

September 12, 2016

The Honorable Elizabeth Warren
United States Senate

The Honorable Patrick Leahy
United States Senate

The Honorable Barbara Boxer
United States Senate

The Honorable Richard J. Durbin
United States Senate

The Honorable Jack Reed
United States Senate

The Honorable Bernard Sanders
United States Senate

The Honorable Sherrod Brown
United States Senate

The Honorable Amy Klobuchar
United States Senate

The Honorable Sheldon Whitehouse
United States Senate

The Honorable Jon Tester
United States Senate

The Honorable Tom Udall
United States Senate

The Honorable Al Franken
United States Senate

The Honorable Richard Blumenthal
United States Senate

The Honorable Brian Schatz
United States Senate

The Honorable Tammy Baldwin
United States Senate

The Honorable Joe Donnelly
United States Senate

The Honorable Chris Murphy
United States Senate

The Honorable Mazie Hirono
United States Senate

The Honorable Heidi Heitkamp
United States Senate

The Honorable Edward J. Markey
United States Senate

Dear Senators:

We appreciate your concern in Mylan and the issues related to the pricing of our EpiPen® Auto-Injector product. We understand that your constituents are interested in this topic, and we welcome the chance to respond to the questions in your letter of August 30, 2016.

Mylan's success since its founding in 1961 has been built on three principles: producing high quality medicine, significantly expanding access to those medicines, and helping to lower health care costs. The growth of our company over the past 25 years - from \$100 million in sales to nearly \$11 billion today - is the result of hard work by tens of thousands of employees and a deep company-wide commitment to serving patients.

While EpiPen Auto-Injector is dominating the news about our company, Mylan is much more than one product. In the U.S. we currently offer 635 products, representing 21 billion doses. As outlined in the answers to your questions, our average price per dose - for all prescriptions sold in the U.S. - is approximately 25 cents. Over the last decade, Mylan's products reduced total health expenditures in the U.S. by approximately \$180 billion.

Since acquiring EpiPen Auto-Injector in 2007, we have worked diligently and invested significantly to enhance the product and make it more available. On many fronts we have succeeded. As anyone who has used the product knows, the pen we have in the market today is substantially different than the one we acquired. We continue to invest in product improvements, such as a formulation with a longer shelf life that would extend the period between refills. Forty-eight states now permit epinephrine auto injectors in schools without a prescription for a specific child. And we have donated more than 700,000 EpiPen Auto-Injectors to more than 66,000 participating schools (more than half of all public schools), with no strings attached. More broadly, the total population of people having access to an EpiPen Auto-Injector has increased by 80% in the last few years. Approximately 85 percent of consumers who are prescribed an EpiPen Auto-Injector pay less than \$100 for a 2 unit package, and a majority pay less than \$50.

We believe our record is good, but nobody is perfect. We learned what we could have done better, and we acted immediately. We wish we had been better at anticipating the potential financial issues for the growing minority of patients who don't have access to insurance, a patient access program or have large deductibles that affect the price they pay for an EpiPen Auto-Injector.

We also did an inadequate job of explaining the pricing structure and process. Our efforts in this arena have left people with the false impression that Mylan is receiving more than \$600 for a two unit package of EpiPen Auto-Injectors. This is not the case, and we are working hard to help set the record straight.

To provide additional context for the detailed pricing questions you asked, we would like to briefly review the key facts with respect to the pricing of EpiPen Auto-Injector. We also want to summarize the aggressive actions we have taken in the last month directly in response to feedback we received to help ensure that EpiPen Auto-Injectors are accessible to the widest possible audience.

The wholesale acquisition cost ("WAC") price of EpiPen Auto-Injectors does not reflect what Mylan is paid. Of the \$608 WAC price for each pack of two pens, Mylan receives, on average, \$274 after rebates and other fees. This amount is further reduced by the cost of goods, which is \$69, leaving us \$205 for a 2 unit package. Of the \$102.50 Mylan receives for each EpiPen Auto-Injector, additional expenses for research and development, sales, marketing, regulatory compliance, distribution, various access programs, and acquisition costs, must be deducted. Therefore, Mylan's profit is approximately \$100 per two-pack, or \$50 per pen. Among other things, this profit is used to fund research and development and our facilities, in which we will invest \$1.2 billion this year alone, or more than \$3 million every day. Mylan's profit will be further reduced upon launch of the generic version of EpiPen Auto-Injector.

