

EpiPen maker finalizes settlement for government overcharges

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This Oct. 10, 2013, file photo, shows an EpiPen epinephrine auto-injector, a Mylan product, in Hendersonville, Texas. Mylan has finalized a \$465 million federal agreement settling allegations it overbilled Medicaid for its emergency allergy injectors for a decade, charges brought after rival Sanofi filed a whistleblower lawsuit and tipped off the government. (AP Photo/Mark Zaleski, File)

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agreement settling allegations it overbilled Medicaid for its emergency allergy injectors for a decade—charges brought after rival Sanofi filed a whistleblower lawsuit and tipped off the government.

It's the second settlement with the Department of Justice that Mylan has made since 2009 for allegedly overcharging the government for its medicines.

Mylan NV, technically based in England but with operational headquarters near Pittsburgh, became a poster child for pharmaceutical industry greed for hiking the list price of EpiPens repeatedly. It raised the price per pair from \$94 in 2007 to \$608 last year, while experts estimate it costs less than \$10 to produce one EpiPen.

Last September, a House panel grilled Mylan CEO Heather Bresch about the skyrocketing cost of the devices, which patients inject in the thigh to stop a runaway allergic reaction to foods such as nuts and eggs or insect bites and stings.

On Thursday, the Department of Justice disclosed that its EpiPen case began when Sanofi-Aventis US LLC filed a lawsuit against Mylan under the False Claims Act.

The law allows individuals and companies to sue on behalf of the government over improper charges to government programs and to receive a share of any money recovered. Sanofi is to receive about \$38.7 million. The federal government and all 50 states will split the bulk of the settlement.

Sanofi made a rival auto-injector called Auvi-Q. The French drugmaker recalled nearly 500,000 of its devices from the market in 2015, due to some not administering the correct dose of the hormone epinephrine to reverse a severe allergic attack.

EpiPens have long dominated the market and continue to do so, between their name recognition and deals Mylan has made to get preferable or exclusive coverage from insurers and prescription benefit managers.

According to the Justice Department, Mylan paid Medicaid, the joint federal-state health program for the poor and disabled, too-low rebates for EpiPens by improperly classifying the brand-name product as a generic. Drugmakers are required to pay Medicaid rebates of 13 percent for generic products it purchases, versus a 23.1 percent rebate for brand-name drugs, which cost far more.

EpiPen has been incorrectly classified since late 1997 as a generic product under Medicaid. Mylan acquired rights to EpiPen in 2007 and didn't change its classification.

In addition, Mylan wasn't paying Medicaid a second rebate required whenever a brand-name drug's price rises more than inflation, which averaged less than 2 percent a year from 2007 through 2016.

Last fall, members of Congress grilled the federal Centers for Medicare & Medicaid about the discrepancies and whether it was taking any action. Announcement of a tentative \$465 settlement soon followed.

"DOJ is letting Mylan get off on the cheap for ripping off the government, and with no admission of wrongdoing," Robert Weissman, president of the consumer watchdog group Public Citizen, said in a statement. He added that the Health and Human Services Department's Office of Inspector General's investigation concluded that Medicaid programs paid Mylan \$1.27 billion more than they should have between 2006 and 2016.

Senate Judiciary Committee Chairman Chuck Grassley, R-Iowa, who has investigated EpiPen price increases, agreed in a statement.

"It looks like the settlement amount shortchanges the taxpayers," wrote Grassley, who authored parts of the False Claims Act. "The Justice Department doesn't say how it arrived at \$465 million. ... Did the Justice Department consider the inspector general estimate?"

In the finalized settlement, Mylan agreed to enter a corporate integrity agreement requiring it to have intensive outside scrutiny of its pricing practices with Medicaid for five years.

Such agreements are commonplace when drugmakers settle fraud charges with the government, but they don't always prevent future misconduct.

Mylan was one of four companies that in October 2009 settled charges they didn't pay appropriate rebates to state Medicaid programs for multiple medicines. The companies paid back a combined total of \$124 million.

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