Mylan may have overcharged US government by $1.27 billion

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5 June 2017

Mylan Pharmaceuticals came to public attention in August of last year for hiking the price of its life-saving EpiPen by more than 500 percent, from $100 for a two-pack of EpiPens in 2004 (adjusting for inflation) to $600 in 2016. Sales from the EpiPen make up 40 percent of the company's profits. The company acquired the drug through its 2007 purchase of Merck's generic division.

Last week the Office of the Inspector General (OIG) for Health and Human Services (HSS) issued a letter to the US Senate Committee on the Judiciary, which had requested an estimate of how much Mylan overcharged Medicaid. The letter was released by Senator Chuck Grassley, a Republican from Iowa and chairman of the committee that has been leading the investigation into the EpiPen overcharges.

Between 2006 and 2016, Mylan misclassified its EpiPen Auto-Injector, used to treat anaphylaxis due to allergic reactions, as a generic product instead of a branded product.

"It looks like Mylan overcharged the taxpayers for years with the knowledge EpiPen was misclassified," Senator Chuck Grassley said in a statement on his Senate web site. "The fact that Mylan is unwilling to cooperate and provide documents voluntarily makes me wonder what there is to hide and whether a subpoena is the only way to get to the bottom of this."

According to the OIG, Mylan overcharged taxpayers by as much as $444 million between 2006 and 2014, and by $826 million between 2015 and 2016, bringing the grand total over 10 years to $1.27 billion.

The Medicaid Drug Rebate Program, administered jointly by the Center for Medicare and Medicaid Services and State Medicaid Agencies, requires pharmaceutical companies, if they wish to have their drugs covered by Medicaid, to pay a certain percentage of their revenues (rebates) to states to assist with the costs of prescription drugs under the Medicaid program. Around 600 drug manufacturers participate.

Makers of generic drugs (classified as "non-innovator multiple source" drugs) are charged 13 percent of the drug's average manufacturing price (AMP). Producers of branded drugs (classified as "innovator drugs"), however, are charged either 23.1 percent of the AMP or the difference between the AMP and the Best Price (the lowest negotiated price), whichever is higher. (Pricing data is provided by the drug manufacturer.) Even higher rebates can be charged if the price of the branded drug rises above the rate of inflation.

The "innovator drugs" are charged a higher rate because they have monopoly protection; generic or "non-innovator multiple source" drugs generally have multiple competitors.

The statute covering the program states that in order for a drug to be classified as a generic, there must be at least one competing drug product that is "therapeutically equivalent."

The EpiPen has never faced a competing device that was considered therapeutically equivalent, although after its price hikes sparked outrage the company now provides its own generic version of the device. And Mylan has done everything in its power to prevent an equivalent device from coming to market.

Soon after Mylan acquired the EpiPen, the unit in Pfizer that makes the device for Mylan sued Teva Pharmaceuticals for patent infringement. Teva had been developing a generic version of the EpiPen, but the resulting 2012 settlement prevented the company from introducing a competing product until late 2015.

In early 2015, Mylan submitted a petition to the US Food and Drug Administration requesting that the agency not approve Teva's upcoming generic version. The FDA rejected Teva's application in February of last year.

Last month, Sanofi-Aventis filed a lawsuit against Mylan alleging that Mylan offered deep discounts to drug suppliers as long as they agreed not to purchase Sanofi's competing product, the Auvi-Q. Mylan currently controls around 70 percent of the market for emergency treatments for allergic reactions—in the past, it has controlled as much as 90 percent of the market.

Mylan's case for its classification of the EpiPen rests on the flimsiest of logic. The company points to the 1997 designation by the HHS of the EpiPen, then marketed by

Dey Laboratories, as a non-innovator. However, unlike Dey Laboratories, Mylan has taken out at least one additional patent on the design of the EpiPen (the pen's easy to remove orange cap), giving it monopoly protections until at least 2025.

The company was informed of its misclassification, but nonetheless never changed the designation. Federal regulators revealed Mylan's overcharges in September of last year after three Senators asked the Justice Department if it was going to investigate Mylan.