As concerns about access to EpiPen Auto-Injectors developed, we took immediate and unprecedented action to address the problem and ensure that everyone who needs an EpiPen Auto Injector is able to get one:

- 1) We increased our My EpiPen Savings Card program benefit from \$100 to \$300;
- 2) We doubled the eligibility threshold of our Patient Assistance Program to \$97,200 for a family of four;
- 3) We are introducing the first ever generic version of EpiPen Auto-Injector , cutting the WAC price in half from \$608 to \$300. We anticipate that the generic will capture more than 85% of the market, resulting in a savings to patients and the healthcare system of approximately \$1 billion.

Speaking candidly, we want to help address the underlying issues that lead to these pricing controversies. We understand and accept that Mylan and EpiPen Auto-Injector are the subject of review today. But the pricing puzzle that frustrates you and your constituents, and everyone in the health care system, transcends this product and our company.

We have a great health care system in the U.S., but we all know it needs fundamental reform. We hope you can see that our approach to this issue hasn't been to debate or delay. We have acted decisively and boldly. The initiatives we have implemented will expand access and reduce the cost of an important medication. We hope we can work with you and your staff and our industry colleagues to make the sort of reforms that will help minimize these issues in the future.

Responses To Interrogatories

Interrogatory 1

The My EpiPen Savings Card™ (“Savings Card”) offers consumers a \$300 savings credit, per pack, for three EpiPen 2-Pak® cartons. Only consumers with commercial insurance can use the Savings Card.¹ Until recently, when your Savings Card offered only a \$100 credit, Mylan claimed that, “80% of commercially insured patients using [Savings Card] received [an] EpiPen® Auto-Injector for \$0.”²

(a) In the past 12 months, how many consumers used the Savings Card and how many filled prescriptions without the Savings Card?

¹ Mylan, "My EpiPen Savings Card™" (online at <https://www.activatethecard.com/epipen/?ga=1.113892615.1859762553.1471903476>).

² Mylan, "Mylan's Commitment to EpiPen® (epinephrine injection, USP) Auto-Injector Access" (August 22, 2016) (online at <http://newsroom.mylan.com/access>).

For the period of September 5, 2015 through September 2, 2016, 682,396 customers have used the My EpiPen Savings Card™ (“Savings Card”) to fill 856,186 prescriptions. 2,995,108 prescriptions were filled without the Savings Card benefit.³

(b) In the past 12 months, how many of those consumers who used the Savings Card had to pay a co-payment to fulfill an EpiPen prescription? What was the average co-pay, per prescription, for those consumers? What was the maximum co-pay for those consumers?

For the period of September 5, 2015 through September 2, 2016, 25.3% of the consumers who used the Savings Card had to make a co-payment on their prescription. 74.7% of Savings Card users had a \$0 co-pay. The average co-pay for this time period was \$52.38 per EpiPen 2-Pak® (“2-Pak”) carton. The maximum co-pay amount would have been the retail price charged to the customer by the retail pharmacy, minus the Savings Card benefit.

(c) For the past 12 months and for 2009, what was the total cost of EpiPens to commercial health insurers for prescriptions filled by consumers using Savings Cards? For the past 12 months and in 2009, what was the average price paid for an EpiPen by commercial health insurers who allow the use of Savings Card, and how does that cost compare to the EpiPen's list price during the respective time period?

Mylan is unable to determine this information as we lack visibility into the arrangements that exist in the distribution channel beyond our own terms with our customers.

(d) In the past 12 months, how many consumers using the Savings Card were covered by insurance obtained through the Affordable Care Act state or federal health insurance exchanges? What was the average co-pay, per prescription, for these consumers? What was the average amount paid, per prescription, by the health insurance plan, and how does that price compare to the list price?

Mylan does not have the information requested by this interrogatory.

(e) After congressional scrutiny, Mylan recently increased the value of its Savings Card credit from \$100 to \$300. How many customers does Mylan anticipate it will reach with its new Savings Card in the next 12 months? Of those customers, how many does Mylan anticipate will pay a \$0 co-pay? How many will pay a co-pay of under \$100? Of above \$100?

Following the generic EpiPen product launch, we anticipate that over the course of 2017, 85% of the prescriptions will shift to the generic product. For the remaining prescriptions, we anticipate that 42% will be filled with use of the Savings Card.

(f) How did Mylan determine that the \$100 coupon covered the copayments of 80 percent of its commercially insured patients?

³ For a description of the eligibility criteria for the Savings Card, see response to interrogatory no. 2(a).

Mylan's Savings Card program administrator provided this information regarding the patient co-pay amounts.

