

Pricing the EpiPen: This is Going to Sting

The headlines were not exactly what Heather Bresch, CEO of Mylan Inc. (Mylan), was hoping to see. The *New York Times* read, “EpiPen Price Rise Sparks Concern for Allergy Sufferers,”¹ and the *Washington Post* read, “How EpiPen’s Maker Raised Prices, and Hackles, So Much.”² *Forbes* and the *Los Angeles Times* signaled that the business might face even broader scrutiny with their articles titled “CEO of EpiPen Maker Mylan Sees 671% Compensation Increase in 8 Years”³ and “Another Reason to Hate Mylan, which Jacked up Price of Life-Saving EpiPens: It’s a Tax Dodger,” respectively.⁴

As if the media attention was not enough, the government was now getting involved as well. Bresch had just received inquiries from several U.S. senators demanding to know more about how pricing decisions were made. Senator Chuck Grassley, the Republican chair of the U.S. Senate Committee on the Judiciary, wanted to know how Mylan could justify its price increases and what the company was doing to defray the costs of EpiPens for those patients who needed financial help (**Exhibit 1**). This governmental scrutiny was both a business concern and a personal one for Bresch, as her father, Joe Manchin, was a U.S. senator.

Bresch did have at least one defender in Martin Shkreli, former CEO of Turing Pharmaceuticals. Shkreli faced a similar media firestorm the previous year after dramatically raising the price of Daraprim, a medication used to treat malaria and HIV, from \$13.50 to \$750 per dose. Shkreli defended Mylan’s price increase for the EpiPen, arguing that as a generic drug maker, the company earned a relatively low 8.9% net profit, so it was not gouging consumers. He further noted that insurers should think of a \$300 EpiPen as a good deal when compared to a \$20,000 trip to the emergency room.⁵ Given Shkreli’s general infamy and the fact that eight months prior he was federally indicted for securities fraud, it was not clear whether his support helped or simply exacerbated the problem.

¹ Tara Parker-Pope and Rachel Rabkin Peachman, “EpiPen Price Rise Sparks Concern for Allergy Sufferers,” *New York Times*, August 22, 2016, <http://nyti.ms/2byh8JN> (accessed Aug. 29, 2016).

² Linda A. Johnson, “How EpiPen’s Maker Raised Prices, and Hackles, So Much,” *Washington Post*, August 23, 2016, https://www.washingtonpost.com/national/health-science/how-epipens-maker-raised-prices-and-hackles-so-much/2016/08/23/?hpid=hp-health-science%3Aepipens-maker-raised-prices-and-hackles-so-much%3Ahomepage%2Ft-HE6-91cb-ecb5418830e9_story.html (accessed Aug. 29, 2016).

³ Emily Willingham, “CEO of EpiPen Maker Mylan Sees 671% Compensation Increase in 8 Years,” *Forbes*, August 23, 2016, <http://www.forbes.com/sites/emilywillingham/2016/08/23/ceo-of-mylan-pharmaceuticals-sees-671-salary-increase-in-8-years/#623cb3884b23> (accessed Aug. 29, 2016).

⁴ Michael Hiltzik, “Another Reason to Hate Mylan, which Jacked up the Price of Life-Saving EpiPens: It’s a Tax Dodger,” *Los Angeles Times*, August 23, 2016, <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-mylan-inversion-20160823-snap-story.html> (accessed Aug. 29, 2016).

⁵ Vinita Nair, “Ex-Pharma CEO Martin Shkreli Weighs in on Skyrocketing EpiPen Prices,” *CBS News*, August 23, 2016, <http://www.cbsnews.com/news/ex-pharma-ceo-martin-shkreli-weighs-in-on-skyrocketing-epipen-prices/> (accessed Aug. 29, 2016).

EpiPen

An EpiPen was a medical device used to automatically inject a measured dose of adrenaline (epinephrine) through a spring-loaded needle (**Figure 1**). It was commonly used to treat anaphylaxis, a potentially life-threatening allergic reaction that could occur quickly when a person was exposed to allergens. Common triggers of anaphylaxis included certain foods (e.g., nuts and shellfish), bee stings, latex, and pharmaceutical drugs, and reactions typically began within 5 to 30 minutes of exposure. In milder cases, breathing might become difficult as the victim's airway became restricted, blood pressure might fall, and the victim could experience a number of other uncomfortable symptoms, such as dizziness, itchy skin, facial swelling, and nausea. In extreme cases, the victim might collapse, stop breathing, and lose consciousness within minutes of exposure, and might die from respiratory or cardiac arrest if not immediately treated.

