

EpiPen maker settles: It'll pay less than what it got by allegedly overcharging



Experts estimate that producing one EpiPen costs less than \$10. (Mark Zaleski / Associated Press)

By **Associated Press**

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EpiPen maker Mylan has finalized a \$465-million government 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 to end allegations it overcharged the government for its medicines.

A prominent senator and a watchdog group both criticized the latest settlement for being far smaller than the amount Medicaid was overcharged.

Mylan, 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 two-pack from \$94 in 2007 to \$608 last year. Experts estimate that producing one EpiPen costs less than \$10.

Last September, a House panel grilled Mylan Chief Executive 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 because some did not administer 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% for generic products that Medicaid buys, versus a 23.1% 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% 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-million settlement soon followed.

The Justice Department “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 Thursday.

Weissman and Senate Judiciary Committee Chairman [Chuck Grassley](#) (R-Iowa) both noted that an investigation by the Health and Human Services Department's Office of Inspector General concluded that Medicaid programs paid Mylan \$1.27 billion more than they should have between 2006 and 2016.

“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 the company to have intensive outside scrutiny of its pricing practices with Medicaid for five years.

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

Mylan was among four companies that in October 2009 settled charges that 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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