Interrogatory 2

The patient assistance program provides uninsured consumers at incomes up to 400% of the federal poverty level with free access to EpiPens.⁴

(a) Please provide a description of the terms and conditions of the patient assistance program.

Patients are eligible for the Mylan EpiPen 2-Pak Auto-Injector Patient Assistance Program (MEPAP) who fall at or below 400% of the federal poverty line. The patient (or their legal representative) must complete a MEPAP application and submit documentation demonstrating that he or she satisfies the following eligibility criteria.

- 1) The patient must be a U.S. citizen or a legal resident living in the United States.
- 2) The patient's gross yearly household income must fall below 400% of the current Federal Poverty Guidelines, based upon family size;
- 3) The patient must meet one of the following:
 - a) The patient must not have any prescription insurance coverage, including coverage through (i) Medicaid, Medicare Part D, or TRICARE, (ii) a qualified health plan purchased on a state-based, partnership, or federally-facilitated Exchange, or (iii) any other public or private program or insurer; or
 - b) The patient has commercial prescription drug coverage only for generic products, and the patient must not have prescription insurance coverage through any state or federally funded healthcare program including, without limitation, Medicare, Medicaid, or TRICARE.

Additionally, the physician is directed to complete a MEPAP Application acknowledging that the patient is in need of assistance and satisfies the MEPAP eligibility criteria. The physician is directed to certify that he/she will not submit a claim for any payment for the free product or resell, trade, barter or return for credit any free product received from MEPAP. The physician is also directed to contact the MEPAP if there are changes to the patient's insurance coverage, dosage, or if the patient discontinues therapy.

The terms and conditions of the program, as well as the application, are available online.

⁴ RxAssist, "Program Details: MYLAN EpiPen 2-Pak Auto-Injector Patient Assistance Program EpiPen (epinephrine)" (online at http://www.rxassist.org/search/prog-details?program_Id=626&PD_Id=626&Drug_Id=3220&Company_Id=135&search_type=2); Austen Hufford and Jonathan D. Rockoff, "Mylan Boosts Assistance for EpiPen After Pricing Backlash," Wall Street Journal (August 25, 2016) (online at <http://www.wsj.com/articles/under-pressure-for-raising-prices-mylan-boosts-assistance-on-epipen-1472125304>).

(b) In the past 12 months, how many EpiPens did Mylan provide through the program?

For the period beginning September 5, 2015 through September 2, 2016, Mylan has provided 3,042 2-Paks (6,084 individual devices) under the MEPAP.

(c) In the past 12 months, how many consumers did Mylan serve through the patient assistance program?

For the period beginning September 5, 2015 through September 2, 2016, Mylan has served 2,965 customers through the MEPAP.

(d) Does Mylan have programs in place to direct uninsured consumers towards insurance options, such as the Affordable Care Act health insurance exchanges, Medicare, or Medicaid? If so, please provide an overview of those programs. In the past 12 months, how many uninsured consumers has Mylan converted to insured consumers, and what forms of insurance did those consumers purchase?

No, Mylan does not have programs that direct uninsured consumers to specific insurance options, either commercial insurance options or government programs. Mylan does encourage patients to inform themselves about their own insurance coverage circumstances.

(e) After congressional scrutiny, Mylan recently increased eligibility for its patient assistance program from 200% to 400% of the federal poverty level. How many more customers does Mylan anticipate reaching with this new program in the next 12 months, and how many EpiPens does it anticipate handing out? How does Mylan plan on alerting newly-eligible consumers about the patient assistance program? How much will it cost to implement the program?

Mylan does not presently have projections for additional patients who will enroll in the MEPAP. We, therefore, do not have projections on how many EpiPen devices will be dispensed through the program. Mylan has issued a press release and updated its program materials. Apart from foregone sales represented by the increase in pens Mylan anticipates distributing through the MEPAP, Mylan has not quantified the amounts and expenses incurred to implement the program.

Interrogatory 3

The EpiPen4Schools® program provides American schools with four free EpiPen or EpiPen Jr. Auto Injectors each calendar year, including a free “replenishment product” should an EpiPen be used in response to a life-threatening allergic reaction.⁵

(a) Please provide a description of the terms and conditions of the EpiPen4Schools® enrollment program. Do schools pay to enroll in the program and receive access to their four free EpiPens?

