

Mylan: The Pricing of EpiPen

In 2016 Mylanⁱ, the company that supplied EpiPens, was accused of price gouging after a significant increase in prices. What, if anything, did Mylan owe its customers?

Epinephrine, EpiPen, and Severe Allergic Reaction

An allergy occurs when your body reacts negatively to a foreign substance (an allergen).

Allergies are common: in the US, more than 50 million people experience themⁱⁱ. Most are mild, but around 1 in 50 allergy sufferers may experience anaphylaxis, a severe allergic reaction. Signs of anaphylaxis include: breathing difficulty, tight chest, hoarse voice, itching/red rash/hives, fainting, stomach cramping, nausea/vomiting, and swelling. Anaphylaxis is most commonly triggered by food, insect bites, and medicineⁱⁱⁱ.

Epinephrine, a common drug, acts to slow the progression of anaphylaxis and allows the muscles around the lungs to relax^{iv}. Most people who experience anaphylaxis do not die, but without treatment it can be fatal. For example, in the US more than 100 people die each year from insect bites.

Epinephrine is needed as soon as symptoms of anaphylaxis show. It is possible to use a syringe to administer the drug, but this is difficult and dangerous as calibrating the dosage is challenging. For this reason, auto-injectors—the best known of which is EpiPen—are used to calibrate the dosage and allow anyone to administer this potentially lifesaving treatment.

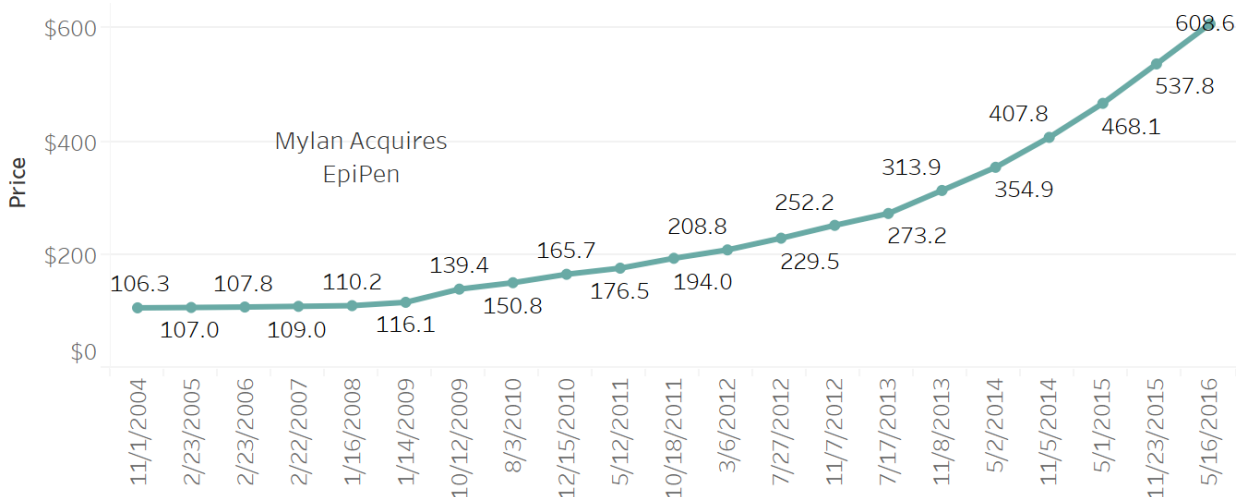
Doctors recommend having two doses available, so EpiPen sells in two-packs. (Prices quoted below are for two-packs, which is the pricing format available after 2012^v). Those at risk of

anaphylaxis are recommended to carry the two-pack with them at all times. Epinephrine expires, so EpiPens need to be replaced every twelve months to ensure they remain effective^{vi}.

Mylan Buys EpiPen and Raises the Price

Mylan was launched in the 1960s and grew through a series of acquisitions, including the 2007 acquisition of the generics division of Merck KGaA for \$6.6 billion. This acquisition included the rights to market EpiPen^{vii}.

Figure 1. Price of EpiPen Under Mylan^{viii}



Mylan promptly began a series of price increases for EpiPen (see Figure 1). When asked about the price raises, Mylan Chairman Robert Coury reportedly made vulgar gestures and offensive, sexual comments about his critics and the Food and Drug Administration^{ix}. In 2016, at the height of the controversy, Coury stepped back to a non-employee chairman role. He received compensation of \$97.6 million, and an additional \$66.3 million in retirement benefits associated with this change.

CEO Heather Bresch, daughter of West Virginia Senator Joe Machin, remained Chief Executive. Her compensation was also questioned, as it had risen from \$2.4 million in 2007 to \$19 million in 2015 before dropping to \$13.8 million in 2016^x.

The EpiPen price increases were condemned by Republican and Democratic politicians^{xi}, the wider public, and even Martin Shkreli, the “pharma bro.” An unlikely patient advocate, Shkreli had acquired and raised the price 5,000% on an anti-malarial/toxoplasmosis drug used in HIV-positive patients. Shkreli was reported as saying: “These guys are really vultures,” and asked “What drives this company’s moral compass?”^{xii}

Cheaper Alternatives and Cost to the Patient

Schools often keep several EpiPens available in case they are needed. Mylan agreed to offer free EpiPens, and buy-in-bulk discounts, to schools. In 2015, the discounted price was \$112.10. This was initially available only to schools that promised not to buy any other type of epinephrine auto-injector. This requirement was dropped sometime before 2016^{xiii}.

