

September 8, 2016

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley:

Mylan is responding to your healthcare letter of August 22, 2016, regarding your concerns about the pricing of Mylan's EpiPen® Auto-Injector.

Before turning in detail to the EpiPen Auto-Injector and the actions we have taken in relation to this product, we believe it is important for you to better understand Mylan and the meaningful role Mylan plays in the U.S. healthcare system. Access to medicine and addressing unmet medical needs has been core to Mylan since our founding 55 years ago, and with one in 13 prescriptions (brand or generic) in the U.S. being filled with a Mylan product,¹ access remains the core of our mission today. We also recognize that the cost of healthcare in the U.S. is an important and complex problem that deserves a holistic and in-depth discussion with all stakeholders and a willingness to consider new solutions that help patients and reduce costs. For its part, Mylan has been a key part of the solution to the cost of healthcare throughout our history, saving the U.S. healthcare system \$180 billion over the course of the past decade and today supplying more than 10% of the generic drugs used by U.S. patients.

Mylan is much more than any one product. We manage a portfolio of more than 2,700 separate products in 165 countries and territories.² In the U.S. alone, Mylan sells 21 billion doses annually of 635 products, at an average selling price of approximately \$0.25 per dose across all of our specialty and generic products, including the EpiPen Auto-Injector. We are able to do this because we have invested significantly in building one of the industry's largest, most efficient and reliable supply chains. It is noteworthy that since 2008 we have invested more than \$4 billion in research and development, and more than \$2.5 billion in capital expenditure globally to produce more than 80 billion doses of medicine. And we are continuing to use our revenues to reinvest to bring additional competition and savings to U.S. patients. In fact, this year alone we expect to spend approximately \$750 million in research and development. The platform we have built allows us to bring patients hundreds of products every year, invest significantly in innovation, disease education and patient services, all while delivering significant savings to the U.S. healthcare system and its patients. As a result of the significant number of cost reductions we take annually across our portfolio, our entire U.S. business, including EpiPen® Auto-Injector, has had an average annual price decrease of 1% over the last five years.

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Turning to the EpiPen Auto-Injector, we welcome this opportunity to answer your questions and correct the many misperceptions in the public dialogue about Mylan and this product.

¹ IMS National Prescription Audit for the three months ending July 2016.

² June 30, 2016 Form 10-Q

Upon acquiring the EpiPen® Auto-Injector, Mylan undertook significant research in order to better understand anaphylaxis and the role of epinephrine in its treatment. What we found was that the general awareness of anaphylaxis and its treatment was low, and those vulnerable to life-threatening allergic reactions were likely to be unprepared for an emergency. Additionally, we found that numerous obstacles hindered access to epinephrine as a first line treatment. Physicians often encouraged the use of products ineffective for the treatment of anaphylaxis, such as Benadryl®. Parents and caregivers often lacked the confidence to timely administer the auto-injector, and federal and local laws did not permit trained people at public venues, such as nurses at schools, the latitude to administer undesignated epinephrine auto-injector to, for instance, a student or school visitor unexpectedly suffering from anaphylaxis. We were devastated to hear of tragic deaths, including those in school yards, restaurants and other public places that result from poor understanding of anaphylaxis and the role of epinephrine, or lack of timely access to epinephrine. Through this work, we came to view epinephrine for anaphylaxis as critical as a defibrillator is to someone suffering from cardiac arrest.

Our understanding of this unmet need for this very important patient population drove our willingness to invest approximately \$1 billion over the past eight years to increase awareness of anaphylaxis risk, ensure preparedness should anaphylaxis occur, and increase access to epinephrine auto-injectors. We also launched a next-generation EpiPen Auto-Injector in 2009 which represented a complex and innovative re-design of the device. This sterile injectable drug-in-device includes 26 separate parts and delivers the epinephrine drug within seconds. As a result of these ongoing efforts, the number of prescriptions written for epinephrine auto-injectors have doubled from 2 million³ to 4 million,⁴ thereby ensuring millions more patients are prepared and protected. However, with 43 million⁵ patients at risk for anaphylaxis and 1 in 13 children affected by food allergies,⁶ there is still much work to be done.

Additionally, we have also worked with various advocacy partners and concerned federal and state legislators to remove barriers to access to epinephrine starting with the most vulnerable population, kids in schools. As a result, 48 states now permit undesignated epinephrine in schools. Given the financial constraints facing schools in this country, we launched our EpiPen4Schools® program in 2012, and have donated 700,000 free EpiPen devices to more than 66,000 participating schools. This program provides these EpiPen® devices free of charge, with no restrictions, to any school with a prescription that requested them thereby helping to ensure access to this important product. And we applaud all of those who worked tirelessly with us to make this possible. As a result of this program, according to a survey conducted by the Institute for Asthma and Allergy in 2014 of 10% of schools participating in the program, our free EpiPen® devices were used at least 402 times throughout just one school year, potentially saving lives.⁷

Mylan believes that cost should not be a barrier to access to the EpiPen Auto-Injector. To this end, we have offered a Patient Assistance Program (PAP) and the My EpiPen Savings Card® program since 2013. We regret that our programs did not keep pace with the evolving healthcare system, and, as a result, some patients are facing out-of-pocket costs that were never intended, potentially leading to stress upon them and their families. This is why we recently took immediate and unprecedented actions to ensure greater access to the EpiPen device and reduce the cost of this product to patients and the healthcare system.