⁵ Mylan, “EpiPen4Schools®” (online at <https://www.epipen4schools.com/>)

Public or private kindergarten, elementary, middle and high schools in the United States permitted to stock epinephrine, and administer epinephrine to patients who have not been prescribed the medicine, under applicable law are eligible to participate in the Free EpiPen® (epinephrine injection, USP) Auto-Injector EpiPen4Schools® Program (“EpiPen4Schools”) by having a school nurse or other authorized school representative complete the order and certification forms available online at www.EpiPen4Schools.com. A school or school district enrolling in the program represents, among other things, that the school has presented a valid prescription (or standing order or other documentation as required by applicable law) for the product, and that neither the school, nor any health care professional associated with or providing medical services on behalf of the school, will bill any patient or any third-party payor/government program for any free EpiPen or EpiPen Jr® Auto-Injector (“EpiPen Jr”) administered to any patient.

Schools do not pay to enroll in the program in order to receive four free EpiPen devices. Each school year, authorized schools are eligible to receive at no cost four EpiPen devices in the form of two EpiPen 2-Pak cartons or two EpiPen Jr 2-Pak cartons, or one of each 2-Pak cartons. A single school district ordering for multiple schools may order up to two 2-Pak cartons per school and is asked to provide a list of the name and address for each of the schools for which the school district is ordering. We depend on the school district to be as complete as it is able in providing this information.

The EpiPen4Schools program also offers the following: (1) a storage unit, Epilocker™, to store EpiPen cartons received through the program, (2) a training video that includes a step-by-step demonstration of how to administer the EpiPen in accordance with the FDA-approved full prescribing information, (3) training devices, EpiPen Trainers, that contain no drug product or needle to practice administering the EpiPen, and (4) a "Signs and Symptoms of Anaphylaxis" poster to educate about the most common indicators of anaphylaxis.

During the school year, Mylan will replenish at no cost an EpiPen device obtained through the EpiPen4Schools program that was used to respond to a life-threatening allergic reaction. The EpiPen4Schools program does not require a school to purchase any EpiPen products or any other Mylan Specialty products. If any school requests any more quantities of EpiPen devices above the two free 2-Paks of product, Mylan’s program administrator directs the inquiry to Mylan for its review and consideration. For schools that have a demonstrated need for more EpiPen devices, Mylan may approve additional free quantities for the school. If a school, however, in its sole discretion, decides it requires more EpiPen devices beyond the free EpiPen devices which have already been provided, without any further obligation by the school, Mylan offers for sale to the school EpiPen devices at a discounted price.

Since the start of the EpiPen4Schools initiative in 2012, more than 700,000 free EpiPen devices have been distributed, and more than 66,000 schools, approximately half of all U.S. schools, have participated in the program.

(b) In the past 12 months, how many schools have purchased additional EpiPens from the EpiPen4Schools® program? How many additional EpiPens, in total, were purchased? What is the average cost to schools per additional EpiPen?

For the period of September 5, 2015 through September 2, 2016, 1,348 schools purchased 6,605 pens at a cost of \$56.05 per pen.

(c) Please provide a list of all schools, including their location, that have received EpiPens under this program.

A list of schools that have received EpiPen devices under this program is provided in native electronic form as Attachment A.

(d) It has been reported that Mylan, at least for a period of time, conditioned the receipt of free products on the school's promise not to purchase alternative products.⁶ During what period was this condition in place? What was the purpose of the restriction? If no longer being used, why did Mylan eliminate it?

Mylan did not condition the receipt of either initial or free products on a school's promise not to purchase additional alternative products. As discussed above, schools could receive up to four EpiPen devices for free under the EpiPen4Schools program. This benefit has never been conditioned on a school's promise to only purchase products from Mylan.

No exclusive purchase requirement was imposed on schools either. The report noted in your question was referencing an old order form for the purchase of EpiPen devices beyond the four that a school could receive for free. But even in those circumstances, Mylan did not condition the purchase of pens on exclusively buying Mylan products. If a school wanted to purchase EpiPen devices, it had two options: it could pay a highly discounted price, or it could pay an ever more deeply discounted price if the school certified that it would not purchase competitive products to EpiPen over the following twelve months. No school had to agree to purchase exclusively from Mylan in order to receive an EpiPen – whether for free or for purchase at a discounted price. Schools that chose not to take advantage of the larger discount provided under the program could still receive discounted rates for the purchase of pens.

As of July 2016, Mylan no longer offered the two-tier discount program for schools that choose to purchase pens. Mylan currently offers four free EpiPen devices to each eligible school, together with an option to purchase EpiPen devices under a discount program at a single price, with no purchase or exclusivity requirements.