As for general users, those without insurance could sometimes get deals, but US medical insurance plans varied in their coverage of EpiPens. Insured patients could find themselves paying full price. High costs meant that some people used EpiPens beyond their expiry dates, while others chose not to buy the medicine. To mitigate the problem for the insured, Mylan instituted a \$0 co-pay card. This, however, was not a guarantee and large co-pays continued for many insured patients^{xiv}.

Generics and Competitors

In 2013 Sanofi, a French manufacturer, launched a rival, Auvi-Q, but this faced concerns about correct dosage and saw a voluntary recall^{xv}. Teva applied to the Food and Drug Administration

for permission to sell a generic version of EpiPen but was rejected in early 2016, removing another possible alternative^{xvi}.

When Auvi-Q returned to the market, it was being manufactured by a private firm, Kaléo. The list price was set at \$4,500, but no one paid that. Insured patients earning less than \$100k could get it for free. Given that some insurance plans did not pay for Auvi-Q, Kaléo seemed willing to accept that they would gain no payment at all on some sales. Other patients, including the uninsured, paid \$360, about half EpiPen's price.^{xvii}

In September 2016, Mylan moved to launch a generic version of EpiPen. Generics are non-branded versions of a drug. This move was somewhat unusual in that generics are often launched by competitors. In 2022, EpiPen was retailing at major pharmacies for \$650 to \$735. The generic version could typically be found for around \$300 less^{xviii}.

Mylan said that the generic EpiPen would be identical to the existing product but will have a wholesale list price of \$300 for a pack of two, half the price of the brand name EpiPen.^{xix}

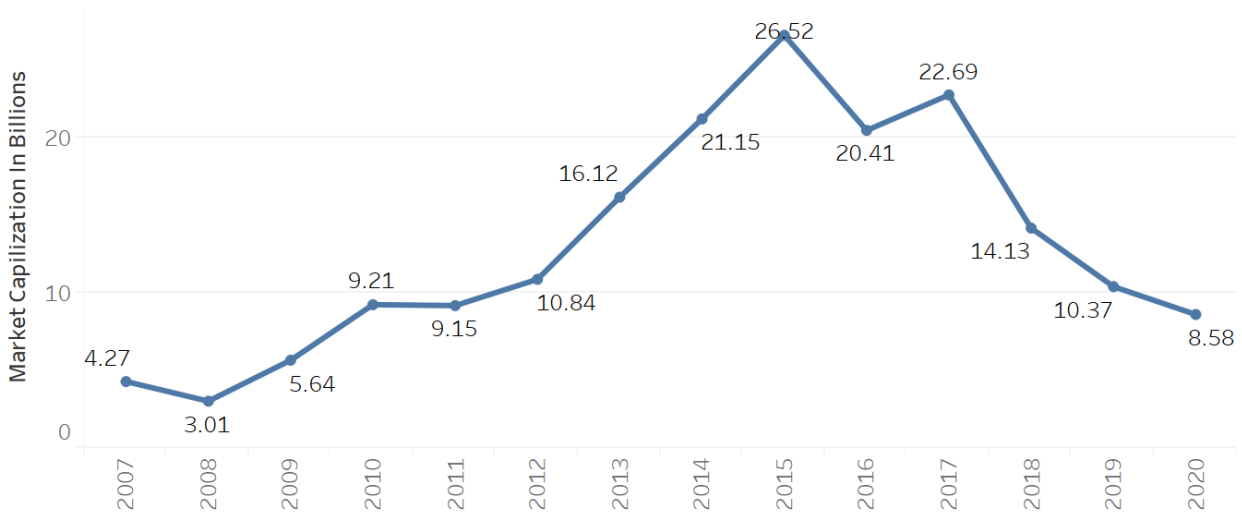
Another competitor was the branded auto-injector Adrenaclick, which used the same drug but a different injecting mechanism^{xx}. With new competition, the market share of the branded EpiPen fell from around 90% in 2014-2016 to little more than 10% by end of 2017. Teva's EpiPen was finally approved in 2018^{xxi} as generic versions of EpiPen (60% market share) and Adrenaclick (30%) came to dominate the market^{xxii}.

What Happened Next?

In 2016, Mylan settled with the US Justice Department for \$465 million. Mylan had improperly classified EpiPen as a generic. (The US government pays a higher percentage of the list price for generics).

In November 2020, Mylan merged with Pfizer’s Upjohn to form Viatris Inc.^{xxiii} At the time of the merger, Mylan was valued (market capitalization) at around \$8.5 billion, about one-third of its year-end high in 2015.

Figure 2. Mylan Market Capitalization (Market Value of All The Firm’s Shares)



Heather Bresch retired in 2020 around the time of the merger; she had gained compensation of \$113,565,411 between 2011 and 2019^{xxiv}. Robert Coury returned to the role of Executive Chairman at Mylan in 2020^{xxv}.

In 2022, Viatris agreed to settle a \$264 million class action lawsuit that accused Mylan of “unlawfully exercising its monopoly power.” In court filings, one Arizona mother stated that she had paid \$2,475 for EpiPens to protect her son who has an allergy to tree nuts^{xxvi}. As of May 2022, Robert Coury remains the Executive Chairman of Viatris^{xxvii}.

Endnotes

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