

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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August 30, 2016

Ms. Heather Bresch
Chief Executive Officer
Mylan N.V.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317

Dear Ms. Bresch:

We are conducting oversight of the availability and pricing of Mylan's EpiPen®. Numerous news outlets have reported that Mylan increased the cost of its EpiPen® by more than 400 percent since acquiring rights to the epinephrine auto-injector in 2007.¹ We would like more information to understand Mylan's pricing of its EpiPen® and how the company is ensuring that patients suffering from allergic emergencies have access to these life-saving products.

When Mylan acquired the EpiPen® in 2007, the wholesale cost of the product was \$57.² Today, the list price of a dual EpiPen® package is over \$600.³ Aggressive marketing and price increases led to EpiPen® sales of over \$1 billion in 2015, which accounted for approximately 40% of Mylan's profits.⁴ Mylan reported \$1.1 billion net sales of the EpiPen 2-Pak® on August

¹ Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, Forbes (Aug. 21, 2016) (www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epi-pen-prices-400-because-they-could).

² Cynthia Koons and Robert Langreth. *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, Bloomberg (Sept. 23, 2015) (www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epi-pen-into-a-billion-dollar-business).

³ Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, Forbes (Aug. 21, 2016).

⁴ Koons and Langreth. *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, Bloomberg (Sept. 23, 2015).

25, 2016.⁵ The EpiPen® is an emergency use product, delivering approximately \$1 worth of life-saving epinephrine per dose.⁶ Epinephrine, i.e. adrenaline, at the correct dose opens up a person's airways and can give those suffering from anaphylaxis precious time to seek out emergency medical attention. An EpiPen® typically has a shelf life of one year, and therefore those at risk of anaphylaxis must purchase the product on an annual basis.⁷

Earlier this month, in response to the recent media coverage regarding the price increase, Mylan issued the following statement:

Mylan has worked tirelessly over the past years advocating for increased anaphylaxis awareness, preparedness and access to treatment for those living with potentially life-threatening (severe) allergies. Ensuring access to epinephrine – the only first-line treatment for anaphylaxis – is a core part of our mission.⁸

We are interested in learning more about how Mylan's 400 percent price increase of its EpiPen® furthers this stated mission and what steps Mylan is taking to ensure this life-saving product is accessible to those in need. Therefore, we are requesting that you provide a response to the following questions:

1. We would like to better understand how Mylan priced its EpiPen®. To assist us, please address the following questions:
 - a. Why did Mylan increase the cost of the EpiPen® by 400 percent? Mylan has stated that product improvements have driven up the costs of the EpiPen®. Please provide additional information regarding the factors Mylan took into consideration when increasing the cost of the EpiPen®. In particular, please provide specific details on product improvements and investments made by Mylan, such as specific product changes that improved safety, efficacy, or convenience, or increased advertising and marketing that could help explain such a drastic increase.
 - b. We have heard from many constituents about the negative impact the cost increase is having on their lives and lives of family members. Access and use of the EpiPen® is a matter of life and death for some patients, and we have heard from far too many over the past several weeks about how patients are feeling

⁵ Mylan N.V., *The Entire Economic Story of the U.S. Pharmaceutical Supply Chain*, PR Newswire (Aug. 25, 2016) (photos.prnewswire.com/prnfull/20160825/401225-INFO).

⁶ Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, Forbes (Aug. 21, 2016).

⁷ *Id.*

⁸ Mylan N.V., *Mylan's Commitment to EpiPen (epinephrine injection, USP) Auto-Injector Access*, (Aug. 22, 2016) (press release) (newsroom.mylan.com/access).

forced to go without due to the increased cost. What, if any, research did Mylan conduct on the patient impact of such a drastic price increase? Did Mylan consult with patient advocacy groups, hospitals, insurance providers, or other stakeholders before increasing the list price of EpiPen®?