Figure 1. The EpiPen



Source: "EpiPen," posted to public domain under Creative Commons (CC BY-SA 3.0) by "Sean William," September 30, 2006, <https://commons.wikimedia.org/wiki/File:EpiPen.jpg> (accessed Aug. 26, 2016).

Adrenaline treated anaphylaxis by increasing blood flow and by reducing swelling in the airways. An EpiPen was the preferred method of delivery because it was fast, easy, and consistent. While it was possible to deliver adrenaline through a standard syringe, this method was less preferable because it was more difficult to administer in a time-sensitive crisis and by those inexperienced with syringe use.

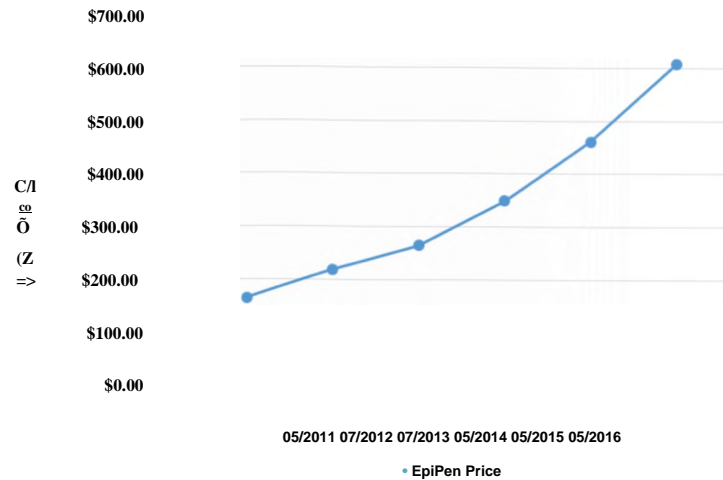
Mylan acquired the EpiPen line of products, which had been available in the U.S. market for more than 25 years, from Merck in 2007. Through Mylan's marketing investments, the EpiPen brand had become so well known among people with allergies that it had become a genericized trademark, or the "Kleenex" of auto injectors. The number of patients using EpiPens had grown 67% over the past seven years, and EpiPen revenue had grown from \$200 million to more than \$1 billion.⁶

Over the past five years, Mylan increased the price of the EpiPen by more than three and a half times (**Figure 2**). People questioned whether this price increase was driven by increased production costs.⁷ Adrenaline had been in use for decades and cost less than \$1 per dose to produce. Manufacturing costs for the device were thought to be less than \$1 too.⁸

⁶ Cynthia Koons and Robert Langreth, "How Marketing Turned the EpiPen into a Billion-Dollar Business," Bloomberg, September 23, 2015, <http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business> (accessed Aug. 29, 2016).

⁷ <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-mylan-inversion-20160823-snap-story.html>.

⁸ "Epinephrine," International Drug Price Indicator Guide, http://erc.msh.org/dmpguide/resultsdetail.c6n?language=english&code=zADRIA&year=2014&year=2014&str=1%20mg%2Fml&desc=Epinephrine&pack=new&frm=AMPOULE&rte=INJ&class_code2=&supplement=&dass_name=%2803%2E%29Antiallergics%20and%20medicines%20used%20in%20anaphylaxis%3Cbt%3E%2812%2E2%2E%29.Xntiarhythmic%2Qmedicines%3Cbr%3E%28%29%3Cbr%3E (accessed Aug. 29, 2016).

Figure 2. EpiPen price increase, 2011-2016.⁹

Source: Created by author.

Mylan did offer discounts to promote greater access to EpiPens by defraying costs for some consumers. The “My EpiPen Savings Card” provided up to \$100 for each EpiPen two-pack carton refill (**Figure 3**). In a press release, the company stated that nearly 80% of commercially insured patients who used the savings card received an EpiPen for free in 2015.¹⁰

Figure 3. My EpiPen Savings Card.



