

Mylan to pay \$465 mn over EpiPen overcharges to Medicaid

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Mylan will pay \$465 million to resolve accusations from some regulators that it overbilled the federal Medicaid program for the EpiPen allergy medication, the drugmaker announced Friday.

The settlement with the Department of Justice and some other regulators resolves questions about Mylan's classification of EpiPen as a generic drug, the drugmaker said. Mylan said it did not admit fault in the agreement.

Federal health care regulators have said the misclassification contributed to a swelling of payments to Mylan, which nearly monopolizes the market for the allergy injectors, for EpiPen under federal health care programs.

Had EpiPen been correctly classified, Mylan would have been forced to pay higher rebates to federal and state officials, officials with the US Center for Medicare and Medicaid Services (CMS) have said.

Mylan, which has been under strong attack from politicians and the public for jacking up the price of EpiPens— essential for severe allergy sufferers to block life-threatening attacks—touted the settlement.

"This agreement is another important step in Mylan's efforts to move forward and bring resolution to all EpiPen Auto-Injector related matters," said Mylan chief executive Heather Bresch.



Despite news of the settlement, Mylan alluded to a fresh federal investigation in an SEC filing, saying it had received a document request Friday from enforcement officials "seeking communications with the CMS and documents concerning Mylan products sold and related to the Medicaid Drug Rebate Program, and any related complaint."

"Mylan intends to fully cooperate with the SEC's investigation," it added.

A CMS official declined substantive comment on the settlement.

"Today, through an SEC filing, Mylan Pharmaceutical announced that it has come to an agreement in principle with the federal government over a dispute over the misclassification of Epipen in the Medicaid Drug Rebate Program," a CMS spokesperson said.

"We have no further comment at this time."

A Justice Department spokeswoman declined comment, adding, "the Justice Department does not confirm or deny the existence of an investigation."

Mylan has been under fire since August over the soaring price of the lifesaving EpiPen injectors, for which it faces virtually no competition in the market.

A pack of two of the devices soared to more than \$600 from less than \$100 in 2007, when Mylan bought the rights to the technology.

Mylan in August boosted patient assistance programs to help defray costs for EpiPen, eliminating immediate out-of-pocket costs for the uninsured and under-insured.

Bresch endured a bruising hearing on Capitol Hill last month where she



was pressed on swelling compensation for executives at the company that was tied in part to the rising income from EpiPen sales.

Bresch defended the company's pricing, saying some of the higher cost was due to payments to insurers and others in the health care industry.

However, the company was forced to back off a claim that a two-pack of EpiPens yielded a profit of just \$100 after it emerged that the figure deducted for an unrealistically high amount of taxes.

Mylan shares rose 8.5 percent in after-hours trade.

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