³ IMS National Prescription Audit, 2007.

⁴ IMS National Prescription Audit, 2015.

⁵ Neugut AI, Ghatak AT, Miller RL, “Anaphylaxis in the United States. Archives of Internal Medicine. 2001; 161: 15 – 21.

⁶ Gupta RS, Springston EE, Warrier MR, et al. The prevalence, severity and distribution of childhood food allergy in the United States. Pediatrics. 2011;128(1):e9-e17.

⁷ White M, et. al., A Comprehensive View of Anaphylaxis in Schools: Results of the EPIPEN4SCHOOLS Survey Combined Analysis, *Pediatric Allergy, Immunology and Pulmonology*, 2016, in press.

Specifically, we increased our My EpiPen Savings Card program benefit from \$100 to \$300, empowering the vast majority of patients to obtain EpiPen Auto-Injector at little or no out-of-pocket cost. We also have doubled the eligibility threshold for our Patient Assistance Program and announced the introduction of the first-ever generic version of the EpiPen device to be offered at half of the Wholesale Acquisition Cost ("WAC") of the brand. Bringing the generic now required an amendment to our current contract with our partner. We anticipate that more than 85% of prescriptions will shift to the generic, potentially saving patients and the healthcare system more than \$1 billion.⁸

Mylan has always been an engaged and committed partner to the severe allergy community and we have and continue to take their feedback seriously. We believe everyone who needs an EpiPen device should be able to access one, and we are committed to helping to ensure that access through the array of measures we have already taken, as well as continuing to work with payors and others on additional potential solutions.

For instance, under federal regulations, high deductible health plans are permitted to cover certain types of preventive care drugs with no cost to the patient. In fact, the Patient Protection and Affordable Care Act (PPACA) *requires* that certain drugs be included in health plans' preventive drug lists. These recommendations are meant to help prevent disease and are updated periodically to reflect new advances in science and medicine. Such classification could potentially reduce or even eliminate out-of-pocket expense for consumers. Mylan is working closely with insurance companies and others to explore EpiPen Auto-Injector's treatment as a preventive drug in order to further access for consumers.

Before we respond to the specific areas of inquiry in your letter, it is important to address at least one of what appear to be a number of fundamental and widely held misunderstandings about the function of the EpiPen product's WAC and its relationship to the costs ultimately borne by consumers. Many observers appear to believe that our WAC is the "price" paid by most patients. This is not accurate. For those patients with traditional commercial insurance or the majority of members of a government-sponsored healthcare plan – approximately 85 percent of patients – the EpiPen Auto-Injector's WAC is *not* their out-of-pocket expense. These patients pay less than \$100 out-of-pocket for their prescription, and most pay less than \$50 per prescription.⁹

The current Congressional and public interest in EpiPen Auto-Injector has, however, re-focused our attention on the reality that approximately 15 percent of patients – including uninsured and ineligible for our Patient Assistance Program, Medicare Part D beneficiaries at certain points of their coverage period, or participants in high deductible health plans – may pay an out-of-pocket cost influenced by the product's WAC. Our important recent expansion of our EpiPen Auto-Injector's patient programs (Savings Card and PAP as described above) and through our plan to introduce a generic alternative have been targeted directly at improving the circumstances of those patients. And in fact, they will reduce the cost of EpiPen® to these patients by at least 50%.

Please find below Mylan's responses to the five specific inquiries contained in your letter of August 22:

⁸ Assumption based on 88% generic utilization rate as reported in Generic Pharmaceutical Association. Generic Drug Savings in the U.S. Seventh Annual Edition: 2015.

⁹ IMS Formulary Impact Analyzer data for January 2015 through December 2015.

Question One

What analyses were conducted by Mylan in determining the price of EpiPens?