Source: EpiPen website, <https://www.epipen.com/copay-offer/> (accessed Aug. 30, 2016).

⁹ Jake Novack, “EpiPen Prices Are out of Control! Here’s How We Fix the Problem,” CNBC, August 23, 2016, <http://www.cnbc.com/2016/08/23/epipen-prices-are-out-of-control-heres-how-we-fix-the-problem-commentary.html> (accessed Aug. 29, 2016).

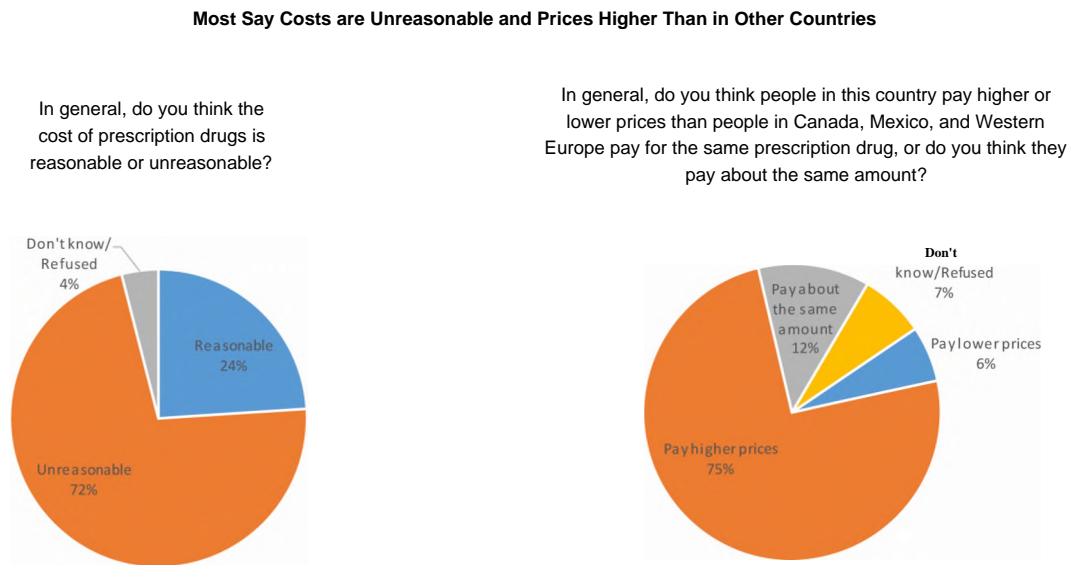
¹⁰ “Mylan’s Commitment to EpiPen® (epinephrine injection, USP) Auto-Injector Access,” Mylan press release, August 22, 2016, <http://!newsroom.mylan.com/2016-08-25-Mylan-Taking-Immediate-Action-to-Further-Enhance-Access-to-EpiPen-Epinephrine-Injection-USP-Auto-Injector> (accessed Aug. 31, 2016).

Until 2015, French pharmaceutical company Sanofi S.A. made a competing autoinjector called Auvi-Q. The company voluntarily withdrew that product from the market in 2015 because it was found to potentially deliver inaccurate dosages. The other similar product available in the United States, Adrenaclick, had only captured 7% of the market since its réintroduction in mid-2013. While Adrenaclick was less expensive (Wal-Mart priced Adrenaclick for only \$142),¹¹ users were reluctant to switch products.

Broader Concerns about Pharmaceutical Drug Pricing

Even prior to the furor over the EpiPen, Americans' anger about the overall cost of pharmaceutical drugs had been simmering. A Kaiser Family Foundation survey (**Figure 4**) found that 72% of Americans thought that the cost of pharmaceutical drugs was unreasonable, and that 74% of Americans thought that they paid higher prices than people in Canada, Mexico, and Western Europe for the same drug.^{11 12} A study by Frank Lichtenberg corroborated this finding, showing that drug prices could vary widely across countries (**Exhibit 2**).

Figure 4. Kaiser Family Foundation Survey results.



Source: Created by author.

The EpiPen was no exception to this rule. Consumers could purchase a two-pack for the equivalent of \$85¹³ in France and \$131¹⁴ in Canada. Commenting on the difference in prices across countries, Bresch

¹¹ Ginger Skinner, "Can You Get a Cheaper EpiPen?," *Consumer Reports*, August 11, 2016, <http://www.consumerreports.org/drugs/can-you-get-a-cheaper-epipen/> (accessed Aug. 29, 2016).