Interrogatory 4

Mylan recently announced that it is "opening a pathway so that patients can order EpiPen® Auto-Injector directly from the company, thereby reducing the cost."⁷ How much money does Mylan anticipate charging customers, per EpiPen, that order directly from the company?

⁶ Ike Swetlitz and Ed Silverman, "Mylan may have violated antitrust law in its EpiPen sales to schools, legal experts say," STAT(August 25, 2016) (online <https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/>).

⁷ Mylan, "Mylan Taking Immediate Action to Further Enhance Access to EpiPen® (Epinephrine Injection, USP)_Auto-Injector" (August 25, 2016) (online at <http://newsroom.mylan.com/2016-08-25-Mylan-Taking-Immediate-Action-to-Further-Enhance-Access-to-EpiPen-Epinephrine-Injection-USP-Auto-Injector>).

The current WAC for the brand EpiPen product is \$608.61. Upon launch, we anticipate that the WAC for the generic will be \$300.00.

Interrogatory 5

It is illegal for consumers covered under Medicare or Medicaid to use the Savings Card, nor can these consumers access EpiPens through the patient assistance program.⁸

(a) What safeguards does Mylan have in place to ensure that it does not provide Savings Cards to Medicare or Medicaid beneficiaries?

The EpiPen Savings Card bears conspicuous notices stating that patients are not eligible: if prescriptions are paid by any state or federally funded program, including but not limited to any state pharmaceutical assistance program, Medicare (Part D or otherwise), Medicaid, Medigap, VA or DOD, or TRICARE (regardless of whether EpiPen is covered by such government program); if the patient is Medicare eligible and enrolled in an employer-sponsored health plan or prescription benefit program for retirees; or where otherwise prohibited by law. The Savings Card also instructs pharmacists that when they use the Savings Card, they are certifying that they have not submitted and will not submit a claim for reimbursement under any federal, state, or other governmental programs for the prescription. Furthermore, as an additional safeguard, cash paying consumers are prohibited from using the Savings Card to protect against circumvention of the above exclusions.

The patient must activate the EpiPen Savings Card before the Savings Card can be redeemed at the pharmacy. The patient must visit the Savings Coupon website and respond to questions that address the requirements for eligibility. The website asks the patient whether he or she has: (1) Commercial insurance; (2) No insurance; or (3) Government-funded insurance (e.g. Medicare, Medicaid or TRICARE). If the patient presses 2 or 3 in response to this question, the patient will be ineligible for the program and cannot activate his or her Savings Card.

In addition to the above activation requirements, Mylan has contracted with an industry leading third-party administrator for the administration of the Savings Card program. Mylan's program administrator ("Vendor") employs proprietary government exclusion logic when pharmacies process the Savings Card at the point of sale. This government exclusion logic is designed to screen out potential claimants who are government healthcare program beneficiaries; it uses information inputted by the pharmacist to identify whether the patient's primary insurance is a government healthcare program, including Medicare or Medicaid. If the government exclusion logic identifies the patient's primary insurance as a government healthcare program, the system will block the claim and inform the pharmacist in real-time at point of sale so that the pharmacist can inform the patient that he or she is not eligible to use the Savings Card. In addition, when entering patient identification and insurance information, there is an NCPDP data field that allows the pharmacist to enter identifying information pertaining to whether the patient's primary payer is a Medicare or Medicaid plan. If the Vendor's system identifies that the claim is for a

⁸ See, for example, Department of Health and Human Services Office of Inspector General, "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs" (September 2014) (online at <https://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf>).

Medicare or Medicaid beneficiary, it will not allow the Savings Card benefit to be applied to the claim.

(b) How has Mylan worked to ensure access to these patients?

The EpiPen product is covered by Medicare Part D prescription drug plans and by state Medicaid programs. Mylan pays rebates under these programs.

(c) What is the average co-pay per EpiPen paid by individuals covered by Medicare Part D? What is the average co-pay per EpiPen paid by individuals covered by Medicaid?

Co-pays for Medicare Part D participants vary from plan-to-plan. As required under the Affordable Care Act, Mylan provides a 50% discount off the cost for participants in the “donut hole.” If a Medicare Part D participant’s catastrophic coverage has been triggered, that individual would pay \$30.43 for an EpiPen 2-Pak. Medicaid participants have a blended average co-pay of \$5.52 on a prescription for the 2-Pak.

(d) What is the average amount paid by Medicare Part D plans for EpiPens, and how does that compare to the list price of an EpiPen? What is the average amount paid by Medicaid?

Mylan does not have access to the information requested by this portion of the interrogatory.