- c. Mylan has also indicated that pharmacy benefit managers, insurers, wholesalers, and pharmacy retailers played a role in the increased costs of the EpiPen® to patients. As the only company currently marketing an epinephrine auto-injector, Mylan can play a role in influencing the final list price. In fact, according to a graphic published by Mylan on August 25, 2016, the company is responsible for nearly half the list price of the EpiPen®. Please provide additional information regarding what internal reviews Mylan is conducting regarding the list price for EpiPen®, as well as what discussions, if any, Mylan has undertaken with its partners in the supply chain regarding the list price of the EpiPen®.
2. After news of the EpiPen® price increase, Mylan announced on August 25, 2016, it was expanding its savings card program. Under the program, a person with commercial insurance with up to a \$300 co-pay will pay nothing for the EpiPen®, and those with high deductibles who must pay the full price of over \$600 will receive \$300 off.⁹ Mylan also announced it is expanding a financial assistance program for uninsured or underinsured patients to provide the EpiPen® for free to families that make up to four times the poverty level. To help us better understand the development and utilization of this program, please address the following questions:
 - a. I am sure you are aware that it is illegal for government programs to participate in Mylan's savings card program. More than 100 million Americans, collectively, are enrolled in health coverage through federal health programs, and a 2013 study found that one in 50 Americans are at risk for anaphylaxis¹⁰. Therefore, it is reasonable to assume that the government pays for a significant number of EpiPen® prescriptions and that the savings card program will leave the U.S. taxpayer to pay for the 400 percent EpiPen® cost increase. What information does Mylan have on how many EpiPen® products are purchased by federal programs? To what extent did Mylan take into account the cost to American taxpayer when attempting to control costs through a savings card program versus an overall price decrease?
 - b. Critics of the savings card program argue that it is ineffective and will ultimately harm patients because, despite immediate consumer savings, insurance companies still must pay the high price of the drug. A July 2016 U.S. Government

⁹ Mylan N.V., *EpiPen Auto-Injector Expanded Access Program*, PR Newswire (Aug. 25, 2016) (photos.prnewswire.com/prnfull/20160825/401226-INFO).

¹⁰ R.A. Wood, et al., *Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States*, 133 *Journal of Allergy and Clinical Immunology*, Feb. 2014, at 461–467 (October 21, 2013).

Accountability Office (GAO) study found that “coupon programs may allow manufacturers to increase their sales of these drugs and extract higher prices from health care providers and other drug purchasers”, and further that Medicare may be paying more than necessary for drugs with coupon programs.¹¹ As we have seen in the past, insurance companies generally pass these costs to patients in the form of higher insurance premiums. To what extent did Mylan consider the unintended consequences its savings card program may have? Did Mylan consult with insurance companies or other experts in this field when developing this program to help ensure it would actually benefit public health versus harming consumers in the long-term?

- c. Why did Mylan opt to utilize a savings card program versus an overall price decrease? What percentage of patients prescribed the EpiPen® will realize a benefit from the program?
3. We are concerned about the adverse impact this cost increase may have on those caring for patients suffering from anaphylaxis. As you know, the Energy and Commerce Committee played a role in passage of legislation that would authorize the U.S. Department of Health and Human Services to give grant funding preference to states that allow schools to maintain and administer an emergency supply of epinephrine. Mylan was one of the leading supporters of this legislation.
 - a. The EpiPen4Schools® Program offers up to four EpiPen® or EpiPen Jr® Auto-Injectors, along with EpiPen® Trainers, a detailing training video, and storage locker to qualifying schools. How many schools currently participate in the EpiPen4Schools® Program? How many EpiPen® or EpiPen Jr® Auto-Injectors have been provided to schools for free since the program’s inception?
 - b. Mylan also offers schools access to discounted EpiPen®s. What is the discounted price of the EpiPen® for participating schools? How many schools have participating in this purchasing discount?
 - c. A June 2015 certification form for schools or school districts participating in the EpiPen4Schools® Program required schools to certify to Mylan that the school “will not in the next twelve (12) months purchase any products that are competitive products to EpiPen® Auto-Injectors.”¹² Please explain how this requirement furthers Mylan’s stated goal of ensuring access to epinephrine, and how this requirement has been enforced by the company.

¹¹ U.S. Government Accountability Office, *Data on Coupon Discounts Needed to Evaluate Methodology for Setting Drug Payment Rates*, (July 2016).

¹² Mylan N.V., *Free Certification Form: EpiPen (epinephrine injection) Auto-Injector EpiPen4Schools Program*, (June 2015).