¹² Bianca DiJulio, Jamie Firth, and Mollyann Brodie, "Kaiser Health Tracking Poll; August 2015," The Henry J. Kaiser Family Foundation, August 20, 2015, <http://kff.org/hcal/th-costs/poll-finding/kaiser-health-tracking-poll-august-2015/> (accessed Aug. 29, 2016).

¹³ <http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business>.

¹⁴ Emma Court, "Mylan's EpiPen Price Increases are Valeant-Like in Size, Shkreli-Like in Approach," *MarketWatch*, August 18, 2016, <http://www.marketwatch.com/story/mylan-epipen-price-increases-are-valeant-like-in-size-shkreli-like-in-approach-2016-07-20> (accessed Aug. 29, 2016).

remarked, “We do subsidize the rest of the world...and as a country we’ve made a conscious decision to do that. And I think the world’s a better place for it.”¹⁵

Americans worried about their health would go to great lengths to obtain an EpiPen. For example, a social worker in Seattle cried when she found out that her EpiPen would cost \$350. She said, “I was terrified because there’s this life-saving medicine that I needed, and I couldn’t afford it.” She was able to buy two pens in Canada for about half as much.¹⁶

Conclusion

Bresch had a lot to consider in a short period of time. She needed to answer some tough questions from Congress and put out a growing media firestorm. She also needed to stop the decline of Mylan shares, which had decreased by more than 10% in the past week. Her next steps could drastically alter both her career and the shape of the company. What should she do?

¹⁵ Dan Mangan and Anita Balakrishnan, “Mylan CEO Bresch: ‘No One’s More Frustrated than Me’ about EpiPen Price Furor,” CNBC, August 25, 2016, <http://www.cnbc.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs-after-charges-of-price-gouging.html> (accessed Aug. 29, 2016).

¹⁶ <http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business>.

Exhibit 1
 Pricing the EpiPen: This is Going to Sting
 Senator Grassley's Letter¹

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

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United States Senate
 COMMITTEE ON THE JUDICIARY
 WASHINGTON, DC 20510-6275

Kelise L. Davis, Chief Counsel and Staff Director
 Kostick J. LuOvS, Democrat Chief Counsel and Staff Director

August 22, 2016

VIA ELECTRONIC TRANSMISSION

Ms. Heather Bresch
 Chief Executive Officer
 Mylan
 1000 Mylan Boulevard
 Canonsburg, PA 15317

Dear Ms. Bresch,

I am writing to request information regarding recent consumer concerns, including those expressed to me by lowans, and media reports about the high cost of the Mylan EpiPen (epinephrine injection) Auto-Injector, which is used in emergency treatment for life-threatening allergic reactions. Access to epinephrine can mean the difference between life and death, especially for children. That is why the School Access to Emergency Epinephrine Act was signed into law in 2013¹¹. The law provides an incentive to states to boost the stockpile of epinephrine at schools. In addition, a number of states have passed laws requiring public schools to have epinephrine.

In 2007, Mylan purchased EpiPen from The Merck Group. Since the acquisition, the cost of EpiPen has risen over 400 percent¹².

The substantial price increase has caused significant concern among patients. I have heard from one father in Iowa who recently purchased a refill of his daughter's EpiPen prescription. He reported that to fill the prescription, he had to pay over \$500 for one EpiPen. From other lowans I have heard concerns about the cost of EpiPens and the need to replace them once a year when they expire. The high cost has also caused some first responders to consider making their own kits with epinephrine vials and syringes. For example, first responders in Seattle have developed such a kit and have sold them to public health agencies in five other states. Furthermore, there is a demonstration project in New York called "Check and Inject New York" which trains first responders to use syringe epinephrine kits in place of EpiPens to save money¹³.

In addition, schools are feeling the budgetary effects of needing EpiPens on hand in order to be prepared for emergency situations.

