United States Senate
WASHINGTON, DC 20510

August 30, 2016

Ms. Heather Bresch
Chief Executive Officer
Mylan
1000 Mylan Boulevard
Canonsburg, PA 15317

Dear Ms. Bresch,

We are writing today to express our concern with the repeated and significant price increases for Mylan's EpiPen Auto-Injector ("EpiPen"), and to request information about Mylan's efforts to increase access to EpiPens by expanding its patient assistance programs and introducing a generic version of the EpiPen.

The EpiPen auto-injector delivers a life-saving dose of epinephrine to patients suffering from anaphylaxis.[1] Anaphylactic shock can lead to serious injury or death if untreated; thus, making sure the EpiPen is readily available for use is a critical part of life for millions of Americans living with severe allergies.[2] The need is so great that Congress recently passed legislation that helps ensure schools have EpiPens on hand for children who experience anaphylactic shock.[3]

The EpiPen, however, has become so exorbitantly expensive that access to this life-saving combination product is in jeopardy for many Americans. As of May 2016, Mylan had increased the price of EpiPens in the United States by over 480%, from $103.50 for a set of two in 2009 to $608.61 today.[4] Some Americans who are unable to afford this cost increase have resorted to carrying expired EpiPens—or carry no EpiPens at all.[5] Emergency medical responders, meanwhile, have reported injecting epinephrine using manual syringes—a less expensive but more difficult[6], and thus more dangerous, method of treating anaphylaxis.[7]

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[1] Mylan, "Frequently Asked Questions About EpiPen (epinephrine injection) Auto-Injector and Anaphylaxis" (2016) (online at https://www.epipen.com/about-epipen/faq).
[2] Asthma and Allergy Foundation of America, "Anaphylaxis in America" (2014) (online at http://www.aafa.org/page/anaphylaxis-in-america.aspx).
[3] See, for example, H.R. 2094: The School Access to Emergency Epinephrine Act, signed into law November 13, 2013 (online at https://www.congress.gov/bill/113th-congress/house-bill/2094/).
[4] "Rising cost of potentially life-saving EpiPen puts pinch on families," *CBS News* (August 16, 2016) (online at http://www.cbsnews.com/news/allergy-medication-epipen-epinephrine-rising-costs-impact-on-families/); Tara Parker-Pope and Rachel Rabkin Peachman, "EpiPen Price Rise Sparks Concern for Allergy Sufferers," *New York Times* (August 22, 2016) (online at http://well.blogs.nytimes.com/2016/08/22/epipen-price-rise-sparks-concern-for-allergy-sufferers/).
[5] Tara Parker-Pope and Rachel Rabkin Peachman, "EpiPen Price Rise Sparks Concern for Allergy Sufferers," *New York Times* (August 22, 2016) (online at http://well.blogs.nytimes.com/2016/08/22/epipen-price-rise-sparks-concern-for-allergy-sufferers/).
[6] Ike Swetlitz, "America has a dangerous EpiPen Crisis," *The Week* (July 28, 2016) (online at http://theweek.com/articles/634878/america-dangerous-epipen-crisis).
[7] Ike Swetlitz, "High price of EpiPens spurs consumers, EMTs to resort to syringes for allergic reactions," *STAT* (July 6, 2016) (online at https://www.statnews.com/2016/07/06/epipen-prices-allergies/?s_campaign=fb).

Mylan's near monopoly on the epinephrine auto-injector market has allowed you to increase prices well beyond those that are justified by any increase in the costs of manufacturing the EpiPen.[8] At the same time, your company – based in Pennsylvania – moved its tax address to the Netherlands through a "corporate inversion"[9] to avoid paying its fair share of corporate taxes. Your own total annual compensation, meanwhile, increased from a reported $2.4 million in 2007 to $18.9 million in 2015—an increase of over 670%.[10]