(e) What is the total amount paid by the Department of Health and Human Services (HHS) via Medicare Part D catastrophic coverage over the past 12 months for EpiPens?

Mylan does not have access to the information requested by this interrogatory.

(f) What is the total amount Mylan has received in reimbursement from the federal government over the last 12 months for EpiPens? In 2009?

Mylan does not receive reimbursement from the federal government from sales of EpiPen products.

Interrogatory 6

Has Mylan estimated the cost to the company of its Savings Card and patient assistant program expansions? If so, what is the cost? What is the anticipated revenue to the company as a result of the expansions?

Prior to announcing our plan to launch a generic auto-injector, Mylan anticipated that the expanded Savings Card Program would cost between \$50 – 60 million annually based on current program cost estimates. Once the generic product is launched, we anticipate that these costs will be reduced by virtue of increased utilization of the generic product.

Interrogatory 7

On August 29, 2016, Mylan announced that it would offer an "authorized generic" version of the EpiPen for \$300.⁹

(a) What regulatory approvals does Mylan need before it can sell an authorized version of EpiPen, and, typically, how long does it take for the Food and Drug Administration to grant approval?

Because an “authorized generic” is manufactured and marketed under a new drug application for the branded drug, the approval of the branded product as safe and effective applies to the authorized generic as well. What differs is the language and content of the packaging and labeling, because the authorized generic auto-injectors will not have the “EpiPen® Auto-Injector” name.

(b) What production issues (such as designing a new label) must occur before the product is released, and how long do those steps typically take? Please provide a timeline, including the steps that must occur, for the introduction of the authorized generic version of the EpiPen.

Before Mylan can offer the generic for sale a number of action items must be addressed including (1) assuring that sufficient inventory will be available to meet anticipated orders, (2) creating the necessary packaging for the product, and (3) creating the necessary labelling for the product. For example, the EpiPen name and artwork must be updated for new labeling and other components, including the auto-injector/container, carton, prescribing information, patient information/instructions for use, and carrier tube caps. All of the activities to prepare, proof, print, and otherwise execute these changes must be conducted under exacting standards by qualified personnel at qualified facilities. Once the relevant product materials have been created, operational use must be appropriately evaluated and sufficient quantities will then be manufactured to fulfill anticipated orders. We are diligently working to complete these efforts in order to provide the generic as soon as possible.

(c) Mylan claims that the branded version of the EpiPen and the "authorized generic" are "identical." Given that the \$300 generic and \$600 branded EpiPen are functionally equivalent, how does Mylan justify the higher price of the branded EpiPen?

Given the distribution channel that will be utilized, Mylan will be able to offer a generic version at a price that is half of the branded version; we anticipate that 85% of prescriptions will shift to the generic product, saving customers more than \$1 billion.¹⁰

(d) Does Mylan have plans to expand its patient assistance programs to consumers seeking the generic EpiPen? If not, how does Mylan plan on ensuring that consumers seeking the authorized generic can access it?

⁹ Mylan, "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" (August 29, 2016) (online at <http://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>).

¹⁰ Based on 88% generic utilization rate as reported in Generic Pharmaceutical Association. Generic Drug Savings in the U.S. Seventh Annual Edition: 2015.

Mylan currently has no plans to modify the MEPAP, with the enhancements announced on August 25, 2016.

(e) Typically, when a generic alternative enters the market, it takes a dramatic share of the branded products sales quickly.¹¹ Once Mylan begins to sell an authorized generic version of EpiPen, what percent of epinephrine auto-injector sales will be for the authorized generic product versus the branded EpiPen? Will Mylan commit to filling all orders for the authorized generic version of the EpiPen so the generic alternative is available to all epinephrine auto-injector consumers? Will Mylan commit to not shifting production from the authorized generic version to branded EpiPen if it will result in delaying the ability of Mylan to fill orders for the authorized generic? Will Mylan commit to not rationing the product or sale of the authorized generic version of EpiPen?

Mylan anticipates that within the first 12 months that the generic is on the market, 85% of the EpiPen branded utilization will shift over to the prescriptions for the discounted generic version. Mylan will launch the generic once it has taken reasonable steps to ensure sufficient supply for the anticipated demand for the product.

* * * * *

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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¹¹ For example, the FTC estimated that, within a year of generic entry, the generic has taken 90 percent of the branded company's sales. *See* Federal Trade Commission, "Pay for Delay: How Drug Company PayOffs Cost Consumers Billions" (January 20 10) (online at <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>), p. 8.