The pricing of any pharmaceutical product is a complex and difficult endeavor that involves a multitude of factors, including but not limited to the following: (1) contract negotiations with entities in the distribution channel, (2) competition in the marketplace, (3) cost of goods, and (4) the manufacturer's objective to increase revenue which permits investment into patient education and additional research and development of other therapies. In short, Mylan's pricing for the EpiPen product has been determined by consideration of these and other factors, some of which we have neither direct nor indirect control over. For example, Sanofi introduced its competing epinephrine injector, Auvi-Q®, in 2013, and during the year raised the WAC for its product so that it was 10% higher than Mylan's WAC.¹⁰ Likewise, at the time Auvi-Q® injector was recalled from the market in 2015, its WAC was higher than that of the EpiPen. While the ever-changing supply and demand conditions in the market also are important factors in pricing decisions, our goal is to ensure that every person who needs an EpiPen Auto-Injector in an emergency will be able to count on one being available in that time of need.

Currently, approximately 85 percent of patients obtaining the EpiPen Auto-Injector do not pay the WAC price.¹¹ Mylan has recently taken direct steps to help the remaining patients. On August 29, 2016, we announced that we will launch the first generic of EpiPen Auto-Injector for both the 0.15 mg and 0.30 mg strengths with a WAC of \$300 per generic two-pack carton. By making available a generic version of the EpiPen product, Mylan is able to provide patients without private insurance coverage or who do not qualify for coverage under a government healthcare plan with a discount of more than 50% from the WAC of our brand product. The generic will provide the same high quality, safety and reliability as the brand version. In addition to offering this product through pharmacies, we will be launching a direct ship program to ensure no patients pays more than \$300 per two-pack.

We anticipate launching the generic once the necessary labeling revisions are completed and we are able to ensure sufficient inventory is available to meet patient demand. Mylan's offer of the generic is not intended to be a substitute for patient assistance for those purchasing the brand EpiPen Auto-Injector. Mylan will maintain both its Savings Card and PAP on the brand program and also offer the PAP for the generic.

We have been asked: "Why are you not lowering the list price of EpiPen®?" The short answer is this: Mylan assessed available options under the existing pharmacy billing models to achieve the goal of delivering cost savings for patients with high out-of-pocket expenses and concluded that offering a generic version of EpiPen Auto-Injector would yield significantly greater and more sustainable cost savings for patients than a reduction in WAC of the brand version would. In fact, we expect that, in the future, the vast majority (more than 85%) of epinephrine auto-injector prescriptions will be written for or filled with the less expensive generic version of EpiPen Auto-Injector. By ensuring the generic is priced well below the brand, we will be able to help ensure robust generic utilization and savings for patients and the healthcare system.

Finally, as noted above, price increases support significant investment in anaphylaxis awareness and access initiatives in order to meet unmet needs. Increased revenue has supported the \$4 billion in innovative research and development investments, \$2.5 billion in capital expenditure investment as well as the costs to service debt incurred by Mylan since 2008 in order to bring to market generic versions of

¹⁰ IMS National Sales Perspective data.

¹¹ IMS Health NPA Extended Insights Report from January 1, 2015 to December 31, 2015.

complex products currently costing the healthcare system billions while still respecting and serving our other stakeholders.

Question Two

What was Mylan's advertising budget for EpiPen in first half of 2016 as well as 2015?

The total marketing budget for the EpiPen product was \$98 million in 2015 and \$43 million for the first half of 2016. These figures are over-inclusive, though, in that they include the full scope of marketing functions of which advertising is but one component. Furthermore, it should be noted that Mylan's paid advertising also addresses disease awareness generally and is not always directed to promoting EpiPen Auto-Injector.

Question Three

Mylan has stated that the EpiPen has changed over time to better reflect important product features and the value the product provides. 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.

Since acquiring the EpiPen Auto-Injector, Mylan has made significant improvements to the design of the medical device portion of the product. In 2009, we launched a next-generation EpiPen Auto-Injector which represented a complex and innovative re-design of the device. This sterile injectable drug-in-device includes 26 separate parts and delivers the epinephrine drug within seconds. Other design enhancements include the "Never See" needle and the flip-top case. These improvements were aimed at making EpiPen Auto-Injectors easier to safely carry, hold, and administer and reduce the risk to users from the device's needle, which is extremely important to our patients. Particularly, in light of the fact that these are devices that children are trained to use in the absence of adult supervision.

Further, Mylan presently is investing substantial amounts in research into additional improvements, such as a formulation with a significantly longer shelf life that would extend the period between replacement of unused auto-injectors. We also continue to work relentlessly to ensure the supply, continuity and reliability in order to deliver the sterile epinephrine injection in an emergency situation, and that we have the capacity to meet demand.

As you may be aware, a competing epinephrine injector was recalled by another manufacturer in 2015 due to concerns about the quality and reliability of the device's dosing capability. Earlier this year, another competing epinephrine injector was delayed from entering the market because of regulatory delays. Mylan's experience, as well as our competitors' experience, demonstrates that delivering a quality, reliable epinephrine injector is a complex task. Mylan's EpiPen Auto-Injector has a reputation for being the best product on the market.

Question Four

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?