"The facts laid out above suggest that Mylan may have knowingly misclassified EpiPens, potentially in violation of the False Claims Act and other statutes," said Senators Amy Klobuchar, Richard Blumenthal, and Grassley in a letter to the attorney general dated September 28, 2016.

"CMS has, on multiple occasions, provided guidance to the industry and Mylan on the proper classification of drugs, and has expressly advised Mylan that their classification of EpiPen for the purposes of the Medicaid Drug Rebate Program was incorrect," CMS spokesperson Aaron Albright told CNBC at the time.

In October, Mylan reached a settlement with the Department of Justice (DOJ) in which the company would pay $465 million, less than half of what it owes, and would admit no guilt in the matter. It appears that this settlement is no longer on the table. The DOJ, according to Stat News, now says "there is no settlement to report."

"Mylan's outrageous multiyear classification has cost American taxpayers not just millions but billions," Senator Blumenthal, a Democrat from Connecticut, said on the release of the letter from the OIG, according to CNBC. "The Department of Justice's [$465 million] deal is completely insufficient—a shadow of what it should be."

Mylan has reportedly agreed to meet with Senator Grassley this week to discuss his ongoing investigation.

The revelation of the amount overcharged by Mylan, along with the lavish pay given to top company executives, has led to a semi-revolt among a handful of institutional investors in the company. The New York City pension fund, the California State Teachers' Retirement System, and the Dutch pension fund PGGM are all calling on Mylan shareholders to reject the reelection of six company directors at the June 22 annual meeting. Together, the institutional investors hold around 4.3 million Mylan shares.

"If [the charges are] true, Mylan not only forced massive price hikes on consumers, but also overcharged American taxpayers more than a billion dollars for a life-saving drug," New York City's comptroller, Scott Stringer, told CNBC. Stringer oversees New York City's pension fund.

"At the same time, [Mylan's] board granted enormous pay packages to top executives. It's improper and it's immoral. Now. Mylan's shareowners are suffering the consequences. This is ultimately a Board failure—that's why investors are demanding change," Stringer said.

The company's chairman and former CEO Robert Coury received $97.6 million in compensation last year. According to *FiercePharma*, Coury was the highest paid executive in the pharmaceutical industry in 2016. Heather Bresch, Mylan's current CEO, has seen her compensation rise from $2.5 million in 2007 to $18.9 million in 2015.

Mylan has a history of questionable business practices.

As the company raised the price of the EpiPen after acquiring it in 2007, it also sought to expand the market for the device by spending heavily on marketing and pulling political strings—Mylan CEO Bresch's father is a Democratic Senator from West Virginia, Joe Manchin—to get requirements that public schools purchase EpiPens.

In addition to the EpiPen, Mylan has significantly hiked the prices of a number of their other drugs, including a 542 percent price increase of a generic treatment for gallstones (Ursodiol), a 444 percent increase of a generic treatment for gastroesophageal reflux (Metoclopramide), and a 400 percent increase of a treatment for irritable bowel syndrome (Dicyclomine).

The company also has a history of cornering the market on a product and then jacking up the prices. The company settled charges by the Federal Trade Commission (FTC) that it had illegally restricted trade by agreeing to pay $147 million in 2000. According to the FTC, after gaining exclusive access to the raw materials used to produce two widely prescribed anti-anxiety drugs, Mylan raised the price of one from $11.36 a bottle to $377 (clorazepate) and the price of the other from $7 to $190 (lorazepam).

In September of last year, Bresch was called to testify before the House Oversight and Government Reform Committee. While Representatives criticized the actions of Mylan, the real purpose of the hearing was to quell public anger by throwing shots at an easy target, while ensuring that the industry as a whole could continue to price gouge the public without political interference.

As Representative Elijah Cummings noted at the hearings: "After Mylan takes our punches they'll fly back to their mansions in their private jets and laugh all the way to the bank."

The same could be said about the likely outcome of Mylan's latest scandal of overcharging Medicaid.