

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

Wednesday, September 21, 2016

Good afternoon Chairman Chaffetz, Ranking Member Cummings and members of the committee.

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 EpiPens.

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 and worked through 15 different roles in the company until I reached my current position.

When I started with Mylan, our sales were approximately \$100 million, with less than 500 employees. Today, our sales are in excess of \$11 billion, with more than 40,000 employees. And 1 in 13 U.S. prescriptions is filled with one of Mylan's medications.

I would like 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. Over the last 55 years, we have grown to offer more than two thousand, seven hundred different products, predominantly generics, made at more than 50 manufacturing facilities, capable of producing up to 80 billion doses annually, and we see the need to do more.

This year alone, we will invest approximately \$1.2 billion in research and development and manufacturing, or roughly \$3 million per day, to bring affordable access to many more complex products, such as insulin and biosimilars.

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 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 anaphylaxis – 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, many times self-administered by the person in the state of anaphylaxis.

Before Mylan acquired the company that owned EpiPen in 2007, 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. We read stories of children dying at school because they did not have access to an epinephrine auto-injector or due to a lack of education about the need. We saw this as an unacceptable and largely preventable health problem.

We have worked diligently and invested to enhance EpiPen and make it more available. In fact, we have invested more than one billion dollars in these efforts over the last few years and have succeeded on many fronts.

We put a much improved EpiPen device on the market in 2009.

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 have made great strides in providing access to EpiPens in public places, starting with schools. In the last four years alone, Mylan provided seven hundred thousand free EpiPens to more than 66,000 schools across America, with no strings attached. And our pens were used hundreds of times, including on many children with no known allergies.

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

Recent EpiPen price increases have not yielded the revenue to Mylan that many assume. In the complicated world of pharmaceutical pricing there is something known as the Wholesale Acquisition Cost. Since 2014, the Wholesale Acquisition Cost for a 2 unit pack of EpiPen Auto-Injectors increased from \$401 to \$608, or 51%.

But the net revenue to Mylan after rebates and various fees – what we actually received – increased from \$235 to \$274. In other words, the annual increase to Mylan for the last 2 years was approximately 8% per year, or only 16.6% cumulatively during this period.

From that, you must subtract our cost of goods which is \$69. This leaves a balance of \$205. After subtracting all EpiPen related costs our profit is \$100, or approximately \$50 per pen.

In the last few weeks, we have 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.

With these changes, our profit per pen will be substantially lower than it was previously.

I'm honored and proud to be the CEO of Mylan and I've spent my entire career working to break down barriers, expand access to high quality

medicine and lower healthcare costs.

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 wholesale acquisition cost price or more. We never intended this. We listened and focused on this issue and came up with a sustainable solution.

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