations that they violated the False Claims Act by knowingly misclassifying EpiPen, a branded epinephrine auto-injector drug, as a generic drug to avoid paying rebates owed to Medicaid. Mylan Inc. and Mylan Specialty L.P. are both wholly owned subsidiaries of Mylan N.V., a Dutch-registered entity headquartered in Canonsburg, Penn.

Congress enacted the Medicaid Drug Rebate Program to ensure that state Medicaid programs were not susceptible to price gouging by manufacturers of drugs that were available from only a single source. It therefore subjected such single-source, or brand name drugs, to a higher rebate that includes any difference between the drug's current price and the price the drug would have had if its price had increased only at the general rate of inflation. In contrast, generic drugs originating from multiple manufacturers are subject to lower rebates that, at least until recently, did not include an inflationary component.

The government contends that Mylan improperly avoided paying state Medicaid programs the higher rebates for branded drugs by misclassifying EpiPen as a generic drug, even though EpiPen had no FDA-approved therapeutic equivalents and even though Mylan marketed and priced EpiPen as a brand name drug. Mylan raised the price of EpiPen by approximately 400% between 2010 and 2016.

"Mylan misclassified its brand name drug, EpiPen, to profit at the expense of the Medicaid program," said Acting United States Attorney William D. Weinreb. "Taxpayers rightly expect companies like Mylan that receive payments from taxpayer-funded programs to scrupulously follow the rules. We will continue to root out fraud and abuse to protect the integrity of Medicaid and ensure a level playing field for pharmaceutical companies. We commend Sanofi for bringing this matter to our attention."

"This settlement demonstrates the Department of Justice's unwavering commitment to hold pharmaceutical companies accountable for schemes to overbill Medicaid, a taxpayer-funded program whose purpose is to help the poor and disabled," said Acting Assistant Attorney General Chad A. Readler of the Department of Justice's Civil Division. "Drug manufacturers must abide by their legal obligations to pay appropriate rebates to state Medicaid programs."

As part of this settlement, Mylan has also entered into a corporate integrity agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires, among other things, an independent review organization to annually review multiple aspects of Mylan's practices relating to the Medicaid drug rebate program.

"Our five-year corporate integrity agreement requires intensive outside scrutiny to assess whether Mylan is complying with the rules of the Medicaid Drug Rebate Program," said Gregory E. Demske, Chief Counsel to the Inspector General for the U.S. Department of Health and Human Services. "In addition, the CIA requires individual accountability by Mylan board members and executives."

A competing pharmaceutical manufacturer, Sanofi, raised this matter with the United States Attorney's Office in 2014. At the time, Sanofi was selling another epinephrine auto-injector drug called AUVI-Q and was reporting it to the Medicaid Drug Rebate Program as a brand name drug. In 2016, Sanofi filed a complaint against Mylan under the qui tam provisions of the False Claims Act, which permits private parties to sue on behalf of the government and to receive a share of any recovery. See United States ex rel. sanofi-aventis US LLC v. Mylan Inc., et al., No. 16cv11572 (D. Mass.). As a result of today's settlement, Sanofi will receive $38.7 million as its share of the federal recovery, plus a share of the states' recovery.

Acting U.S. Attorney Weinreb, Acting Deputy Assistant Attorney General Raab, and HHS OIG Chief Counsel Demske made the announcement today. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Kriss Basil of Weinreb's Office, and by Trial Attorneys Augustine Ripa and Nicholas Perros of the Justice Department's Civil Division.

Topic(s):
Prescription Drugs

Component(s):
USAO - Massachusetts

Updated August 17, 2017