

US price of EpiPen for allergic reactions skyrockets

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The price of the EpiPen, relied on by millions to treat severe allergic reactions, has increased by 450 percent in the United States since 2004. The price surge has made it more difficult for patients to afford the potentially life-saving device, leading many to hold on to expired EpiPens or turn to the riskier method of administering the hormone epinephrine using manual syringes.

While a two-pack of EpiPens cost about \$100 in 2004 (adjusting for inflation), it now costs over \$600. Some emergency medical services pay upwards of \$900 for the drug device from medical supply companies. The EpiPens must be replaced each year when they expire.

The EpiPen Auto-Injector, marketed by the pharmaceutical company Mylan, is used to treat anaphylaxis, a severe and potentially deadly allergic reaction to food, medication or insect bites. The device uses a spring-loaded needle to quickly deliver a controlled dosage of epinephrine (also known as adrenaline). The device was developed in the mid-1970s by engineers at the Bethesda, Maryland-based company, Survival Technology, and first introduced in 1980.

The administration of epinephrine is the treatment of choice for anaphylaxis, and it is recommended that individuals with a history of severe allergic reactions carry an EpiPen.

An estimated 2 to 5 percent of the population experience anaphylaxis over the course of their lifetime, according to a 2014 study in the *Journal of Allergy and Clinical Immunology*. A survey published in the journal *Pediatrics* in 2011 found that 8 percent of the children had a food allergy, while nearly 40 percent of these individuals had a history of severe reactions.

An estimated 200,000 people visit emergency rooms each year due to food allergies, while nearly 10,000 end up staying in a hospital. When deaths do occur, it is almost always associated with not having access to epinephrine.

The dramatic price hikes of the EpiPen by Mylan, however, have made it increasingly difficult for working class families, even those with health insurance, to have access to the device.

Dr. Michael Pistiner, an allergist and member of the American Academy of Allergy, Asthma & Immunology in Milwaukee, Wisconsin, has observed these difficulties among his patients.

“I am hearing some of the families are opting to carry expired

auto-injectors,” Pistiner told Milwaukee Public Radio, “or, if they have a high deductible sometimes they say do they really want their auto-injector, and do they really need it?”

Amie Violet De Montbel, a mother living in Troy, Virginia, has a young son who is severely allergic to milk. When she went to fill a prescription for two 2-packs of EpiPens, she was shocked by the \$1,212 price tag. “I don’t even pay that much for my mortgage,” she told *Stat News*. Since her health insurance has a \$4,000 deductible, she would have to cover the entire cost. She had to turn down the potentially life-saving device. Her older son currently carries an expired EpiPen.

In response to the price increases, patients, such as Violet De Montbel, and emergency responders are increasingly resorting to the use of manual syringes instead of EpiPens, reports an article last month in *Stat News*. This substitution raises a number of safety concerns.

“Anyone using this approach would require extensive medical training to do it effectively and safely, without contamination or accidental intravenous injection,” Dr. James Baker, Jr., CEO and chief medical officer of Food Allergy Research & Education, told *Stat News*.

At least 10 states have pushed for training EMT’s to give epinephrine injections using manual syringes to reduce costs.

An article published by *Bloomberg* in September of last year shed light on how Mylan transformed the EpiPen into a real moneymaker, bringing in annual revenue of \$1 billion, which constitutes 40 percent of the company’s profits.

Mylan acquired the EpiPen through its purchase of Merck’s generic division in 2007. Led by the company’s CEO Heather Bresch, Mylan’s marketing strategy combined branding with a massive public awareness campaign, which sought to get EpiPens stocked in schools and other places. The company hired consultants who had worked with Medtronic to make defibrillators widely available in public places.

With support from Bresch’s father, Senator Joe Manchin (Democrat-W.Va.), new federal guidelines were established recommending patients with severe allergic reactions be prescribed two doses, and the FDA revised the drug’s label to allow its use by anyone at risk, not just those who had already experienced anaphylaxis.

In response to the high-profile death of a student at a Virginia

school in 2013, Congress passed legislation encouraging states to stock public schools with epinephrine devices, which is now a requirement in 47 states.