Your company has responded to concerns about the high cost of the EpiPen by arguing that its three EpiPen accessibility programs ensure consumer access to the product, despite the high cost.[11] In fact, on August 25, 2016, you announced expansions to your accessibility programs: increasing the maximum value of your savings card from $100 to $300 and expanding eligibility for your patient assistance program to customers at or below 400% of the federal poverty level. You did not, however, agree to lower the price of brand-name EpiPens.[12] Instead, you announced on August 29, 2016, that Mylan would offer the first generic to the EpiPen for $300, a 50% discount from the brand price.[13]

These changes will help some customers who are struggling to afford EpiPens. Your discount programs, however, represent a well-defined industry tactic to keep costs high through a complex shell game. When patients receive short-term co-pay assistance for expensive drugs, they may be insulated from price hikes, but insurance companies, the government, and employers still bear the burden of these excessive prices. In turn, those costs are eventually passed on to consumers in the form of higher premiums.[14] Because couponing can massively

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[8] The EpiPen delivers $1 worth of epinephrine. See Cynthia Koons and Robert Langreth, "How Marketing Turned the EpiPen Into a Billion Dollar Business," *Bloomberg* (September 23, 2015) (online at http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business).

[9] Liz Claman, "EpiPen Price Gouging Came as Mylan Pulled Off Tax Inversion," *Fox Business* (August 24, 2016) (online at http://www.foxbusiness.com/markets/2016/08/24/epipen-price-gouging-came-as-mylan-pulled-off-tax-inversion.html).

[10] See Ben Popken, "Mylan Execs Gave Themselves Raises As They Hiked EpiPen Prices," *NBC News* (August 23, 2016) (online at http://www.nbcnews.com/business/consumer/mylan-execs-gave-themselves-raises-they-hiked-epipen-prices-n636591); Mylan Inc., Schedule 14A: Information Required in Proxy Statement (2010) (online at https://www.sec.gov/Archives/edgar/data/69499/000095012310032130/l39062def14a.htm#130); and Mylan N.V., Form 10-K/A Amendment 1 (for fiscal year ending December 31, 2015) (online at http://www.mylan.com/-/media/mylancom/files/company/corporate%20governance/184592_10ka_bmk.pdf).

[11] Mylan, "Mylan's Commitment to EpiPen® (epinephrine injection, USP) Auto-Injector Access" (August 22, 2016) (online at http://newsroom.mylan.com/access). These programs include a coupon card (the My EpiPen Savings Card™) to cover copays for insured patients, a patient assistance program for uninsured patients, and the EpiPen4Schools® program.

[12] Jonathan D. Rockoff, "Mylan Boostst 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).

[13] 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).

[14] See, for example, David H. Howard, Ph.D., "Drug Companies' Patient-Assistance Programs—Helping Patients or Profits?" *New England Journal of Medicine* 371:2 (July 10, 2014): 97-99 (online at http://www.nejm.org/doi/pdf/10.1056/NEJMp1401658); Joseph S. Ross, M.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H., "Prescription-Drug Coupons—No Such Thing as a Free Lunch," *New England Journal of Medicine*

inflate costs, this practice has been outlawed by the government in Medicare and Medicaid.[15] But couponing practices are perfectly legal for commercial insurance and Affordable Care Act exchange coverage.

While your announcement of a $300 authorized generic could ease the financial burdens of insurers and consumers, that depends on whether Mylan will make the product available to the same degree an independent competitor would. Further, the generic raises additional questions about Mylan's pricing of EpiPens. The price of the generic, for example, is still three times higher than the cost of the branded EpiPen in 2007.[16] And Mylan asserts that the generic is "identical to the branded product"—further calling into question the excessively high price of branded EpiPens.[17]

To help us better understand the impact of Mylan's recent efforts to increase access to EpiPens on consumers and taxpayers, please provide answers to the following questions no later than September 12, 2016:

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.[18] 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."[19]

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

    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?

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369:13 (September 26, 2013): 1188-1189 (online at http://www3.med.unipmn.it/papers/2013/NEJM/2013-09-26_nejm/nejmp1301993.pdf).

[15] See Department of Justice Office of Inspector General, "Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries" (August 2002) (online at https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf); Department of Health and Human Services Office of Inspector General, "Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons" (September 2014) (online at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf).

