Testimony of Mylan CEO Heather Bresch before the United States House of Representatives Committee on Oversight and Government Reform

Wednesday, September 21, 2016

I'm Heather Bresch, the CEO of Mylan.

I appreciate the chance to be with you today. Before I answer your questions, I would like to share with you some information on my background and Mylan, and tell you what we have done in the last few weeks to address concerns about the price and availability of EpiPen® Auto-Injectors.

I grew up in a small town in West Virginia, in a close family with a strong work ethic. I joined Mylan in 1992 as an entry level clerk, performing basic administrative tasks in the basement of the company's manufacturing facility.

I've worked in 15 different roles since joining the company. When I started with Mylan, our sales were approximately $100 million. Today, our sales are in excess of $11 billion, and 1 in 13 U.S. prescriptions is filled with one of Mylan's medications.

I'm proud to be the CEO of Mylan, but I never expected to be here under these circumstances—discussing the price of EpiPen Auto-Injectors. I've spent my entire career working to break down barriers, expand access to high quality medicines and lower healthcare costs.

As with anyone, our record isn't perfect - and I know you have many important questions you want to ask - but what's also extremely important is the tremendous amount of good Mylan has done for millions of patients in the U.S and around the world.

I want to highlight two facts about Mylan. First, we aren't the kind of niche pharmaceutical company that offers only a handful of products. In fact, we are the exact opposite. Today, we offer more than two thousand, seven hundred different products. Over the last 55 years, we have grown to more than 40,000 employees, with more than 50 manufacturing facilities, capable of producing up to 80 billion doses annually.

As primarily a generic pharmaceutical company, we must invest heavily in research and development and manufacturing in order to produce billions of doses and bring hundreds of new products to market every year. This year, for example, we will spend approximately $1.2 billion on R&D and manufacturing facilities, or roughly $3 million per day.

Second, our business is predicated on high volumes of hundreds of products. In the U.S. alone, we offer a portfolio of 635 products, which translated last year to more than 21 billion doses made available to patients, at an average price to Mylan of 25 cents per

dose. Over the last decade, Mylan's medicines reduced U.S. healthcare costs by approximately $180 billion.

This is the EpiPen device...

It may look simple, but it is actually quite complex. In the event of a severe allergic reaction, the more than 15 critical component parts in this device must work EVERY TIME...IN SECONDS...to deliver medicine to treat life threatening symptoms quickly and without fail.

For millions of families, the presence of an EpiPen Auto-Injector in a purse, briefcase, backpack or medicine cabinet is a source of enormous comfort and an invaluable insurance policy against a potential tragic event.

It troubles me greatly that the EpiPen product has become a source of controversy. I understand the focus of this hearing is primarily about our pricing of EpiPen Auto-Injectors. I'm prepared to address that issue in depth. At the same time, the issue of EpiPens has two equally critical dimensions - price and access. With the current focus on pricing, I'm very concerned that the access part of the equation is being minimized.

When Mylan acquired the company that owned EpiPen Auto-Injectors in 2007, not only was there low awareness of anaphylaxis, but fewer than 1 million of the 43 million people at risk had access to an epinephrine auto injector. At the same time, it was estimated that anaphylaxis was causing 1,500 deaths annually, or more than 4 per day. And many people who suffer a severe allergic reaction requiring epinephrine had no known history of a severe allergy. We read stories of children dying on playgrounds because schools didn’t have access to epinephrine to use on children without a prescription in their name. We saw this as an unacceptable and largely preventable health problem.

In the more than 8 years we have owned the EpiPen product, we have worked diligently and invested to enhance the product and make it more available. In fact, we have invested more than one billion dollars in the efforts. On many fronts we have succeeded. We put a much improved EpiPen device on the market in 2009. We’ve also invested so that we can soon offer a longer shelf life, which means patients will go longer before needing a refill.

We have now reached 80% more patients. And today, approximately 85 percent of EpiPen patients pay less than $100 for a 2 unit package and a majority pay less than $50.

