

Sanofi Blew Whistle On Mylan's EpiPen Rebate Woes: Feds

By **Brian Amaral**

Law360, Boston (August 17, 2017, 12:54 PM EDT) -- Mylan will pay \$465 million to resolve allegations that it ripped off the government by underpaying rebates for the EpiPen, federal authorities said Thursday, revealing for the first time that competitor Sanofi first blew the whistle in a False Claims Act suit.



Mylan has been under scrutiny from consumers and regulators for the skyrocketing price of the EpiPen. Sanofi, meanwhile, will take home \$38.7 million of the \$465 million settlement for blowing the whistle. (AP)

Mylan had previously announced the settlement in principle late last year, along with a dollar figure. On Thursday, prosecutors announced that the deal had been finalized, and provided new details into how the issue over the treatment for potentially fatal allergic reactions first arose.

"We will continue to root out fraud and abuse to protect the integrity of Medicaid and ensure a level playing field for pharmaceutical companies," acting U.S. Attorney William Weinreb, the top federal prosecutor in Massachusetts, said in an emailed statement. "We commend Sanofi for bringing this matter to our attention."

Sanofi will take home \$38.7 million of the settlement for blowing the whistle, along with a share of what the states will get as part of the state and federal health programs' recovery. It's still suing Mylan in New Jersey federal court in a **separate antitrust case**.

Mylan has been under scrutiny from consumers and regulators for the skyrocketing price of the EpiPen, a fast-acting and life-saving drug injector that is used to treat people who are going into anaphylactic shock, a potentially fatal allergic reaction.

The price for a two-pack of the EpiPen recently rose from \$100 in 2009 to \$600.

According to the government, drugmakers must pay Medicaid in the form of rebates to avoid price gouging. Drugmakers have to pay a higher rebate for drugs that are only available through a single source — the difference between the current price and the price the drug would have cost if it had only increased by the rate of inflation.

But, the government contends, Mylan misclassified the EpiPen as a generic, meaning it paid lower rebates than it should have.

"As we said when we announced the settlement last year, bringing closure to this matter is the right course of action for Mylan and our stakeholders to allow us to move forward," Mylan CEO Heather Bresch said in a statement. "Over the course of the last year, we have taken significant steps to enhance access to epinephrine auto-injectors, including bringing a solution to the fast-changing healthcare landscape in the U.S. by launching an authorized generic version at less than half the wholesale acquisition cost of the brand and meaningfully expanding our patient access programs."

Mylan said Thursday that the EpiPen had been classified as a non-innovator since before it acquired the drug, and that it followed longstanding federal guidance. The company did not admit liability in the settlement.

The False Claims Act rebate allegations came in the form of a lawsuit from competitor Sanofi-Aventis. The French company had filed a FCA suit under seal, alleging that when it was developing its own epinephrine injector, it learned Mylan was abusing Medicaid rebates. False Claims Act suits allow private parties to sue on behalf of the government when a defendant allegedly bills the government for services that aren't actually provided.

Sanofi said Mylan tried to block its own epinephrine injector, Auvi-Q, by forcing insurance companies to not cover Auvi-Q or to put it at a disadvantage on drug formularies.

"Although we no longer own the rights to Auvi-Q, we continued to move this matter forward because it was the right thing to do," Sanofi said in an emailed statement. "The practices used by Mylan injured consumers by unfairly restricting access to other epinephrine auto-injectors including Auvi-Q."

The nearly half-billion settlement has come under fire from critics of Mylan, including Sen. Richard Blumenthal, a Connecticut Democrat.

"This settlement amount is completely insufficient — a feeble fraction of the \$1.27 billion Mylan swindled out of Connecticut and American taxpayers," Blumenthal said in an emailed statement. "Quite simply, the Department of Justice is letting this deceptive pharmaceutical behemoth off the hook."

The government is represented by Assistant U.S. Attorneys Gregg Shapiro and Kriss Basil in Massachusetts and trial attorneys Augustine Ripa and Nicholas Perros of the Justice Department's Civil Division.

Sanofi is represented by Chan Lee, Robert M. Thomas Jr. and Suzanne Durrell.

Mylan is represented by Brian S. Roman and Mitchell E. Zamoff.

The case is United States ex rel Sanofi-Aventis US v. Mylan Inc. et al, case number 1:16-cv-11572, in the U.S. District Court for the District of Massachusetts.

—Additional reporting by Jeff Overley. Editing by Emily Kokoll.

Update: This story has been updated with a comment from Sen. Richard Blumenthal.