[16] Sarah Karlin-Smith, "Mylan to launch a generic EpiPen amid pricing outrage," *Politico Pro Health Care Whiteboard* (August 29, 2016).

[17] 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).

[18] Mylan, "My EpiPen Savings Card™" (online at https://www.activatethecard.com/epipen/?_ga=1.113892615.1859762553.1471903476).

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

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?

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?

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?

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

2. The patient assistance program provides uninsured consumers at incomes up to 400% of the federal poverty level with free access to EpiPens.[20]

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

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

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

   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?

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[20] 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 Booststt 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).

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?

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.[21]

   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?

   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?

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

   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.[22] 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?

4. Mylan recently announced that it is "opening a pathway so that patients can order EpiPen® Auto-Injector directly form the company, thereby reducing the cost."[23] How much money does Mylan anticipate charging customers, per EpiPen, that order directly from the company?

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.[24]

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[21] Mylan, "EpiPen4Schools®" (online at https://www.epipen4schools.com/).
[22] 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/).
[23] 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).
[24] 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).

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

b. How has Mylan worked to ensure access to these patients?

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?

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?

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?

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

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?

7. On August 29, 2016, Mylan announced that it would offer an "authorized generic" version of the EpiPen for $300.[25]

   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?

   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.

   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?

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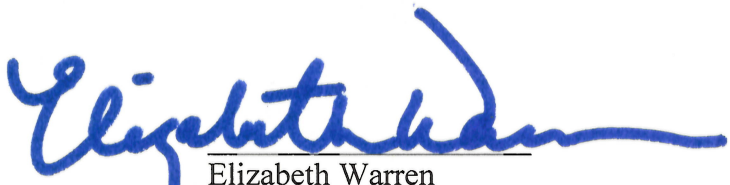
[25] Mylan, "Mylan to Launch First Generic to EpiPen® Auto-Injector at a List Price of $300 per Two-Pack Carton, a More than 50% Discount to the Brand Product" (August 29, 2016) (online at http://newsroom.mylan.com/2016-08-29-Mylan-to-Launch-First-Generic-to-EpiPen-Auto-Injector-at-a-List-Price-of-300-per-Two-Pack-Carton-a-More-than-50-Discount-to-the-Brand-Product).

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?

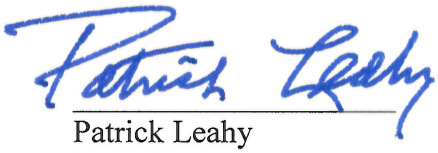
e. Typically, when a generic alternative enters the market, it takes a dramatic share of the branded products sales quickly.[26] Once Mylan begins to sell an authorized generic version of EpiPen, what percent of epinephrine auto-injector sales will be for the authorized generic product versus the branded 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?

Thank you for your prompt response. We look forward to working with you to ensure that all Americans have access to life-saving medication.

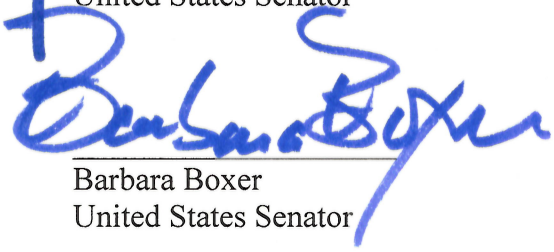
Sincerely,



Elizabeth Warren
United States Senator

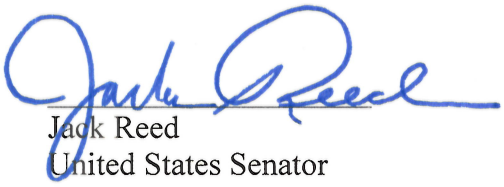


Patrick Leahy
United States Senator



Barbara Boxer
United States Senator

Richard J. Durbin
United States Senator



Jack Reed
United States Senator

Bernard Sanders
United States Senator

[26] 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 Pay Offs Cost Consumers Billions" (January 2010) (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.

Sherrod Brown
United States Senator

Amy Klobuchar
United States Senator

Sheldon Whitehouse
United States Senator

Jon Tester
United States Senator

Tom Udall
United States Senator

Al Franken
United States Senator

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