¹¹ <https://www.congress.gov/bills/113/congress/house-bill/2094/text>

¹² <http://www.nbcnews.com/business/economy/epipen-price-hike-has-parents-kids-allergies-scrumbling-ahead-school-n633071>

¹³ <http://thecheck.com/articles/634878/america-dangerous-epipen-crisis>

¹ Charles E. Grassley to Heather Bresch, August 22, 2016, <http://www.grassley.senate.gov/sites/default/files/constituents/upload/2016-08-22%20CEG%20to%20Mylan%20%28EpiPen%29.pdf> (accessed Sept. 1, 2016).

Exhibit 1 (continued)

The cost of an EpiPen prescription has implications for the federal taxpayers as well. Over 40% of children are insured through Medicaid or the Children's Health Insurance Program (CHIP). It follows that many of the children who are prescribed EpiPens are covered by Medicaid and therefore the taxpayers are picking up the tab for this medication.

In the case of EpiPens, I am concerned that the substantial price increase could limit access to a much-needed medication. In addition, it could create an unsafe situation for patients as people, untrained in medical procedures, are incentivized to make their own kits from raw materials.

In order to fully understand the pricing for EpiPens, please provide the following information:

1. What analyses were conducted by Mylan in determining the price of EpiPens?
2. What was Mylan's advertising budget for EpiPen in first half of 2016 as well as 2015?
3. Mylan has stated that the EpiPen has changed over time to better reflect important product features and the value the product provides^[4]. Please explain the changes Mylan has made to EpiPen since the acquisition that have caused it to increase the price and reflects the value the product provides.
4. Does Mylan provide a patient assistance program to help defray the cost of EpiPens to patients who need that help? If so, how much monetary assistance has been provided to patients in the past 5 years? Does Mylan have an arrangement with a non-profit organization in order to provide patient assistance for EpiPens? If so, what is the non-profit? And if so, how much monetary assistance has been provided to patients via the non-profit in the past 5 years?
5. What assistance programs exist to help school systems purchase EpiPens in order to be used, without a prescription, in an emergency situation? If such programs exist, how many school systems through the U.S. have used such a service in the past 5 years?

Thank you in advance for your cooperation with this request. Please number your responses according to their corresponding questions and respond no later than September 6, 2016. If you have questions, please contact my Health Policy Director, Karen Summar at Karen.summar@grassley.senate.gov or (202) 224-5225.

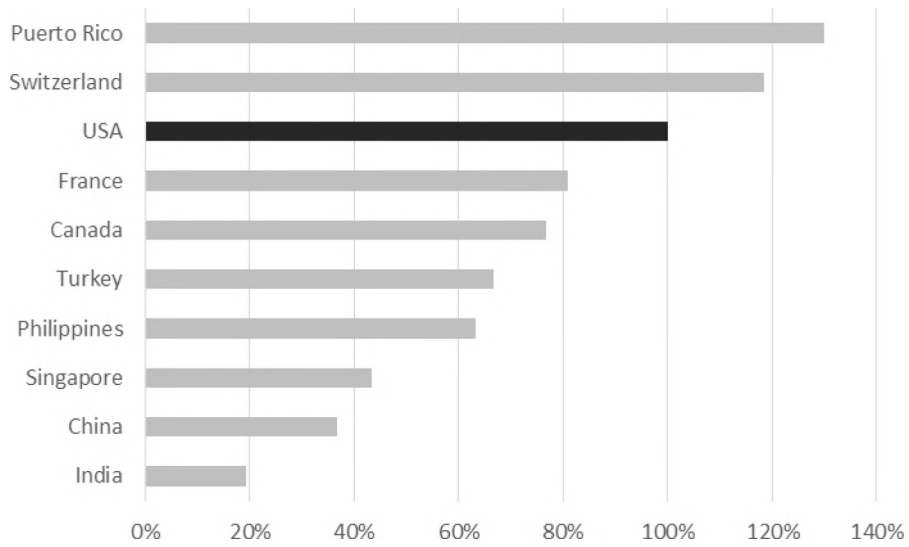
Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary

Exhibit 2
Pricing the EpiPen: This is Going to Sting
Drug Price Variation across Countries

Mean Price Relative to U.S. Price



Source: An author adaptation of Frank R. Lichtenberg, "Pharmaceutical Price Discrimination and Social Welfare," *Capitalism and Society* 5, no. 1 (2010), <http://www.bepress.com/cas/vol5/iss1/art2> (accessed Aug. 30, 2016).