And we've made great strides in providing access to EpiPen Auto-Injectors in public places, starting with schools. In the last four years alone, Mylan provided seven hundred thousand free EpiPen Auto-Injectors to more than 66,000 schools across America, with no strings attached.

I hope these facts will be considered in the larger discussion about price. Price and access exist in a balance, and we believe we have struck that balance. But we don't want to go back to a time - not that long ago - when awareness of anaphylaxis was much lower and epinephrine auto injectors were only available in schools with a prescription for an individual child. Achieving this level of expansion of awareness requires significant investment.

I know there is considerable concern and skepticism about the pricing of EpiPen Auto-Injectors. I think many people incorrectly assume we make $600 off each EpiPen. This is simply not true.

In the complicated world of pharmaceutical pricing there is something known as the Wholesale Acquisition Cost or WAC. The WAC for a 2 unit pack of EpiPen Auto-Injectors is $608. After rebates and various fees, Mylan actually receives $274. Then you must subtract our cost of goods which is $69. This leaves a balance of $205. After subtracting all EpiPen Auto-Injector related costs our profit is $100, or approximately $50 per pen.

The misconception about our profits is understandable, and at least partly due to the complex environment in which pharmaceutical prices are determined. The pricing of a pharmaceutical product is opaque and frustrating, especially for patients.

In the last few weeks, we've confronted the EpiPen issue head on. Our program has four parts:

We announced the first ever generic version of the EpiPen product, which will be priced at $300. This unprecedented move is the fastest and most direct way to reduce the price for all patients.

Second, we are creating a direct ship option, allowing patients to purchase the generic product directly from Mylan for $300.

Third, we increased our My Epipen Savings Card program benefit for the brand product from $100 to $300.

Fourth, we doubled the eligibility of patients receiving free pens from $48,600 to $97,200 for a family of four.

Looking back, I wish we had better anticipated the magnitude and acceleration of the rising financial issues for a growing minority of patients who may have ended up paying the full WAC price or more. We never intended this. We listened and focused on this issue and came up with a sustainable solution.

I understand your concern about EpiPen Auto-Injectors, but I ask that you look at our overall record for this patient population and our response to the challenge.

Going forward, we will continue our leadership in developing high quality medicines and expanding access.

Committee on Oversight and Government Reform
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

Name:
Heather Bresch

1. Please list any federal grants or contracts (including subgrants or subcontracts) you have received since October 1, 2012. Include the source and amount of each grant or contract.

None.

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

I am testifying for Mylan, N.V., for which I am the Chief Executive Officer, and testifying for Mylan, N.V.'s subsidiary, Mylan Specialty, L.P., which markets and sells the EpiPen® Auto-Injector.

3. Please list any federal grants or contracts (including subgrants or subcontracts) received since October 1, 2012, by the entity(ies) you listed above. Include the source and amount of each grant or contract.

Since October 1, 2012, Mylan Speciality has had sales for its products offered to various federal customers (including the Veterans Administration and the Department of Defense) of, at least, $181,220,007. I am not aware of any grants with the Federal Government but will supplement if necessary.

If you would like additional information about these contracts, please contact Mylan.

I certify that the above information is true and correct.
Signature:

Date: 19 SEP 15

Summary Biography of Mylan Chief Executive Officer Heather Bresch

Heather Bresch is chief executive officer of Mylan, one of the world's leading pharmaceutical companies. She also serves on the company's board of directors. As CEO, she is responsible for a workforce of more than 40,000, a powerful global research and development platform, a manufacturing footprint comprising more than 50 facilities, and a portfolio of more than 2,700 generic and branded pharmaceuticals sold in more than 165 countries and territories.