Mylan has made robust long-term investments to support access to the EpiPen Auto-Injector for patients who need assistance with out-of-pocket expenses. Our investments have included Mylan's [My EpiPen Savings Card](#), a program to which we have devoted nearly \$143 million since its inception in 2013. In the past 12 months alone, 646,746 patients have benefitted from this program. In fact, in 2015, nearly 80 percent of commercially insured patients using Mylan's [My EpiPen Savings Card](#) received EpiPen Auto-Injector with no out-of-pocket cost (*i.e.*, zero cost to the patient).

Prior to August 25, 2016, our Savings Card program offered up to \$100 in savings for each EpiPen 2-Pak carton per prescription, up to a total of three EpiPen 2-Pak or EpiPen Jr 2-Pak cartons. Given that a growing number of patients were responsible for higher deductibles, we recognize, however, that in today's rapidly evolving healthcare landscape that these programs were in some cases insufficient. So, as of August 25, 2016, Mylan increased the maximum value of the Savings Card benefit threefold. For patients with commercial insurance, the Savings Card will now cover up to \$300 for each EpiPen 2-Pak carton per prescription, up to a total of six EpiPen 2-Pak or EpiPen Jr 2-Pak cartons.¹² For those with an out-of-pocket insurance cost of \$300 or less, the Savings Card will eliminate any cost for the EpiPen 2-Pak carton. And patients whose co-pays are more than \$300 will receive \$300 off of the out-of-pocket costs dictated by their insurance plan.

Mylan also is significantly expanding the availability to uninsured patients the benefits of the Mylan EpiPen 2-Pak Auto-Injector PAP. Our PAP, which is not run in conjunction with any not-for-profit entity, offers free or low cost EpiPen Auto-Injectors to eligible individuals who are unable to pay for their medication. Mylan is doubling the PAP's income eligibility threshold, resulting in many more eligible patients and families:

- Uninsured patients and families earning up to four times the federal poverty level will now qualify for this program instead of the prior limit of two times the federal poverty level.
- This means a family of four with a household income level of up to \$97,200 will now qualify for the program. Previously, families of similar size only qualified with a household income of \$48,600 or less.
- The program also has expanded to cover underinsured patients whose pharmacy coverage is limited to generics.
- Some patients will qualify to receive the EpiPen Auto-Injector at no cost at all.
- We have established customer relations points of contact so that qualifying patients can learn what they need to know to participate in our PAP¹³.

Question Five

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?

In 2012, recognizing that 1 in 13 children are affected by food allergies, Mylan initiated, in collaboration with a number of advocacy partners and state legislators, its public initiative to help increase patient access to epinephrine through legislation permitting undesignated epinephrine in the school setting. As a result, 48 states now have laws allowing schools to stock epinephrine auto-injectors for emergency

¹² These Savings Cards can be accessed at EpiPen.com and through coupon cards available in many healthcare professionals' offices.

¹³ Patients can reach us by either calling Mylan Customer Relations at 800.796.9526 or via email at customer.service@mylan.com.

use. As discussed earlier, in the same year, Mylan launched its *EpiPen4Schools*® program, which provides free EpiPen devices to qualifying schools.

Again, more than 700,000 free EpiPen Auto-Injectors, with a value of more than \$80 million, have been distributed through this program to schools nationwide. To date, more than 66,000 schools, approximately half of all U.S. schools, have participated in the program. The findings from a recent survey of approximately 6,500 schools participating in the *EpiPen4Schools*® program during the 2013-2014 academic year underscore the importance of access to epinephrine in this setting and the positive impact of the program. Survey results included the following:

- (1) More than 1,000 episodes of anaphylaxis were reported.
- (2) More than 75 percent of the anaphylactic episodes were treated with epinephrine auto-injectors. Of those anaphylactic events treated with epinephrine auto-injectors, nearly 40% were treated with an EpiPen Auto-Injector provided through the *EpiPen4Schools* program. Put another way, nearly 400 free EpiPen devices were used in incidents of anaphylaxis.
- (3) 25 percent of reported anaphylaxis events occurred in individuals with no previously known allergies, highlighting the impact of Mylan's donation of non-assigned EpiPen devices to schools.

Additionally, we are continuing our work to expand access to epinephrine in public places such as restaurants, colleges and universities so emergency responders and caregivers are equipped to assist individuals experiencing anaphylaxis in these various settings as well. Mylan also regularly donates EpiPen devices to a variety of other non-profit organizations, including first responders, summer camps, and community programs.

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Mylan takes seriously its role in providing access to high quality prescription drugs. We hope that the information provided above assists you in understanding the meaningful role that Mylan plays in the U.S. healthcare system and how our team at Mylan works every day to meet our commitment to maintain and expand public access to the EpiPen Auto-Injector.

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cc: Senator Patrick Leahy, Ranking Member
T. Reed Stephens
Stephen M. Ryan
David Ransom