To popularize the brand, Mylan spent \$35.2 million on EpiPen TV ads in 2014, compared to \$4.8 million spent in 2008. It also issued free EpiPens, which have to be replaced each year, to 59,000 schools. As a result, EpiPen use has grown by 67 percent since 2008. Over 3.6 million prescriptions were written for EpiPen last year.

As Mylan captured more of the epinephrine market, while simultaneously expanding the market through public awareness campaigns, it drove up the price of a 2-pack of EpiPens to over \$600.

The price increases “reflect the multiple, important product features and the value the product provides,” Mylan told *Stat News*, while declining to state what exactly these product features were.

To counter backlash from patients and the public, Mylan offers a savings program that it refers to as the “\$0 co-pay card.” However, it only covers \$100, leaving patients who have insurance plans with high deductibles, increasingly common under Obamacare, to pick up the remainder.

When Nicole Smith, the founder of an online support community for families with allergies, went to fill a prescription for a 2-pack of EpiPens at Walgreens for her child, she was astounded by the price: \$600, or \$500 with Mylan’s “\$0 co-pay card.”

The price is “higher than some people’s homeowners insurance, higher than renter insurance by far,” Smith told *MarketWatch*. “With the cost of them, you’re not going to buy one for each place” where your child might need one. “You’re hoping the diaper bag goes everywhere that kid goes.”

Smith says that she has heard of people driving to Canada where Mylan’s EpiPen is sold at pharmacies for only \$131.

Although the EpiPen has been available since 1980, it still faces little competition. When doctors write prescriptions, they are generally for the most well-known product, EpiPen. Patients cannot substitute generic alternatives with the prescription because the FDA says the devices are not similar enough. Moreover, these generic alternatives, Adrenaclick and Auvi-Q, are priced similar to EpiPen.

Since its introduction in 2013, Sanofi’s Auvi-Q has only captured 10 percent of epinephrine prescriptions, compared to the 85 percent share held by Mylan’s EpiPen. In 2015, Sanofi had to recall its product in the US and Canada due to a potential inaccurate dosage delivery. Since then, Sanofi has indicated that it may abandon the product completely, leaving Mylan with 95 percent of the market.

This will continue into the near future as the FDA rejected Teva Pharmaceutical’s generic EpiPen earlier this year, delaying the launch until at least 2017.

Mylan Pharmaceuticals was founded in West Virginia in 1961. The company focused on manufacturing over-the-counter

products and soon switched to the production of generic pharmaceuticals. The company began to diversify in the mid-1990s, acquiring the pharmaceutical firm Bertek Inc. in 1993.

In 2000, the company agreed to pay \$147 million in order to settle charges by the Federal Trade Commission that Mylan had illegally restricted trade. The company had set up exclusive licensing agreements in 1998 that allowed it to monopolize the market for the raw materials necessary for two widely prescribed anti-anxiety drugs, clorazepate and lorazepam, and then respectively raised their prices from \$11.36 a bottle to \$377 and from \$7 to \$190.

“What makes this behavior even more unconscionable,” Betty D. Montgomery, the attorney general of Ohio, told the *New York Times* in 2000, “is that these drugs, especially lorazepam, are antianxiety medications frequently prescribed for nursing homes and hospice patients, including those suffering from long-term debilitating conditions such as Alzheimer’s disease.”

“We continue to believe we acted properly,” Milan Puskar, the company’s CEO, stated at the time.

The company continued to grow through mergers and acquisitions. In 2007, it acquired a controlling interest in Matrix Laboratories, an Active Pharmaceutical Ingredients supplier, and the generics division of Merck KGaA, which included the EpiPen. More recently, it acquired the generics division of Abbott Laboratories for \$5.3 billion in 2015 and purchased the Swiss drug maker Meda in a \$9.9 billion deal earlier this month.

The company, which is now incorporated in the Netherlands, is expected by financial experts to pull in \$12 billion in annual revenue as a result of its acquisition of Meda.

Heather Bresch, who became the company’s CEO in 2012, took home \$25.8 million in total compensation in 2014, according to *FiercePharma*. After the company distributed free EpiPens to schools in a bid to expand the product’s market, she told the *New York Times* in 2012, “I think this goes to the heart of being able to do good and do well.”



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