Career at Mylan

Throughout her 24-year career with Mylan, Bresch, who started with the company as a data-entry clerk, has held roles of increasing responsibility in more than 15 functional areas. Prior to becoming CEO, Bresch served as Mylan's president, where she was responsible for the day-to-day operations of the company. Before that, she served as Mylan's chief operating officer and chief integration officer, leading the successful integration of two international acquisitions – Matrix Laboratories and Merck KGaA's generics business – which more than doubled the size of the company and transformed Mylan from a purely U.S. company to a global one.

Leading the Next Chapter of Mylan's Growth and Performance

As CEO, Bresch is leading the next chapter of Mylan's growth and performance, and further differentiating the company from its competitors by transforming it from a pharmaceutical company into a healthcare company. This strategy includes plans to double the size of Mylan's product portfolio, manufacturing capacity and earnings between 2012 and 2018, enhance its technologies and capabilities, expand its reach across geographies and commercial channels, and develop new services that further enhance Mylan's relationship with customers and patients.

In executing on this strategy and continuing to satisfy unmet needs, Mylan is developing and launching hundreds of new generic, specialty and over-the-counter products annually. Additionally, Mylan has continued to serve as a leading consolidator in the industry, with recent transactions including Abbott's non-U.S. developed markets specialty and branded generics business and Meda, a leading international specialty pharmaceutical company that sells both prescription and over-the-counter products. Mylan also continues to focus on complex and difficult-to-manufacture products and is developing portfolios of complex biologic, insulin and respiratory products.

To achieve Mylan's goals, Bresch emphasizes a collaborative company culture focused on leading, learning, teaching and performing to inspire innovation and help set new standards in healthcare.

Providing Passionate Global Leadership on Key Issues

Mylan's mission is to provide the world's 7 billion people access to high quality medicine and to "do good while doing well." Over the course of her career at the company, Bresch has been a champion of initiatives and policy changes aimed at removing barriers that hinder access.

Among her policy priorities is ensuring that everyone living with HIV/AIDS has access to high quality, affordable drugs and advocating for treatment soon after diagnosis to produce better health outcomes, reduce HIV transmission and create long-term cost savings. Approximately 50% percent of patients being treated for HIV/AIDS in the developing world today rely on a Mylan product.

Bresch also has been a leading advocate for global competitiveness and global quality standards. For instance, driven by Mylan's unmatched commitment to quality, Bresch was instrumental in the development of the Generic Drug User Fee Act (GDUFA) which aims to hold all drugs sold in the U.S. to one quality standard. In addition, she advocated for changes to the Federal Food, Drug and Cosmetic Act of 1938 to arm the U.S. Food and Drug Administration (FDA) with the resources and authority needed to regularly inspect U.S. and foreign plants at the same rate. Both of these provisions were included in the Food and Drug Administration Safety and Innovation Act (FDASIA), landmark legislation that was signed into law in July 2012.
Moreover, Bresch is actively advocating for the implementation of a viable abbreviated approval pathway for safe and effective generic versions of biologic drugs, which will provide patients with access to lower-cost versions of these life-saving products. In addition, Bresch is passionate about increasing awareness of and preparedness for life-threatening allergic reactions, called anaphylaxis, and has advocated for measures that provide people immediate access to Epinephrine auto-injectors, as the drug is considered the first-line treatment for anaphylaxis.

Earlier in her career, Bresch played a vital role in the passage of the 2003 Medicare Modernization Act, a congressional revision to the Hatch-Waxman Act of 1984, which helped to ensure consumer access to affordable pharmaceuticals.

Bresch was elected to serve as chair of the Generic Pharmaceutical Association's board of directors in 2016. Previously, she served two one-year terms as the chair of the association in 2004 and 2005 and two one-year terms as vice chair in 2003 and 2006. She is a frequent speaker on issues such as affordable healthcare and global competitiveness, and has testified before the U.S. Congress and FDA on issues related to access to medicine. Heather is the pharmaceutical industry's first female CEO of a Fortune 500 company, and has been named by *Fortune* magazine as one of its "50 Most Powerful Women."

Bresch earned her undergraduate degree from West Virginia University.