- d. Concerns regarding access to epinephrine have also been raised by emergency medical service providers. What steps has Mylan taken to ensure the EpiPen® is accessible to emergency medical service providers and that the cost increase does not put these products out of reach for those charged with providing patients with safe, effective, and high-quality prehospital care?
4. Currently, the EpiPen® is the only epinephrine auto-injector on the market as in 2015, Sanofi removed Auvi-Q®, a brand name competitor to EpiPen®, from the market due to the potential for inaccurate dosing of the drug.¹³ However, in recent years generic competitors have attempted to enter the market to provide an alternative to the EpiPen®. For example, in 2014 Teva Pharmaceuticals filed an Abbreviated New Drug Application (ANDA) for an epinephrine auto-injector with the FDA. We understand Mylan has taken proactive steps to delay and discourage generic competition to its EpiPen®.

During FDA's review of Teva's application, Mylan filed a Citizen Petition requesting that FDA not approve Teva's ANDA. Among other things, Mylan argued that because of the differences in design and operation between Mylan's EpiPen® and Teva's generic epinephrine auto-injector, EpiPen® users would not be able to safely or effectively use the product.¹⁴ Mylan requested FDA refrain from approving Teva's ANDA until the company conducted human factor studies that demonstrate Teva's product's comparability to the EpiPen®.¹⁵ Mylan noted in its Citizen Petition that FDA has previously recognized such human factor data are beyond the scope of what may be submitted in an ANDA.¹⁶ In Mylan's August 29, 2016 press release announcing it was authorizing a generic EpiPen®, Mylan stated, "Generic drugs have a long, proven track record of delivering significant savings to both patients and the overall healthcare system." Please explain how assertions Mylan made in its 2015 citizen petition to discourage FDA approval of a generic competitor support this statement.

5. Mylan announced on August 29, 2016, that it was authorizing its U.S. subsidiary to launch a generic EpiPen® at a list price of \$300 per EpiPen® two-pack. When did Mylan make the decision to launch an authorized generic of EpiPen®? Further, please explain why Mylan chose to authorize a generic product versus reducing the cost of its brand name EpiPen® - a brand American consumers have consistently relied on for decades.

¹³ Sanofi, *UPDATED: Sanofi US Issues Voluntary Nationwide Recall of All Auvi-Q® Due to Potential Inaccurate Dosage Delivery*, (Oct. 30, 2015) (press release) (news.sanofi.us/2015-10-28-Sanofi-US-Issues-Voluntary-Nationwide-Recall-of-Auvi-Q-Due-to-Potential-Inaccurate-Dosage-Delivery).

¹⁴ Mylan, *Citizen Petition*, Regulations.gov (Jan 16, 2015) (www.regulations.gov/document?D=FDA-2015-P-0181-0001).

¹⁵ *Id.*

¹⁶ *Id.*

6. We understand that the cost of the life-saving EpiPen® has consistently increased since Mylan acquired the product¹⁷ and are interested in the timing of Mylan's recent announcements regarding access. Why did Mylan wait until August 25, 2016 to expand its EpiPen® access program?¹⁸ Why did Mylan wait until August 29, 2016 to announce it would be releasing a generic version of the EpiPen®?¹⁹

We would appreciate your response to this request as soon as possible, but no later than September 12, 2016. If you have any questions regarding this request, please contact Kimberlee Trzeciak or Megan Velez of the minority staff at 202-225-3641.

Sincerely,



Frank Pallone, Jr.
Ranking Member



Gene Green
Ranking Member
Subcommittee on Health



Diana DeGette
Ranking Member
Subcommittee on Oversight and
Investigations

¹⁷ Jayne O'Donnell, et al., *EpiPen's steady price increases masked until deductibles rose*, USA Today (Aug. 25, 2016) (www.usatoday.com/story/news/politics/2016/08/23/epipens-steady-price-increases-masked-until-deductibles-rose/89123786).

¹⁸ Mylan N.V., *Mylan Taking Immediate Action to Further Enhance Access to EpiPen (Epinephrine Injection, USP) Auto-Injector* (Aug. 25, 2016) (press release) (newsroom.mylan.com/2016-08-25-Mylan-Taking-Immediate-Action-to-Further-Enhance-Access-to-EpiPen-Epinephrine-Injection-USP-Auto-Injector).

¹⁹ Mylan N.V., *Mylan to Launch First Generic to EpiPen Auto-Injector at a List Price of \$300 per Two-Pack Carton, a more than 50% Discount to the Brand Product*, (Aug. 29, 2016) (press release) (newsroom.mylan.com/2016-08-29-Mylan-to-Launch-First-Generic-to-EpiPen-Auto-Injector-at-a-List-Price-of-300-per-Two-Pack-Carton-a-More-than-50-Discount-to-the-Brand-Product).